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 REPLY BRIEF AND ACCOMPANYING DOCUMENTS IN FURTHER SUPPORT OF JANSSEN'S 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 Reply Brief in Further Support of their Motion to Modify the Protective Order to Permit Filing of a New Action (Janssen's "Reply Brief"), 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* Dkt. No 64, Plaintiffs' Motion to Modify the Proposed Protective Order to Permit Filing of a New Action].

3. In Janssen's Reply 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 the Declaration of Irena Royzman, which accompanies Janssen's Reply 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.

5. In 22 of Janssen's 23 exhibits (Exhibits 1-21 and 23) 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.

6. Janssen has therefore agreed to file its Reply Brief in Support of its Motion to Modify the Protective Order, and accompanying materials, under seal.

7. Janssen will file publicly available, redacted versions of its Reply Brief in Further Support 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.

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

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

JANSSEN BIOTECH, INC. and
NEW YORK UNIVERSITY,

By their attorneys,

/s/ Alison C. Casey

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Dated: September 18, 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/ Alison C. Casey

CERTIFICATE OF SERVICE

I certify that on September 18, 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/ Alison C. Casey

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-MLW **CONFIDENTIAL – FILED UNDER SEAL**

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

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Plaintiff Janssen Biotech, Inc. ("Janssen") respectfully submits this reply brief in support of its Motion to Modify the Protective Order to Permit the Filing of a New Action, *see* ECF No. 69, and in response to Defendants' Opposition to Janssen's Motion to Modify the Stipulated Protective Order; Cross-Motion to Stay ("Opp. Br."). *See* ECF No. 73.

PRELIMINARY STATEMENT

Discovery pursuant to the stipulated Protective Order has revealed that Celltrion[1] and third-party [redacted] have been infringing Janssen's '083 patent for years. Janssen seeks leave to modify the Protective Order to enable it to file a claim of infringement. A request to bring a new lawsuit constitutes good cause, and such motions are thus invariably granted. The courts consistently rule that a protective order cannot be used to immunize a party from suit. Celltrion does not cite a single case denying such a request.

Having no legal basis to object to Janssen's motion, Celltrion resorts to rhetoric. As Celltrion sees it, Janssen's straightforward motion asking this Court to modify the Protective Order, as the Order expressly permits, is an attempt to "evade" the order. *See* Opp. Br. at 2, 10. Similarly, Celltrion claims that its compliance with its discovery obligations, pursuant to a standard Protective Order limiting the use of the material to this case, somehow would never have occurred but for a "bait-and-switch" tactic by Janssen. *See id*. at 2.

And where rhetoric won't do, Celltrion turns to outright deception. Celltrion claims that Janssen always knew that Celltrion's cell media practiced the claims of Janssen's '083 patent (or, perhaps, Janssen always knew that Celltrion's cell media did not practice the claims of the '083 patent), and Janssen always knew that [redacted] manufactured the cell media in the United States, so there are no changed circumstances warranting modification of the Protective Order.

[1] "Celltrion" refers collectively to Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc.

In fact, the record unequivocally demonstrates that Celltrion aggressively misled Janssen about both the fact and the location of infringement, and Janssen did not have information sufficient to assert its new claims until, at the earliest, June 8 – after the Protective Order had been agreed upon. The relevant terms of the Protective Order did not change after May 26, and the parties were exchanging information pursuant to its terms as of that date. The stipulated Protective Order was submitted to the Court on May 29.

Janssen did not receive the formula for [redacted] cell media – essential to beginning any infringement analysis – until May 28. The analysis took several weeks thereafter. Meanwhile, [redacted] did not reveal that it manufactured the cell media in the United States until June 8. Having concluded that the cell media infringed under the doctrine of equivalents and that the media were made in the United States, Janssen promptly advised Celltrion on June 16 that it wished to assert new claims.

Janssen's motion should be granted. The purpose of a protective order is to protect sensitive business information from public dissemination, not to immunize infringers from lawsuits. Celltrion's business information will remain protected in a new lawsuit just as it is here. Indeed, Celltrion has not identified any legally cognizable harm to its business or competitive interests by virtue of the proposed modification. Having to defend on the merits a well-grounded lawsuit is not a legally cognizable harm; the Protective Order does not entitle Celltrion to infringe Janssen's patent with impunity.

ARGUMENT

A. Janssen Did Not Have Sufficient Information to Assert Infringement of the '083 Patent Until June 8, 2015

The details of Janssen's discovery of Celltrion's infringement of the '083 patent, and Celltrion's efforts to mislead Janssen, are set out in the Declaration of Irena Royzman ("Royzman Decl."). They fall into two categories.

[redacted] This was very much hide-the-ball. We now know, but did not for months, that Celltrion has the cell media made to its custom order – thereby inducing infringement – by [redacted] *Id.* ¶¶ 31, 39.

[redacted] There was no way for Janssen to know the answer until [redacted] finally revealed it on June 8. *Id.* ¶ 39. Prior to that date, the written record shows repeated requests for that information that were ignored or dismissed by Celltrion. *Id.* ¶¶ 32-33, 35, 37. As late as June 4, Celltrion insisted that Janssen's "requests going to territorial issues are irrelevant." *Id.* ¶ 36. Finally, on June 8, 2015, counsel for [redacted] answered the question: its "custom media is made in [redacted]." *Id.* ¶ 39.

