UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

UNOPPOSED MOTION FOR LEAVE TO FILE A MOTION TO MODIFY THE PROTECTIVE ORDER TO PERMIT FILING OF A NEW ACTION UNDER SEAL

Pursuant to Local Rules 7.1 and 7.2 of the United States District Court for the District of Massachusetts, plaintiffs Janssen Biotech, Inc. ("Janssen") and New York University move for leave to file their Motion to Modify the Protective Order to Permit Filing of a New Action (Janssen's "Motion to Modify the Protective Order"), and accompanying documents, under seal. In support of this motion, Plaintiffs states as follows:

1. On May 29, 2015, Plaintiffs filed a Joint Motion with Defendants to enter a Stipulated Protective Order. [Dkt. No. 64].

2. During the course of this case, Plaintiffs have developed good cause to modify the Proposed Protective Order. [*See* Plaintiffs' Redacted Brief in Support of its Motion to Modify the Proposed Protective Order to Permit Filing of a New Action, attached hereto].

3. In Janssen's Brief in Support of its Motion to Modify the Protective Order, it intends to include information that Defendants have stated would cause them competitive injury within the industry.

4. In three of Janssen's five exhibits (Exhibits A, D, and E) in support of its Motion to Modify the Protective Order, Janssen intends to include information that Defendants have stated would cause them competitive injury within the industry.

5. Janssen has therefore agreed to file its Motion to Modify the Protective Order, and accompanying materials, under seal.

6. Janssen will file publicly available, redacted versions of its Motion to Modify the Protective Order, along with the accompanying materials, through the electronic filing system to minimize the impact beyond what is necessary.

7. The granting of this motion will not prejudice the parties.

8. Defendants have no objection to the relief sought by this motion.

JANSSEN BIOTECH, INC. and
NEW YORK UNIVERSITY,

By their attorneys,

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Dated: August 12, 2015

LOCAL RULE 7.1 CERTIFICATION

Pursuant to Local Rule 7.1(A)(2), I certify that plaintiffs' counsel conferred with defendants' counsel on the subject of this motion, and was advised that defendants do not oppose or object to this motion.

/s/ Heather B. Repicky

CERTIFICATE OF SERVICE

I certify that on August 12, 2015 this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing.

/s/ Heather B. Repicky

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC., AND NEW YORK UNIVERSITY, Plaintiffs, v. CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC. Defendants.	Civ. Action No. 1:15-cv-10698 Hon. Mark L. Wolf

PLAINTIFFS' MOTION TO MODIFY THE PROTECTIVE ORDER
TO PERMIT FILING OF A NEW ACTION

Plaintiffs Janssen Biotech, Inc. and New York University (collectively "Plaintiffs") hereby move this Court to modify the Protective Order to permit the filing of a new action. As set forth more fully in Plaintiffs' memorandum of law and accompanying declaration and exhibits, Plaintiffs learned during discovery that Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc. (together, "Celltrion"), together with non-party [redacted], have been infringing Plaintiffs' patent covering a particular cell culture media (U.S. Patent No. 7,598,083, the "'083 patent") for years. Plaintiffs wish to use that information to file a new patent infringement lawsuit against Celltrion and [redacted], so that all the known infringement of the '083 patent can be adjudicated. Celltrion and [redacted], however, have refused to permit Plaintiffs to use the information that they produced in discovery to file a new lawsuit against them for current and past infringement. Therefore, Plaintiffs file this motion seeking modification of the Protective Order to permit them to enforce their patent rights.

Accordingly, the Court should modify the protective order to permit filing of a new action.

REQUEST FOR ORAL ARGUMENT

Plaintiffs believe that oral argument may assist the court and hereby request oral argument on this motion.

Dated: August 12, 2015

Respectfully Submitted,

/s/ Heather B. Repicky

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Attorneys for Janssen Biotech, Inc. and New York University

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that on August 12, 2015 counsel for Plaintiffs conferred with counsel for Defendants and, in good faith, attempted to resolve or narrow the issues presented in this motion. Defendants oppose the relief sought herein.

/s/ Heather B. Repicky
Heather B. Repicky

CERTIFICATE OF SERVICE

I certify that on August 12, 2015, this document, filed conventionally under seal, will be sent electronically to Defendants' counsel and that this document, with redacted versions of its declarations and exhibits, will be filed through the ECF system and sent electronically to the registered participants identified on the Notice of Electronic Filing and sent to those indicated as non-registered participants.

/s/ Heather B. Repicky
Heather B. Repicky

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

BRIEF IN SUPPORT OF JANSSEN'S MOTION TO MODIFY THE PROTECTIVE ORDER TO PERMIT FILING OF A NEW ACTION

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PRELIMINARY STATEMENT

In this lawsuit, plaintiffs Janssen Biotech, Inc. ("Janssen") and New York University accuse Defendants Celltrion Healthcare Co., Ltd., Celltrion Inc., and Hospira Inc. (together, "Celltrion") of infringing a Janssen patent covering a particular "cell culture media" (U.S. Patent No. 7,598,083, the "'083 patent"), which Celltrion uses to make its proposed biosimilar of Janssen's Remicade biologic drug product. During discovery, Janssen learned that Celltrion, together with non-party [redacted], has been infringing Janssen's '083 patent for years. Since at least 2010, at Celltrion's order, [redacted] has custom made a version of Janssen's patented cell culture media in [redacted]. Celltrion, in turn, has used [redacted] infringing cell culture media to make its biosimilar of Remicade, which it has sold outside the United States since at least 2012. This is the same cell culture media Celltrion will use in making its proposed biosimilar for sale in the United States if it is approved by the FDA. Janssen wishes to use that information to file a new patent infringement lawsuit against Celltrion and [redacted], so that all the known infringement of the '083 patent can be adjudicated.

Celltrion and [redacted] have refused to permit Janssen to use the information that they produced in discovery to file a new lawsuit against them for current and past infringement. They contend that because they produced this information pursuant to the Protective Order in this case, such use is forbidden. That objection is baseless. The purpose of a protective order is to prevent dissemination of sensitive business information – not to provide infringers with immunity from suit. *See Go-Video, Inc. v. Motion Picture Ass'n of Am.*, 10 F.3d 693, 696 (9th Cir. 1993) ("Privacy of proprietary information, not immunity from suit, was the legitimate purpose of the protective order.")

