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** **Civil Action No. 1:16-cv-11117** **CONFIDENTIAL - FILED UNDER SEAL** REQUEST FOR ORAL ARGUMENT

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION *IN LIMINE* NO. 1: TO PRECLUDE EVIDENCE AND ARGUMENT REGARDING ALLEGED COPYING

I. INTRODUCTION

The court should exclude all evidence and argument of alleged "copying" by HyClone Laboratories, Inc.[1] In multiple submissions to this Court, Janssen has seemingly implied that GE HyClone "copied" a specific embodiment of the '083 patent, known as "MET 1.5." *See, e.g.*, Dkt. 282 at ¶¶ 1-4; Case No. 1:16-cv-11117, Dkt. 1 at ¶¶ 64-68. But both the Supreme Court and the Federal Circuit have "specifically rejected the proposition that copying is relevant to infringement as asserted under the doctrine of equivalents." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336,1351 (Fed. Cir. 2002) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 36 (1997)). The evidence should, thus, be excluded under Rules 401 and 402.

Beyond mere irrelevance, the evidence should be excluded under Rule 403 because such evidence would substantially prejudice the Defendants given the natural "lay biases and pejorative flavor the word 'copy' carries" (Kenneth R. Adamo, *et al.*, *The Curse of "Copying,"*

[1] HyClone was acquired by GE Healthcare and is now called GE Healthcare HyClone ("GE HyClone").

7 J. Marshall Law Rev. Intell. Prop. L. 296, 297 (2008))—even though there is absolutely nothing wrong with copying, absent actual patent infringement. The evidence also would confuse and mislead the jury away from considering the proper infringement inquiry—a comparison of the properly construed claims with the accused products. The jury instead would be invited to improperly substitute alleged "improper" copying for evidence of infringement, which is why so many courts have specifically held that evidence of "copying" is ***not*** relevant to infringement issues. This Court, too, should exclude evidence of purported copying.

II. FACTUAL BACKGROUND

Janssen has implied that it plans to infect this jury trial with allegations of copying. The '083 patent inventor testified that [redacted] "MET 1.5," which is the only embodiment disclosed in the '083 patent. *See* Ex. 1, Epstein Dep. Tr. at 131:8-132:23. [redacted] *See* Ex. 2, Whitford Dep. Ex. 3; *see also* Ex. 3, Whitford Dep. Ex. 4. This was prior to Janssen's filing of the '083 patent, which took place in October 2005, and about a decade before "Janssen notified Defendants of the '083 patent . . . in December 2014." Dkt. 1-4 at (22); Dkt. 281 at 13. Moreover, [redacted] Ex. 4, Cho Dep. Tr. at 14:9-21; *id*. at 10:19-20.

But the precise recipe of "MET 1.5"—including a list of specific ingredients and concentrations—is recited by claim 6, which Janssen has ***not*** asserted in this action. *Compare* Dkt. 1-4 at 6:5-7:6 *with* Dkt. 1-4 at 12:13-13:10. [redacted] *Compare* Dkt. 1-4 at 6:5-7:6 *with* Ex. 5, Glacken Reb. Rep. at ¶ 51. [redacted]

[redacted]

[redacted] *Compare* Dkt. 1-4 at 6:32, 6:64 *with* Ex. 5, Glacken Reb. Rep. at ¶ 51. In addition, the accused products include 29 extra ingredients that are not present at all in MET 1.5. *Compare* Dkt. 1-4 at 6:5-7:6 *with* Ex. 5, Glacken Reb. Rep. at ¶ 51. Thus, the accused products are different from MET 1.5 [redacted]

III. ARGUMENT

A. Evidence of Alleged Copying of the Subject Matter of the '083 Patent is Irrelevant to any Fact at Issue in this Action

Evidence, as well as argument, of alleged copying should be excluded under Rules 401 and 402 because it has no "tendency to make a fact more or less probable" for any fact "of consequence in determining the action." Fed. R. Evid. 401. At the very least, the evidence should be excluded under Rule 403 because the prejudice resulting from insinuations about "copying" as some alleged misconduct far outweighs any purported relevance.