Second, Celltrion provided only limited and misleading disclosure of the ingredients in the cell media. [redacted] The patented cell media claims 61 different ingredients in varying amounts. It was necessary for Janssen to have, and study, the complete formula for [redacted] media before it could come to a reasoned conclusion about infringement. [redacted].

Although the science is complex, one example makes the point. Celltrion claimed the [redacted] cell media did not infringe because it contained [redacted] Janssen reviewed the information provided by [redacted] promptly and by June 16 concluded that the actual ingredients in [redacted] formula infringed Janssen's '083 patent under the doctrine of equivalents. *Id*. ¶¶ 30-40; *see Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 114 F.3d 1161, 1164 (Fed. Cir. 1997) (holding that even a 10-fold variation from a claimed range infringed under the doctrine of equivalents).

When this case was filed on March 6, 2015, Janssen had only limited information to support a claim of infringement. Janssen had identified its '083 patent as potentially infringing, but Celltrion was arguing that there was no infringing activity in the United States and that [redacted] cell media did not meet the limitations of the '083 patent. Janssen did not have factual information either to confirm or refute Celltrion's allegations. Nonetheless, Celltrion

"agree[d]" (even demanded) that Janssen "shall" file suit in March because Celltrion was trying to short-circuit the so-called patent dance. Royzman Decl. ¶¶ 5, 14.

Even with Celltrion's consent, Janssen was able to file suit consistent with Rule 11 of the Fed. R. Civ. P. only because 35 U.S.C. § 271(e)(2)(C)(ii) provides that it is a technical act of infringement for a biosimilar applicant to fail to provide the required information to the innovator. Janssen expressly relied on § 271(e)(2)(C)(ii) in its Complaint and its infringement analysis: "[B]ased on the information currently available to Janssen and Defendants' refusal to provide the required information, Defendants have infringed claims 1-11 of the 083 Patent under 35 U.S.C. § 271(e)(2)(C)(ii) . . . ." Royzman Decl. ¶ 14; ECF No. 1 ¶¶ 170-174.

Celltrion fully recognized the technical nature of Janssen's Complaint, and it (slowly) provided information for the purpose of persuading Janssen to drop its claim. Thus, Celltrion understood that before the disclosures of late May and early June – after the Protective Order was agreed upon – Janssen did not have a factual basis to assert that [redacted] cell media met the limitations of Janssen's '083 patent and did not have a factual basis to allege that [redacted] manufacturing activity took place in the United States. Upon learning those facts – both necessary to an infringement claim – Janssen proceeded promptly to seek permission to institute claims against Celltrion and [redacted] Royzman Decl. ¶¶ 40-43.

B. The BPCIA's Confidentiality Restrictions Do Not Apply

Celltrion spends some effort arguing that this motion is governed by the confidentiality restrictions of the BPCIA, not the Protective Order. *See, e.g.*, Opp. Br. at 3-5, 10-11. Although it would not matter if this motion were under the BPCIA, Celltrion's argument is incorrect. This is a straightforward motion to modify the Protective Order, nothing else.

As the BPCIA makes clear, its confidentiality terms control only until the Court enters a protective order or the parties otherwise agree on how to treat confidential information. *See* 42

U.S.C. § 262(*l*)(1)(F) (use of confidential information governed by BPCIA "until such time as a court enters a protective order"); § 262(*l*)(1)(A) (information exchange covered by BPCIA "[u]nless otherwise agreed to" by the parties).

Here, the parties have agreed to operate under the Protective Order and agreed that it is binding upon them, even prior to being signed by the Court. Royzman Decl. ¶¶ 24-27; ECF No. 64 ¶ 25. By the time Janssen's suit was filed, Celltrion claimed that it had no further discovery obligations under the BPCIA and that any further information would be produced only "under an appropriate confidentiality order or agreement." Royzman Decl. ¶ 14. Thus, when [redacted] produced the cell media formula to Janssen on May 28, 2015, it stated explicitly that it was doing so "under the confidentiality restrictions of the draft protective order." *Id.* ¶ 27. Likewise, when [redacted] admitted on June 8 that it made the cell media in the United States, it did so pursuant to the parties' previous agreement to rely on the Protective Order (and other restrictions negotiated between Janssen and [redacted]). *Id.* ¶ 39. Neither disclosure referred in any way to the BPCIA.

C. Janssen Has Shown Good Cause to Modify the Protective Order

The Protective Order provides that it "may be modified" by the Court. ECF No. 64 ¶ 19. Under the "lenient standards" applied by the First Circuit, modification of a protective order is appropriate, for example, "where the party seeking modification has pointed to some relevant change in the circumstances under which the protective order was entered." *Public Citizen v. Liggett Group, Inc.*, 858 F.2d 775, 791 (1st Cir. 1988).