Janssen files this motion to seek modification of the Protective Order to permit it to enforce its patent rights. The First Circuit (like most circuits) applies "lenient standards," often described as "good cause," to requests to modify protective orders. Janssen readily meets that test here. When Janssen filed this case, it did not know either the extent of Celltrion's infringement of its '083 patent, or the fact of [redacted] infringement. Janssen only learned this information as a result of discovery in this case. That changed circumstance constitutes good cause under controlling case law and merits modification of the protective order. Meanwhile, denial of Janssen's motion would be fundamentally unfair. It would effectively immunize Celltrion and [redacted] from having to defend current and past infringement charges under the '083 patent.

Celltrion and [redacted] have no countervailing interests against modification. To the extent information relating to their infringement involves legitimate privacy or competitive-interest concerns, those interests will be protected by a protective order in the new case. The Protective Order in this case should be modified to permit Janssen to file a new action against Celltrion and [redacted].

BACKGROUND

A. Janssen's Remicade and its '083 Patent

Janssen manufactures and distributes Remicade in the United States and around the world. Remicade is a medicine known as a biological medicine or biologic that treats many serious autoimmune diseases including Crohn's disease, ulcerative colitis, and rheumatoid arthritis. By annual revenue and profits, Remicade is Janssen's most successful product.

In the early 2000s, Janssen invented the cell culture media of the '083 patent. A cell culture media is used for growing the cells that have been modified to make biologic products

like Remicade. Janssen's patent formula includes 61 different ingredients and is optimal for the production of antibodies, such as Remicade. Use of a cell culture media is critical to obtain the desired characteristics of the biologic, and any substantial changes in the cell culture media being used to make a biologic product will change the nature of the biologic product.

B. Celltrion Markets a Remicade Biosimilar Drug Product Around the World and Is Seeking to Market It in the United States

Celltrion has developed and sold around the world (but not in the United States) a biosimilar to Janssen's Remicade. A biosimilar is a product that is similar, but not identical, to the innovator's biological product. Celltrion has sold and continues to sell its Remicade biosimilar in roughly 30 countries worldwide, but it has not received FDA approval to sell the product in the United States.

Celltrion submitted an Investigational New Drug ("IND") application for its proposed biosimilar in October 2013, which permitted Celltrion to conduct studies of its proposed biosimilar for use in an application for regulatory approval in the United States. Celltrion then submitted an abbreviated Biologic License Application ("aBLA") for this proposed biosimilar product in August 2014, and the FDA accepted that application for review in October 2014. The aBLA is Celltrion's application to market its proposed biosimilar product in the United States.

In connection with its sales of its biosimilar product worldwide and development of a proposed biosimilar product for sale in the United States, Celltrion has engaged [redacted], a non-party here, to custom make cell culture media in [redacted], for the production of Celltrion's product. Celltrion's product is otherwise made in [redacted].

C. Celltrion Refused to Produce Relevant Manufacturing Information

Shortly after its aBLA was accepted for review by FDA in October 2014, Celltrion provided a copy of its aBLA to Janssen under the confidentiality restrictions of the Biologics Price Competition and Innovation Act ("BPCIA"). Although Celltrion provided its aBLA, it did not provide any "other information that describes the process or processes used to manufacture the biological product that is the subject of such application," as set forth in the statute so Janssen could evaluate whether any of its patents were infringed. 42 U.S.C. § 262(*l*)(2)(A). In particular, Celltrion did not produce sufficient information relating to the composition of its cell culture media or whether there was activity in the United States relating to the cell culture media. Celltrion maintained its position even after Janssen identified the '083 patent as potentially infringed by Celltrion's media and after Janssen repeatedly asked for both the composition of the media and the identification of any activity relating to the media in the United States. *See, e.g.,* Ex. A (Dec. 16, 2014 email from J. Weil to O. Berson) and Ex. B at 4-5 (Feb. 25, 2015 Letter from D. Elderkin to C. Klein). Rather than provide the needed information, Celltrion insisted that it would produce the information only after a lawsuit was filed and a protective order entered. *See* Ex. C at 4 (March 4, 2015 Letter from C. Klein to D. Elderkin).

D. Janssen Files Suit on the '083 Patent, and the Parties Stipulate to a Protective Order

Attempting to short-circuit the procedural requirements of the BPCIA, Celltrion demanded that Janssen file suit on the '083 patent (among others) by March 7, 2015. Janssen's Complaint was filed in this Court on March 6, 2015. *See* ECF No. 1. It asserted, *inter alia*, that Celltrion's filing of its aBLA in the United States while failing to produce manufacturing information infringed the '083 patent under 35 U.S.C. § 271(e)(2)(C)(ii). *Id.* ¶¶ 121, 170-74.

Shortly after the lawsuit was filed, Janssen and Celltrion stipulated to the terms of a Protective Order that would govern the use of the parties' confidential information. It was filed with the Court on May 29, 2015. *See* ECF No. 64-1. (The Order has not yet been signed by the Court.) The Protective Order aimed to "preserve the legitimate business and other interests of the parties, and . . . to prevent unnecessary dissemination or disclosure of such confidential information." *See id.* at 2.

The Protective Order states that confidential information produced in the case could be used "solely for purposes of this litigation." *Id.* ¶ 9. Furthermore, it prohibits a recipient's use of confidential information as "evidence or supporting materials in disputes or petitions to . . . 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 . . . ." *Id.* The parties are bound by the Protective Order's terms pending entry by the Court. *Id.* ¶ 25.

By its terms, the Protective Order "may be modified [by] . . . further order of the Court." *Id.* ¶ 19.

E. Pursuant to the Protective Order, Janssen Learned The Extent of Celltrion's and [redacted] Infringement of the '083 Patent

Pursuant to the Protective Order (and an additional confidentiality agreement with [redacted](*see* Ex. D at 1 (May 27, 2015 Letter from M. Wolf to I. Royzman)), Janssen learned the composition of the cell culture media used by Celltrion. That discovery confirmed Janssen's infringement allegations of the '083 patent and also revealed that the infringement was widespread, well beyond Janssen's allegations in this case.