A determination of infringement has nothing to do with "copying" and instead requires two straightforward steps: "construing the claims and comparing the properly construed claims to the accused product." *Advanced Steel Recovery, LLC v. X-Body Equip., Inc.*, 808 F.3d 1313, 1316 (Fed. Cir. 2015). Thus, the jury's task is to evaluate infringement, which "is determined by comparing the accused devices ***not with products made by the patentee*** but ***with the claims*** of the patent as properly construed." *Allen Eng'g Corp.*, 299 F.3d at 1351 (Fed. Cir. 2002) (emphasis added).

Evidence or argument about copying is therefore irrelevant. As the Federal Circuit has explained, copying "is of no import on the question of whether the claims of an issued patent are infringed." *Id.*; *see also DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1336 (Fed. Cir. 2009) (citing *Allen Eng'g Corp.*, 299 F.3d at 1351). Numerous district courts

have reached the same conclusion. *Apple, Inc. v. Samsung Elecs. Co.*, 920 F. Supp. 2d 1116, 1131 (N.D. Cal. 2013) ("Evidence of copying, however, is not evidence of infringement or knowledge thereof."); *Zest IP Holdings, LLC v. Implant Direct Mfg. LLC*, No. 10CV541-GPC(WVG), 2015 WL 1510755, at *21 (S.D. Cal. Feb. 3, 2015) ("[E]vidence of copying is 'of no import on the question of whether the claims of an issued patent are infringed,' either literally or by equivalents."); *Hayes Lemmerz Int'l, Inc. v. Epilogics Grp.*, No. 03-CV-70181-DT, 2008 WL 183546, at *2 (E.D. Mich. Jan. 18, 2008) ("[Counter-plaintiff] has failed to demonstrate a palpable defect in the court's finding that copying is irrelevant to the infringement analysis."); *CCP Sys. AG v. Samsung Elecs. Corp.*, No. 09-CV-4354 DMC-JAD, 2010 WL 5080570, at *5 (D.N.J. Dec. 7, 2010) ("[E]vidence demonstrating that the [Defendants] copied [Plaintiff's] software would be relevant to copyright infringement but may be irrelevant to patent infringement.").

The Supreme Court also has specifically found copying to be irrelevant to infringement under DOE, noting "that intent plays no role in the application of the doctrine of equivalents." *Warner-Jenkinson Co.*, 520 U.S. at 36. The Federal Circuit has similarly noted that "the Supreme Court has specifically rejected the proposition that copying is relevant to infringement as asserted under the doctrine of equivalents." *Allen Eng'g Corp.*, 299 F.3d at 1351 (citing *Warner-Jenkinson Co.*, 520 U.S. at 35-36). Again, many district courts reached the same conclusion. *Competitive Techs., Inc. v. Fujitsu Ltd.*, 333 F. Supp. 2d 858, 883 (N.D. Cal. 2004), *aff'd*, 185 F. App'x 958 (Fed. Cir. 2006) ("[T]he Federal Circuit has determined that copying is not relevant to the doctrine of equivalents inquiry."); *Blunt Wrap U.S.A., Inc. v. Royal Blunts, Inc.*, No. CIV.A. 02-1990, 2003 WL 30422, at *8 (E.D. La. Jan. 2, 2003) ("The Supreme Court specifically rejected the proposition that copying is relevant to infringement as asserted under the

doctrine of equivalents, because infringement is determined by comparing the accused devices not with products made by the patentee but with the claims of the properly construed patent."); *Stairmaster Sports/Med. Prod., Inc. v. Groupe Procycle, Inc.*, 25 F. Supp. 2d 270, 285 n.11 (D. Del. 1998), *aff'd*, 232 F.3d 909 (Fed. Cir. 2000) ("As the Supreme Court has specifically referred to 'copying' as an intent-based doctrine, the Court declines to consider it in a doctrine of equivalents analysis.").

The Court should follow this overwhelming precedent and thus exclude as irrelevant any evidence or argument about alleged copying. At the very least, the Court should exclude copying evidence under Rule 403, because of the highly prejudicial and confusing nature of such evidence. Given Janssen's extraordinary position—that products twelve or more ways different from the asserted claims nevertheless infringe—any "copying" insinuations would only distract from the core question of "comparing the properly construed claims to the [product] accused of infringing." *Markman v. Westview Instrum.*, 52 F.3d 967, 976 (Fed. Cir. 1995).