Here, the facts are well-documented: Janssen did not know that the [redacted] cell media were made in the United States until June 8, and it was not able to begin to analyze the [redacted] media formula until May 28. Royzman Decl. ¶¶ 28, 30, 39. Based on that new information showing infringement of its '083 patent in the United States, Janssen promptly advised Celltrion that it wished to file suit. When Celltrion objected, Janssen filed this motion. *Id.* ¶¶ 40-41.

Janssen thus has demonstrated good cause. ***Indeed, we are aware of no case anywhere that has denied such relief and allowed a protective order to immunize a party from litigation.*** Rather, courts routinely modify protective orders to permit the filing of lawsuits based on information uncovered in discovery. *E.g., Principle Solutions LLC v. Feed.Ing BV,* No. 13-C-223, 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."); *Verizon Cal. Inc. v. Ronald A. Katz Tech. Licensing, L.P.*, 214 F.R.D. 583 (C.D. Cal. 2003) (protective order modified to permit patentee to use discovered information in a separate action for patent infringement against the same party). As the Ninth Circuit has observed, "[p]rivacy of proprietary information, not immunity from suit, was the legitimate purpose of the protective order." *Go-Video v. Motion Picture Ass'n of Am.*, 10 F.3d 693, 696 (9th Cir. 1993).

Celltrion cites a litany of inapposite cases in which motions to modify protective orders were denied for a host of unrelated reasons, most often to protect private information from public disclosure.[2] The only relevant case cited by Celltrion (actually miscited by Celltrion) is *OfficeMax, Inc. v. Sousa*, No. 09-cv-00361, 2011 U.S. Dist. LEXIS 3972 (D. Me. Jan. 14, 2011). In *OfficeMax*, a party sought permission to modify the protective order so that it could use materials obtained during discovery in a new lawsuit against the same party. The Court noted

[2] *See Heffernan v. City of Chicago*, 286 F.R.D. 332 (N.D. Ill. 2012) (municipality sought to keep informant's file secret); *Paine v. City of Chicago*, No. 06-C-3173, 2006 U.S. Dist. LEXIS 78182 (N.D. Ill. Oct. 26, 2006) (party wanted to make public certain Chicago Police Internal Affairs documents); *United States v. Swartz*, 945 F. Supp. 2d 216 (D. Mass. 2013) (party sought to publicly reveal identities of individuals who had been subjected to threats and harassment); *Omega Homes, Inc. v. Citicorp. Acceptance Co*., 656 F. Supp. 393 (W.D. Va. 1987) (party wanted to share defendant's confidential information with plaintiffs in other cases); *Ares-Serono, Inc. v. Organon Int'l B.V.*, 862 F. Supp. 603 (D. Mass. 1994) (defendant sought additional protections against disclosure of documents under protective order); *Chicago Mercantile Exch., Inc. v. Tech. Research Grp., LLC*, 276 F.R.D. 237 (N.D. Ill. 2011) (party sought patent prosecution bar on its litigation counsel lifted); *Fairchild Semiconductor Corp. v. Third Dimensions Semiconductor, Inc*., No. 08-158-P-H, 2009 U.S. Dist. LEXIS 37445 (D. Me. Apr. 30, 2009) (party wanted return of all its confidential documents from opposing counsel).

that OfficeMax did *not* "need[] to 'use' these materials in order to formulate its complaint under Rule 11 of the Federal Rules of Civil Procedure," and it observed that such need *would* constitute good cause to modify the protective order. *Id.* at *7. But "[i]n the absence of the 'use' of the materials to formulate a complaint, I cannot think of any 'good cause' reason to modify the confidentiality order prior to suit actually being filed . . . ." *Id.* at *8. Once the lawsuit was actually instituted, then "good cause would be shown for the modification . . . to save the parties in the new lawsuit unnecessary time and expense duplicating discovery that has already been provided." *Id.*

The proposed complaint here is not brought under the BPCIA and cannot rely on technical acts of infringement. Rather, Janssen needs to use the information produced in discovery – the fact that the cell media is made in the United States and its specific formula – in order to file a complaint that complies with Rule 11. Absent relief from the Protective Order, Janssen cannot file its claim, and both Celltrion and [redacted] will be immunized from liability for their infringement of Janssen's patent. That is the epitome of good cause.

Every other argument that Celltrion makes is off point. Celltrion argues that courts apply a higher standard for modification when the parties themselves negotiated the protective order. *See* Opp. Br. at 14-15. That is not so. The First Circuit has adopted the prevailing view that "lenient standards" of good cause should govern modification of a protective order, and it has not distinguished between protective orders negotiated by the parties (as is the norm) or imposed by a court. *See* ECF No. 69-2 at 9 n.1; *Liggett*, 858 F.2d at 791. None of the cases Celltrion cites alters the "lenient" good-cause standard of the First Circuit.[3]

[3] *See Omega Homes*, 656 F. Supp. 393 (pre-*Liggett* case from the Fourth Circuit where the court did not apply a higher standard); *Fairchild Semiconductor*, 2009 U.S. Dist. LEXIS at *6 n.5 (the court explicitly did not reach the issue of applying a higher standard); *Ares-Serono*, 862 F. Supp. at 609 (magistrate judge refers to a higher standard but cites only a case from the Eastern District of Pennsylvania).