Initially, discovery confirmed Janssen's infringement allegations. [redacted] 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. The formula for that media, set forth in detail in the '083 patent, claims no less than 61 different ingredients in various concentration ranges. [redacted] Discovery has thus confirmed Janssen's infringement case on the '083 patent.

Discovery also demolished one of Celltrion's principal non-infringement defenses. Celltrion had argued in its non-infringement contentions under the BPCIA that it could not be liable for infringement in the United States because it used the cell culture media only in [redacted], where it manufactured its biosimilar. Through discovery, Janssen has learned that, although Celltrion *uses* the cell culture media in [redacted], the cell culture media are *made* for Celltrion in the United States. The manufacturer is [redacted], which custom makes the cell culture media to Celltrion's specifications in [redacted]. Thus, Celltrion is (at the least) inducing infringement in the United States by custom ordering the cell culture media from [redacted]. Further discovery may reveal that Celltrion's involvement in the manufacture of the cell culture media is such that it is a direct infringer, as well an indirect infringer.

All of this discovery will be used in the pending case, which accuses Celltrion of infringing the '083 patent with respect to its proposed sales in the United States. But the same discovery revealed that Celltrion's infringement of the '083 patent is much more widespread and

that [redacted] should be added as a defendant. As to Celltrion, the current case is brought under the BPCIA and is necessarily focused on infringement that will result if Celltrion is licensed by the FDA to sell its product in the United States. That is, the alleged infringement is an artificial or technical "act of infringement," rather than an actual act of infringement, because the BPCIA specifies that the filing of an aBLA permits the patent owner to bring suit earlier than otherwise permitted. *See* 35 U.S.C. § 271(e)(2)(C). But Janssen now understands that, unrelated to the BPCIA, Celltrion has used infringing cell culture media – custom made to its order by [redacted] in the United States – to produce its biosimilar version of Remicade, which Celltrion has been selling around the world for years. [redacted] infringement in the United States, induced and possibly controlled by Celltrion, is an actual act of infringement under Section 271 of the Patent Act. As a result, Janssen now wishes to institute a new lawsuit against Celltrion, unrelated to the BPCIA, alleging actual infringement under Section 271 of the Patent Act and based on Celltrion's infringement of Janssen's patent – in the United States – to support its worldwide sales.

As to [redacted], Janssen wishes to file suit based on the same allegations. The facts of [redacted] infringement are disturbing. When Janssen developed the formula set forth in the '083 patent, and before the formula was made public in the '083 patent, Janssen hired [redacted] to manufacture quantities of the cell culture media for its experiments. Janssen agreed to indemnify [redacted] for its work, and [redacted] produced custom made cell culture media for Janssen beginning in early 2004. Unknown to Janssen, [redacted] began working with Celltrion later in 2004. We do not yet know the details of its development program, or whether [redacted] complied with its confidentiality obligations to Janssen. But we do know that its development program with Celltrion led to the creation of a cell culture media for Celltrion's biosimilar

version of Remicade [redacted] We assume that Celltrion indemnified [redacted], just as Janssen did, but whoever is ultimately responsible, [redacted] infringement of Janssen's '083 patent has supported Celltrion's worldwide sales of its biosimilar version of Remicade.

F. Celltrion Objects to the Filing of Janssen's New Lawsuit

The new allegations that Janssen seeks to make would use information developed in this case under the Protective Order. Upon being advised of Janssen's intentions, Celltrion objected to the filing of new allegations because, it claimed, any new complaint would be "based on a misuse of confidential information—*e.g.*, the composition of [redacted] cell media and its use abroad in the manufacture of Celltrion biosimilar infliximab products—that [Janssen Biotech] received in this litigation subject to the terms of the protective order." *See* Ex. E at 2 (July 14, 2015 Letter from C. Klein to I. Royzman).

ARGUMENT

The Protective Order requires that confidential information produced under it be used only in "this litigation." This Court should modify the Protective Order to allow Janssen to use information obtained in discovery in this case to commence and prosecute a new action seeking redress for Celltrion's and [redacted] infringement of the '083 patent.

I. RELEVANT LEGAL STANDARDS FOR MODIFYING A PROTECTIVE ORDER

"Control of pretrial discovery, including the entry or modification of a protective order, is a matter falling peculiarly within the discretion of the district court." *Public Citizen v. Liggett Group, Inc.*, 858 F.2d 775, 790 (1st Cir. 1988). This includes "cases where the parties have

stipulated or created their own protective orders." *Hayes v. McGee*, 2014 U.S. Dist. LEXIS 3765, Civ. No. 10-40095-TSH, at *12 (D. Mass. Jan. 13, 2014).

In *Liggett*, the First Circuit adopted the prevailing view that "lenient standards" should govern modification of a protective order. 858 F.2d at 791.[1] *See* Wright, Miller, & Marcus, FEDERAL PRACTICE & PROCEDURE, § 2044.1 at 271 (2010) (collecting cases). While *Liggett* did not identify all the circumstances that would warrant modification of a protective order, it agreed that modification would be appropriate "where the party seeking modification has pointed to some relevant change in the circumstances under which the protective order was entered." *Id.* Applying *Liggett* more generally, courts in this Circuit have routinely held that "good cause" is the standard for the modification of protective orders.[2] *See United States v. Bulger*, 283 F.R.D. 46, 54 (D. Mass. 2012) (citing *U.S. ex. rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 2004 U.S.

