UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Janssen Biotech, Inc. et al., Plaintiffs, v. Celltrion Healthcare Co., Ltd. et al., Defendants.	)	Civil Action No.. 1:15-cv-10698-MLW

DEFENDANTS' UNOPPOSED MOTION FOR LEAVE TO FILE OPPOSITION AND CROSS-MOTION TO STAY IN RESPONSE TO PLAINTIFF'S PROPOSED MOTION TO MODIFY THE PROTECTIVE ORDER TO PERMIT FILING OF A NEW ACTION

Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira Inc. (collectively "Defendants") hereby move this Court for leave to file its Opposition and a Cross-Motion to Stay in response to Plaintiffs' proposed Motion To Modify The Protective Order To Permit Filing Of A New Action ("Motion to Modify") [*Dkt 69-1*]. As grounds for this Motion, Defendants state as follows:

1. On August 12, 2015, Plaintiffs filed their Unopposed Motion for Leave to File A Motion to Modify the Protective Order to Permit Filing of a New Action Under Seal ("Motion for Leave") [*Dkt 69*]. Plaintiffs' proposed Motion to Modify was attached to the Motion for Leave. [*Dkt 69-1*]. Plaintiffs' supporting Brief, Affidavit and Exhibits were filed as attachments to the Motion to Modify. [*Dkt 69-2, 69-3*].
2. On August 13, 2015, the parties filed a Joint Motion for Proposed Scheduling Order for Briefing on Plaintiffs' Motion to Modify the Protective Order ("Joint Motion"), anticipating that the unopposed Motion for Leave to file the Motion to Modify would be

allowed. [*Dkt 70*]. In the Joint Motion the parties proposed September 4, 2015 as the deadline for Defendants' Opposition to Plaintiffs' Motion to Modify. [*Dkt 70, 70-1*].

3. To date, the Court has not yet ruled on either Plaintiffs' Motion for Leave [*Dkt 69*] or the Joint Motion [*Dkt 70*].
4. Defendants respectfully submit that, if the Court allows Plaintiffs' Motion for Leave [*Dkt 69*], and Plaintiffs' Motion to Modify is filed or deemed filed [*Dkt 69-1*], then Defendants should be granted leave to file an Opposition and a Cross Motion in response to the Motion to Modify. Defendants' proposed Opposition and a Cross Motion is attached hereto for the Court's reference.
5. Plaintiffs have stated that they do not oppose this Motion for Leave.

WHEREFORE, Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira Inc. respectfully request that the Court grant them leave to file the attached Opposition and Cross-Motion.

Dated: September 4, 2015

Respectfully submitted,

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

By their attorneys,

/s/Andrea L. Martin

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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 and that Plaintiffs do not oppose this Motion as set forth herein.

/s/Andrea L. Martin, Esq.
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 4, 2015.

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

4829-9396-4072.1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DEFENDANTS' OPPOSITION TO JANSSEN'S MOTION TO MODIFY THE STIPULATED PROTECTIVE ORDER; CROSS-MOTION TO STAY

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INTRODUCTION

Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. (together, "Celltrion") and Hospira, Inc. seek to launch a less-expensive, biosimilar version of Janssen's Remicade biologic product in the United States. As Janssen puts it, "Remicade is Janssen's most successful product" (Br. 2), earning billions of dollars each year. But Janssen's monopoly is about to end. As discussed in an unrelated motion, Janssen's patent covering the drug itself presently stands rejected by the Patent Office. (*See* Dkt. No. 8, 41.) Janssen's patent covering one of the approved treatments is similarly weak and, regardless, expires in ten months. As for the remaining patents that concern manufacturing, Janssen cannot even allege literal infringement.

So Janssen now seeks leave of Court to evade the Biologics Price Competition and Innovation Act ("BPCIA") and a stipulated protective order. It seeks to use highly confidential information produced under the statute to support a brand-new lawsuit against Defendants and third-party [redacted] That new lawsuit would allege what Janssen calls "widespread" infringement of one of the patents-in-suit claiming cell culture media—U.S. Patent No. 7,598,083 ("the '083 patent"). (Br. 6-7.) But unlike in this case, Janssen would try to seek damages for the sales of Defendants' biosimilar products outside of the United States. (*Id.* at 7.)

As we will demonstrate if necessary, there is no infringement, much less "widespread" infringement. Indeed, Janssen's threatened lawsuit is meritless. As Janssen concedes, the accused products do not meet [redacted] patent claim limitations. (*Id.* at 6.) This proposed lawsuit is not just a stretch—as far as we can tell, it is unprecedented. So why would Janssen try to bring such a transparently weak lawsuit? Janssen apparently hopes to disrupt the relationship between Celltrion and its supplier. This is Janssen's last chance to delay competition.

To that end, Janssen hopes to circumvent the BPCIA, which contains strict confidentiality restrictions, and the stipulated (but not yet entered) protective order—which says in no uncertain

terms: "[a]ll Confidential Information disclosed pursuant to this Order *shall be used by any recipient thereof solely for the purposes of this litigation*. Any Confidential Information shall not be used by any recipient thereof for any business, commercial, competitive, or other purpose...." (Ex. 1, Stipulated Protective Order (Dkt. No. 64), ¶ 9 (emphasis added).) Janssen admits that it seeks to evade these terms. (Br. 8.) But it tries to modify the parties' stipulation by arguing that there have been "changed circumstances." (*Id.* at 12-13.) Not so.

Before finalizing the stipulated protective order, Defendants provided disclosures pursuant to the BPCIA, including detailed patent contentions, that notified Janssen of the key facts underlying its proposed new complaint. Yet, at no time during the negotiations did Janssen reveal its intent to use confidential information to support a new damages claim unrelated to Celltrion's biosimilar application. If Janssen wanted to loosen the confidentiality reins to allow a brand-new claim based on what it knew and suspected, it should have bargained for that contingency before agreeing to the stipulation. This Court should follow the lead of other courts and reject this type of bait-and-switch, i.e., where Janssen induced disclosure under a negotiated protective order and now asks "the court to come in and change those rules." *See, e.g.*, *Omega Homes, Inc. v. Citicorp. Acceptance Co.*, 656 F. Supp. 393, 404 (W.D. Va. 1987).

At a minimum, the Court should stay Janssen's motion pending resolution of its claim for infringement of the '083 patent in this case. That claim is based on the same weak infringement allegation. If, as we expect, that allegation is rejected, the proposed new lawsuit would be pointless. There is thus no need for the Court to even consider Janssen's motion until it resolves the '083 patent claim asserted in this case.

[redacted]

BACKGROUND

A. Congress incorporated strict confidentiality protections in the BPCIA.

In 2010, Congress enacted the BPCIA to allow the filing of an abbreviated Biologics License Application ("aBLA") that seeks approval by the Food and Drug Administration ("FDA") of a "biosimilar" to an approved biologic product. 42 U.S.C. § 262(k). The BPCIA sets forth a process under which the biosimilar applicant ("applicant") may disclose its aBLA to the reference product sponsor ("sponsor"), triggering what has been called the "patent dance"—an information exchange designed to identify and resolve relevant patent disputes. *See generally id.* § 262(*l*); 35 U.S.C. § 271(e)(2)(C).

Congress recognized that information in the biosimilar application is proprietary and highly confidential and thus expressly ensured applicants that their information will remain confidential and not be used for purposes unrelated to the aBLA. By statute, the biosimilar applicant's aBLA and manufacturing information disclosed to the sponsor are designated "confidential information." 42 U.S.C. § 262(*l*)(1)(B)(i), (2)(A). And such "[c]onfidential information shall be used for the *sole and exclusive purpose* of determining ... whether a claim of patent infringement could reasonably be asserted" under the BPCIA. 42 U.S.C. § 262(*l*)(1)(D) (emphasis added). As the statute emphasizes, this confidential information "is, and shall remain, the property" of the producing party, and thus the sponsor cannot disclose the applicant's information to "any other person or entity." *Id.* § 262(*l*)(1)(C), (E).

The BPCIA thus provides for dual layers of protection—prohibiting not only the public disclosure of confidential information, but also the "*use*[]" of any confidential information for purposes other than asserting patent infringement under the BPCIA. *Id.* § 262(*l*)(1)(C), (D). To induce applicants to produce their highly confidential information, Congress took pains to ensure that these confidentiality restrictions are taken very seriously—the statute states that any

violation "shall be deemed to cause the [biosimilar] applicant to suffer irreparable harm...." *Id.* § 262(*l*)(1)(H). And to ensure no gaps in confidentiality treatment, the statute further states that the parties "shall continue to be governed by the terms of" these confidentiality restrictions "until such time as a court enters a protective order regarding the information." *Id.* § 262(*l*)(1)(F).

If Janssen were successful in overriding the BPCIA's strict confidentiality protections, this would have broad implications for the biosimilar industry. For example, a ruling by this Court granting Janssen's motion could erode the incentive for biosimilar applicants to produce their confidential information—a production the Federal Circuit has now held is not mandated by the statute. *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499, 2015 WL 4430108, at *7 (Fed. Cir. Jul. 21, 2015) (petitions for rehearing pending).

B. Celltrion disclosed to Janssen confidential information under the BPCIA upon which Janssen relies to support its proposed new complaint.

FDA first approved Janssen's Remicade® (infliximab) product in August 1998. Janssen has enjoyed market exclusivity free of biosimilar competition in the United States for the entirety of Remicade's 17-year history (and free of biosimilar competition worldwide for nearly all of that history). According to Janssen, Remicade has become its "most successful product." (Br. 2.) But competition is coming.

In the late summer and fall of 2014, Celltrion filed and timely produced to Janssen a copy of its aBLA that included confidential information "under the confidentiality restrictions of the [BPCIA]." (Br. 4.) In February 2015, during the course of the parties' "patent dance," Defendants provided Janssen with additional confidential information in the form of a "detailed statement" of the factual and legal basis that the asserted patents are invalid, unenforceable, or not infringed. (*See* Ex. 2, Celltrion Detailed Statement.) There is no dispute that these

[redacted]

productions constitute "confidential information" as defined and protected by the BPCIA. *See* 42 U.S.C. § 262(*l*)(1)(B)(i).

This confidential information includes, [redacted] With the exception of [redacted] location, none of this information would have been available to Janssen absent Defendants' confidential disclosure.

C. Janssen sued Defendants alleging (among other things) that Celltrion uses [redacted] cell media that infringes the '083 patent.

Janssen filed this lawsuit on March 6, 2015, after Defendants agreed that Janssen could sue on each of the six patents it identified in the "patent dance." The complaint alleges that the filing of Celltrion's aBLA infringes all six patents under the BPCIA. (Dkt. No. 1.) One of those patents is the '083 patent (*id.* ¶¶ 170-74), which does not protect Remicade or its approved methods of treatment. Instead, that patent claims certain cell culture media compositions comprising 61 ingredients (two of which are optional) in specific concentration ranges that may be used to manufacture biological products.

[redacted]

[redacted] [1] (Ex. 2 at 52-53.) Yet, in April 2015, Janssen served a detailed statement under the BPCIA contending that [redacted]

D. The parties then negotiated a stipulated protective order to limit Janssen's use of confidential information to this litigation concerning the aBLA.

Since the beginning of this litigation, Defendants have worked with Janssen to expedite discovery of information that they believe confirms "Janssen has no viable infringement claim as to [the manufacturing patents]." (*See, e.g.*, Ex. 7, Apr. 8, 2015 Ltr. to Janssen, at 3.) For example, in its complaint, Janssen alleges that Celltrion did not timely produce the cell culture media formulae proprietary to its supplier, [redacted] [2] (Dkt. No. 1, ¶ 110.) To moot this dispute, Celltrion worked with its supplier [redacted] to get Janssen the information it was seeking—information that confirms what Celltrion represented in its non-infringement contentions. Not surprisingly, both Defendants and [redacted] insisted that any such disclosure of confidential information be "produced under an appropriate confidentiality order or agreement." (Ex. 7 at 3.)

On April 20, 2015, Janssen prepared and circulated a draft protective order. (*See* Ex. 8, Apr. 20, 2015 Draft Protective Order.) This draft included proposed language—never altered by the parties—making it clear that "[a]ll Confidential Information disclosed pursuant to this Order shall be used by any recipient thereof *solely for the purposes of this litigation*." (*Id.* at 8

[1] Janssen speculates that [redacted] acted improperly in developing its cell culture media. (Br. 7). This accusation is unsupported, does not concern any of the Defendants and, therefore, does not warrant a reply.

[2] The BPCIA does not require the applicant (here, Celltrion) to disclose such third-party confidential information. *See* 42 U.S.C. § 262(*l*)(1)(E) (referring to "confidential information disclosed" under the Act as "the property of the [biosimilar] applicant").

[redacted]

(emphasis added).) This language continues the confidentiality restriction of the BPCIA, which says that the "sole and exclusive purpose" of confidential information is the BPCIA litigation. 42 U.S.C. § 262(*l*)(1)(D).

On May 13, 2015, Defendants agreed to Janssen's proposed language and further suggested specific examples of improper uses for the sake of clarity. (*See* Ex. 9, May 13, 2015 Draft Protective Order at 9-10.) Defendants revised Paragraph 9 to emphasize further that confidential information cannot be used in disputes "other than this present litigation":

> Any Confidential Information shall not be used by any recipient thereof for any business, commercial, competitive, or other purpose, including, but not limited to ... (iii) *using as evidence or supporting materials in disputes or petitions to any regulatory agencies or courts in any jurisdiction or forum, regardless of country (other than this present litigation*) relating to marketing approval or sale of any infliximab or biosimilar infliximab product ...

(*See* Ex. 10, May 26, 2015 Draft Protective Order at 10.) Janssen agreed to this specific revision. (*See* Ex. 11, May 28, 2015 Email to Klein ("We can accept your proposed edit to paragraph 9."); Ex. 12, May 28, 2015 Draft Protective Order at 9-10.) On May 29, 2015, after finalizing other provisions, the parties jointly filed the stipulated protective order, which has not yet been entered by the Court. (*See* Ex. 1.)

By the time the parties agreed to the protective order terms, Janssen already had been made aware that: [redacted] and (4) both Celltrion and Hospira sell infliximab products outside of the United States. (Ex. 4 at 1; Ex. 2 at 52-53; Ex. 3 at 11, 12, 16, 20, 21, 25, 26; Dkt. No. 1 ¶ 93.) And, again, by this time, Janssen had specifically contended that [redacted] cell media infringes the '083 patent. (Ex. 6 at 76-84 (pertinent portions).)

[redacted]

Before reaching agreement on the stipulated protective order, Janssen thus had information to support the precise allegations it hopes to make in its new complaint. Yet, at no time during the negotiations of the parties' stipulated protective order did Janssen ever express any intent to use confidential information to support such new cause of action.

E. In reliance on the stipulated protective order, third-party [redacted] disclosed its confidential formulas and confirmed what Defendants previously disclosed confidentially to Janssen.

Janssen and [redacted] separately negotiated an agreement for the disclosure and inspection of the composition of [redacted] cell culture media "under the conditions set forth in the Protective Order," among other terms. (*See* Ex. 13, Inspection Agreement, at 1.) According to the agreed terms, on May 28, 2015, [redacted]

[redacted] proprietary information concerning the compositions of its cell culture media confirmed what Defendants previously disclosed confidentially to Janssen. [redacted]

[redacted] Put simply, [redacted] production provided no new information—just confirmation of what Janssen learned when Celltrion served its aBLA and detailed statement months before the parties submitted the stipulated protective order.

F. Janssen seeks to use Celltrion's and [redacted] confidential information to support a new and transparently meritless complaint.

A couple of weeks later, during a June 16, 2015 teleconference, Janssen first disclosed its intent to file a new complaint based on disclosed confidential information. The most recent draft of Janssen's proposed complaint confirms that it intends to rely on confidential information it

[redacted]

received in this litigation under the protections of the BPCIA and the stipulated protective order. (*See, e.g.*, Ex. 14, Janssen's Aug. 11, 2015 Draft Compl., ¶¶ 5, 28-31, 53-57, 61-65.)