Celltrion also argues that it relied on the Protective Order in producing information, and such reliance weighs against modification. *See* Opp. Br. at 14-16. In fact, it relied on a Protective Order that it agreed "may be modified" by the Court. ECF No. 64 ¶ 19. Moreover, reliance on a protective order is properly limited to maintaining privacy of information, not immunizing accused infringers from suit. *See Liggett*, 858 F.2d at 791 ("unfair" to induce a party to produce information by promising confidentiality and then "remove that order's protection"). There is no such privacy concern here. The parties will enjoy substantially the same (if not identical) business-interest protections in both cases. [redacted] formula will not be made public.[4]

Finally, Celltrion argues that Janssen's motion "raises third-party concerns" concerning [redacted] confidential information. Opp. Br. at 17. But just as Celltrion has no legitimate privacy or secrecy concerns, neither does [redacted]. Its confidential information will be completely protected from the public and from competitors in any new patent infringement case.[5] Indeed, it is notable that although [redacted] was served with a copy of Janssen's motion, it has not sought to intervene to object to Janssen's request. Celltrion speaks for Celltrion alone.

[4] The cases cited by Celltrion on the reliance point are inapt. *Valentin By & Through Valentin v. Richardson*, 110 F.R.D. 622, 625 (D. Mass. 1986) (reliance interest of a witness in not having deposition testimony disclosed to law enforcement at a later date); *United States v. Bulger*, 283 F.R.D. 46, 54 (D. Mass. 2012) (reliance is a less important factor when the parties are operating under a blanket protective order); *Chicago Mercantile*, 276 F.R.D. at 240 (holding that parties had relied upon prosecution bar).

[5] Again, the cases Celltrion cites for this point are irrelevant. *United States v. O'Brien*, No. 12-40026-FDS, 2014 U.S. Dist. LEXIS 6279, at *2 (D. Mass. Jan. 17, 2004) (granting motion to unseal records that contained names of public employees where release of such names would cause little harm); *Swartz*, 945 F. Supp. 2d at 220 (denying in part motion to modify protective order where such modification would have revealed the identities of individuals who had been subjected to threats and harassment).

D. Janssen's Motion Should Not be Stayed Because It Has a Need to Prosecute Its Case in Timely Fashion

Finally, Celltrion argues that the Court should stay consideration of Janssen's motion to modify the Protective Order until the entry of judgment on Janssen's infringement case against Celltrion – perhaps many years in the future while the statute of limitations ticks away. Opp. Br. at 19-20. Such an extraordinary delay is not warranted here.

Janssen seeks to sue a third party, [redacted]. [redacted] is a direct infringer of the '083 patent, while Celltrion is an indirect infringer alleged to have induced infringement by [redacted]. As an indirect infringer, Celltrion cannot be liable unless it can be shown that Celltrion *knew* that "induced acts constitute patent infringement." *Commil USA, LLC v. Cisco Sys.*, 135 S. Ct. 1920, 1926 (2015). A direct infringer like [redacted] has no such state-of-mind defense. *Id*. at 1926 ("Direct infringement is a strict-liability offense."). Thus, as Celltrion admits, Opp. Br. at 18, Celltrion could theoretically prevail in this case for reasons unrelated to [redacted] liability. A long delay of the case against [redacted] for such a reason makes no sense.

Meanwhile, time is of the essence. Celltrion expects FDA approval early next year to sell its biosimilar in the United States. A launch will cause irreparable injury to Janssen's Remicade business. *See* ECF No. 35 (Declaration of Michael Yang). As a result, it is imperative that Janssen retain the ability to seek a preliminary injunction under the '083 patent to protect its rights. A stay would deny Janssen to the ability to seek preliminary relief against [redacted].

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: September 18, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on September 18, 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/ Alison C. Casey
Alison C. Casey

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 **CONFIDENTIAL – FILED UNDER SEAL**

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. ("Janssen") and New York University, and as such I am familiar with the facts stated here.

2. Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc. (collectively, "Celltrion") submitted an abbreviated Biologic License Application ("aBLA") for their proposed biosimilar infliximab drug product in August 2014, and the FDA accepted that application for review in October 2014.

3. Several weeks 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. 42 U.S.C. § 262(l)(2)(A). As relevant here, Celltrion did not produce any information about the composition of the cell culture media used to manufacture its biological product or where the cell culture media was made.

4. Celltrion's aBLA identifies [redacted] as the manufacturer of the cell growth media used by Celltrion for its proposed biosimilar infliximab, but it does not provide the composition of the cell growth media nor does it establish where the cell growth media are produced. Based on Celltrion's refusal to provide the composition of its media, Janssen identified U.S. Patent No. 7,598,083 (the "'083 patent") pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) as potentially infringed by Celltrion's media based on Celltrion's aBLA. 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. 1 (Dec. 16, 2014 email from J. Weil to O. Berson) and Ex. 2 at 4-5 (Feb. 25, 2015 Letter from D. Elderkin to C. Klein). Celltrion refused to provide the information. *See* Ex. 3 (March 4, 2015 letter from C. Klein to D. Elderkin).