[1] *See Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 790 (3d Cir. 1994) (holding that the movant "should not be saddled with a burden more onerous than explaining why his need for the materials outweighs existing privacy concerns"); *Meyer Goldberg, Inc. v. Fisher Foods, Inc.*, 823 F.2d 159, 163-164 (6th Cir. 1987) (finding that even a good cause standard may be too high and that "access should be granted even if the need for the protected materials is minimal"); *Wilk v. Am. Med. Ass'n*, 635 F.2d 1295, 1300 (7th Cir. 1980) (holding that the court's prior invocation of the extraordinary circumstances test was "an unfortunate choice of words"); *Foltz v. State Farm Mut. Auto Ins. Co.*, 331 F.3d 1122, 1131 (9th Cir. 2003) (noting that the Ninth Circuit "strongly favors access to discovery materials to meet the needs of parties engaged in collateral litigation. Allowing the fruits of one litigation to facilitate preparation in other cases advances the interests of judicial economy by avoiding the wasteful duplication of discovery"); *United Nuclear Corp. v. Cranford Ins. Co.*, 905 F.2d 1424, 1428 (10th Cir. 1990) (agreeing with the Seventh Circuit in *Wilk*, which held: "Where an appropriate modification of a protective order can place private litigants in a position they would otherwise reach only after repetition of another's discovery, such modification can be denied only where it would tangibly prejudice substantial rights of the party opposing modification"); *Tavoulareas v. Washington Post Co.*, 737 F.2d 1170, 1172 (D.C. Cir. 1984) (suggesting that the good cause standard of Rule 26(c) governs modifications of protective orders).

[2] *See, e.g., Trs. of Boston Univ. v. Everlight Elecs. Co.*, 2014 U.S. Dist. LEXIS 146542, 12-cv-12330-PBS, *9 (D. Mass. July 8, 2014) ("Good cause is also required to modify a protective order."); *Fairchild Semiconductor Corp. v. Third Dimension Semiconductor, Inc.*, 2009 U.S. Dist. LEXIS 37445, Civ. No. 08-158, *6 (D. Me. Apr. 30, 2009) (citing *Liggett* and applying good cause standard).

Dist. LEXIS 18548, No 99-3298, *6 (D.D.C. May 17, 2004) ("Good cause implies changed circumstances or new situations.")).

New information supporting the filing of new allegations is a sufficient change of circumstances to warrant modification of a protective order. The purpose of a protective order is to prevent dissemination of sensitive business information – not to immunize infringers from being sued. *See Go-Video v. Motion Picture Ass'n of Am.*, 10 F.3d 693, 696 (9th Cir. 1993) ("Privacy of proprietary information, not immunity from suit, was the legitimate purpose of the protective order."); *Principle Sols. LLC v. Feed.Ing BV*, 2015 U.S. Dist. LEXIS 1877, *12 (E.D. Wisc. Jan 8, 2015) ("[T]he protective order was designed to protect the privacy of information, not shield Principle from such a lawsuit.").[3]

Numerous cases hold that good cause exists where a party seeks to use the information developed in one case in another case. "Ordinarily, the most forceful case can be made for access to use material as evidence in other litigation so that later litigants do not have to 'reinvent the wheel.' This conclusion flows from the key purpose of discovery — to develop information for use in litigation." Wright & Miller § 2044.1 at 273; *see Verizon Cal. Inc. v. Ronald A. Katz Tech. Licensing, L.P.*, 214 F.R.D. 583 (C.D. Cal. 2003) (holding that the patentee was entitled to modification of protective order to permit it to use discovered information in a separate action for patent infringement against the same party).

The burden on a party seeking modification of a protective order – particularly for use in a new case – is therefore minimal. The movant "should not be saddled with a burden more onerous than explaining why his need for the materials outweighs existing privacy concerns."

[3] *See also* Wright & Miller § 2044.1 at 259 ("Where modification is designed to enable litigants to use information in other cases, modification can serve important efficiency and litigation fairness goals.").

Pansy, 23 F.3d at 790 (quoting Note, *Nonparty Access to Discovery Materials in the Federal Courts*, 94 Harv. L. Rev. 1085, 1092 (1981)). Requests to modify a confidentiality order to allow discovery materials to be used in collateral litigation "should generally be granted" where, as here, "reasonable restrictions on collateral disclosure will continue to protect an affected party's legitimate interests in privacy." *Foltz*, 331 F.3d at 1132.

Courts in this Circuit have agreed. Based on the First Circuit's holding in *Liggett*, "it is highly unlikely that the First Circuit would find it an abuse of discretion to modify a protective order to permit use of confidential information from this litigation in [a] subsequent litigation involving the same plaintiff, particularly if the litigants in that subsequent litigation were to be made subject to the provisions of a substantially similar protective order." *OfficeMax Inc. v. Sousa*, 2011 U.S. Dist. LEXIS 3972, 09-cv-631-JAW, *4 (D. Me. Jan. 14, 2011). This is because maintaining privacy of confidential business information — not shielding parties from lawsuits — is the central purpose of a protective order.

Once a court has determined whether good cause exists to modify a protective order, the court should "balance the interests" to determine whether modification is appropriate. *Pansy*, 23 F.3d at 790; *United States v. Bulger*, 283 F.R.D. 46, 53 (D. Mass. 2012) ("[T]he applicable standard involves weighing and balancing a number of relevant factors . . . ."). Factors courts analyze in balancing the interests are: (1) whether modification would promote fairness and efficiency, *Pansy*, 23 F.3d at 790; (2) whether the modification would violate privacy interests or prejudice other substantial rights, *id*. at 787; *Wilk*, 635 F.2d at 1299; and (3) the parties' reliance on the protective order in producing information, *Liggett*, 858 F.2d at 791; *Foltz*, 331 F.3d at 1132-33.

II. MODIFYING THE PROTECTIVE ORDER IS APPROPRIATE HERE

There are strong reasons to modify the Protective Order here. Documents that Celltrion and [redacted] produced in this case show that Celltrion's custom-made cell culture media from [redacted] infringes Janssen's '083 patent, which Janssen would never have learned absent discovery in this case. Indeed, Celltrion refused to provide the information prior to the filing of this case. Janssen should be able to use that information to bring and prosecute a new action seeking redress for Celltrion's and [redacted] infringement. The requested modification would be fair and would not impair Celltrion's or [redacted] legitimate confidentiality interests because the information would enjoy the same confidentiality protections in the new case as here.