Janssen intends to rely on such confidential information to expand dramatically its meritless claim of infringement of the '083 patent asserted in this case, which currently is limited to the filing of the aBLA. While boldly asserting that the alleged "infringement was widespread," Janssen admits that [redacted] (Br. 5-6 (emphasis added).)

The differences between the accused formulations and the patent claims are highly significant. As Janssen itself explains: "The '083 inventors spent two years of laborious scientific work to create a cell culture media that was *optimally suited* for the growth of antibody-producing cells, such as those that produce Remicade." (Br. 5-6 (emphasis added).) Janssen even emphasized that "any substantial changes in the cell culture media being used to make a biologic product will change the nature of the biologic product." (*Id.* at 3.) [redacted] (*See* Ex. 15, Jul. 14, 2015 Ltr. to Janssen, at 4.)

Of course, the absence of just one claim limitation—[redacted]—is sufficient to defeat Janssen's claim of direct infringement against third-party [redacted] *See, e.g.*, *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 19 (1997). Defendants thus notified Janssen that its proposed complaint is not only meritless, they suggested that Janssen may be attempting to file a sham lawsuit to further anticompetitive goals. (Ex. 15 at 4-5.) Janssen nonetheless has attempted to proceed with its meritless lawsuit—undeterred.

[redacted]

ARGUMENT

As discussed below, the Court should deny Janssen's motion to modify the stipulated protective order. First, Janssen concedes that it seeks to evade the strict confidentiality terms of the BPCIA, thus giving rise to a presumption of irreparable harm. Second, Janssen has failed to meet its burden of showing good cause to modify the stipulated protective order in a manner that would allow it to circumvent the statutory protections.

I. Janssen's admitted intent to evade the confidentiality protections of the BPCIA triggers the statutory presumption of irreparable harm.

The confidential information at issue in Janssen's motion is subject to the BPCIA's heightened confidentiality protections. As Janssen admits, "Celltrion provided a copy of its aBLA," [redacted] "to Janssen under the confidentiality restrictions of the [BPCIA]." (Br. 4.) Those restrictions similarly protect Defendants' disclosure of further details about [redacted] formulations, details on which Janssen relies to support its proposed complaint. (Ex. 2 at 52-53.) The BPCIA expressly limits use of this "confidential" information for "*the sole and exclusive purpose*" of this litigation. 42 U.S.C. § 262(*l*)(1)(D) (emphasis added).

Janssen admittedly seeks to use such confidential information for an entirely different purpose. (Br. 7, 12.) As Janssen explains, it hopes to sue Defendants and [redacted] "*unrelated to the BPCIA* ... to seek redress against Celltrion for its worldwide sales" of Celltrion's biosimilar product—sales that have no relation to the pending aBLA, or United States sales of the underlying biosimilar products. (*Id*. (emphasis added).) Janssen seeks leave of Court to make such use of the confidential information, and tacitly concedes it lacks a sufficient basis to bring its new complaint without the confidential information.

[redacted]

As discussed, the broad use of confidential information proposed by Janssen is presumed—by statute—to cause "irreparable harm," such that Congress has decreed that "the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation … ." 42 U.S.C. § 262(*l*)(1)(H). These BPCIA protections continue to govern "until such time as a court enters a protective order regarding the information." *id.* § 262(*l*)(1)(F), which has not yet happened. Yet, Janssen has made no effort to address, much less rebut, this presumption of irreparable harm. The practical effect of Janssen's request to evade the BPCIA's confidentiality protections is to undermine Congress' assurances to biosimilar applicants that their confidential information will be protected from expansive use.

To be sure, Janssen is not proposing that it disclose Defendants' confidential information publicly. But the statutory presumption of irreparable harm is not limited to that type of situation. It applies equally here, where Janssen seeks to expand the *use* of confidential information produced for a very limited purpose (pursuing this litigation). *Id.* § 262(*l*)(1)(D).

In short, Defendants are entitled to rely on the strict confidentiality protection afforded by statute. The congressional policy in prohibiting expansive use of confidential information disclosed under the BPCIA, alone, warrants denial of Janssen's motion.

II. Janssen has failed to show "good cause" to modify the stipulated protective order.

Even putting aside the statutory presumption of irreparable harm, Janssen also has failed to meet its burden of showing the requisite "good cause" for modifying a protective order. *OfficeMax, Inc. v. Sousa*, 2011 WL 143916, at *2 (D. Me. Jan. 14, 2011); *see also Fairchild Semiconductor Corp. v. Third Dimension Semiconductor, Inc.*, 2009 WL 1210638, at *1 (D. Me. Apr. 30, 2009) ("Fairchild, as the party seeking to modify the protective order, bears the burden of showing good cause for the modification.").

[redacted]

"To determine 'good cause,' a court must balance various factors, including change in circumstances, parties' reliance on the protective order, and third-party privacy interests." *United States v. O'Brien*, 2014 WL 204695, at *4 (D. Mass. Jan. 17, 2014). Janssen attempts to show such "good cause" by purportedly pointing to "[n]ew information supporting the filing of new allegations[.]" (Br. 10.) Indeed, absent such a showing, Janssen's request should be denied. This is because "[m]odifying or lifting an existing protective order implies a changed circumstance or a new situation warranting such relief." *United States v. Bulger*, 283 F.R.D. 46, 54 (D. Mass. 2012); *see also Pub. Citizen v. Liggett Group., Inc.*, 858 F.2d 775, 791 (1st Cir. 1988) (good cause can be shown "where the party seeking modification has pointed to some relevant change in the circumstances under which the protective order was entered").[3]

As shown below, Janssen has failed to show good cause—due to changed circumstances or otherwise. Its motion should be denied because Defendants have relied on the protective order as stipulated by the parties, and because Janssen's motion implicates the privacy interest of third-party [redacted]

A. No changed circumstances warrant modifying the stipulated protective order.

According to Janssen, it "has good cause for seeking modification because it did not know before discovery that [redacted] was making infringing cell culture media *in the United States* or that Celltrion was using that infringing cell culture media, made in *the United States*, to make its Remicade biosimilar for sale around the world." (Br. 12.) Nonsense.

[3] *See also U.S. ex rel. Franklin v. Parke-Davis*, 210 F.R.D. 257, 261 (D. Mass. 2002) ("With respect to the requirement that a party seeking a modification demonstrate changed circumstances, the Court points out that none of the circumstances that might have supported a broad order exist."); *Infineon Technologies AG v. Green Power Technologies Ltd.*, 247 F.R.D. 1, 2 (D.D.C. 2005) ("'Good cause' implies changed circumstances or new situations; a continuing objection to the terms of an order does not constitute good cause to modify or withdraw a protective order.").

[redacted]

Janssen clearly knew that "[redacted] was making [its allegedly] infringing cell culture media *in the United States*." (*Id.*) The nature and place of [redacted] business was no mystery to Janssen. [redacted] website confirms that [redacted] (Ex. 5, [redacted] Website, at 2.) Indeed, Janssen itself was familiar with [redacted] having "hired [redacted] to manufacture quantities of the cell culture media for its experiments." (Br. 7.) Janssen thus cannot credibly represent to this Court it "discover[ed]" that [redacted] was making "cell culture media *in the United States*" only after the stipulated protective order was filed.

Nor can Janssen credibly represent that it learned any new facts after the stipulated protective order that support its allegation that Celltrion was using an allegedly infringing [redacted] cell culture media to make infliximab. Janssen learned the underlying facts through confidential disclosures well before the parties agreed to the protective order in May 2015. Again, Janssen has known [redacted] no later than October 2014, when Celltrion produced its aBLA. (Ex. 3 at 20; Ex. 4 at 1.) This fact was reiterated in February 2015, when Celltrion served its BPCIA contentions, where Celltrion explained that [redacted] (Ex. 2 at 52-53.) Then, in April 2015—a month *before* the stipulated protective order was filed—Janssen specifically contended that [redacted] cell culture media, as used by Celltrion to manufacture infliximab, infringes the '083 patent. (Ex. 6 at 76-77.)

Indeed, the same day the stipulated protective order was filed, Janssen's counsel admitted: "Our understanding is that [redacted] and that the media are made there. (Ex. 16, May 29, 2015 E-mail from I. Royzman.) This "understanding" is precisely what

[redacted]

Janssen would have the Court believe it learned only through productions after the stipulated protective order was filed.

In short, there are no changed circumstances. And Janssen's purported "good cause" is nothing of the sort. It is a contrived argument designed to justify the bait-and-switch litigation tactic described in more depth below. *See, e.g.*, *O'Brien*, 2014 WL 204695, at *4 (declining to modify protective order after finding no change in circumstances); *see also Heffernan v. City of Chicago*, 286 F.R.D. 332, 335 (N.D. Ill. 2012) (citing cases).

B. The stipulated protective order deserves greater deference because the parties negotiated it, and Defendants relied on it.

Courts have explained that where, as here, the parties negotiated a protective order, "there is a higher burden on the movant to justify modification of the order." *Ares-Serono, Inc. v. Organon Int'l B.V.*, 862 F. Supp. 603, 609 (D. Mass. 1994) (quotation omitted); *Fairchild Semiconductor Corp.*, 2009 WL 1210638, at *1 n.5 ("When a party to a stipulated protective order seeks to modify that order, that party must demonstrate particular good cause to obtain relief.") (quoting *Guzhagin v. State Farm Mut. Auto Ins. Co.*, 2009 WL 294305, at *2 (D. Minn. Feb. 5, 2009)).

When the protective order is "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." *Omega Homes*, 656 F. Supp. at 404. This rule holds particularly firm where, as here, the non-moving party relied on the negotiated language of the stipulated protective order. While Janssen gives this consideration short shrift (Br. 14), reliance on a protective order is "a *major factor* to take into account when deciding whether or not to allow disclosure ...." *Valentin By & Through Valentin v. Richardson*, 110 F.R.D. 622, 625 (D. Mass. 1986) (emphasis added); *see also Bulger*,

[redacted]

283 F.R.D. at 54 (D. Mass. 2012) ("[I]t is appropriate to consider and evaluate the reliance of a party to the protective order … ."); *Chicago Mercantile Exch., Inc. v. Tech. Research Grp., LLC*, 276 F.R.D. 237, 240 (N.D. Ill. 2011) (discussing the reliance factor).

Because protective orders reduce conflict and "facilitate[] the flow of information through discovery, ... changing the ground rules later is to be avoided because protective orders that cannot be relied upon will not foster cooperation through discovery." 8A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2044.1 (3d ed.); *see also AT & T Corp. v. Sprint Corp.*, 407 F.3d 560, 562 (2d Cir. 2005) ("It is 'presumptively unfair for courts to modify protective orders which assure confidentiality and upon which the parties have reasonably relied.'") (quoting *S.E.C. v. TheStreet.com*, 273 F.3d 222, 230 (2d Cir. 2001)). Some courts view a negotiated order "as a contract, and once parties enter an agreed protective order they are bound to its terms, absent good cause to modify or vacate the protective order." *Paine v. City of Chicago*, 2006 WL 3065515, at *2 (N.D. Ill. Oct. 26, 2006); *see also Chicago Mercantile Exch., Inc.*, 276 F.R.D. at 240 (viewing a modification of a protective order negotiated by the parties "with a critical eye.").

The entry of the protective order on May 29, 2015, resulted from weeks of negotiation—again, after Janssen already had (and "under[stood]," Ex. 16) the facts underlying its proposed complaint. The provisions of the protective order that Janssen seeks to modify was the focus of much of that negotiation. (*See supra* Background at Part D.) During those negotiations, however, Janssen never suggested it intended to (or even might) use confidential information to bring a new complaint in strict violation of the agreed terms seeking damages for sales overseas.

Indeed, Janssen was well-aware that Defendants were unwilling to produce additional information beyond Celltrion's aBLA and contentions (which are protected by the BPCIA), in

[redacted]

particular third-party confidential information, until the parties fully negotiated a protective order. (*See, e.g.*, Ex. 7 at 3.) But at Janssen's request, Defendants agreed to negotiate—and then relied on—the stipulated protective order. (*See* Ex. 17, May 15, 2015 Ltr. to Janssen, at 1.) Under the agreed terms, Defendants produced additional confidential information and, more importantly, facilitated the production of confidential information from third-party [redacted] (*Id.* at 2-4) Operating under a negotiated inspection agreement that is "[s]ubject to the terms of the Confidentiality Agreement Protective Order," [redacted] produced to Janssen the formulae for its cell culture media. (Ex. 13 at 1.)

Janssen convinced Defendants to make and facilitate these productions based on assurances that the confidential information would be subject to the protections of the stipulated protective order—including a confidentiality provision Janssen itself drafted. Again, not once did Janssen disclose its intent to loosen the stipulated confidentiality restrictions and use the disclosed information to support a new and wide-reaching lawsuit addressing sales overseas, much less a new lawsuit against third-party [redacted]

Janssen's almost-immediate about face—i.e., its request to modify key provisions of the stipulated protective order just weeks after it was filed—deserves close scrutiny. Its bait-and-switch litigation is, to borrow Janssen's term, "disturbing." (Br. 7.) Another district court reached the same conclusion under similar circumstances: "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. Omega's motion to modify the stipulated protective order will be denied." *Omega Homes*, 656 F. Supp. at 404. The same result—denial of the motion to modify—is warranted here.

[redacted]

C. Janssen's motion also raises third-party concerns.

[redacted] interests also weigh in favor of denying Janssen's motion. Courts in the First Circuit have recognized the importance of third-party interests. *See O'Brien*, 2014 WL 204695, at *2 ("Protection of third-party privacy is an important interest."); *United States v. Swartz*, 945 F. Supp. 2d 216, 220 (D. Mass. 2013) ("The interests of third parties bear particular emphasis because much of the discovery materials sought were produced by victims … and the information sought to be disclosed involves the identities of their representatives.").

Despite Janssen's repeated requests, Defendants were not authorized to produce [redacted] confidential information absent consent. Through the negotiated protective order, Janssen induced [redacted]—a third party to this case—to produce its highly confidential and proprietary formulae. Now, despite its assurances in the stipulated protective order, Janssen seeks to use that disclosure (which confirmed Celltrion's earlier confidential disclosures) to justify a new complaint against [redacted] This is fundamentally unfair not just to Defendants, but also to [redacted] These third-party concerns, too, thus support denying Janssen's motion.

D. Janssen's intervenor cases and policy arguments are irrelevant.

To support its position, Janssen relies throughout its analysis on an inapposite line of cases where a "collateral litigant," or intervenor, sought to reduce the burden of discovery in collateral litigation by amending a protective order that the intervenor played no role in drafting. (*See, e.g.*, Br. 9, 11.) But Janssen is not an intervenor. Instead, Janssen is proposing to modify language that it proposed, negotiated, and ultimately decided to live with.

The court in *OfficeMax Inc. v. Sousa*, cited by Janssen, faced a similar situation. There, the plaintiff (OfficeMax) asked the court to modify the protective order so it could use materials in a forthcoming lawsuit against a third party. 2011 WL 143916, at *1. In denying the motion, the court noted that it was OfficeMax, not the collateral litigant, seeking to modify the protective

[redacted]

order. *Id.* at *2. The court denied the motion to amend the order, finding that OfficeMax did not show "good cause to modify the consent confidentiality order." *Id.* at *2. The same is true here.

Janssen also argues that its stipulated protective order should be modified to avoid shielding Defendants from liability, but this argument misses the point. *Before* stipulating to the protective order terms, Defendants already provided Janssen with information it now argues is sufficient to support a new complaint. Thus, during the protective order negotiations designed to continue the confidentiality protections afforded by the BPCIA, Janssen could have tried to bargain for a provision allowing it to use Defendants' and [redacted] confidential information to support such a complaint. But Janssen elected not to bargain for such a provision. It should be held to the bargain it struck. This is particularly true here, where the BPCIA makes clear that the purpose of the confidential disclosure is limited, and disclosed information cannot be used for other litigation matters. Janssen has provided no basis to circumvent congressional intent.