5. On February 5, 2015, Celltrion provided its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B). [redacted]

[redacted]

6. In its detailed statement, [redacted]

[redacted]

[redacted]

7. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

8. [redacted]

9. Not only was Celltrion's statement unsupported, but it was also far too incomplete to permit Janssen to perform an infringement analysis. [redacted]

[redacted]

10. [redacted]

11. Meanwhile, deviations from the ranges claimed in the patent do not mean that the cell media do not infringe. In the leading Supreme Court case on the doctrine of equivalents, the patent claimed a pH range of "approximately 6.0 to 9.0" and the allegedly infringing product had a pH of 5.0. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). Since pH is on a logarithmic scale, that is a 10-fold variation from the bottom of the range. *See id.* at 21, n.1. Nonetheless, the product was found to infringe under the doctrine of equivalents. *See Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 114 F.3d 1161, 1164 (Fed. Cir. 1997) (on remand from 520 U.S. 17). [redacted]

12. After Celltrion provided its statement ([redacted]), Janssen asked again for additional manufacturing information that was sufficient to perform an actual infringement analysis. *See* Ex. 2 at 4-5 (Feb. 25, 2015 letter from D. Elderkin to C. Klein). Janssen pointed out that counsel for Celltrion contended that its cell culture media "lack certain ingredients required by the claims" of the '083 patent, but Celltrion had not provided information concerning "what ingredients these media ***do*** contain." *Id*. at 4 (emphasis added). At that point Celltrion had "only provided Janssen with its aBLA and nothing else." *Id.* Janssen noted that "[t]he 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." *Id*. at 5.

13. Rather than provide the needed information, Celltrion again stated that "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***. This point, alone, is dispositive." *See* Ex. 3 at 3 (March 4, 2015 Letter from C. Klein to D. Elderkin) (emphasis added). [redacted] Instead, Celltrion insisted that it "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." *Id.* This was not entirely correct. As I pointed out to counsel for Celltrion, Celltrion had relied on the very information it refused to

provide to Janssen in preparing Celltrion's noninfringement contentions under the BPCIA, which it disclosed in part.

14. Celltrion claimed that it had provided all the information required by the BPCIA, *id*. at 2, and that it would produce the additional requested information only after a lawsuit was filed and a protective order entered. *Id*. at 3-4. Although Celltrion did not provide sufficient information for Janssen to determine whether Celltrion's cell media infringed the '083 patent or whether the cell media was made in the United States, on March 6, 2015, Janssen filed a complaint in this Court asserting infringement of, among other patents, the '083 patent. Janssen filed this Complaint at Celltrion's insistence and with its consent under 35 U.S.C. § 271(e)(2)(C)(ii), which makes it a technical act of infringement of "a patent that could be identified pursuant to [42 U.S.C. § 262(*l*)(3)(A)(i)]" for a biosimilar applicant to submit an aBLA to the FDA where it "fails to provide the application ***and information*** required under [42 U.S.C. § 262(*l*)(2)(A)]." 35 U.S.C. § 271(e)(2)(C)(ii) (emphasis added); *see* ECF No. 1 at ¶¶ 170-174. Janssen also asserted a claim against Celltrion for violating the procedures set forth in 42 U.S.C. § 262(*l*). *See* ECF No. 1 ¶¶ 137-144.

15. After filing its complaint, Janssen again requested that Celltrion produce manufacturing information relevant to the '083 patent, "as well as documents that support the lawyer arguments" in Celltrion's detailed statement. *See* Ex. 5 at 1 (March 25, 2015 Letter from B. Mullin to C. Klein).

16. [redacted]

[redacted]

17. [redacted]

[redacted]

18. [redacted]

[redacted]

[redacted]

19. On April 24, 2015, I requested manufacturing information from Celltrion beyond the information contained in Celltrion's aBLA. *See* Ex. 8 (April 24, 2015 letter from I. Royzman to C. Klein). The letter was written specifically after counsel for Celltrion asked for a "letter specifying the information that is needed to fully assess infringement of the manufacturing patents," including the '083 patent. *Id*. at 1. I asked for [redacted] Again, based on Celltrion's disclosures, Janssen was unaware of any relevant activities in the United States by [redacted] I also again requested documents "sufficient to show the identity of the ingredients (and their respective amounts) of all cell growth media used in the manufacture, testing, or release of" Celltrion's proposed biosimilar infliximab drug product. *Id*. at 2.

20. In response to Janssen's requests about the composition of the cell growth media, counsel for Celltrion for the first time directed Janssen to counsel for [redacted] because "[h]e represents [redacted] interests in connection with this matter." Ex. 9 (April 29, 2015 email from C. Klein to I. Royzman). Celltrion did not, however, reveal that [redacted] manufactured the cell media in the United States.