A. Janssen Has Good Cause to Seek Modification of the Protective Order, and It Would Be Unfair To Prevent Janssen From Enforcing Its Legitimate Patent Rights

Janssen 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. Without that connection to infringement in the United States, there was no basis for Janssen to seek redress against Celltrion for its worldwide sales and no basis to seek redress against [redacted] at all.

Typically, for patents covering a product, a patentee can obtain and analyze a competitor's product to determine whether it infringes. But [redacted] was making cell culture media exclusively for Celltrion. Neither the composition of the [redacted] cell culture media nor the fact that it was being made for Celltrion in the United States was publicly known. Indeed, for patents that cover part of the manufacturing process, such as the '083 patent, information about

infringement generally is not available without information from defendants.[4] The disclosure of information during discovery that supports new allegations against Celltrion and [redacted] represents materially changed circumstances sufficient to warrant modification of the Protective Order. *Liggett*, 858 F.2d at 791.

Moreover, modification would be fair. *Pansy*, 23 F.3d at 787 (holding that courts should take into account whether the modification "would promote fairness and efficiency" when determining whether to modify a protective order). The purpose of the Protective Order is to protect Celltrion's and [redacted] business secrets, not to permit them to infringe Janssen's patent with impunity. Such an outcome would be fundamentally unfair to Janssen, which has no other way to enforce its legitimate patent rights.

Modification will also serve the public interest in enforcing the patent laws. As the Federal Circuit has explained, "[t]he public interest favors the enforcement of . . . patent rights." *Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 931 (Fed. Cir. 2012). The proposed modification would serve the public's interest favoring enforcement of patent rights by allowing Janssen to seek redress for Celltrion's and [redacted] infringement of the '083 patent.

B. Modification Does Not Risk Exposing Celltrion's or [redacted] Confidential Business Information

Modification also would not raise any privacy concerns nor cause any undue prejudice to Celltrion or [redacted]. *Pansy* 23 F.3d at 787; *Wilk*, 635 F.2d at 1299. The requested modification would not result in disclosure of Celltrion's or [redacted] confidential information

[4] *See Hoffman-LaRoche, Inc. v. Invamed, Inc.*, 213 F.3d 1359, 1363 (Fed. Cir. 2000) (finding that plaintiffs were "unable" to determine if defendants' manufacturing process infringed patents on a method of manufacture without information from defendants); *Dome Patent L.P. v. Permeable Techs., Inc.*, 190 F.R.D. 88, 92 (W.D.N.Y. 1999) (noting that information concerning a company's manufacturing process usually is "within the [company's] exclusive knowledge and control" before discovery).

to any entity that is not already in possession of that information. Janssen would be the plaintiff in the new case, as it is in the existing case. Celltrion would be a defendant in the new case. Based on the new information that Janssen has learned, [redacted] would also be named as a defendant – a risk it undertook by agreeing to manufacture cell culture media for Celltrion and for which it is presumably indemnified. (Even if it is not indemnified, there is no unfairness in asking [redacted] to defend itself against Janssen's charge of infringement.)

Moreover, there is no risk of inappropriate disclosure of confidential business secrets as a result of a new case. The new case would include a Protective Order that would be substantially similar (if not identical) to the one here. As a result, Celltrion and [redacted] would enjoy the same privacy protections they now have, and no new parties would learn any confidential information as a result of the new lawsuit. There is thus no risk that Celltrion's or [redacted] confidential information would be compromised.

At the same time, Celltrion and [redacted] cannot use their legitimate confidentiality interests to shield them from liability for their infringing acts. The Protective Order serves to preserve the parties' "legitimate business . . . interests" and "prevent unnecessary dissemination or disclosure of such confidential information." *See* ECF No. 64-1 at 2. The Protective Order was not designed to shield Celltrion and [redacted] from having to defend against legitimate patent infringement claims.

Finally, there is no countervailing reliance interest here that would prevent modification of the protective order. *See Liggett*, 858 F.2d at 791; *Foltz,* 331 F.3d at 1132-33. In *Liggett*, the court was concerned that a party relied on a protective order's guarantees of privacy in turning over a broad array of documents that would have been exposed to the public upon modification

of the protective order.[5] *Liggett*, 858 F.2d at 791. There is no such privacy concern here. The same information is relevant to both the new case and the existing case, and the parties will enjoy substantially the same (if not identical) privacy and business-interest protections in both cases. *See Foltz*, 331 F.3d at 1134 ("Any trade secrets [or] financial information . . . can be protected by placing the Private Intervenors under the same use and disclosure restrictions contained in the original protective order.").

[5] *See Liggett*, 858 F.2d at 791 (holding that to induce a party to produce information by promising confidentiality only to later "remove that order's protection" to make the information public would "seem unfair"); *see also Foltz*, 331 F.3d at 1132-33 (holding no appropriate reliance where a blanket protective order was in place without good-cause determinations made on a document-by-document basis).

CONCLUSION

For the foregoing reasons, the Court should grant Janssen's motion to modify the Protective Order so Janssen can file a new lawsuit for patent infringement under the '083 patent against Celltrion and [redacted]

Dated: August 12, 2015

Respectfully submitted,

/s/ Heather B. Repicky

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Attorneys for Janssen Biotech, Inc. and New York University

CERTIFICATE OF SERVICE

I certify that on August 12, 2015, this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing and if not so registered, that copies will be electronically mailed to such parties or their counsel.

/s/ Heather B. Repicky
Heather B. Repicky

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 IRENA ROYZMAN IN SUPPORT OF PLAINTIFFS' MOTION TO MODIFY THE PROTECTIVE ORDER TO PERMIT FILING OF A NEW ACTION

I, Irena Royzman, declare and state as follows:

1. I am a partner at the law firm Patterson Belknap Webb & Tyler LLP, counsel for Janssen Biotech, Inc. and New York University, and as such I am familiar with the facts stated herein.

2. Attached hereto as Exhibit A is a true and correct copy of an email dated December 16, 2014 from Jason Weil to Olga Berson.

3. Attached hereto as Exhibit B is a true and correct copy of a letter dated February 25, 2015 from Dianne B. Elderkin to Charles B. Klein.

4. Attached hereto as Exhibit C is a true and correct copy of a letter dated March 4, 2015 from Charles B. Klein to Dianne B. Elderkin.