Moreover, Defendants have no infringement liability to be shielded—because Janssen's proposed complaint is transparently meritless. First, as discussed above, Janssen readily concedes that the cell culture media at issue do not meet [redacted] claim elements. (Br. 6.) Second, Janssen could not prove direct infringement by Defendants even if the cell culture media did meet all claim elements, because [redacted][4] Third, Janssen could not prove the required specific intent for induced infringement, because Defendants plainly have a

[4] [redacted]

[redacted]

reasonable belief that the cell culture media, [redacted] is not infringing. *See, e.g.*, *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1351 (Fed. Cir. 2009) (holding that a reasonable belief of non-infringement supported a jury verdict that the accused infringer lacked the intent required for induced infringement). Fourth, Janssen cannot leverage its U.S. cell culture media patent to threaten a lost-profits damages award based on foreign sales of Defendants' biosimilar products. *See WesternGeo L.L.C. v. ION Geophysical Corp.*, 791 F.3d 1340, 1350-51 (Fed. Cir. 2015) ("[W]e find neither compelling facts nor a reasonable justification for finding that [the patentee] is entitled to 'full compensation' in the form of damages based on loss of sales in foreign markets which it claims were a foreseeable result of infringing conduct in the United States.") (citation omitted).

For these reasons, Janssen's motion should be denied.

CROSS-MOTION TO STAY JANSSEN'S MOTION

As discussed above, the Court should deny Janssen's motion. But if this Court were inclined to give Janssen's motion serious consideration, the Court should, instead, stay that motion pending resolution of the '083 patent claim in this case. Such a stay would avoid unnecessary litigation and preserve judicial resources.

Janssen already has sued Defendants for infringing the '083 patent based on the "same allegations" underlying its proposed new complaint—namely, that [redacted] manufactures cell culture media that infringes under the doctrine of equivalents. (Br. 6-7.) Again, this allegation is meritless. And if (as we expect) the Court rejects Janssen's unprecedented application of the doctrine of equivalents, such a ruling would doom Janssen's proposed complaint as well.

Thus, if this Court were not inclined to deny Janssen's motion outright, prudence would dictate that the Court decide the '083 infringement claim in this case first and then, only if necessary, address whether Janssen's proposed second case is warranted. Of course, the Court

[redacted]

"may, in its discretion, defer or abate proceedings where another suit, involving identical issues, is pending in either a federal or state court, and where it would be duplicative, uneconomical, and vexatious to proceed otherwise." *Salomon S.A. v. Scott USA Ltd. P'ship*, 117 F.R.D. 320, 321 (D. Mass. 1987); *cf. Small v. Wageman*, 291 F.2d 734, 735 (1st Cir. 1961) ("[T]he power of one federal district court to enjoin a party from undertaking to litigate the same question with the same opponent in another federal district court has most often been exercised in patent … litigation."). Although Janssen's proposed complaint also names [redacted] as a defendant, adding a new party to litigation does not warrant litigation of duplicative issues. *See Foster Wheeler Corp. v. Aqua-Chem, Inc.*, 277 F. Supp. 382, 385 (E.D. Pa. 1967) ("[I]t is a general rule that an action may and will be stayed in a court of concurrent federal jurisdiction which receives the case after another court already has an action pending involving issues and parties that are substantially identical … and even where the formal parties in the two suits are not identical.").

These principles, designed to avoid duplicative litigation, support staying Janssen's motion until entry of judgment on the '083 patent. Such a stay would prevent needless duplication of time and resources for simultaneous litigation as well as possible counterclaims.[5]

CONCLUSION

Defendants request that this Court deny Janssen's motion to modify the stipulated protective order to permit filing of a new action or, in the alternative, grant Defendants' cross-motion to stay Plaintiffs' motion pending this Court's judgment on the '083 patent.

[5] Janssen cannot justify its proposed new complaint by pointing to its prayer for preliminary injunctive relief. For example, controlling precedent bars preliminary injunctive relief where the defendant "raises a substantial question concerning ... infringement[.]" *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361, 1366 (Fed. Cir. 2013). Defendants have raised such a question here given Janssen's heavy reliance on the doctrine of equivalents. *See Jeneric/Pentron, Inc. v. Dillon Co., Inc.*, 205 F.3d 1377, 1384 (Fed. Cir. 2000) (noting, when affirming a denial of preliminary injunction, that the "highly factual inquiry" involved in allegations "under the doctrine of equivalents" "rarely comes clear on a premature record").

[redacted]

Dated: September 4, 2015

Respectfully submitted,

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

By their attorneys,

By: /s/Andrea L. Martin
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Attorneys for Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc.

[redacted]

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 4, 2015.

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

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

DEFENDANTS' CROSS-MOTION TO STAY

Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira Inc. (collectively "Defendants"), hereby cross-move this Court to stay action on Plaintiffs' Motion to Modify the Protective Order to Permit Filing of a New Action ("Motion to Modify") [*Dkt 69-1*]. As set forth more fully in Defendants' contemporaneously filed Brief (pages 19-20), Plaintiffs seek to modify the stipulated Protective Order to bring a separate lawsuit based on a patent infringement allegation presently before this Court. To the extent the Court were not inclined to deny Plaintiffs' Motion to Modify outright, a stay of Plaintiff's proposed Motion to Modify would prevent needless duplication of time and resources devoted to simultaneous litigation and would preserve judicial resources.

WHEREFORE, Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira Inc. respectfully request that this Court at least stay Plaintiffs' Motion to Modify the Protective Order and grant such other and further relief as this Court deems just.

Dated: September 4, 2015

Respectfully submitted,

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

By their attorneys,

/s/Andrea L. Martin

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LR 7.1(a)(2) CERTIFICATION

I, Andrea L. Martin, hereby certify that Defendants' counsel has conferred with Plaintiffs' counsel and attempted in good faith to resolve or narrow the issue raised in this motion. Plaintiffs assert that they will oppose this Cross-Motion.

/s/Andrea L. Martin, Esq.
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 4, 2015.

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

4817-8253-2136.1

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

DECLARATION OF DAN H. HOANG IN SUPPORT OF DEFENDANTS' OPPOSITION TO JANSSEN'S MOTION TO MODIFY THE STIPULATED PROTECTIVE ORDER AND CROSS-MOTION TO STAY

I, Dan H. Hoang, declare as follows:

1. I am an attorney at the Chicago office of Winston & Strawn representing Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc. in the above-captioned case. I am a member in good standing of the Bar of the State of Illinois and have been admitted to practice *pro hac vice* by Order of this Court dated April 8, 2015, Dkt. 33.

2. I offer this declaration in support of Defendants' Opposition to Janssen's Motion to Modify the Stipulated Protective Order and Cross-Motion to Stay, filed concurrently herewith.

3. Attached hereto as **Exhibit 1** is a true and correct copy of the Stipulated Protective Order, Dkt. No. 64.

4. Attached hereto as **Exhibit 2** is a true and correct copy of the Detailed Statement of Celltrion, Inc. Pursuant to the Biologics Price Competition and Innovation Act of 2009, 42 U.S.C. § 262(*l*)(3)(B), for aBLA 125544 for Reference Product Remicade® (Infliximab).

5. Attached hereto as **Exhibit 3** is an excerpted copy of Section 3.2.S.2.3 (Control of Materials) from Celltrion's aBLA 125544.

6. Attached hereto as **Exhibit 4** is a true and correct copy of a Certificate of Analysis from Celltrion's third-party supplier from the Appendix to Section 3.2.S.2.3 (Certificate of Analyses of Raw Materials) from Celltrion's aBLA 125544.

7. Attached hereto as **Exhibit 5** is a true and correct copy of the website of Celltrion's third-party supplier (last accessed on August 31, 2015).

8. Attached hereto as **Exhibit 6** is a true and correct copy of the Detailed Statement of Janssen Biotech, Inc. and New York University Pursuant to 42 U.S.C. § 262(*l*)(3)(C) for aBLA 125544.

9. Attached hereto as **Exhibit 7** is a true and correct copy of the April 8, 2015 Letter from Charles B. Klein to Dianne B. Elderkin.

10. Attached hereto as **Exhibit 8** is a true and correct copy of the April 20, 2015 draft of the Stipulated Protective Order from Janssen.

11. Attached hereto as **Exhibit 9** is a true and correct copy of the May 13, 2015 draft of the Stipulated Protective Order from Defendants.

12. Attached hereto as **Exhibit 10** is a true and correct copy of the May 26, 2015 draft of the Stipulated Protective Order from Defendants.

13. Attached hereto as **Exhibit 11** is a true and correct copy of the May 28, 2015 email from Barbara L. Mullin to Charles B. Klein.

14. Attached hereto as **Exhibit 12** is a true and correct copy of the May 28, 2015 draft of the Stipulated Protective Order from Janssen.

15. Attached hereto as **Exhibit 13** is a true and correct copy of the May 27, 2015 inspection agreement between Celltrion's third-party supplier and Janssen.

16. Attached hereto as **Exhibit 14** is a true and correct copy of the August 11, 2015 draft Complaint by Janssen.

17. Attached hereto as **Exhibit 15** is a true and correct copy of the July 14, 2015 letter from Charles B. Klein to Irena Royzman and Barbara L. Mullin.

18. Attached hereto as **Exhibit 16** is a true and correct copy of the May 29, 2015 e-mail from Irena Royzman to Charles B. Klein.

19. Attached hereto as **Exhibit 17** is a true and correct copy of the May 15, 2015 Letter from Charles B. Klein to Barbara L. Mullin and Irena Royzman.

20. Attached hereto as **Exhibit 18** is a true and correct copy of the Supply Agreement Between Celltrion, Inc. and its supplier.

Executed in Chicago, Illinois on September 4, 2015.

/s/ Dan H. Hoang

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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 4, 2015.

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

4812-8655-5688.1

EXHIBIT 1

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. **Defendants.**	)	

STIPULATED PROTECTIVE ORDER

WHEREAS, Plaintiffs Janssen Biotech, Inc. and New York University (collectively "Plaintiffs") and Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira, Inc. (collectively "Defendants"), the parties to this action (collectively the "parties"), possess confidential information which may be disclosed in litigating this action and which must be protected in order to preserve the legitimate business and other interests of the parties, and

WHEREAS, the parties have, through counsel, stipulated to the entry of this Protective Order to prevent unnecessary dissemination or disclosure of such confidential information,

IT IS HEREBY ORDERED that:

Definitions

1. The following definitions shall apply to this Order:

a. The term "Confidential Information" as used in this Order is to include all information that the Designating Party believes constitutes, discloses, or relates to research and development information (including, but not limited to, processes, operations, technical materials, or production); regulatory information (including, but not limited to, correspondences with the FDA); financial information (including, but not limited to, marketing, sales, or shipments); private or confidential personal information; proprietary data or information of commercial value (including, but not limited to, trade secrets); or any other information that the Designating Party believes in good faith to be entitled to protection under Rule 26(c)(1) of the Federal Rules of Civil Procedure. It may include, without limitation: documents produced in this action, during formal discovery or otherwise; documents and information produced by third parties which the Designating Party is under an obligation to maintain in confidence; pleadings, portions of briefs, memoranda, or other writings filed with the Court; answers to interrogatories and

responses to requests for admission or other discovery requests; deposition or trial transcripts; infringement contentions and noninfringement contentions; and tangible things or objects that are designated confidential pursuant to this Order. The information contained therein and all copies, abstracts, excerpts, analyses or other writings that contain, reflect, reveal, suggest or otherwise disclose such Confidential Information shall also be deemed Confidential Information. Information originally designated as Confidential Information pursuant to this agreement shall not retain Confidential status after any ruling by any Court denying such status.

b. The term "Designating Party" means the party producing or designating documents or information as Confidential Information under this Order.

c. The term "Receiving Party" shall mean any person to whom Confidential Information is disclosed.

Designation of Confidential Information

2. Any party who produces or discloses any material that it believes comprises Confidential Information shall designate the same by marking "CONFIDENTIAL" prominently on the face of each document containing the Confidential Information.

3. If a Designating Party elects to produce original files and records for inspection and the inspecting party desires to inspect those files, the Designating Party shall give notice of the confidentiality of any files or records in advance of the initial inspection, and the party inspecting such files and records shall maintain the confidentiality of all those original files and records that it reviews. Thereafter, upon selection of specified documents for copying by the inspecting party, the Designating Party shall mark the copies of such documents as may contain

Confidential Information with the appropriate designation at the time the copies are produced to the inspecting party.

4. If any Confidential Information is produced by a third party to this litigation, such third party shall be considered a Designating Party within the meaning of that term as it is used in the context of this Order and all parties to this Order should be treated as Receiving Parties.

5. Confidential Information that originated with a third party, subject to the terms of any confidentiality obligation to that third party, may be designated as "CONFIDENTIAL" and shall, once designated, be subject to the restrictions on disclosure specified in Paragraph 7. The parties may agree to additional restrictions to satisfy third party confidentiality concerns.

6. In the event any Designating Party produces Confidential Information that has not been designated "CONFIDENTIAL" or not correctly designated, the Designating Party may designate or redesignate the information to the same extent as it may have designated the information before production. The Designating Party may do so by a subsequent notice to all parties in writing specifically identifying the redesignated information accompanied by a replacement set of such misdesignated documents bearing a "CONFIDENTIAL" designation thereon. Upon receiving such notice, the parties shall henceforth treat such information in accord with this Protective Order, and shall undertake their best efforts to correct any disclosure of such information contrary to the redesignation. Further, the Receiving Party shall immediately dispose of or return to the Designating Party the documents that lacked the "CONFIDENTIAL" designation upon receiving the replacement set of documents bearing the "CONFIDENTIAL" designation. No showing of error, inadvertence, or excusable neglect shall be required for such redesignation.