21. I contacted counsel for [redacted] by email the next day, seeking "manufacturing information . . . relating to Celltrion/Hospira's infringement of Janssen's growth media patents. . . . [W]e are seeking documents sufficient to show the identity of the ingredients (and their respective amounts) of all cell growth media used in manufacture, testing, or release of the product that is the subject" of Celltrion's proposed biosimilar infliximab drug product. Ex. 10 at 2 (April 30, 2015 email from I. Royzman to M. Wolf). In response to [redacted] expressed concern that the requested documents were "highly sensitive," I said that Janssen would be "happy to review the documents on an outside counsel only basis (with our experts) to address any confidentiality concerns and to expedite getting these issues resolved." Ex. 10 at 1 (April 30, 2015 email from I. Royzman to M. Wolf).

22. I also spoke by telephone with counsel for [redacted] several times, and I explained that we could not conduct a fair infringement analysis of the '083 patent without reviewing [redacted] ingredients for the cell growth media and the concentrations of those ingredients.

23. [redacted]

24. In the meantime, Janssen and Celltrion were negotiating the terms of a Protective Order to govern the use of confidential information in the case. Janssen provided a draft protective order on April 20, 2015, and Celltrion made several substantive revisions to the Protective Order on May 13, 2015. After the parties held a meet and confer, Celltrion offered several additional revisions on May 19, 2015. *See* Ex. 12 (May 19, 2015 email from D. Hoang

to B. Mullin et al.). On May 26, 2015, Janssen agreed to the Protective Order as drafted with Celltrion's revisions on May 19, 2015. *See* Ex. 13 (May 26, 2015 email from B. Mullin to C. Klein et al.). Later that day, Celltrion offered an additional revision to the Protective Order, adding the limitation on using confidential information from this case as evidence in other cases. *See id.* (May 26, 2015 email from C. Klein to B. Mullin). While some additional minor revisions were made on May 28 and May 29, 2015, the Protective Order as agreed to on May 26, 2015 was, in sum and substance, the same as the one the parties submitted to the Court on May 29, 2015.

25. Accordingly, Celltrion (and non-party [redacted]) were operating under the terms of the Protective Order as of May 26, 2015, when counsel for Celltrion and [redacted] permitted Janssen's expert Dr. Jayme access to Celltrion's aBLA "under the confidentiality restrictions of the draft protective order." *See* Ex. 14 (May 26, 2015 email from C. Klein to I. Royzman and May 26, 2015 email from M. Wolf to C. Klein). There is no reference in these communications to the confidentiality provisions of the BPCIA, and counsel for Celltrion had previously asserted that Celltrion believed it had completed all of its information disclosures under the BPCIA. *See supra* ¶ 14.

26. The parties submitted the Protective Order to the Court on May 29, 2015. *See* ECF No. 64. By its terms, the Protective Order was binding upon agreement of the parties pending entry by the Court. *See id.* ¶ 25. (The Court has not yet entered the Protective Order.)

27. [redacted] agreed to provide to Janssen information to "show the identity of all ingredients (and their respective amounts and concentrations) of all [redacted] cell growth media" used in Celltrion's proposed biosimilar drug product "under the conditions set forth in the Protective Order," as well as additional confidentiality terms imposed by [redacted]. *See* Ex.

15 at 1 (May 27, 2015 Letter from M. Wolf to I. Royzman). Again, there is no reference in this communication to the confidentiality provisions of the BPCIA.

28. On May 28, 2015, [redacted] purported to produce information sufficient to show the identity of the ingredients (and their respective amounts) of all cell growth media used in manufacture of Celltrion's proposed biosimilar infliximab drug product. The information supplied by [redacted] specifically identified for the first time the complete composition, including all ingredients and concentrations, for Celltrion's cell growth media.

29. Celltrion fully recognized the technical nature of Janssen's pending claims of patent infringement, and it told Janssen that it was providing information that it knew Janssen did not possess for the purpose of persuading Janssen to drop the claims. *See* Ex. 16 at 3-4 (June 4, 2015 email from C. Klein to I. Royzman) ("The purpose of [Celltrion's and [redacted]] voluntary production [of the cell growth media formula] (i.e. not required under the BPCIA or Federal Rules) was to allow Plaintiffs to confirm Defendants' contentions . . . that the cell media do not contain several ingredients required by all claims of the ['083] patent[]."). [redacted]

30. Janssen proceeded to review [redacted] documents to conduct an infringement analysis as promptly as possible. This process took several weeks beginning on May 28 and was the first time that Janssen was able to perform an infringement analysis based on knowledge of the relevant facts.

31. At about this time, Janssen began considering where [redacted] manufactured the cell media, which neither Celltrion nor [redacted] had revealed. One of the documents included in Celltrion's aBLA was [redacted], which reflected that

[redacted] custom-made the cell growth media to Celltrion's order. *See* Ex. 17 ([redacted]. [redacted] included a [redacted] address in [redacted], which might suggest that the cell media was made at that site. [redacted] Based on the COA, Janssen began to suspect, but did not know, that [redacted] made the cell growth media to Celltrion's order in the United States.

32. On May 29, 2015, I therefore asked Celltrion and [redacted] several pertinent questions about the locations of their manufacturing activities for Celltrion's cell growth media:

> We have a few questions relating to the [redacted] media. ***Can you confirm that the [redacted] media are custom made for Celltrion/Hospira in the U.S.?*** Our understanding is that [redacted] and that the media are made there. Also, where do Celltrion/Hospira take possession of the media and is the media shipped to any other locations in the U.S. on behalf of Celltrion/Hospira, [redacted]? It would also be helpful if you could provide documents sufficient to reflect this.