5. Attached hereto as Exhibit D is a true and correct copy of a letter dated May 27, 2015 from Matthew M. Wolf to Irena Royzman.

6. Attached hereto as Exhibit E is a true and correct copy of a letter dated July 14, 2015 from Charles B. Klein to Irena Royzman and Barbara L. Mullin.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: August 12, 2015

/s/ Irena Royzman

Irena Royzman (admitted *pro hac vice*)
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CERTIFICATE OF SERVICE

I certify that on August 12, 2015, this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing and if not so registered, that copies will be electronically mailed to such parties or their counsel.

/s/ Heather B. Repicky

EXHIBIT A

(FILED UNDER SEAL)

EXHIBIT B

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February 25, 2015

VIA E-MAIL

Charles B. Klein
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Washington, DC 20006

RE: Response Regarding Notice of Commercial Marketing and Detailed Statement

Dear Chuck:

We write on behalf of Janssen in response to your two letters dated February 5, 2015: one purporting to be a "Notice of Commercial Marketing" on behalf of Celltrion and Hospira (collectively "Celltrion") pursuant to 42 U.S.C. § 262(1)(8)(A), the other purportedly a "Detailed Statement" of Celltrion's defenses pursuant to 42 U.S.C. § 262(1)(3)(B)(ii)(I).

In the "Notice of Commercial Marketing" letter, Celltrion asserts that it intends to begin commercial marketing of the proposed biosimilar product in Abbreviated Biological License Application ("aBLA") No. 125544 as early as 180 days from the date of the letter, i.e., by August 5, 2015. In the "Detailed Statement" letter, Celltrion asserts, among other things, that it has "moot[ed]" the remaining patent exchange provisions of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), and that Janssen must therefore file suit within thirty days, i.e., by March 6, 2015. As explained below, both of these assertions are contrary to the BPCIA. Furthermore, Celltrion has failed to provide Janssen sufficient information to fully evaluate its potential claims. The statutory time periods are therefore needed in order for the parties to complete the good-faith process of narrowing the issues for litigation and, potentially, a preliminary injunction motion.

The "Notice of Commercial Marketing"

With respect to Celltrion's purported "Notice of Commercial Marketing," we are on common ground that the BPCIA requires a subsection (k) applicant to provide "notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(1)(8)(A). Janssen disagrees, however, that the statute provides no "condition precedent to providing notice." On the contrary, the statute clearly states that the notice must pertain to a "biological product ***licensed*** under subsection (k)," meaning that the grant of a biological license is a

condition precedent to providing notice. As you are undoubtedly aware, this was precisely the holding of the sole reported case to address this issue to date. *See Sandoz Inc. v. Amgen Inc*., 2013 U.S. Dist. LEXIS 161233 (N.D. Cal. Nov. 12, 2013) As Judge Chesney concluded, a biosimilar applicant "cannot, as a matter of law, have provided a 'notice of commercial marketing'" prior to obtaining a biological license because until that time the biosimilar product "is not 'licensed under subsection (k).'" *Id*. at *6.

Because Celltrion has not yet received a biological license under Abbreviated Biological License Application No. 125544, its proposed biosimilar product is not a "biological product licensed under subsection (k)." As such, it cannot be the subject of a notice of commercial marketing pursuant to 42 U.S.C. § 262(1)(8)(A).

Celltrion's premature notice is not only contrary to the plain language of the statute, it imposes unnecessary burdens on Janssen and on any Court that might hear an action on listed patents. With benefit of information provided by the completed entire statutory patent provisions and at least some discovery, Janssen and Celltrion would be in a better position to discuss potential agreements that could eliminate the need for expedited court actions with respect to a particular patent or patents.

For example, U.S. Patent No. 5,807,715 (the '715 patent), a patent that Celltrion and Hospira do not dispute that they infringe, expires on September 15, 2015. If Celltrion waited until receiving a biological license to provide its notice of commercial launch, as the statute requires, this patent would expire before commercial marketing commenced and would never need to be litigated. If Celltrion seeks to begin commercial marketing 180 days after its premature notice of February 5, however – i.e. on August 5, 2015 – then Janssen and its licensors may be forced to litigate this patent and the Court to address to it. In addition, unless Celltrion receives a biological license which includes an indication to treat Crohn's disease, U.S. Patent No. 7,223,396 (the '396 patent) would not need to be litigated.

In light of the above, please withdraw the notice of commercial marketing or confirm that Celltrion and Hospira will not begin commercial marketing of their proposed biosimilar product until a date at least 180 days from the provision of a *proper* notice of commercial marketing, which cannot be provided until Celltrion and Hospira's proposed biosimilar product is "licensed under subsection (k)." At a minimum, please confirm that Celltrion and Hospira will not begin commercial marketing of their proposed biosimilar product until after September 15, 2015, the expiration date of the '715 patent.

Celltrion Cannot "Moot" the BPCIA

In its "Detailed Statement," Celltrion states that it "does not seek to restrict or expand" Janssen's list of patents for which Janssen believes a reasonable claim of infringement can be asserted, and asserts that this "moots" the need for the parties to complete the remainder of the statutorily required patent-exchange procedures (see 42 U.S.C. § 262(1)(3)-(l)(5)). As a result, Celltrion contends, Janssen is required to file a lawsuit on all six patents listed by Janssen within thirty days of the "Detailed Statement" pursuant to 42 U.S.C. § 262(1)(6) and will be limited to reasonable royalty damages pursuant to 35 U.S.C. § 271(e)(6)(B) if it fails to do so.