Disclosure of Confidential Information

7. Information designated "CONFIDENTIAL" shall not be given, shown, made available or communicated in any way to any person or entity other than the following:

a. Outside litigation counsel for Plaintiffs, provided that the outside litigation counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action, except as expressly permitted below:

i. Akin Gump Strauss Hauer & Feld LLP (Outside litigation counsel may be involved in any appeal of the reexamination proceedings relating to U.S. Patent 6,284,471 before the Patent Trial and Appeal Board, Federal Circuit, or U.S. Supreme Court, but they may not advise or be involved in any discussion or consideration of claim amendments of the patent or any other patents);

ii. Patterson Belknap Webb & Tyler LLP (Outside litigation counsel may be involved in any appeal of the reexamination proceedings relating to U.S. Patent 6,284,471 before the Patent Trial and Appeal Board, Federal Circuit, or U.S. Supreme Court, but they may not advise or be involved in any discussion or consideration of claim amendments of the patent or any other patents); and

iii. Nutter McClennen & Fish LLP.

b. In-house counsel for Plaintiffs (or Plaintiffs' related corporate entities, such as Johnson & Johnson), provided that the in-house counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any

reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action, except as expressly permitted below:

i. Eric Harris, Assistant General Counsel and Chief Antitrust Counsel, Johnson & Johnson (Mr. Harris may be involved in any appeal of the reexamination proceedings relating to U.S. Patent 6,284,471 before the Patent Trial and Appeal Board, Federal Circuit, or U.S. Supreme Court, but he may not advise or be involved in any discussion or consideration of claim amendments of the patent or any other patents);

ii. Joseph Braunreuther, Deputy General Counsel, Johnson & Johnson (Mr. Braunreuther may be involved in any appeal of the reexamination proceedings relating to U.S. Patent 6,284,471 before the Patent Trial and Appeal Board, Federal Circuit, or U.S. Supreme Court, but he may not advise or be involved in any discussion or consideration of claim amendments of the patent or any other patents); and

iii. Brian Carey, Assistant General Counsel – Patents, Johnson & Johnson and Janssen Research and Development, LLC.

c. Outside litigation counsel for Defendants, provided that the outside litigation counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing,

method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action:

i. Winston & Strawn LLP;

ii. Kirkland & Ellis LLP; and

iii. Burns & Levinson LLP.

d. In-house counsel for Defendants (or Defendants' related corporate entities, such as Hospira, Pty Ltd.), provided that the in-house counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action:

i. Leah Taylor, Vice President of Intellectual Property, Hospira, Pty Ltd.;

ii. Sehoon Kim, Senior Litigation Counsel, Celltrion, Inc.;

iii. David Kim, Litigation Counsel, Celltrion, Inc.; and

iv. Kwisu Park, Patent Attorney, Celltrion, Inc.

e. Members or employees of any of the foregoing law firms assisting in this litigation (e.g., secretarial, paralegal, clerical, data processing personnel) as well as any independent litigation support providers retained by such firms to assist in this litigation (e.g., court reporters, litigation support personnel, outside copy services, graphic artists and visual aid providers, and jury consultants).

f. The Court and Court personnel and stenographic/videographic reporters at depositions taken in this action.

g. Independent consultants or experts and their staff not employed by or affiliated with a party or with a party's licensee or licensor, retained by the attorneys for the parties either as technical consultants or expert witnesses for the purposes of this litigation, provided that (i) such persons have complied with the procedure of Paragraph 12 herein, and (ii) agree in writing to be bound by the provisions of this Order, in the form set forth as Exhibit A, hereto.

h. The category of individuals listed in Paragraphs 7(g) will only be permitted access to Confidential Information in the following circumstances: (1) upon the individual's agreement in writing to be bound by the provisions of this Order, in the form set forth as Exhibit A hereto; and (2) upon either of the following: (i) a grant of consent by the Designating Party; or (ii) the expiration of fourteen (14) days from the date of written notice of intent to disclose without written notice of objection from the Designating Party. In the event the Designating Party does provide notice of objection to disclosure, a party must seek leave of the Court to make the disclosure and may not make such disclosure without an order of the Court authorizing such disclosure.

i. The list of persons to whom Confidential Information may be disclosed may be expanded or modified by mutual agreement in writing by counsel for the Designating Party and the Receiving Party without necessity of modifying this Order.

j. The Receiving Party shall give notice of this Order and advise of the duty to comply with its terms to any person allowed access to Confidential Information prior to allowing said person access to Confidential Information.

No Waiver of Privileges

8. Inadvertent production of documents or information subject to attorney-client privilege, work product immunity, or any other applicable privilege or immunity shall not constitute a waiver of, nor a prejudice to, any claim of such privilege or immunity, provided that the Designating Party notifies the Receiving Party in writing promptly after discovery of such inadvertent production and provides the basis for the claim of privilege or immunity in accordance with Federal Rule of Civil Procedure 26(b)(5)(B). After receiving written notice from the Designating Party that the document or information subject to attorney-client privilege, work product immunity, or any other applicable privilege or immunity has been inadvertently produced, the Receiving Party shall promptly return, sequester, or destroy such inadvertently produced document or information and all copies thereof. No use shall be made of such documents other than to challenge the propriety of the asserted privilege or immunity, nor shall they be shown to anyone who has not already been given access to them subsequent to the request to return or destroy them. No demonstration or proof of error, inadvertence, excusable neglect, or absence of negligence shall be required of the Designating Party in order for such party to avail itself of the provisions of this paragraph. Nothing herein restricts the right of the Receiving Party to challenge the Designating Party's claim of privilege or immunity, if appropriate, within a reasonable time after receiving notice of the inadvertent production.

Use and Control of the Confidential Information

9. Other than by permission of the disclosing party or court order, all Confidential Information disclosed pursuant to this Order shall be used by any recipient thereof solely for the purposes of this litigation. Any Confidential Information shall not be used by any recipient thereof for any business, commercial, competitive, or other purpose, including, but not limited

to: (i) filing a citizen petition to the FDA relating to any infliximab or biosimilar infliximab product, (ii) prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, (iii) using as evidence or supporting materials in disputes or petitions to any regulatory agencies or courts in any jurisdiction or forum, regardless of country (other than this present litigation) relating to marketing approval or sale of any infliximab or biosimilar infliximab product, or (iv) evaluating whether to license or acquire patents relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, except for what is reasonably necessary to permit the parties to engage in meaningful settlement discussions of the present litigation. It shall be the duty of each party and each individual having notice of this Protective Order to comply with this Order from the time of such notice.

10. All depositions shall be marked "CONFIDENTIAL" regardless of whether a designation of confidentiality was made on the record or otherwise and shall be subject to this Protective Order, unless and until the Receiving Party makes a request to the party producing the witness or counsel for the witness to release the deposition or any portion thereof from confidential treatment, and only if, and to the extent that, the party producing the witness or counsel for the witness agrees in writing to the modification of treatment of all or part of the transcript, or unless the Court so orders. If the party producing the witness or counsel for the witness fails to respond to such a request within fourteen (14) days, the Receiving Party may move the Court for an order releasing the requested transcript or portion thereof from confidential treatment.

11. All Confidential Information that is filed with the Court, and any pleadings, motions or other papers filed with the Court disclosing any Confidential Information, shall be filed and maintained in Court under seal. Where practical, only confidential portions of filings with the Court shall be filed under seal.

12. Before any independent consultant or expert may be given access to Confidential Information under Paragraph 7(g), the party seeking to provide such access must give written notice to the attorneys for the Designating Party of the intention to make such disclosure, and provide the following information regarding such independent consultant or expert:

i. Name and address;

ii. Business title and business affiliation;

iii. Resume of his or her background and qualifications, including employment history for the last ten (10) years;

iv. Any past or present relationships with any of the parties;

v. All cases in which the individual has testified in a deposition or at trial in the past four (4) years, and identification of the party on whose behalf the expert testified; and

vi. An executed copy of Exhibit A.

Within fourteen (14) days from the service of such written notice, the Designating Party may object to such disclosure by service of a written notice of objection on the attorneys for the party seeking to make the disclosure, stating the reasons for the objection. No disclosure of Confidential Information to any such person may occur prior to the expiration of fourteen (14) days from the date of service of the written notice of intent to disclose unless consent is granted earlier by the Designating Party. If the Designating Party gives notice of objection to disclosure,

the party seeking to make the disclosure must seek leave of the Court to make the disclosure and may not make such disclosure without an order of the Court authorizing such disclosure.

13. Nothing in this Order shall prevent or otherwise restrict counsel for a party from rendering legal advice to such party with respect to the litigation and, in the course thereof, relying upon an examination of Confidential Information; provided, however, that in rendering such advice and in otherwise communicating with the party, counsel shall not disclose Confidential Information.

14. Nothing herein shall prevent any party from disclosing its own Confidential Information in any manner that it considers appropriate. Additionally, counsel for any party shall be entitled to show or use Confidential Information obtained from a Designating Party, during examination, either at deposition or at any hearing or trial, of any officer, employee, Rule 30(b)(6) designee, or retained expert of that Designating Party. Counsel for any party shall also be entitled to show or use Confidential Information obtained from a Designating Party, during examination, either at deposition or at any hearing or trial, of any person who is apparently an author, creator, or recipient of the Confidential Information (provided that all in attendance are subject to this protective order).

Duration of Order, Objections, Modifications

15. This Protective Order shall remain in force and effect until modified, superseded or terminated by order of this Court, which may be entered pursuant to agreement of the parties hereto. This Protective Order shall continue in effect after termination of this action and continue to be binding upon all persons to whom Confidential Information is disclosed hereunder.

16. Upon final termination of this action (including all appeals) the Receiving Party shall, within thirty (30) days of such termination, either return to the Designating Party or

destroy all Confidential Information in its possession. In either event, the Receiving Party shall certify their return or destruction, with the exception that the outside litigation counsel designated in Paragraphs 7(a) and (c) may retain copies of the pleadings or other papers filed with the Court or served in the course of the litigation, depositions transcripts, deposition exhibits and the trial record. Nothing herein shall restrict the ability of the parties or their counsel to retain information or documents not designated as Confidential Information by the Designating Party.

17. If the Receiving Party learns that Confidential Information produced to it is disclosed to or comes into the possession of any person other than in the manner authorized by this Order, the Receiving Party responsible for the disclosure must immediately inform the Designating Party of such disclosure and shall make a good faith effort to retrieve any documents or things so disclosed and to prevent disclosure by each unauthorized person who received such information.

18. Any Receiving Party may at any time request that the Designating Party remove the "CONFIDENTIAL" designation with respect to any document, object or information. Such request shall be served on counsel for the Designating Party, and shall particularly identify the designated Confidential Information that the Receiving Party contends is not confidential and the reasons supporting its contention. If the Designating Party does not agree to remove the "CONFIDENTIAL" designation within fourteen (14) days, then the party contending that such documents or information are not confidential may file a motion to remove such information from the restrictions of this Order.

Miscellaneous

19. This Protective Order may be modified only by written agreement of the parties or further order of the Court and is without prejudice to the rights of any party or third party to seek additional or different relief from the Court not specified in this Order.

20. The designation by counsel for the Designating Party of any document, material or information as constituting or containing Confidential Information is intended solely to facilitate the preparation and trial of this case, and such designation shall not be construed in any way as an admission or agreement by any party that such document, material or information constitutes or contains any Confidential Information as a matter of law.

21. In the event Confidential Information disclosed during the course of the litigation is sought by any person or entity not a party to this litigation, whether by subpoena in another action or service with any legal process, the party receiving such subpoena or service shall promptly notify in writing outside counsel for the Designating Party if such subpoena or service demands the production of Confidential Information of such Designating Party. Any such person or entity seeking such Confidential Information by attempting to enforce such subpoena or other legal process shall be apprised of this Protective Order by outside counsel for the party upon whom the subpoena or process was served. Nothing herein shall be construed as requiring anyone covered by this Protective Order to contest a subpoena or other process, to appeal any order requiring production of Confidential Information covered by this Protective Order, or to subject itself to penalties for non-compliance with any legal process or order.

22. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the aggrieved party immediately may apply to obtain injunctive relief against any such person violating or threatening to violate any of the terms of this Protective Order, and in the

event that the aggrieved party does so, the responding party, subject to the provisions of this Protective Order, shall not employ as a defense thereto the claim that the aggrieved party possesses an adequate remedy at law.

23. Nothing herein shall prevent any party or non-party from seeking additional or different relief from the Court not specified in this Order.

24. The section titles in this Order are for convenience of organization only, and are not part of, nor are they relevant to the construction of this Order.

25. All parties shall be bound by the terms of this Order pending its entry by the Court.

SIGNED this 29 day of May 2015.

Dated: May 29, 2015

/s/ Charles B. Klein

WINSTON & STRAWN LLP
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1700 K Street, N.W.
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Dated: May 29, 2015

/s/ Heather B. Repicky

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Barbara L. Mullin (admitted *pro hac vice*)
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Attorneys for Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira Inc.

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PATTERSON BELKNAP WEBB & TYLER LLP
Gregory L. Diskant (admitted *pro hac vice*)
Irena Royzman (admitted *pro hac vice*)
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Email: iroyzman@pbwt.com
Email: afischer@pbwt.com
Email: acohen@pbwt.com

Attorneys for Janssen Biotech, Inc. and New York University

IT IS SO ORDERED.

DATED: _____

_____

Honorable Mark L. Wolf,
United States District Senior Judge

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed through the electronic filing system and served electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Heather B. Repicky

EXHIBIT 2

[Filed Under Seal]

EXHIBIT 3

[Filed Under Seal]

EXHIBIT 4

[Filed Under Seal]

EXHIBIT 5

[Filed Under Seal]

EXHIBIT 6

[Filed Under Seal]

EXHIBIT 7

[Filed Under Seal]

EXHIBIT 8

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. **Defendants.**	)	

STIPULATED PROTECTIVE ORDER

WHEREAS, Plaintiffs Janssen Biotech, Inc. and New York University (collectively "Plaintiffs") and Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira, Inc. (collectively "Defendants"), the parties to this action (collectively the "parties"), possess confidential information which may be disclosed in responding to discovery requests or otherwise in this action and which must be protected in order to preserve the legitimate business and other interests of the parties, and

WHEREAS, the parties have, through counsel, stipulated to the entry of this Protective Order to prevent unnecessary dissemination or disclosure of such confidential information,

IT IS HEREBY ORDERED that:

Definitions

1. The following definitions shall apply to this Order:

a. The term "Confidential Information" as used in this Order is to include all information that the Designating Party believes constitutes or discloses or relates to processes, operations, research, technical or developmental information, production, marketing, sales, shipments or other proprietary data or information of commercial value, including, but not limited to, trade secrets. It may include, without limitation: documents produced in this action, during formal discovery or otherwise; documents and information produced by third parties which the Designating Party is under an obligation to maintain in confidence; answers to interrogatories and responses to requests for admission or other discovery requests; deposition transcripts; and tangible things or objects that are designated confidential pursuant to this Order. The information contained therein and all copies, abstracts, excerpts, analyses or other writings that contain, reflect, reveal, suggest or otherwise disclose such Confidential Information shall also be deemed

Confidential Information. Information originally designated as Confidential Information pursuant to this agreement shall not retain Confidential status after any ruling by any Court denying such status.

b. The term "Designating Party" means the party producing or designating documents or information as Confidential Information under this Order.

c. The term "Receiving Party" shall mean any person to whom Confidential Information is disclosed.

Designation of Confidential Information

2. Any party who produces or discloses any material that it believes comprises Confidential Information shall designate the same by marking "CONFIDENTIAL" prominently on the face of all documents containing the information.

3. If a Designating Party elects to produce original files and records for inspection and the inspecting party desires to inspect those files, no confidentiality designations need be made by the Designating Party in advance of the initial inspection, but the party inspecting such files and records shall maintain the confidentiality of all those original files and records that it reviews. Thereafter, upon selection of specified documents for copying by the inspecting party, the Designating Party shall mark the copies of such documents as may contain protected subject matter with the appropriate designation at the time the copies are produced to the inspecting party.

4. If any Confidential Information is produced by a third party to this litigation, such third party shall be considered a Designating Party within the meaning of that term as it is used in the context of this Order and all parties to this Order should be treated as Receiving Parties.

5. Confidential Information that originated with a third party, subject to the terms of any confidentiality obligation to that third party, may be designated as "CONFIDENTIAL" and shall, once designated, be subject to the restrictions on disclosure specified in Paragraph 7. The parties may agree to additional restrictions to satisfy third party confidentiality concerns.

6. In the event any Designating Party produces Confidential Information that has not been designated "CONFIDENTIAL" or not correctly designated, the Designating Party may designate or redesignate the information to the same extent as it may have designated the information before production by a subsequent notice in writing specifically identifying the redesignated information accompanied by a replacement set of such misdesignated documents bearing a "CONFIDENTIAL" designation thereon, in which event the parties shall henceforth treat such information in accord with this Protective Order, and shall undertake their best efforts to correct any disclosure of such information contrary to the redesignation. Further, the Receiving Party shall immediately return the documents that lacked the "CONFIDENTIAL" designation to the Designating Party upon receiving the replacement set of documents bearing the "CONFIDENTIAL" designation. No showing of error, inadvertence, or excusable neglect shall be required for such redesignation.