Ex. 19 (May 29, 2015 email from I. Royzman to D. McMullen and C. Klein) (emphasis added). Neither Celltrion nor [redacted] responded to this inquiry.

33. On June 4, 2015, I again asked Celltrion and [redacted] to provide the information requested on May 29, 2015. Ex. 16 at 5 (June 4, 2015 email from I. Royzman to D. McMullen and C. Klein).

34. Counsel for Celltrion responded to my inquiry by stating that Janssen has "now received information from [redacted] detailing the composition of its cell media. The purpose of that voluntary production (i.e. not required under the BPCIA or Federal Rules) was to allow Plaintiffs to confirm Defendants' contentions . . . that the cell media do not contain several ingredients required by all claims of the ['083] patent[]." Ex. 16 at 3-4 (June 4, 2015 email from C. Klein to I. Royzman). Counsel for Celltrion did not respond to my question about U.S. activity.

35. In a responsive email, I reiterated that Celltrion had "stated repeatedly that there is ***no US activity*** (in contentions and letters). That appears to be incorrect based on the information that has been produced to date and I have followed up for that reason. [redacted] The information we are seeking as to US activity is relevant to our analysis . . . ." Ex. 16 at 3 (June 4, 2015 email from I. Royzman to C. Klein) (emphasis added).

36. Counsel for Celltrion then stated that it would not answer my inquiry regarding its U.S. activity because "[u]nless Plaintiffs have a good-faith basis to assert infringement of all elements of at least one claim, ***your requests going to territorial issues are irrelevant.***" *See* Ex. 16 at 2 (June 4, 2015 email from C. Klein to I. Royzman) (emphasis added).

37. In response, I stated that Janssen was continuing in good faith to conduct its infringement analysis, both literal and under the doctrine of equivalents, based on the [redacted] documents it had received the prior week. *See* Ex. 16 at 1-2 (June 4, 2015 email from I. Royzman to C. Klein). I stated that Celltrion still had not confirmed the threshold issue of whether the [redacted] cell growth media were made in the United States:

> The information that I requested as to US activity is plainly relevant to our analysis of the growth media patents. It is a

> threshold issue. If you have any basis to say that the growth media patents are not infringed for a territorial reason, then you should want us to know that and to provide that information promptly to resolve any unnecessary disputes. ***The statements in Celltrion/Hospira's contentions and letters asserting that there is no U.S. activity appear to be incorrect*** and do not comport with the documents that have been produced. . . . We see no reason that we should not get closure on the territoriality issues immediately . . . .

Id. (emphasis added). I continued the next day:

> I am particularly puzzled by your position since the answers to our questions are readily available and go to a simple and threshold issue. If we were not proceeding based on a good faith belief, we would not be seeking the additional information. ***And we are seeking it because you have made repeated representations (in contentions and letters) about no US activity, which all appear to be incorrect***.

Ex. 16 at 1 (June 5, 2015 email from I. Royzman to C. Klein) (emphasis added). Counsel for Celltrion never responded to this email.

38. Meanwhile, I pursued the same inquiries with [redacted], with more success. In response to my queries about U.S. connections, counsel for [redacted] responded on June 4, 2015 that he had "gathered the relevant responses," but "we are unclear as to what relevance it has to your proceedings." Ex. 16 at 4 (June 4, 2015 email from M. Wolf to I. Royzman et al.). I responded as follows:

> ***These are US patents and so US activity is relevant to infringement of the patents.*** And from the documents we have received to date, ***it appears to us that the media is custom-made for Celltrion/Hospira in the US***. [redacted]. Where Celltrion/Hospira take possession of the media (U.S. or not) is also relevant to infringement. That is the reason for the questions and requested supporting documentation.

Ex. 16 at 4 (June 4, 2015 email from I. Royzman to M. Wolf et al.) (emphases added).

39. In response, counsel for [redacted] on June 8, 2015 answered my question about U.S. production of Celltrion's cell growth media: "[redacted]" Ex. 20 (June 8, 2015 email from M. Wolf to I. Royzman et al.) (emphasis added). This was the first time that Janssen was able to confirm the location of the manufacture of the cell media.

40. On June 16, 2015, I spoke to counsel for Celltrion by telephone and told him that Janssen was planning to file a complaint against Celltrion for infringement of the claims of the '083 patent based on its infringement in the United States to support sales of its infliximab biosimilar drug product.

41. Celltrion objected to Janssen filing a complaint based on the cell growth media information [redacted] had provided, citing the Protective Order's restriction on using such information outside of this litigation. Ex. 21 at 2-3 (July 14, 2015 letter from C. Klein to I. Royzman and B. Mullin).

42. I sent counsel for Celltrion an email on August 6, 2015, setting forth case law holding that a party cannot use the production of documents under a protective order in a particular case to immunize itself from suit. Ex. 22 at 1-2 (Aug. 6, 2015 email from I. Royzman to C. Klein). Nevertheless, Celltrion maintained its objection to Janssen filing a complaint. Janssen's Motion to Modify the Protective Order to Permit Filing of a New Action followed. *See* ECF No. 69.