Celltrion's reading of the statute is mistaken. Celltrion asserts that its "Detailed Statement" is the document required by paragraph 3(B) of the BPCIA's patent exchange provisions, 42 U.S.C. § 262(1)(3)(B). But the BPCIA does not allow a subsection (k) applicant to "moot" the remaining statutory procedures at this stage, and it certainly does not require the sponsor to file suit within thirty days if the applicant purports to do so. On the contrary, the remaining statutory procedures are mandatory and unconditional: After the applicant's detailed statement of defenses pursuant to paragraph 3(B), the reference product sponsor "***shall*** provide" its responses within sixty days (paragraph 3(C), 42 U.S.C. § 262(1)(3)(C)), and thereafter the parties "***shall*** engage in good faith negotiations" regarding which, if any, patents should be litigated immediately (paragraph 4(A), 42 U.S.C. § 262(1)(4)(A)). The reference sponsor is required to bring suit only after these mandatory procedures are complete: within thirty days after the "subsection (k) applicant and the reference product sponsor agree on patents ***as described in paragraph (4)***" or, in the absence of agreement, they proceed to "the exchange of lists ***under paragraph (5)(B)***." 42 U.S.C. § 262(1)(6)(A)-(B). Because the parties have not yet engaged in the good-faith negotiations required by paragraph 4 or the exchange of lists required (in the absence of agreement) under paragraph 5(B), Janssen is not required to file suit within thirty days pursuant to 42 U.S.C. § 262(1)(6). Further, although Celltrion states that it "agrees" all six listed patents should be litigated, Janssen is not in a position to reach any agreement without further information from Celltrion and Hospira.

Contrary to Celltrion's apparent assumption, the remaining statutory exchange provisions are not for the sole benefit of the subsection (k) applicant. Among their clear purposes, and effects, is to provide the reference sponsor with a total of at least 90 days – not thirty days – to evaluate the applicant's defenses before filing suit, and to require ***both*** parties, during this period, to make good-faith efforts to narrow the issues for litigation in order to avoid unnecessary burdens on the parties and the Court. These pre-litigation procedures are necessary here, because Celltrion has now asserted a number of new defenses, some of which

may affect Janssen's decision about what patents to sue on, and because, as discussed above, one of the patents, the '715 patent, will expire shortly and litigation on it may be avoidable in the course of the parties' statutorily required good-faith negotiations.

In addition, as explained below, Celltrion has refused to provide Janssen with information needed for evaluating whether to assert three of the listed patents in a lawsuit against Celltrion.

Please confirm that Celltrion does not intend to assert that Janssen is limited to reasonable royalty damages if it does not bring a lawsuit by March 6, 2015 and that Celltrion will comply with the statutory procedures required under the BPCIA, including its obligation to negotiate in good faith as to the patents that should be litigated.

Celltrion Has Failed to Provide Required Information Regarding Its Manufacturing Processes

As you know, the BPCIA requires a subsection (k) applicant to provide to the reference product sponsor, in addition to its aBLA, "other information that describes the process or processes used to manufacture the biological product." 42 U.S.C. § 262(l)(2)(A). Celltrion has failed to do so; it has only provided Janssen with its aBLA and nothing else.

Because Janssen has at least three patents related to manufacturing that may be infringed based on the information in the aBLA alone, we reached out to Celltrion on December 16, 2014, asking for specific information relating to the process or processes used to manufacture Celltrion's infliximab product. In response, Celltrion stated that "[a]ll relevant information needed to generate a list of patents for which a claim of patent infringement can reasonably be asserted by Janssen is included in Celltrion's BLA," and provided no further information.

Although Celltrion asserts in its "Detailed Statement" that these patents are not infringed, it does so based on representations signed by litigation counsel, and fails to provide the manufacturing information that would decide the issue. For example, Celltrion asserts that the cell media it uses lack certain ingredients required by the claims of the '056 patent or the '083 patent, but neither the aBLA nor the "Detailed Statement" sets forth what ingredients these media do contain. As to the '600 patent regarding methods of purification, Celltrion denies infringement based, in part, on features of its purification process that it admits are not mentioned in its aBLA, and as to which it provides no documentary evidence.

Akin Gump
STRAUSS HAUER & FELD LLP

We again request that Celltrion produce the manufacturing information requested on December 16 as well as the documents that support the lawyer arguments in the Detailed Statement. The production of this information is not only required by the statute but necessary for Janssen to provide its mandatory Infringement Contentions and for the parties to determine which patents need to be litigated. It is not in the interest of the parties or the Court to litigate patents that do not need to be litigated.

***

We look forward to hearing back from you promptly on each of the above three subjects.

Sincerely,

Dianne Elderkin

Dianne B. Elderkin

cc: Gregory L. Diskant, Esquire

EXHIBIT C

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VIA EMAIL

March 4, 2015

Dianne B. Elderkin
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Re: Hospira and Celltrion's February 5, 2015 Notice of Commercial Marketing and Detailed Statement Pursuant to the Biologics Price Competition and Innovation Act of 2009 ("BPCIA")

Dear Dianne:

I write on behalf of Hospira, Inc. and Celltrion, Inc. in response to your February 25, 2015, letter addressing Celltrion's Detailed Statement under 42 U.S.C. § 262(l)(3)(B) and the notice of commercial marketing under 42 U.S.C. § 262(l)(8)(A). As discussed below, we dispute the points raised in your letter. Nonetheless, in the interest of moving the parties forward, we are proposing a compromise in the discussions below.

Celltrion's Notice Of Commercial Marketing Was Proper

On February 25, 2015, Celltrion gave proper notice to Janssen of its intent to begin commercial marketing of its infliximab biosimilar product pursuant to its abbreviated biologic license application ("aBLA") 125544 in accordance with 42 U.S.C. § 262(1)(8)(A). Janssen does not object to the substance, but solely to the timing, of Celltrion and Hospira's notice of commercial marketing.

In particular, Janssen asserts that the notice is premature until the FDA has approved Celltrion's aBLA. This position, however, misconstrues the plain language of the BPCIA:

> The subsection (k) applicant shall provide notice to the reference product sponsor no later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

Id. The notice of commercial marketing provision of the BPCIA does not provide for any prerequisite before notice can be given. *Id.* The only requirement is that notice must be given, and that the biosimilar applicant cannot market its biosimilar product until 180 days after it provides such notice. *Id.* Requiring FDA approval as a prerequisite for any biosimilar applicant to provide effective notice of commercial

marketing would create an additional 180-days of market exclusivity for the reference product sponsor. This is contrary to the plain language of the statute, and there is nothing in the BPCIA or its legislative history indicating that Congress intended this result.