Disclosure of Confidential Information

7. Information designated "CONFIDENTIAL" shall not be given, shown, made available or communicated in any way to any person or entity other than the following:

a. Litigation counsel for Plaintiffs:

i. Akin Gump Strauss Hauer & Feld LLP

ii. Patterson Belknap Webb & Tyler LLP

iii. Nutter McClennen & Fish LLP

b. In-house counsel for Plaintiffs:

i. Eric Harris, Assistant General Counsel and Chief Antitrust Counsel, Johnson & Johnson. To the extent that Mr. Harris may have knowledge or involvement in the reexamination proceedings relating to U.S. Patent 6,284,471, he will not be involved in any discussion or consideration of claim amendments.

ii. Joseph Braunreuther, Deputy General Counsel, Johnson & Johnson. To the extent that Mr. Braunreuther may have knowledge or involvement in the reexamination proceedings relating to U.S. Patent 6,284,471, he will not be involved in any discussion or consideration of claim amendments.

iii. Brian Carey, Assistant General Counsel – Patents, Johnson & Johnson and Janssen Research and Development, LLC. Mr. Carey is not responsible for patent prosecution work relevant or related to Remicade®.

c. Litigation counsel for Defendants:

i. Winston & Strawn LLP

ii. Kirkland & Ellis

iii. Burns & Levinson

d. In-house counsel for Defendants:

i. Leah Taylor, Vice President of Intellectual Property, Hospira, Inc. Ms. Taylor is not responsible for patent prosecution work relevant or related to any Remicade® biosimilar.

ii. Jen Embry, Intellectual Property Counsel, Hospira, Inc. Ms. Embry is not responsible for patent prosecution work relevant or related to any Remicade® biosimilar.

iii. Sehoon Kim, Senior Litigation Counsel, Celltrion, Inc. Mr. Kim is not responsible for patent prosecution work relevant or related to any Remicade® biosimilar.

iv. David Kim, Litigation Counsel, Celltrion, Inc. Mr. Kim is not responsible for patent prosecution work relevant or related to any Remicade® biosimilar.

v. Kwisu Park, Patent Attorney, Celltrion, Inc. Mr. Park is not responsible for patent prosecution work relevant or related to any Remicade® biosimilar.

e. Members or employees of any of the foregoing law firms assisting in this litigation as well as any independent litigation support providers retained by such firms to assist in this litigation (e.g., outside copy services, graphic artists and visual aid providers, and jury consultants).

f. The Court and Court personnel and stenographic/videographic reporters at depositions taken in this action.

g. Independent consultants or experts and their staff not employed by or affiliated with a party or with a party's licensee or licensor, retained by the attorneys for the parties either as technical consultants or expert witnesses for the purposes of this litigation, provided that (i) such persons have complied with the procedure of Paragraph 12 herein, and (ii) agree in writing to be bound by the provisions of this Order, in the form set forth as Exhibit A, hereto.

h. The category of individuals listed in Paragraphs 7(g) will only be permitted access to Confidential Information in the following circumstances: (1) upon the

individual's agreement in writing to be bound by the provisions of this Order, in the form set forth as Exhibit A hereto; and (2) upon either of the following: (i) a grant of consent by the Designating Party; or (ii) the expiration of ten (10) business days from the date of written notice of intent to disclose without written notice of objection from the Designating Party. In the event the Designating Party does provide notice of objection to disclosure, a party must seek leave of the Court to make the disclosure and may not make such disclosure without an order of the Court authorizing such disclosure.

i. The list of persons to whom Confidential Information may be disclosed may be expanded or modified by mutual agreement in writing by counsel for the Designating Party and the Receiving Party without necessity of modifying this Order.

j. The Receiving Party shall give notice of this Order and advise of the duty to comply with its terms to any person allowed access to Confidential Information prior to allowing said person access to Confidential Information.

k. Limitations on in-house counsel access to Confidential Information: Except for Brian Carey, the in-house counsel identified above in Paragraphs 7(b) and (d), and those that may be added later, may receive Confidential Information presented in pleadings, contentions, discovery responses, depositions (except for exhibits thereto), and expert reports (except for exhibits thereto), but will not have access to the underlying documents containing Confidential Information. In addition to this, Brian Carey will have full access to Celltrion's aBLA.

No Waiver of Privileges

8. Inadvertent production of documents or information subject to attorney-client privilege, work product immunity, or any other applicable privilege or immunity shall not

constitute a waiver of, nor a prejudice to, any claim that such or related material is privileged or protected by the work product immunity, provided that the Designating Party notifies the Receiving Party in writing promptly after discovery of such inadvertent production. Such inadvertently produced documents and all copies thereof shall promptly be returned to the Designating Party upon request, or destroyed. No use shall be made of such documents other than to challenge the propriety of the asserted privilege or immunity, nor shall they be shown to anyone who has not already been given access to them subsequent to the request to return or destroy them. No demonstration or proof of error, inadvertence, excusable neglect, or absence of negligence shall be required of the Designating Party in order for such party to avail itself of the provisions of this paragraph.

Use and Control of the Confidential Information

9. All Confidential Information disclosed pursuant to this Order shall be used by any recipient thereof solely for the purposes of this litigation, and not for any business or competitive or other purposes. It shall be the duty of each party and each individual having notice of this Protective Order to comply with this Order from the time of such notice.

10. All depositions shall be marked "CONFIDENTIAL" regardless of whether a designation of confidentiality was made on the record or otherwise and shall be subject to this Protective Order, unless and until the Receiving Party makes a request to the party producing the witness or counsel for the witness to release the deposition or any portion thereof from confidential treatment, and only if, and to the extent that, the party producing the witness or counsel for the witness agrees in writing to the modification of treatment of all or part of the transcript, or unless the Court so orders. If the party producing the witness or counsel for the witness fails to respond to such a request within 14 days, the Receiving Party may move the

Court for an order releasing the requested transcript or portion thereof from confidential treatment.

11. All Confidential Information that is filed with the Court, and any pleadings, motions or other papers filed with the Court disclosing any Confidential Information, shall be filed and maintained in Court under seal. Where practical, only confidential portions of filings with the Court shall be filed under seal.

12. Before any person may be given access to Confidential Information under Paragraph 7(g), the party seeking to provide such access must give written notice to the attorneys for the Designating Party of the intention to make such disclosure, stating the name, address, and a resume of the background and qualifications of the person to whom disclosure is proposed, as well as the individual's employment history, past or present relationships with any of the Parties, and all cases in which the individual has testified in a deposition or at trial in the past four (4) years. Within ten (10) days from the service of such written notice, the Designating Party may object to such disclosure by service of a written notice of objection on the attorneys for the party seeking to make the disclosure, stating the reasons for the objection. No disclosure of Confidential Information to any such person may occur prior to the expiration of ten (10) days from the date of service of the written notice of intent to disclose unless consent is granted earlier by the Designating Party. If the Designating Party gives notice of objection to disclosure, the party seeking to make the disclosure must seek leave of the Court to make the disclosure and may not make such disclosure without an order of the Court authorizing such disclosure.

13. Nothing in this Order shall prevent or otherwise restrict counsel for a party from rendering legal advice to such party with respect to the litigation and, in the course thereof, relying upon an examination of Confidential Information; provided, however, that in rendering

such advice and in otherwise communicating with the party, counsel shall not disclose Confidential Information.

14. Nothing herein shall prevent any party from disclosing its own Confidential Information in any manner that it considers appropriate. Additionally, counsel for any party shall be entitled to show or use Confidential Information obtained from another party, during examination, either at deposition or at any hearing or trial, of any officer, employee or retained expert of the Designating Party. Counsel for any party shall also be entitled to show or use Confidential Information obtained from another party, during examination, either at deposition or at any hearing or trial, of any person who is apparently an author, creator or recipient of the Confidential Information.

Duration of Order, Objections, Modifications

15. This Protective Order shall remain in force and effect until modified, superseded or terminated by order of this Court, which may be entered pursuant to agreement of the parties hereto. This Protective Order shall continue in effect after termination of this action and continue to be binding upon all persons to whom Confidential Information is disclosed hereunder.

16. Upon final termination of this action (including all appeals) the Receiving Party shall, within thirty (30) days of such termination, either return to the Designating Party or destroy all Confidential Information in its possession. In either event, the Receiving Party shall certify their return or destruction, with the exception that outside counsel and the persons designated in Paragraphs 7(a) and (c) may retain (i) copies of the pleadings or other papers filed with the Court or served in the course of the litigation, depositions transcripts, deposition exhibits and the trial record; and (ii) one file copy of all documents produced in the course of discovery. Nothing

herein shall restrict the ability of the parties or their counsel to retain information or documents not designated as Confidential Information by the Designating Party.

17. If the Receiving Party learns that Confidential Information produced to it is disclosed to or comes into the possession of any person other than in the manner authorized by this Order, the Receiving Party responsible for the disclosure must immediately inform the Designating Party of such disclosure and shall make a good faith effort to retrieve any documents or things so disclosed and to prevent disclosure by each unauthorized person who received such information.

18. Any Receiving Party may at any time request that the Designating Party remove the "CONFIDENTIAL" designation with respect to any document, object or information. Such request shall be served on counsel for the Designating Party, and shall particularly identify the designated Confidential Information that the Receiving Party contends is not confidential and the reasons supporting its contention. If the Designating Party does not agree to remove the "CONFIDENTIAL" designation within 14 days, then the party contending that such documents or information are not confidential may file a motion to remove such information from the restrictions of this Order.

Miscellaneous

19. This Protective Order may be modified only by written agreement of the parties or further order of the Court and is without prejudice to the rights of any party or third party to seek additional or different relief from the Court not specified in this Order.

20. The designation by counsel for the Designating Party of any document, material or information as constituting or containing Confidential Information is intended solely to facilitate the preparation and trial of this case, and such designation shall not be construed in any way as

an admission or agreement by any party that such document, material or information constitutes or contains any Confidential Information as a matter of law.

21. In the event Confidential Information disclosed during the course of the litigation is sought by any person or entity not a party to this litigation, whether by subpoena in another action or service with any legal process, the party receiving such subpoena or service shall promptly notify in writing outside counsel for the Designating Party if such subpoena or service demands the production of Confidential Information of such designating party. Any such person or entity seeking such Confidential Information by attempting to enforce such subpoena or other legal process shall be apprised of this Protective Order by outside counsel for the party upon whom the subpoena or process was served. Nothing herein shall be construed as requiring anyone covered by this Protective Order to contest a subpoena or other process, to appeal any order requiring production of Confidential Information covered by this Protective Order, or to subject itself to penalties for non-compliance with any legal process or order.

22. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the aggrieved party immediately may apply to obtain injunctive relief against any such person violating or threatening to violate any of the terms of this Protective Order, and in the event that the aggrieved party does so, the responding party, subject to the provisions of this Protective Order, shall not employ as a defense thereto the claim that the aggrieved party possesses an adequate remedy at law.

23. Nothing herein shall prevent any party or non-party from seeking additional or different relief from the Court not specified in this Order.

24. The section titles in this Order are for convenience of organization only, and are not part of, nor are they relevant to the construction of this Order.

SIGNED this _____ day of _____ 2015.

_____

EXHIBIT A

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. **Defendants.**	)	

DECLARATION OF COMPLIANCE

I, _____ do declare and state as follows:

1. I live at _____. I am employed as

_____ (position) by _____ (name and address of employer).

2. I have read the Protective Order entered in this case, a copy of which has been given to me.

3. I understand and agree to comply with and be bound by the provisions of the Protective Order and consent to the jurisdiction of the district court to enforce the terms of the

Protective Order, including that upon receipt of any Confidential Information, I will be personally subject to it, and to all of its requirements and procedures.

4. Further, I declare, as provided by 28 U.S.C. § 1746, under penalty of perjury under the laws of the United States of America, that the foregoing is true and correct.

Date: _____

EXHIBIT 9

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. **Defendants.**	)	

STIPULATED PROTECTIVE ORDER

WHEREAS, Plaintiffs Janssen Biotech, Inc. and New York University (collectively "Plaintiffs") and Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira, Inc. (collectively "Defendants"), the parties to this action (collectively the "parties"), possess confidential information which may be disclosed in litigating this action and which must be protected in order to preserve the legitimate business and other interests of the parties, and

Deleted: responding to discovery requests or otherwise in

WHEREAS, the parties have, through counsel, stipulated to the entry of this Protective Order to prevent unnecessary dissemination or disclosure of such confidential information,

IT IS HEREBY ORDERED that:

Definitions

1. The following definitions shall apply to this Order:

Deleted:

a. The term "Confidential Information" as used in this Order is to include all information that the Designating Party believes constitutes, discloses, or relates to research and development information (including, but not limited to, processes, operations, technical materials, or production); regulatory information (including, but not limited to, correspondences with the FDA); financial information (including, but not limited to, marketing, sales, or shipments); private or confidential personal information; proprietary data or information of commercial value (including, but not limited to, trade secrets); or any other information that the Designating Party believes in good faith to be entitled to protection under Rule 26(c)(1) of the Federal Rules of Civil Procedure. It may include, without limitation: documents produced in this action, during formal discovery or otherwise; documents and information produced by third parties which the Designating Party is under an obligation to maintain in confidence; pleadings, portions of briefs, memoranda, or other writings filed with the Court; answers to interrogatories and

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Deleted: ,

Deleted:

responses to requests for admission or other discovery requests; deposition or trial transcripts; infringement contentions and noninfringement contentions; and tangible things or objects that are designated confidential pursuant to this Order. The information contained therein and all copies, abstracts, excerpts, analyses or other writings that contain, reflect, reveal, suggest or otherwise disclose such Confidential Information shall also be deemed Confidential Information. Information originally designated as Confidential Information pursuant to this agreement shall not retain Confidential status after any ruling by any Court denying such status.

b. ____The term "Designating Party" means the party producing or designating documents or information as Confidential Information under this Order.

c. ____The term "Receiving Party" shall mean any person to whom Confidential Information is disclosed.

Designation of Confidential Information

2. ____Any party who produces or discloses any material that it believes comprises Confidential Information shall designate the same by marking "CONFIDENTIAL" prominently on the face of each document containing the Confidential Information.

Deleted: all documents

Deleted: information

3. ____If a Designating Party elects to produce original files and records for inspection and the inspecting party desires to inspect those files, the Designating Party shall give notice of the confidentiality of any files or records in advance of the initial inspection, and the party inspecting such files and records shall maintain the confidentiality of all those original files and records that it reviews. Thereafter, upon selection of specified documents for copying by the inspecting party, the Designating Party shall mark the copies of such documents as may contain

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Confidential Information with the appropriate designation at the time the copies are produced to the inspecting party.

4. ____If any Confidential Information is produced by a third party to this litigation, such third party shall be considered a Designating Party within the meaning of that term as it is used in the context of this Order and all parties to this Order should be treated as Receiving Parties.

5. ____Confidential Information that originated with a third party, subject to the terms of any confidentiality obligation to that third party, may be designated as "CONFIDENTIAL" and shall, once designated, be subject to the restrictions on disclosure specified in Paragraph 7. The parties may agree to additional restrictions to satisfy third party confidentiality concerns.

6. ____In the event any Designating Party produces Confidential Information that has not been designated "CONFIDENTIAL" or not correctly designated, the Designating Party may designate or redesignate the information to the same extent as it may have designated the information before production. The Designating Party may do so by a subsequent notice to all parties in writing specifically identifying the redesignated information accompanied by a replacement set of such misdesignated documents bearing a "CONFIDENTIAL" designation thereon. Upon receiving such notice, the parties shall henceforth treat such information in accord with this Protective Order, and shall undertake their best efforts to correct any disclosure of such information contrary to the redesignation. Further, the Receiving Party shall immediately dispose of or return to the Designating Party the documents that lacked the "CONFIDENTIAL" designation upon receiving the replacement set of documents bearing the "CONFIDENTIAL" designation. No showing of error, inadvertence, or excusable neglect shall be required for such redesignation.