Even worse, allegations of copying would severely and unfairly prejudice the jury against the Defendants. It is well recognized that "there is significant prejudice associated with [copying] evidence, as a jury may use evidence of copying to unfairly conclude that Defendant's products *infringe* the patents-in-suit . . . even though the two analyses must necessarily be distinct." *Finjan, Inc. v. Blue Coat Sys., Inc.*, No. 13-CV-03999-BLF, 2015 WL 4129193, at *6 (N.D. Cal. June 8, 2015) (emphasis in original). The term "copying" also carries a connotation of unsavory practices and is often used by patentees to "portray an accused infringer in the most negative light." Kenneth R. Adamo, *et al., The Curse of "Copying,"* 7 J. Marshall Law Rev. Intell. Prop. L. 296, 297 (2008). "In a jury case, the term is doubly damning, in that a juror's

everyday experience, stemming from earliest school days, generates the lay biases and pejorative flavor the word 'copy' carries." *Id.*

In this case, the resulting prejudice would be ***triply*** damning. Inducement requires a patentee to "prove that ***once the defendants knew of the patent***, they 'actively and knowingly aid[ed] and abet[ted] another's direct infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006). Any alleged "copying" here occurred [redacted] (Ex. 4, Cho Dep. Tr. at 14:9-21, 10:19-20) and also a ***decade before*** "Janssen notified Defendants of the '083 patent . . . in December 2014." *See* Dkt. 281 at 13. Allegations of copying may confuse the jury to wrongfully impute such allegations on Defendants. However, Defendants cannot and should not be tainted with alleged copying occurring [redacted] or knew about the '083 patent.

B. Copying Cannot Be Raised To Rebut Obviousness and Would Require A Substantial Rebuttal Case on an Irrelevant, Non-disclosed Theory.

Theoretically, copying could be relevant as a so-called "secondary consideration" rebuttal to an obviousness challenge. But Janssen never asserted "copying" as a relevant secondary consideration, and it is too late now. Defendants served a contention interrogatory requesting "identification of all secondary considerations/objective indicia of nonobviousness (including . . . copying . . .)." Ex. 6, Defs.' August 11, 2015 First Set of Interrogs. at 8. But Janssen declined to provide ***any*** substantive response, including evidence or even allegations of copying. *See* Ex. 7, Pls.' September 22, 2015 Objs. and Responses to Defs.' First Set of Interrogs. at 6-8. And Janssen never supplemented its response to add any copying allegations even after Defendants

provided its preliminary obviousness theories and expert reports. *See* Ex. 8, Defs.' March 31, 2016 Prelim. Invalidity Contentions at 15-29.

That is dispositive. "Rule 26(e) requires that as theories mature . . . responses to . . . contention interrogatories be corrected or supplemented," which never happened here. *Woods v. DeAngelo Marine Exhaust, Inc.*, 692 F.3d 1272, 1279-83 (Fed. Cir. 2012). And Rule 37(c)(1) is a self-executing sanction that "requires the near automatic exclusion of Rule 26 information that is not timely disclosed." *Wilson v. Bradlees of New England, Inc.*, 250 F.3d 10, 20-21 (1st Cir. 2001); *Esposito v. Home Depot U.S.A., Inc.*, 590 F.3d 72, 81 (1st Cir. 2009); *Trs. of Boston Univ. v. Epistar Corp.*, 310 F.R.D. 203 (D. Mass. 2015). Moreover, "[i]f a party fails to provide information . . . as required by Rule 26(a) or (e), the party is not allowed to use that information. . . to supply evidence . . . at a trial, unless the failure was substantially justified or is harmless". Fed R. Civ. P. 37(c)(1); *see also* Fed. R. Civ. P. 26(e) ("A party . . . who has responded to an interrogatory . . . must supplement or correct its disclosure or response in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect . . .."). Janssen cannot show its failure is justified or harmless and any allegation of copying must be excluded. Indeed, courts have granted motions *in limine* and been affirmed in these circumstances where a party seeks to present evidence or argument at trial on a legal theory "not properly raised during discovery." *Becton, Dickinson and Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1261 (Fed. Cir. 2010).