Janssen relies on a decision by Judge Chesney of the Northern District of California that construed, *sua sponte*, the notice provision of the BPCIA. *See Sandoz Inc. v. Amgen Inc.*, 2013 U.S. Dist. LEXIS 161233 (N.D. Cal. Nov. 12, 2013). This aspect of Judge Chesney's decision, however, was not addressed by the Federal Circuit's decision in that case. The district court decision thus carries no precedential value, and we believe it does not accurately construe the BPCIA for at least the reasons discussed above.

Janssen's Damages Are Limited To A Reasonable Royalty Unless It Files Suit By March 7, 2015

Janssen also misconstrues the BPCIA as requiring the parties to engage in "good faith negotiations" even though Celltrion has consented to Janssen's patent list. Here, "the subsection (k) applicant [Celltrion] and the reference product sponsor [Janssen] agree on patents as described in paragraph (4)"—that is, Celltrion has agreed to the "patents listed" by Janssen by not seeking to restrict or expand that list. 42 U.S.C. § 262(l)(4)(A), (6)(A). As the statute makes clear, Janssen must bring suit "not later than 30 days after such agreement"—otherwise, its "sole and exclusive remedy" is a reasonable royalty. *Id.* § 262(l)(6)(A); 35 U.S.C. § 271(e)(6)(B).

Janssen cannot avoid this plain reading of the statute by claiming that it remains uncertain about which of the patents Janssen *itself listed* will be asserted when, in fact, there already has been an "agreement" under the statute. Thus, Celltrion reserves all of its rights if Janssen elects not to bring suit by March 7, 2015—including the right to limit Janssen's remedy for any judgment of infringement to a reasonable royalty.

Janssen Is Not Entitled To Additional Manufacturing Information

Janssen requests additional manufacturing information, but Celltrion has faithfully fulfilled its obligations to produce information regarding its manufacturing processes pursuant to 42 U.S.C. § 262(l)(2)(A). On October 27, 2014, Celltrion provided Janssen a copy of its aBLA 125544, including information that describes the processes used to manufacture Celltrion's infliximab biologic product. Janssen has not shown that it is entitled to, or even needs, documents providing further detail of the steps of Celltrion's manufacturing process.

As for the '600 patent, Celltrion's Detailed Statement provides pages of information sufficient to support its non-infringement defense. According to Janssen, however, "Celltrion denies infringement based, in part, on features of its purification process that *it admits are not mentioned in its aBLA, and as to which it provides no documentary evidence*." *See* Feb. 25, 2015 Letter (emphasis added). Notably, Janssen cites nothing in the Detailed Statement to support this assertion. As that Detailed Statement makes clear, Celltrion's non-infringement position regarding this patent is based on information found in the aBLA—*e.g.*, references and diagrams that are provided in Module 3 of the aBLA, where the purification process steps are described in detail. Janssen has failed to explain how additional information would inform the infringement analysis.

As for the '056 and '083 patents, Janssen has failed to explain how it has a good-faith basis to assert infringement for any acts by Celltrion that are conducted entirely outside the territorial reach of its U.S. patents. *See, e.g.*, *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1302 (Fed. Cir. 2012) ("[P]urely extraterritorial conduct cannot constitute direct infringement of a U.S. patent, as § 271(a) includes express language limiting its scope to domestic acts."). This point, alone, is dispositive.

Nevertheless, Celltrion has produced additional information regarding its manufacturing processes necessary for Janssen to reasonably assess its allegations of patent infringement. While Janssen seeks information as to "what ingredients [the cell] media do contain," as shown in Celltrion's aBLA, Celltrion relies on a third-party supplier to provide the cell media and does not have the authority to reveal the supplier's proprietary and trade secret information. Regardless, the exact composition and ingredients of the media are irrelevant, because Celltrion already has provided enough information for Janssen to conclude what elements are explicitly missing from the claimed limitations.

For at least these reasons, Celltrion has provided the necessary information regarding its manufacturing process that is required by the BPCIA.

* * *

Notwithstanding Celltrion's positions stated above, we suggest the following compromise to resolve the issues addressed above:

1. *Janssen's patent contentions.* By April 6, 2015, Janssen must disclose: (a) its detailed statement that describes, with respect to each of the patents listed in its December 26, 2015 letter (with the exclusion of the '715 patent), on a claim by claim basis, the factual and legal basis of its opinion that these patents will be infringed by the commercial marketing of Celltrion's aBLA 125544; and (b) its response to Celltrion's detailed statement concerning the validity and enforceability of these patents.

2. *Lawsuit.* By April 6, 2015, Janssen must sue both Hospira and Celltrion on any patents for which Janssen is not willing to provide a covenant not-to-sue. If (and only if) sued by that date, Hospira and Celltrion would agree to waive their argument that Janssen is limited to a reasonable royalty under 35 U.S.C. § 271(e)(6)(B) for its delay in brining suit.

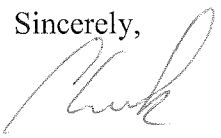
3. *Agreement to delay launch.* Hospira and Celltrion will agree to delay commercial marketing of the infliximab biosimilar product pursuant to aBLA 125544 until after September 15, 2015—thus mooting any infringement allegations related to the '715 patent.

4. *Preliminary Injunction scheduling.* The parties will jointly request an evidentiary preliminary injunction hearing on the merits in July 2015 (or an alternative date around July 2015 suitable to the court) and also jointly request a ruling by September 15, 2015. The parties will negotiate a reasonable preliminary injunction briefing and discovery schedule in light of these deadlines. The briefing in connection with the PI will also address (a) whether the notice of commercial marketing was effective, and (b) any legal challenges to infringement.

5. *Manufacturing discovery.* Any remaining disputes over manufacturing information will be addressed after suit is filed. And, to the extent additional information is produced, it would be done so pursuant to a protective order. Celltrion, however, will not produce documents that reveal the supplier's confidential information without the supplier's consent.

I look forward to hearing your response to our proposal.

Sincerely,



Charles B. Klein

EXHIBIT D

(FILED UNDER SEAL)

EXHIBIT E

(FILED UNDER SEAL)