43. Meanwhile, I also spoke with counsel for [redacted] on August 6, 2015, provided the same case law that I provided to counsel for Celltrion, and asked whether [redacted] would oppose Janssen's Motion to Modify the Protective Order. *See* Ex. 22 at 1 (Aug. 6, 2015

email from I. Royzman to M. Wolf) and Ex. 23 at 1-2 (Aug. 11 and 12, 2015 emails from I. Royzman to M. Wolf). [redacted] did not object to Janssen's filing the motion or otherwise respond to my questions. Janssen served its Motion to Modify the Protective Order and accompanying papers on counsel for [redacted] on August 12, 2015. *See id.* at 1 (Aug. 12, 2015 email from J. Gould to M. Wolf).

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

Dated: September 18, 2015

/s/ Irena Royzman
Irena Royzman

CERTIFICATE OF SERVICE

I certify that on September 18, 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/ Alison C. Casey

EXHIBITS 1–21 & 23

(Filed Under Seal)

EXHIBIT 22

From: Royzman, Irena (x2081)
Sent: Thursday, August 06, 2015 4:00 PM
To: Matthew.Wolf@aporter.com
Subject: FW: Janssen v. Celltrion/Hospira - motion to modify protective order to file a new suit
Attachments: Go-Video v. Motion Picture Ass_n of Am. _In re Dual-Deck Video Cassette ....pdf; Principle Solutions LLC v. Feed.Ing BV_ 2015 U.S. Dist. LEXIS 1877 (1).pdf; Public Citizen v. Liggett Group_ Inc._ 858 F.2d 775.pdf; Pansy v. Borough of Stroudsburg_ 23 F.3d 772.pdf; Meyer Goldberg_ Inc. v. Fisher Foods_ 823 F.2d 159.pdf; Wilk v. American Medical Ass_n_ 635 F.2d 1295 (1).pdf; Foltz v. State Farm Mut. Auto. Ins. Co._ 331 F.3d 1122.pdf; United Nuclear Corp. v. Cranford Ins. Co._ 905 F.2d 1424.pdf; Tavoulareas v. Washington Post Co._ 737 F.2d 1170.pdf; OfficeMax Inc. v. Sousa_ 2011 U.S. Dist. LEXIS 3972.pdf

Hi Matt,

Here are the cases as promised. Talk to you soon.

Irena

From: Royzman, Irena (x2081)
Sent: Thursday, August 06, 2015 3:06 PM
To: 'Klein, Chuck'
Subject: Janssen v. Celltrion/Hospira - motion to modify protective order to file a new suit

Dear Chuck,

Here are a few cases that make clear that a party cannot use the production of documents under a protective order in a particular case to immunize itself from a new suit.

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 Solutions LLC v. Feed.Ing BV*, 2015 U.S. Dist. LEXIS 1877 (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."); *see* 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.").

These cases are attached. (The decision from the case that I had on this exact issue in the District of New Jersey last year and that resulted in the protective order being modified to allow the filing of a new complaint still remains sealed and so I am not able to attach that.)

Also, in the First Circuit, in *Public Citizen v. Liggett Group, Inc.*, 858 F.2d 775, 790 (1st Cir. 1988), the court rejected the Second Circuit's "extraordinary circumstances" test for modifying a protective order, and observed that many Circuits have adopted "lenient standards for modification." 858 F.2d at 791. In fact, the Third, Sixth, Seventh, Ninth, Tenth, and D.C. Circuits have all adopted such "lenient" standards. *See Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 784 (3d Cir. 1994); *Meyer Goldberg, Inc. v. Fisher Foods*, 823 F.2d 159, 163-164 (6th Cir. 1987); *Wilk v. American Medical Ass'n*, 635 F.2d 1295, 1300 (7th Cir. 1980); *Foltz v. State Farm Mut. Auto Ins. Co.*, 331 F.3d 1122 (9th Cir. 2003); *United Nuclear Corp. v. Cranford Ins. Co.*, 905 F.2d 1424, 1428 (10th Cir. 1990); *Tavoulareas v. Washington Post Co.*, 737 F.2d 1170, 1172 (D.C. Cir. 1984). That "lenient"

approach is the "prevailing approach" for modification of confidentiality orders. Wright, Miller, & Marcus, FEDERAL PRACTICE & PROCEDURE, § 2044.1 at 271 (2010) (collecting cases). These cases are also attached.

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." *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 the First 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.

Given that the parties in a new lawsuit will be the same as those that have produced documents here and that there will be a substantially similar (if not identical) protective order in place, there can be no legitimate concern about privacy or the dissemination of confidential business information. Moreover, Janssen Biotech cannot enforce its patent rights otherwise.

We plan to file the motion to amend the protective order next week. But, as I said yesterday, this should not require motion practice. There is no legitimate basis to oppose. And there is no need for the motion if you consent to the filing of a new complaint and will not argue that it is a violation of the protective order. Let me know by Tuesday August 11 if we need to file our motion.

Thanks

Irena

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