Far from timely disclosing any copying theory, both of Janssen's technical experts addressed secondary considerations ***without*** offering any copying opinion. *See* Ex. 9, Wurm Reb. Rep. at ¶¶ 103-105; Ex. 10, Butler Reb. Rep. at ¶¶ 156-158. "[M]atters not disclosed in [an expert's] expert report or deposition" are properly excluded. *Siemens Med. Sols. USA, Inc. v.*

Saint-Gobain Ceramics & Plastics, Inc., 637 F.3d 1269, 1286-87 (Fed. Cir. 2011); *accord Asetek Danmark A/S v. CMI USA, Inc.*, No. 13-CV-00457-JST, 2014 WL 6997670, at *1-2 (N.D. Cal. Dec. 9, 2014) (excluding expert testimony that was "not part of [the expert's] expert report"); *see also* Fed. R. Civ. P. 26(a)(2)(B) (noting that an expert report "must contain a complete statement of all opinions the witness will express and the basis and reasons for them").

Even if Janssen ***had*** properly disclosed a copying theory, any such theory ***still*** should be excluded because proper copying evidence "***requires*** the ***replication*** of a specific product." *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) (emphasis added); *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1370 (Fed. Cir. 2011) ("Copying requires evidence of efforts to replicate a specific product."); *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (same); *R.H. Murphy Co. v. Illinois Tool Works, Inc.*, 409 F. Supp. 2d 53, 76 (D. Mass. 2006), *aff'd*, 208 F. App'x 841 (Fed. Cir. 2006) (same).

Here, Janssen cannot argue that GE HyClone "replicated" "MET 1.5," which is covered by ***unasserted*** Claim 6. MET 1.5 differs from both of the accused products [redacted] as the accused products include ***29 additional ingredients*** and [redacted] *Compare* Dkt. 1-4 at 6:5-7:6 *with* Ex. 5, Glacken Reb. Rep. at ¶ 51. [redacted] *Compare* Dkt. 1-4 at 6:32, 6:64 *with* Ex. 5, Glacken Reb. Rep. at ¶ 51.

Inserting a flawed copying theory into the case at the eleventh hour would be enormously prejudicial to Defendants. Janssen would effectively create a belated, irrelevant and highly prejudicial sideshow, which would require an extensive rebuttal case that Defendants have not prepared. The Court should thus preclude Janssen from misleading the jury with evidence and

argument that, due to the law and Janssen's own decisions during discovery, is wholly irrelevant to the jury's task.

IV. CONCLUSION

For all of the foregoing reasons, Defendants respectfully request that the Court grant Defendants' motion *in limine* regarding evidence of alleged copying of the subject matter of the '083 patent.

Dated: January 12, 2017

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

By: */s/*Andrea L. Martin

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CERTIFICATE OF SERVICE

I, Andrea L. Martin, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on January 12, 2017.

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

Defendants' Motion *in Limine* No. 1 Exhibit 1 (Filed Under Seal)

Defendants' Motion *in Limine* No. 1
Exhibit 2
(Filed Under Seal)

Defendants' Motion *in Limine* No. 1
Exhibit 3
(Filed Under Seal)

Defendants' Motion *in Limine* No. 1
Exhibit 4
(Filed Under Seal)

Defendants' Motion *in Limine* No. 1
Exhibit 5
(Filed Under Seal)

Defendants' Motion *in Limine* No. 1 Exhibit 6

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

CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., AND HOSPIRA INC.'S FIRST SET OF INTERROGATORIES

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, and the applicable Local Civil Rules of the United States District Court for the District of Massachusetts, including particularly L. Civ. R. 26.1 and 33.1, Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. (together "Celltrion"), and Hospira, Inc. ("Hospira") (collectively "Defendants") propound the following interrogatories to Plaintiffs Janssen Biotech, Inc. and New York University (collectively, "Plaintiffs") and requests that they be answered within thirty (30) days of service.

To the extent that any answer to any of these interrogatories may at any time be incomplete or incorrect due to information acquired by Plaintiffs subsequent to the service of each of their answers, Defendants request that Plaintiffs promptly serve and file supplemental answers reflecting the complete and correct information, pursuant to Rule 26 of the Federal Rules of Civil Procedure.

INTERROGATORIES

INTERROGATORY NO. 1

Describe in detail the complete factual and legal bases for Plaintiffs' contention(s) that each claim of the patents-in-suit is not invalid as anticipated and/or obvious, including identification of all secondary considerations/objective indicia of nonobviousness (including long-felt need, failure of others, industry recognition, expression of skepticism or disbelief, unexpected results, copying, near-simultaneous invention, and commercial success) that purportedly supports their contention, and describe in detail the complete factual and legal basis for that secondary consideration, identify each person with knowledge of the factual basis for that secondary consideration, and identify each document that supports or refutes the existence of that secondary consideration.