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Disclosure of Confidential Information

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7. ____Information designated "CONFIDENTIAL" shall not be given, shown, made available or communicated in any way to any person or entity other than the following:

a. ____Outside litigation counsel for Plaintiffs, provided that the outside litigation counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action:

Deleted: Litigation counsel for Plaintiffs

i. ____Akin Gump Strauss Hauer & Feld LLP;

ii. ____Patterson Belknap Webb & Tyler LLP; and

iii. ____Nutter McClennen & Fish LLP

b. ____In-house counsel for Plaintiffs (or Plaintiffs' related corporate entities, such as Johnson & Johnson), provided that the in-house counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action:

Deleted: In-house counsel for Plaintiffs

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i. ____Eric Harris, Assistant General Counsel and Chief Antitrust Counsel, Johnson & Johnson;

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ii. ____Joseph Braunreuther, Deputy General Counsel, Johnson & Johnson; and

Deleted: To the extent that Mr Braunreuther may have knowledge or involvement in the reexamination proceedings relating to U S Patent 6,284,471, he will not be involved in any discussion or consideration of claim amendments

iii. ___Brian Carey, Assistant General Counsel – Patents, Johnson & Johnson and Janssen Research and Development, LLC.

c. Outside litigation counsel for Defendants, provided that the outside litigation counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action:

i. ____Winston & Strawn LLP;

ii. ____Kirkland & Ellis LLP; and

iii. ___Burns & Levinson.

d. In-house counsel for Defendants (or Defendants' related corporate entities, such as Hospira, Pty Ltd.), provided that the in-house counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action:

i. ____Leah Taylor, Vice President of Intellectual Property, Hospira, Pty Ltd.;

ii. ____Sehoon Kim, Senior Litigation Counsel, Celltrion, Inc.;

iii. ___David Kim, Litigation Counsel, Celltrion, Inc.; and

iv. ___Kwisu Park, Patent Attorney, Celltrion, Inc.,

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Deleted: Mr Park is not responsible for patent prosecution work relevant or related to any Remicade® biosimilar

e. ____Members or employees of any of the foregoing law firms assisting in this litigation (e.g., secretarial, paralegal, clerical, data processing personnel) as well as any independent litigation support providers retained by such firms to assist in this litigation (e.g., court reporters, litigation support personnel, outside copy services, graphic artists and visual aid providers, and jury consultants).

f. _____The Court and Court personnel and stenographic/videographic reporters at depositions taken in this action.

g. _____Independent consultants or experts and their staff not employed by or affiliated with a party or with a party's licensee or licensor, retained by the attorneys for the parties either as technical consultants or expert witnesses for the purposes of this litigation, provided that (i) such persons have complied with the procedure of Paragraph 12 herein, and (ii) agree in writing to be bound by the provisions of this Order, in the form set forth as Exhibit A, hereto.

h. ____The category of individuals listed in Paragraphs 7(g) will only be permitted access to Confidential Information in the following circumstances: (1) upon the individual's agreement in writing to be bound by the provisions of this Order, in the form set forth as Exhibit A hereto; and (2) upon either of the following: (i) a grant of consent by the Designating Party; or (ii) the expiration of fourteen (14) days from the date of written notice of intent to disclose without written notice of objection from the Designating Party. In the event the Designating Party does provide notice of objection to disclosure, a party must seek leave of the Court to make the disclosure and may not make such disclosure without an order of the Court authorizing such disclosure.

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i. ____The list of persons to whom Confidential Information may be disclosed may be expanded or modified by mutual agreement in writing by counsel for the Designating Party and the Receiving Party without necessity of modifying this Order.

j. ____The Receiving Party shall give notice of this Order and advise of the duty to comply with its terms to any person allowed access to Confidential Information prior to allowing said person access to Confidential Information.

No Waiver of Privileges

8. ____Inadvertent production of documents or information subject to attorney-client privilege, work product immunity, or any other applicable privilege or immunity shall not constitute a waiver of, nor a prejudice to, any claim of such privilege or immunity, provided that the Designating Party notifies the Receiving Party in writing promptly after discovery of such inadvertent production. After receiving written notice from the Designating Party that the document or information subject to attorney-client privilege, work product immunity, or any other applicable privilege or immunity has been inadvertently produced, the Receiving Party shall immediately destroy or return to the Designating Party such inadvertently produced document or information and all copies thereof, unless the Receiving Party has a good faith basis for asserting that the document or information is not protected by any privilege or immunity. If the Receiving Party believes it has a good faith basis for challenging the privilege claim, the Receiving Party shall provide the Designating Party a written explanation of the good faith basis for refusing to destroy or return the inadvertently produced document or information within fourteen (14) days after receipt of the Designating Party's written notice, and shall be permitted to retain the inadvertently produced document or information solely for the purposes of challenging the propriety of the asserted privilege or immunity until the dispute has been

Deleted: k Limitations on in-house counsel access to Confidential Information: Except for Brian Carey, the in-house counsel identified above in Paragraphs 7(b) and (d), and those that may be added later, may receive Confidential Information presented in pleadings, contentions, discovery responses, depositions (except for exhibits thereto), and expert reports (except for exhibits thereto), but will not have access to the underlying documents containing Confidential Information In addition to this, Brian Carey will have full access to Celltrion's aBLA ¶

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resolved. In the event that the Receiving Party provides a timely written explanation of the good faith basis for refusing to destroy or return the inadvertently produced document or information, the Designating Party has fourteen (14) days from receipt of the receiving party's written explanation to file a motion seeking an order compelling the destruction or return of the inadvertently produced document or information. Failure of the producing party to file such a motion within fourteen (14) days from receipt of the receiving party's written explanation waives any claim of privilege or immunity as to the inadvertently produced document or information at issue. Until the motion seeking an order compelling the destruction or return of the inadvertently produced document or information is decided, no use shall be made of such documents other than to challenge the propriety of the asserted privilege or immunity, nor shall they be shown to anyone who has not already been given access to them subsequent to the request to return or destroy them. No demonstration or proof of error, inadvertence, excusable neglect, or absence of negligence shall be required of the Designating Party in order for such party to avail itself of the provisions of this paragraph.

Use and Control of the Confidential Information

9. ____All Confidential Information disclosed pursuant to this Order shall be used by any recipient thereof solely for the purposes of this litigation. Any Confidential Information shall not be used by any recipient thereof for any business, commercial, competitive, or other purpose, including, but not limited to: (i) filing a citizen petition to the FDA relating to any infliximab or biosimilar infliximab product, (ii) prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, or (iii) evaluating whether to license or acquire patents relating to any infliximab or biosimilar

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infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product. It shall be the duty of each party and each individual having notice of this Protective Order to comply with this Order from the time of such notice.

10. ___All depositions shall be marked "CONFIDENTIAL" regardless of whether a designation of confidentiality was made on the record or otherwise and shall be subject to this Protective Order, unless and until the Receiving Party makes a request to the party producing the witness or counsel for the witness to release the deposition or any portion thereof from confidential treatment, and only if, and to the extent that, the party producing the witness or counsel for the witness agrees in writing to the modification of treatment of all or part of the transcript, or unless the Court so orders. If the party producing the witness or counsel for the witness fails to respond to such a request within fourteen (14) days, the Receiving Party may move the Court for an order releasing the requested transcript or portion thereof from confidential treatment.

11. ___All Confidential Information that is filed with the Court, and any pleadings, motions or other papers filed with the Court disclosing any Confidential Information, shall be filed and maintained in Court under seal. Where practical, only confidential portions of filings with the Court shall be filed under seal.

12. ___Before any independent consultant or expert may be given access to Confidential Information under Paragraph 7(g), the party seeking to provide such access must give written notice to the attorneys for the Designating Party of the intention to make such disclosure, and provide the following information regarding such independent consultant or expert:

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i. Name and address;

ii. Business title and business affiliation;

iii. Resume of his or her background and qualifications, including employment history for the last ten (10) years;

iv. Any past or present relationships with any of the parties;

v. All cases in which the individual has testified in a deposition or at trial in the past four (4) years, and identification of the party on whose behalf the expert testified; and

vi. An executed copy of Exhibit A.

Within fourteen (14) days from the service of such written notice, the Designating Party may object to such disclosure by service of a written notice of objection on the attorneys for the party seeking to make the disclosure, stating the reasons for the objection. No disclosure of Confidential Information to any such person may occur prior to the expiration of fourteen (14) days from the date of service of the written notice of intent to disclose unless consent is granted earlier by the Designating Party. If the Designating Party gives notice of objection to disclosure, the party seeking to make the disclosure must seek leave of the Court to make the disclosure and may not make such disclosure without an order of the Court authorizing such disclosure.

13. Nothing in this Order shall prevent or otherwise restrict counsel for a party from rendering legal advice to such party with respect to the litigation and, in the course thereof, relying upon an examination of Confidential Information; provided, however, that in rendering such advice and in otherwise communicating with the party, counsel shall not disclose Confidential Information.

14. Nothing herein shall prevent any party from disclosing its own Confidential Information in any manner that it considers appropriate. Additionally, counsel for any party shall be entitled to show or use Confidential Information obtained from a Designating Party, during

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examination, either at deposition or at any hearing or trial, of any officer, employee, Rule 30(b)(6) designee, or retained expert of that Designating Party. Counsel for any party shall also be entitled to show or use Confidential Information obtained from a Designating Party, during examination, either at deposition or at any hearing or trial, of any person who is apparently an author, creator, or recipient of the Confidential Information.

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Duration of Order, Objections, Modifications

15. ___This Protective Order shall remain in force and effect until modified, superseded or terminated by order of this Court, which may be entered pursuant to agreement of the parties hereto. This Protective Order shall continue in effect after termination of this action and continue to be binding upon all persons to whom Confidential Information is disclosed hereunder.

16. ___Upon final termination of this action (including all appeals) the Receiving Party shall, within thirty (30) days of such termination, either return to the Designating Party or destroy all Confidential Information in its possession. In either event, the Receiving Party shall certify their return or destruction, with the exception that the outside litigation counsel designated in Paragraphs 7(a) and (c) may retain copies of the pleadings or other papers filed with the Court or served in the course of the litigation, depositions transcripts, deposition exhibits and the trial record. Nothing herein shall restrict the ability of the parties or their counsel to retain information or documents not designated as Confidential Information by the Designating Party.

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17. ___If the Receiving Party learns that Confidential Information produced to it is disclosed to or comes into the possession of any person other than in the manner authorized by this Order, the Receiving Party responsible for the disclosure must immediately inform the Designating Party of such disclosure and shall make a good faith effort to retrieve any documents

or things so disclosed and to prevent disclosure by each unauthorized person who received such information.

18. ___Any Receiving Party may at any time request that the Designating Party remove the "CONFIDENTIAL" designation with respect to any document, object or information. Such request shall be served on counsel for the Designating Party, and shall particularly identify the designated Confidential Information that the Receiving Party contends is not confidential and the reasons supporting its contention. If the Designating Party does not agree to remove the "CONFIDENTIAL" designation within fourteen (14) days, then the party contending that such documents or information are not confidential may file a motion to remove such information from the restrictions of this Order.

Miscellaneous

19. ___This Protective Order may be modified only by written agreement of the parties or further order of the Court and is without prejudice to the rights of any party or third party to seek additional or different relief from the Court not specified in this Order.

20. ___The designation by counsel for the Designating Party of any document, material or information as constituting or containing Confidential Information is intended solely to facilitate the preparation and trial of this case, and such designation shall not be construed in any way as an admission or agreement by any party that such document, material or information constitutes or contains any Confidential Information as a matter of law.

21. ___In the event Confidential Information disclosed during the course of the litigation is sought by any person or entity not a party to this litigation, whether by subpoena in another action or service with any legal process, the party receiving such subpoena or service shall promptly notify in writing outside counsel for the Designating Party if such subpoena or service

demands the production of Confidential Information of such Designating Party. Any such person or entity seeking such Confidential Information by attempting to enforce such subpoena or other legal process shall be apprised of this Protective Order by outside counsel for the party upon whom the subpoena or process was served. Nothing herein shall be construed as requiring anyone covered by this Protective Order to contest a subpoena or other process, to appeal any order requiring production of Confidential Information covered by this Protective Order, or to subject itself to penalties for non-compliance with any legal process or order.

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22. ___In the event anyone shall violate or threaten to violate the terms of this Protective Order, the aggrieved party immediately may apply to obtain injunctive relief against any such person violating or threatening to violate any of the terms of this Protective Order, and in the event that the aggrieved party does so, the responding party, subject to the provisions of this Protective Order, shall not employ as a defense thereto the claim that the aggrieved party possesses an adequate remedy at law.

23. ___Nothing herein shall prevent any party or non-party from seeking additional or different relief from the Court not specified in this Order.

24. ___The section titles in this Order are for convenience of organization only, and are not part of, nor are they relevant to the construction of this Order.

SIGNED this _____ day of _____ 2015.

_____

EXHIBIT A

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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.	)	
Defendants.	)	

DECLARATION OF COMPLIANCE

I, _____ do declare and state as follows:

1. ____I live at _____. I am employed as

_____ (position) by _____ (name and address of employer).

2. ____I have read the Protective Order entered in this case, a copy of which has been given to me.

3. ____I understand and agree to comply with and be bound by the provisions of the Protective Order and consent to the jurisdiction of the district court to enforce the terms of the Protective Order, including that upon receipt of any Confidential Information, I will be personally subject to it, and to all of its requirements and procedures.

4. ____Further, I declare, as provided by 28 U.S.C. § 1746, under penalty of perjury under the laws of the United States of America, that the foregoing is true and correct.

Date: _____

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EXHIBIT 10

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. **Defendants.**	)	

STIPULATED PROTECTIVE ORDER

WHEREAS, Plaintiffs Janssen Biotech, Inc. and New York University (collectively "Plaintiffs") and Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira, Inc. (collectively "Defendants"), the parties to this action (collectively the "parties"), possess confidential information which may be disclosed in litigating this action and which must be protected in order to preserve the legitimate business and other interests of the parties, and

WHEREAS, the parties have, through counsel, stipulated to the entry of this Protective Order to prevent unnecessary dissemination or disclosure of such confidential information,

IT IS HEREBY ORDERED that:

Definitions

I. The following definitions shall apply to this Order:

a. The term "Confidential Information" as used in this Order is to include all information that the Designating Party believes constitutes, discloses, or relates to research and development information (including, but not limited to, processes, operations, technical materials, or production); regulatory information (including, but not limited to, correspondences with the FDA); financial information (including, but not limited to, marketing, sales, or shipments); private or confidential personal information; proprietary data or information of commercial value (including, but not limited to, trade secrets); or any other information that the Designating Party believes in good faith to be entitled to protection under Rule 26(c)(1) of the Federal Rules of Civil Procedure. It may include, without limitation: documents produced in this action, during formal discovery or otherwise; documents and information produced by third parties which the Designating Party is under an obligation to maintain in confidence; pleadings, portions of briefs, memoranda, or other writings filed with the Court; answers to interrogatories and

responses to requests for admission or other discovery requests; deposition or trial transcripts; infringement contentions and noninfringement contentions; and tangible things or objects that are designated confidential pursuant to this Order. The information contained therein and all copies, abstracts, excerpts, analyses or other writings that contain, reflect, reveal, suggest or otherwise disclose such Confidential Information shall also be deemed Confidential Information. Information originally designated as Confidential Information pursuant to this agreement shall not retain Confidential status after any ruling by any Court denying such status.

b. The term "Designating Party" means the party producing or designating documents or information as Confidential Information under this Order.

c. The term "Receiving Party" shall mean any person to whom Confidential Information is disclosed.

Designation of Confidential Information

2. Any party who produces or discloses any material that it believes comprises Confidential Information shall designate the same by marking "CONFIDENTIAL" prominently on the face of each document containing the Confidential Information.

3. If a Designating Party elects to produce original files and records for inspection and the inspecting party desires to inspect those files, the Designating Party shall give notice of the confidentiality of any files or records in advance of the initial inspection, and the party inspecting such files and records shall maintain the confidentiality of all those original files and records that it reviews. Thereafter, upon selection of specified documents for copying by the inspecting party, the Designating Party shall mark the copies of such documents as may contain

Confidential Information with the appropriate designation at the time the copies are produced to the inspecting party.

4. If any Confidential Information is produced by a third party to this litigation, such third party shall be considered a Designating Party within the meaning of that term as it is used in the context of this Order and all parties to this Order should be treated as Receiving Parties.

5. Confidential Information that originated with a third party, subject to the terms of any confidentiality obligation to that third party, may be designated as "CONFIDENTIAL" and shall, once designated, be subject to the restrictions on disclosure specified in Paragraph 7. The parties may agree to additional restrictions to satisfy third party confidentiality concerns.