INTERROGATORY NO. 2

Identify separately for each asserted claim of the patents-in-suit the earliest claimed priority date, and the dates on which the subject matter of each asserted claim was first conceived and reduced to practice, and for each date identify the documents supporting such date (including communications, invention disclosure forms, and laboratory notebooks where the alleged conception, reduction to practice, and/or invention is recorded) and the persons with knowledge relating to such dates (including the individuals who allegedly conceived, reduced to practice, or assisted in the conception and/or reduction to practice of the subject matter).

INTERROGATORY NO. 3

Identify the source, location, and custodian of any data underlying the examples, figures, tables, or other results appearing in the specification of any patent-in-suit, any patent application

to which any patent-in-suit claims priority, or in any of the declarations or affidavits submitted during the prosecution thereof.

INTERROGATORY NO. 4

Identify and describe in detail all facts relating to, supporting, or contradicting Plaintiffs' assertion of ownership and standing to assert the patents-in-suit, including the identification of all assignments, chains of title, licenses or sub-licenses (whether exclusive or non-exclusive), offers to license, and any other agreements concerning any rights associated with the patents-in-suit; identify each person with knowledge of such facts; and identify all documents that support or contradict such facts.

Dated: August 11, 2015

Respectfully submitted,

By: /s/ *Dan H. Hoang*

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Defendants' Motion *in Limine* No. 1 Exhibit 7

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.	)	No. 15-cv-10698

PLAINTIFFS JANSSEN BIOTECH, INC. AND NEW YORK UNIVERSITY'S OBJECTIONS AND RESPONSES TO DEFENDANTS CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC. AND HOSPIRA, INC.'S FIRST SET OF INTERROGATORIES

Pursuant to Federal Rules of Civil Procedure Rules 26 and 33 and LR 26.1, 26.5, and 33.1, Plaintiffs Janssen Biotech, Inc. and New York University ("Plaintiffs") hereby respond and make the following objections to Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira, Inc.'s ("Defendants") First Set of Interrogatories as follows:

GENERAL STATEMENT

1. Plaintiffs' responses are directed only to U.S. Patent No. 7,598,083 ("the '083 patent"), pursuant to agreement between counsel for the parties. Thus, Plaintiffs have not responded to any interrogatories, and have not interposed any objections to any instructions or interrogatories, to the extent they pertain to any patent-in-suit other than the '083 patent. Plaintiffs do not waive any objections to the extent the requests pertain in any way to the other patents-in-suit.

and/or information produced in response to interrogatories, whether or not such documents, evidence, or other matters are newly discovered or are now in existence but have not been located despite diligent and good faith efforts.

18. The applicable foregoing general objections are incorporated into each of the specific objections and responses that follow. The stating of a specific objection or response shall not be construed as a waiver of Plaintiffs' general objections.

19. Plaintiffs expressly reserve the right to supplement these General Objections.

OBJECTIONS AND RESPONSES TO INTERROGATORIES

INTERROGATORY NO. 1:

Describe in detail the complete factual and legal bases for Plaintiffs' contention(s) that each claim of the patents-in-suit is not invalid as anticipated and/or obvious, including identification of all secondary considerations/objective indicia of nonobviousness (including long-felt need, failure of others, industry recognition, expression of skepticism or disbelief, unexpected results, copying, near-simultaneous invention, and commercial success) that purportedly supports their contention, and describe in detail the complete factual and legal basis for that secondary consideration, identify each person with knowledge of the factual basis for that secondary consideration, and identify each document that supports or refutes the existence of that secondary consideration.

RESPONSE TO INTERROGATORY NO. 1:

Plaintiffs object to this interrogatory as directed to matters which are not relevant to the subject matter at issue in this action and seeking information and/or documents not reasonably calculated to lead to the discovery of admissible evidence.

In their statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Defendants failed to set forth any factual or legal basis for the invalidity or unenforceability of any claim of the '083 patent. Accordingly, Defendants have waived any challenge to the validity or enforceability of the claims of the '083 patent.

Plaintiffs further object to the request in this interrogatory to describe the "complete factual and legal bases . . . that each claim of the patents-in-suit is not invalid as anticipated and/or obvious, including identification of all secondary considerations/objective indicia of nonobviousness . . . and describe in detail the complete factual and legal basis for that secondary consideration" as vague, overbroad, unduly burdensome, and seeking information that is neither relevant nor reasonably calculated to lead to the discovery of admissible evidence.