6. In the event any Designating Party produces Confidential Information that has not been designated "CONFIDENTIAL" or not correctly designated, the Designating Party may designate or redesignate the information to the same extent as it may have designated the information before production. The Designating Party may do so by a subsequent notice to all parties in writing specifically identifying the redesignated information accompanied by a replacement set of such misdesignated documents bearing a "CONFIDENTIAL" designation thereon. Upon receiving such notice, the parties shall henceforth treat such information in accord with this Protective Order, and shall undertake their best efforts to correct any disclosure of such information contrary to the redesignation. Further, the Receiving Party shall immediately dispose of or return to the Designating Party the documents that lacked the "CONFIDENTIAL" designation upon receiving the replacement set of documents bearing the "CONFIDENTIAL" designation. No showing of error, inadvertence, or excusable neglect shall be required for such redesignation.

Disclosure of Confidential Information

7. Information designated "CONFIDENTIAL" shall not be given, shown, made available or communicated in any way to any person or entity other than the following:

a. Outside litigation counsel for Plaintiffs, provided that the outside litigation counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action, except as expressly permitted below:

i. Akin Gump Strauss Hauer & Feld LLP (Outside litigation counsel may be involved in any appeal of the reexamination proceedings relating to U.S. Patent 6,284,471 before the Patent Trial and Appeal Board, Federal Circuit, or U.S. Supreme Court, but they may not advise or be involved in any discussion or consideration of claim amendments of the patent or any other patents);

ii. Patterson Belknap Webb & Tyler LLP (Outside litigation counsel may be involved in any appeal of the reexamination proceedings relating to U.S. Patent 6,284,471 before the Patent Trial and Appeal Board, Federal Circuit, or U.S. Supreme Court, but they may not advise or be involved in any discussion or consideration of claim amendments of the patent or any other patents); and

iii. Nutter McClennen & Fish LLP.

b. In-house counsel for Plaintiffs (or Plaintiffs' related corporate entities, such as Johnson & Johnson), provided that the in-house counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any

reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action, except as expressly permitted below:

i. Eric Harris, Assistant General Counsel and Chief Antitrust Counsel, Johnson & Johnson (Mr. Harris may be involved in any appeal of the reexamination proceedings relating to U.S. Patent 6,284,471 before the Patent Trial and Appeal Board, Federal Circuit, or U.S. Supreme Court, but he may not advise or be involved in any discussion or consideration of claim amendments of the patent or any other patents);

ii. Joseph Braunreuther, Deputy General Counsel, Johnson & Johnson (Mr. Braunreuther may be involved in any appeal of the reexamination proceedings relating to U.S. Patent 6,284,471 before the Patent Trial and Appeal Board, Federal Circuit, or U.S. Supreme Court, but he may not advise or be involved in any discussion or consideration of claim amendments of the patent or any other patents); and

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iii. Brian Carey, Assistant General Counsel – Patents, Johnson & Johnson and Janssen Research and Development, LLC.

c. Outside litigation counsel for Defendants, provided that the outside litigation counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing,

method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action:

i. Winston & Strawn LLP;

ii. Kirkland & Ellis LLP; and

iii. Burns & Levinson LLP.

d. In-house counsel for Defendants (or Defendants' related corporate entities, such as Hospira, Pty Ltd.), provided that the in-house counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action:

i. Leah Taylor, Vice President of Intellectual Property, Hospira, Pty Ltd.;

ii. Sehoon Kim, Senior Litigation Counsel, Celltrion, Inc.;

iii. David Kim, Litigation Counsel, Celltrion, Inc.; and

iv. Kwisu Park, Patent Attorney, Celltrion, Inc.

e. Members or employees of any of the foregoing law firms assisting in this litigation (e.g., secretarial, paralegal, clerical, data processing personnel) as well as any independent litigation support providers retained by such firms to assist in this litigation (e.g., court reporters, litigation support personnel, outside copy services, graphic artists and visual aid providers, and jury consultants).

f. The Court and Court personnel and stenographic/videographic reporters at depositions taken in this action.

g. Independent consultants or experts and their staff not employed by or affiliated with a party or with a party's licensee or licensor, retained by the attorneys for the parties either as technical consultants or expert witnesses for the purposes of this litigation, provided that (i) such persons have complied with the procedure of Paragraph 12 herein, and (ii) agree in writing to be bound by the provisions of this Order, in the form set forth as Exhibit A, hereto.

h. The category of individuals listed in Paragraphs 7(g) will only be permitted access to Confidential Information in the following circumstances: (1) upon the individual's agreement in writing to be bound by the provisions of this Order, in the form set forth as Exhibit A hereto; and (2) upon either of the following: (i) a grant of consent by the Designating Party; or (ii) the expiration of fourteen (14) days from the date of written notice of intent to disclose without written notice of objection from the Designating Party. In the event the Designating Party does provide notice of objection to disclosure, a party must seek leave of the Court to make the disclosure and may not make such disclosure without an order of the Court authorizing such disclosure.

i. The list of persons to whom Confidential Information may be disclosed may be expanded or modified by mutual agreement in writing by counsel for the Designating Party and the Receiving Party without necessity of modifying this Order.

j. The Receiving Party shall give notice of this Order and advise of the duty to comply with its terms to any person allowed access to Confidential Information prior to allowing said person access to Confidential Information.

No Waiver of Privileges

8. Inadvertent production of documents or information subject to attorney-client privilege, work product immunity, or any other applicable privilege or immunity shall not constitute a waiver of, nor a prejudice to, any claim of such privilege or immunity, provided that the Designating Party notifies the Receiving Party in writing promptly after discovery of such inadvertent production and provides the basis for the claim of privilege or immunity in accordance with Federal Rule of Civil Procedure 26(b)(5)(B). After receiving written notice from the Designating Party that the document or information subject to attorney-client privilege, work product immunity, or any other applicable privilege or immunity has been inadvertently produced, the Receiving Party shall promptly return, sequester, or destroy such inadvertently produced document or information and all copies thereof. No use shall be made of such documents other than to challenge the propriety of the asserted privilege or immunity, nor shall they be shown to anyone who has not already been given access to them subsequent to the request to return or destroy them. No demonstration or proof of error, inadvertence, excusable neglect, or absence of negligence shall be required of the Designating Party in order for such party to avail itself of the provisions of this paragraph. Nothing herein restricts the right of the Receiving Party to challenge the Designating Party's claim of privilege or immunity, if appropriate, within a reasonable time after receiving notice of the inadvertent production.

Use and Control of the Confidential Information

9. All Confidential Information disclosed pursuant to this Order shall be used by any recipient thereof solely for the purposes of this litigation. Any Confidential Information shall not be used by any recipient thereof for any business, commercial, competitive, or other purpose, including, but not limited to: (i) filing a citizen petition to the FDA relating to any infliximab or

biosimilar infliximab product, (ii) prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, (iii) using as evidence or supporting materials in disputes or petitions to any regulatory agencies or courts in any jurisdiction or forum, regardless of country (other than this present litigation) relating to marketing approval or sale of any infliximab or biosimilar infliximab product, or (iv) evaluating whether to license or acquire patents relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, except for what is reasonably necessary to permit the parties to engage in meaningful settlement discussions of the present litigation. It shall be the duty of each party and each individual having notice of this Protective Order to comply with this Order from the time of such notice.

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10. All depositions shall be marked "CONFIDENTIAL" regardless of whether a designation of confidentiality was made on the record or otherwise and shall be subject to this Protective Order, unless and until the Receiving Party makes a request to the party producing the witness or counsel for the witness to release the deposition or any portion thereof from confidential treatment, and only if, and to the extent that, the party producing the witness or counsel for the witness agrees in writing to the modification of treatment of all or part of the transcript, or unless the Court so orders. If the party producing the witness or counsel for the witness fails to respond to such a request within fourteen (14) days, the Receiving Party may move the Court for an order releasing the requested transcript or portion thereof from confidential treatment.

11. All Confidential Information that is filed with the Court, and any pleadings, motions or other papers filed with the Court disclosing any Confidential Information, shall be filed and maintained in Court under seal. Where practical, only confidential portions of filings with the Court shall be filed under seal.

12. Before any independent consultant or expert may be given access to Confidential Information under Paragraph 7(g), the party seeking to provide such access must give written notice to the attorneys for the Designating Party of the intention to make such disclosure, and provide the following information regarding such independent consultant or expert:

i. Name and address;

ii. Business title and business affiliation;

iii. Resume of his or her background and qualifications, including employment history for the last ten (10) years;

iv. Any past or present relationships with any of the parties;

v. All cases in which the individual has testified in a deposition or at trial in the past four (4) years, and identification of the party on whose behalf the expert testified; and

vi. An executed copy of Exhibit A.

Within fourteen (14) days from the service of such written notice, the Designating Party may object to such disclosure by service of a written notice of objection on the attorneys for the party seeking to make the disclosure, stating the reasons for the objection. No disclosure of Confidential Information to any such person may occur prior to the expiration of fourteen (14) days from the date of service of the written notice of intent to disclose unless consent is granted earlier by the Designating Party. If the Designating Party gives notice of objection to disclosure,

the party seeking to make the disclosure must seek leave of the Court to make the disclosure and may not make such disclosure without an order of the Court authorizing such disclosure.

13. Nothing in this Order shall prevent or otherwise restrict counsel for a party from rendering legal advice to such party with respect to the litigation and, in the course thereof, relying upon an examination of Confidential Information; provided, however, that in rendering such advice and in otherwise communicating with the party, counsel shall not disclose Confidential Information.

14. Nothing herein shall prevent any party from disclosing its own Confidential Information in any manner that it considers appropriate. Additionally, counsel for any party shall be entitled to show or use Confidential Information obtained from a Designating Party, during examination, either at deposition or at any hearing or trial, of any officer, employee, Rule 30(b)(6) designee, or retained expert of that Designating Party. Counsel for any party shall also be entitled to show or use Confidential Information obtained from a Designating Party, during examination, either at deposition or at any hearing or trial, of any person who is apparently an author, creator, or recipient of the Confidential Information.

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Duration of Order, Objections, Modifications

15. This Protective Order shall remain in force and effect until modified, superseded or terminated by order of this Court, which may be entered pursuant to agreement of the parties hereto. This Protective Order shall continue in effect after termination of this action and continue to be binding upon all persons to whom Confidential Information is disclosed hereunder.

16. Upon final termination of this action (including all appeals) the Receiving Party shall, within thirty (30) days of such termination, either return to the Designating Party or destroy all Confidential Information in its possession. In either event, the Receiving Party shall

certify their return or destruction, with the exception that the outside litigation counsel designated in Paragraphs 7(a) and (c) may retain copies of the pleadings or other papers filed with the Court or served in the course of the litigation, depositions transcripts, deposition exhibits and the trial record. Nothing herein shall restrict the ability of the parties or their counsel to retain information or documents not designated as Confidential Information by the Designating Party.

17. If the Receiving Party learns that Confidential Information produced to it is disclosed to or comes into the possession of any person other than in the manner authorized by this Order, the Receiving Party responsible for the disclosure must immediately inform the Designating Party of such disclosure and shall make a good faith effort to retrieve any documents or things so disclosed and to prevent disclosure by each unauthorized person who received such information.

18. Any Receiving Party may at any time request that the Designating Party remove the "CONFIDENTIAL" designation with respect to any document, object or information. Such request shall be served on counsel for the Designating Party, and shall particularly identify the designated Confidential Information that the Receiving Party contends is not confidential and the reasons supporting its contention. If the Designating Party does not agree to remove the "CONFIDENTIAL" designation within fourteen (14) days, then the party contending that such documents or information are not confidential may file a motion to remove such information from the restrictions of this Order.

Miscellaneous

19. This Protective Order may be modified only by written agreement of the parties or further order of the Court and is without prejudice to the rights of any party or third party to seek additional or different relief from the Court not specified in this Order.

20. The designation by counsel for the Designating Party of any document, material or information as constituting or containing Confidential Information is intended solely to facilitate the preparation and trial of this case, and such designation shall not be construed in any way as an admission or agreement by any party that such document, material or information constitutes or contains any Confidential Information as a matter of law.

21. In the event Confidential Information disclosed during the course of the litigation is sought by any person or entity not a party to this litigation, whether by subpoena in another action or service with any legal process, the party receiving such subpoena or service shall promptly notify in writing outside counsel for the Designating Party if such subpoena or service demands the production of Confidential Information of such Designating Party. Any such person or entity seeking such Confidential Information by attempting to enforce such subpoena or other legal process shall be apprised of this Protective Order by outside counsel for the party upon whom the subpoena or process was served. Nothing herein shall be construed as requiring anyone covered by this Protective Order to contest a subpoena or other process, to appeal any order requiring production of Confidential Information covered by this Protective Order, or to subject itself to penalties for non-compliance with any legal process or order.

22. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the aggrieved party immediately may apply to obtain injunctive relief against any such person violating or threatening to violate any of the terms of this Protective Order, and in the event that the aggrieved party does so, the responding party, subject to the provisions of this

Protective Order, shall not employ as a defense thereto the claim that the aggrieved party possesses an adequate remedy at law.

23. Nothing herein shall prevent any party or non-party from seeking additional or different relief from the Court not specified in this Order.

24. The section titles in this Order are for convenience of organization only, and are not part of, nor are they relevant to the construction of this Order.

SIGNED this _____ day of _____ 2015.

_____

EXHIBIT A

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. **Defendants.**	)	

DECLARATION OF COMPLIANCE

I, _____ do declare and state as follows:

1. I live at _____. I am employed as _____ (position) by _____ (name and address of employer).

2. I have read the Protective Order entered in this case, a copy of which has been given to me.

3. I understand and agree to comply with and be bound by the provisions of the Protective Order and consent to the jurisdiction of the district court to enforce the terms of the Protective Order, including that upon receipt of any Confidential Information, I will be personally subject to it, and to all of its requirements and procedures.

4. Further, I declare, as provided by 28 U.S.C. § 1746, under penalty of perjury under the laws of the United States of America, that the foregoing is true and correct.

Date: _____

_____

EXHIBIT 11

[Filed Under Seal]

EXHIBIT 12

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. **Defendants.**	)	

STIPULATED PROTECTIVE ORDER

WHEREAS, Plaintiffs Janssen Biotech, Inc. and New York University (collectively "Plaintiffs") and Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira, Inc. (collectively "Defendants"), the parties to this action (collectively the "parties"), possess confidential information which may be disclosed in litigating this action and which must be protected in order to preserve the legitimate business and other interests of the parties, and

WHEREAS, the parties have, through counsel, stipulated to the entry of this Protective Order to prevent unnecessary dissemination or disclosure of such confidential information,

IT IS HEREBY ORDERED that:

Definitions

1. The following definitions shall apply to this Order:

a. The term "Confidential Information" as used in this Order is to include all information that the Designating Party believes constitutes, discloses, or relates to research and development information (including, but not limited to, processes, operations, technical materials, or production); regulatory information (including, but not limited to, correspondences with the FDA); financial information (including, but not limited to, marketing, sales, or shipments); private or confidential personal information; proprietary data or information of commercial value (including, but not limited to, trade secrets); or any other information that the Designating Party believes in good faith to be entitled to protection under Rule 26(c)(1) of the Federal Rules of Civil Procedure. It may include, without limitation: documents produced in this action, during formal discovery or otherwise; documents and information produced by third parties which the Designating Party is under an obligation to maintain in confidence; pleadings, portions of briefs, memoranda, or other writings filed with the Court; answers to interrogatories and

responses to requests for admission or other discovery requests; deposition or trial transcripts; infringement contentions and noninfringement contentions; and tangible things or objects that are designated confidential pursuant to this Order. The information contained therein and all copies, abstracts, excerpts, analyses or other writings that contain, reflect, reveal, suggest or otherwise disclose such Confidential Information shall also be deemed Confidential Information. Information originally designated as Confidential Information pursuant to this agreement shall not retain Confidential status after any ruling by any Court denying such status.

b. The term "Designating Party" means the party producing or designating documents or information as Confidential Information under this Order.

c. The term "Receiving Party" shall mean any person to whom Confidential Information is disclosed.

Designation of Confidential Information

2. Any party who produces or discloses any material that it believes comprises Confidential Information shall designate the same by marking "CONFIDENTIAL" prominently on the face of each document containing the Confidential Information.

3. If a Designating Party elects to produce original files and records for inspection and the inspecting party desires to inspect those files, the Designating Party shall give notice of the confidentiality of any files or records in advance of the initial inspection, and the party inspecting such files and records shall maintain the confidentiality of all those original files and records that it reviews. Thereafter, upon selection of specified documents for copying by the inspecting party, the Designating Party shall mark the copies of such documents as may contain

Confidential Information with the appropriate designation at the time the copies are produced to the inspecting party.

4. If any Confidential Information is produced by a third party to this litigation, such third party shall be considered a Designating Party within the meaning of that term as it is used in the context of this Order and all parties to this Order should be treated as Receiving Parties.

5. Confidential Information that originated with a third party, subject to the terms of any confidentiality obligation to that third party, may be designated as "CONFIDENTIAL" and shall, once designated, be subject to the restrictions on disclosure specified in Paragraph 7. The parties may agree to additional restrictions to satisfy third party confidentiality concerns.

6. In the event any Designating Party produces Confidential Information that has not been designated "CONFIDENTIAL" or not correctly designated, the Designating Party may designate or redesignate the information to the same extent as it may have designated the information before production. The Designating Party may do so by a subsequent notice to all parties in writing specifically identifying the redesignated information accompanied by a replacement set of such misdesignated documents bearing a "CONFIDENTIAL" designation thereon. Upon receiving such notice, the parties shall henceforth treat such information in accord with this Protective Order, and shall undertake their best efforts to correct any disclosure of such information contrary to the redesignation. Further, the Receiving Party shall immediately dispose of or return to the Designating Party the documents that lacked the "CONFIDENTIAL" designation upon receiving the replacement set of documents bearing the "CONFIDENTIAL" designation. No showing of error, inadvertence, or excusable neglect shall be required for such redesignation.

Disclosure of Confidential Information

7. Information designated "CONFIDENTIAL" shall not be given, shown, made available or communicated in any way to any person or entity other than the following:

a. Outside litigation counsel for Plaintiffs, provided that the outside litigation counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action, except as expressly permitted below:

i. Akin Gump Strauss Hauer & Feld LLP (Outside litigation counsel may be involved in any appeal of the reexamination proceedings relating to U.S. Patent 6,284,471 before the Patent Trial and Appeal Board, Federal Circuit, or U.S. Supreme Court, but they may not advise or be involved in any discussion or consideration of claim amendments of the patent or any other patents);

ii. Patterson Belknap Webb & Tyler LLP (Outside litigation counsel may be involved in any appeal of the reexamination proceedings relating to U.S. Patent 6,284,471 before the Patent Trial and Appeal Board, Federal Circuit, or U.S. Supreme Court, but they may not advise or be involved in any discussion or consideration of claim amendments of the patent or any other patents); and

iii. Nutter McClennen & Fish LLP.

b. In-house counsel for Plaintiffs (or Plaintiffs' related corporate entities, such as Johnson & Johnson), provided that the in-house counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any

reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action, except as expressly permitted below:

i. Eric Harris, Assistant General Counsel and Chief Antitrust Counsel, Johnson & Johnson (Mr. Harris may be involved in any appeal of the reexamination proceedings relating to U.S. Patent 6,284,471 before the Patent Trial and Appeal Board, Federal Circuit, or U.S. Supreme Court, but he may not advise or be involved in any discussion or consideration of claim amendments of the patent or any other patents);

ii. Joseph Braunreuther, Deputy General Counsel, Johnson & Johnson (Mr. Braunreuther may be involved in any appeal of the reexamination proceedings relating to U.S. Patent 6,284,471 before the Patent Trial and Appeal Board, Federal Circuit, or U.S. Supreme Court, but he may not advise or be involved in any discussion or consideration of claim amendments of the patent or any other patents); and

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iii. Brian Carey, Assistant General Counsel – Patents, Johnson & Johnson and Janssen Research and Development, LLC.

c. Outside litigation counsel for Defendants, provided that the outside litigation counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing,

method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action:

i. Winston & Strawn LLP;

ii. Kirkland & Ellis LLP; and

iii. Burns & Levinson LLP.

d. In-house counsel for Defendants (or Defendants' related corporate entities, such as Hospira, Pty Ltd.), provided that the in-house counsel does not engage directly or indirectly (e.g. by advising) in prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, during the pendency of this action and for one year subsequent to this action:

i. Leah Taylor, Vice President of Intellectual Property, Hospira, Pty Ltd.;

ii. Sehoon Kim, Senior Litigation Counsel, Celltrion, Inc.;

iii. David Kim, Litigation Counsel, Celltrion, Inc.; and

iv. Kwisu Park, Patent Attorney, Celltrion, Inc.

e. Members or employees of any of the foregoing law firms assisting in this litigation (e.g., secretarial, paralegal, clerical, data processing personnel) as well as any independent litigation support providers retained by such firms to assist in this litigation (e.g., court reporters, litigation support personnel, outside copy services, graphic artists and visual aid providers, and jury consultants).

f. The Court and Court personnel and stenographic/videographic reporters at depositions taken in this action.

g. Independent consultants or experts and their staff not employed by or affiliated with a party or with a party's licensee or licensor, retained by the attorneys for the parties either as technical consultants or expert witnesses for the purposes of this litigation, provided that (i) such persons have complied with the procedure of Paragraph 12 herein, and (ii) agree in writing to be bound by the provisions of this Order, in the form set forth as Exhibit A, hereto.

h. The category of individuals listed in Paragraphs 7(g) will only be permitted access to Confidential Information in the following circumstances: (1) upon the individual's agreement in writing to be bound by the provisions of this Order, in the form set forth as Exhibit A hereto; and (2) upon either of the following: (i) a grant of consent by the Designating Party; or (ii) the expiration of fourteen (14) days from the date of written notice of intent to disclose without written notice of objection from the Designating Party. In the event the Designating Party does provide notice of objection to disclosure, a party must seek leave of the Court to make the disclosure and may not make such disclosure without an order of the Court authorizing such disclosure.

i. The list of persons to whom Confidential Information may be disclosed may be expanded or modified by mutual agreement in writing by counsel for the Designating Party and the Receiving Party without necessity of modifying this Order.

j. The Receiving Party shall give notice of this Order and advise of the duty to comply with its terms to any person allowed access to Confidential Information prior to allowing said person access to Confidential Information.

No Waiver of Privileges

8. Inadvertent production of documents or information subject to attorney-client privilege, work product immunity, or any other applicable privilege or immunity shall not constitute a waiver of, nor a prejudice to, any claim of such privilege or immunity, provided that the Designating Party notifies the Receiving Party in writing promptly after discovery of such inadvertent production and provides the basis for the claim of privilege or immunity in accordance with Federal Rule of Civil Procedure 26(b)(5)(B). After receiving written notice from the Designating Party that the document or information subject to attorney-client privilege, work product immunity, or any other applicable privilege or immunity has been inadvertently produced, the Receiving Party shall promptly return, sequester, or destroy such inadvertently produced document or information and all copies thereof. No use shall be made of such documents other than to challenge the propriety of the asserted privilege or immunity, nor shall they be shown to anyone who has not already been given access to them subsequent to the request to return or destroy them. No demonstration or proof of error, inadvertence, excusable neglect, or absence of negligence shall be required of the Designating Party in order for such party to avail itself of the provisions of this paragraph. Nothing herein restricts the right of the Receiving Party to challenge the Designating Party's claim of privilege or immunity, if appropriate, within a reasonable time after receiving notice of the inadvertent production.

Use and Control of the Confidential Information

9. Other than by permission of the disclosing party or court order, all Confidential Information disclosed pursuant to this Order shall be used by any recipient thereof solely for the purposes of this litigation. Any Confidential Information shall not be used by any recipient thereof for any business, commercial, competitive, or other purpose, including, but not limited

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to: (i) filing a citizen petition to the FDA relating to any infliximab or biosimilar infliximab product, (ii) prosecuting patent applications (including any reexamination or post grant review) relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, (iii) using as evidence or supporting materials in disputes or petitions to any regulatory agencies or courts in any jurisdiction or forum, regardless of country (other than this present litigation) relating to marketing approval or sale of any infliximab or biosimilar infliximab product, or (iv) evaluating whether to license or acquire patents relating to any infliximab or biosimilar infliximab product, including any means for manufacturing, method of treatment or use, or packaging of such product, except for what is reasonably necessary to permit the parties to engage in meaningful settlement discussions of the present litigation. It shall be the duty of each party and each individual having notice of this Protective Order to comply with this Order from the time of such notice.

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10. All depositions shall be marked "CONFIDENTIAL" regardless of whether a designation of confidentiality was made on the record or otherwise and shall be subject to this Protective Order, unless and until the Receiving Party makes a request to the party producing the witness or counsel for the witness to release the deposition or any portion thereof from confidential treatment, and only if, and to the extent that, the party producing the witness or counsel for the witness agrees in writing to the modification of treatment of all or part of the transcript, or unless the Court so orders. If the party producing the witness or counsel for the witness fails to respond to such a request within fourteen (14) days, the Receiving Party may move the Court for an order releasing the requested transcript or portion thereof from confidential treatment.

11. All Confidential Information that is filed with the Court, and any pleadings, motions or other papers filed with the Court disclosing any Confidential Information, shall be filed and maintained in Court under seal. Where practical, only confidential portions of filings with the Court shall be filed under seal.

12. Before any independent consultant or expert may be given access to Confidential Information under Paragraph 7(g), the party seeking to provide such access must give written notice to the attorneys for the Designating Party of the intention to make such disclosure, and provide the following information regarding such independent consultant or expert:

i. Name and address;

ii. Business title and business affiliation;

iii. Resume of his or her background and qualifications, including employment history for the last ten (10) years;

iv. Any past or present relationships with any of the parties;

v. All cases in which the individual has testified in a deposition or at trial in the past four (4) years, and identification of the party on whose behalf the expert testified; and

vi. An executed copy of Exhibit A.

Within fourteen (14) days from the service of such written notice, the Designating Party may object to such disclosure by service of a written notice of objection on the attorneys for the party seeking to make the disclosure, stating the reasons for the objection. No disclosure of Confidential Information to any such person may occur prior to the expiration of fourteen (14) days from the date of service of the written notice of intent to disclose unless consent is granted earlier by the Designating Party. If the Designating Party gives notice of objection to disclosure,

the party seeking to make the disclosure must seek leave of the Court to make the disclosure and may not make such disclosure without an order of the Court authorizing such disclosure.

13. Nothing in this Order shall prevent or otherwise restrict counsel for a party from rendering legal advice to such party with respect to the litigation and, in the course thereof, relying upon an examination of Confidential Information; provided, however, that in rendering such advice and in otherwise communicating with the party, counsel shall not disclose Confidential Information.

14. Nothing herein shall prevent any party from disclosing its own Confidential Information in any manner that it considers appropriate. Additionally, counsel for any party shall be entitled to show or use Confidential Information obtained from a Designating Party, during examination, either at deposition or at any hearing or trial, of any officer, employee, Rule 30(b)(6) designee, or retained expert of that Designating Party. Counsel for any party shall also be entitled to show or use Confidential Information obtained from a Designating Party, during examination, either at deposition or at any hearing or trial, of any person who is apparently an author, creator, or recipient of the Confidential Information.

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Duration of Order, Objections, Modifications

15. This Protective Order shall remain in force and effect until modified, superseded or terminated by order of this Court, which may be entered pursuant to agreement of the parties hereto. This Protective Order shall continue in effect after termination of this action and continue to be binding upon all persons to whom Confidential Information is disclosed hereunder.

16. Upon final termination of this action (including all appeals) the Receiving Party shall, within thirty (30) days of such termination, either return to the Designating Party or destroy all Confidential Information in its possession. In either event, the Receiving Party shall

certify their return or destruction, with the exception that the outside litigation counsel designated in Paragraphs 7(a) and (c) may retain copies of the pleadings or other papers filed with the Court or served in the course of the litigation, depositions transcripts, deposition exhibits and the trial record. Nothing herein shall restrict the ability of the parties or their counsel to retain information or documents not designated as Confidential Information by the Designating Party.

17. If the Receiving Party learns that Confidential Information produced to it is disclosed to or comes into the possession of any person other than in the manner authorized by this Order, the Receiving Party responsible for the disclosure must immediately inform the Designating Party of such disclosure and shall make a good faith effort to retrieve any documents or things so disclosed and to prevent disclosure by each unauthorized person who received such information.

18. Any Receiving Party may at any time request that the Designating Party remove the "CONFIDENTIAL" designation with respect to any document, object or information. Such request shall be served on counsel for the Designating Party, and shall particularly identify the designated Confidential Information that the Receiving Party contends is not confidential and the reasons supporting its contention. If the Designating Party does not agree to remove the "CONFIDENTIAL" designation within fourteen (14) days, then the party contending that such documents or information are not confidential may file a motion to remove such information from the restrictions of this Order.

Miscellaneous

19. This Protective Order may be modified only by written agreement of the parties or further order of the Court and is without prejudice to the rights of any party or third party to seek additional or different relief from the Court not specified in this Order.

20. The designation by counsel for the Designating Party of any document, material or information as constituting or containing Confidential Information is intended solely to facilitate the preparation and trial of this case, and such designation shall not be construed in any way as an admission or agreement by any party that such document, material or information constitutes or contains any Confidential Information as a matter of law.

21. In the event Confidential Information disclosed during the course of the litigation is sought by any person or entity not a party to this litigation, whether by subpoena in another action or service with any legal process, the party receiving such subpoena or service shall promptly notify in writing outside counsel for the Designating Party if such subpoena or service demands the production of Confidential Information of such Designating Party. Any such person or entity seeking such Confidential Information by attempting to enforce such subpoena or other legal process shall be apprised of this Protective Order by outside counsel for the party upon whom the subpoena or process was served. Nothing herein shall be construed as requiring anyone covered by this Protective Order to contest a subpoena or other process, to appeal any order requiring production of Confidential Information covered by this Protective Order, or to subject itself to penalties for non-compliance with any legal process or order.

22. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the aggrieved party immediately may apply to obtain injunctive relief against any such person violating or threatening to violate any of the terms of this Protective Order, and in the event that the aggrieved party does so, the responding party, subject to the provisions of this

Protective Order, shall not employ as a defense thereto the claim that the aggrieved party possesses an adequate remedy at law.

23. Nothing herein shall prevent any party or non-party from seeking additional or different relief from the Court not specified in this Order.

24. The section titles in this Order are for convenience of organization only, and are not part of, nor are they relevant to the construction of this Order.

SIGNED this _____ day of _____ 2015.

_____

EXHIBIT A

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. **Defendants.**	)	

DECLARATION OF COMPLIANCE

I, _____ do declare and state as follows:

1. I live at _____. I am employed as _____ (position) by _____ (name and address of employer).

2. I have read the Protective Order entered in this case, a copy of which has been given to me.

3. I understand and agree to comply with and be bound by the provisions of the Protective Order and consent to the jurisdiction of the district court to enforce the terms of the Protective Order, including that upon receipt of any Confidential Information, I will be personally subject to it, and to all of its requirements and procedures.

4. Further, I declare, as provided by 28 U.S.C. § 1746, under penalty of perjury under the laws of the United States of America, that the foregoing is true and correct.

Date: _____

_____

EXHIBIT 13

[Filed Under Seal]

EXHIBIT 14

[Filed Under Seal]

EXHIBIT 15

[Filed Under Seal]

EXHIBIT 16

[Filed Under Seal]

EXHIBIT 17

[Filed Under Seal]

EXHIBIT 18

[Filed Under Seal]