Plaintiffs further object to the request in this interrogatory to "identify each person with knowledge of the factual basis for that secondary consideration" as overbroad, unduly burdensome, and seeking information that is neither relevant nor reasonably calculated to lead to the discovery of admissible evidence.

Plaintiffs further object to the request in this interrogatory to "identify each document that supports or refutes that secondary consideration" as vague, overbroad, unduly burdensome, and seeking information that is neither relevant nor reasonably calculated to lead to the discovery of admissible evidence.

Plaintiffs further object to this interrogatory on the grounds it seeks information protected by the attorney-client privilege, work product doctrine, and any other applicable privilege or protection.

Plaintiffs further object to this interrogatory as seeking legal conclusions and analysis. Plaintiffs further object to this interrogatory as seeking expert testimony.

Plaintiffs further object to this interrogatory as Defendants have not come forward with any contention that the '083 patent are invalid as anticipated and/or obvious over any prior art, and indeed have waived their right to do so. Defendants have not identified anything that they contend is prior art to the '083 patent.

Plaintiffs further object to this interrogatory as effectively seeking answers to multiple interrogatories and exceeding the limit on interrogatories allowed by the applicable provisions.

INTERROGATORY NO. 2:

Identify separately for each asserted claim of the patents-in-suit the earliest claimed priority date, and the dates on which the subject matter of each asserted claim was first conceived and reduced to practice, and for each date identify the documents supporting such date (including communications, invention disclosure forms, and laboratory notebooks where the alleged conception, reduction to practice, and/or invention is recorded) and the persons with knowledge relating to such dates (including the individuals who allegedly conceived, reduced to practice, or assisted in the conception and/or reduction to practice of the subject matter).

RESPONSE TO INTERROGATORY NO. 2:

Plaintiffs object to this request as directed to matters which are not relevant to the subject matter at issue in this action and seeking information and/or documents not reasonably calculated to lead to the discovery of admissible evidence.

In their statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Defendants failed to set forth any factual or legal basis for the invalidity or unenforceability of any claim of the ‘083 patent. Accordingly, Defendants have waived any challenge to the validity or enforceability of the claims of the ‘083 patent.

Plaintiffs further object to this interrogatory on the grounds it seeks information protected by the attorney-client privilege, work product doctrine, and any other applicable privilege or protection.

Plaintiffs further object to this interrogatory as seeking legal conclusions and analysis. Plaintiffs further object to this interrogatory as seeking expert testimony.

Plaintiffs object to this interrogatory as effectively seeking answers to multiple interrogatories and exceeding the limit on interrogatories allowed by the applicable provisions.

Plaintiffs object to this interrogatory as effectively seeking answers to multiple interrogatories and exceeding the limit on interrogatories allowed by the applicable provisions.

Subject to the foregoing general and specific general objections, Plaintiffs respond that they will produce documents relating to ownership of the '083 patent, including assignments, pursuant to Fed. R. Civ. P. 33(d).

Dated: September 22, 2015

Respectfully Submitted,

/s/ Irena Royzman

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Defendants' Motion *in Limine* No. 1
Exhibit 8
(Filed Under Seal)

Defendants' Motion *in Limine* No. 1 Exhibit 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

OPENING VALIDITY EXPERT REPORT OF PROFESSOR FLORIAN M. WURM, DR. RER. NAT

E. Secondary Considerations of Non-Obviousness

103. As mentioned above, there was a long-felt need for chemically-defined cell culture media whose formulations were known and publicly available that were capable of supporting high density cell culture in a bioreactor setting. The '083 patent's invention met that long-felt need. The formulations of chemically-defined media that were successful were not publicly available. The media manufacturers kept these formulations secret. Without knowledge of the secret formulation, a biopharmaceutical manufacturer would not "have known exactly what was in the formulation," and therefore would not have been able to freely "adjust[] or supplement[] as needed for a particular cell line or recombinant protein product." (Glacken Report ¶ 204.) There was a need, as Dr. Glacken recognizes, for media that afforded the user such flexibility. (*Id.*)

104. Relatedly, there was a need for a successful chemically-defined medium formulation that was not in the control of a third-party. In such a situation, as Dr. Glacken recognizes, "[i]f the manufacturing of the third-party medium is shut down for some reason, [a] company may experience significant delays in getting a new medium approved" for use in its biopharmaceutical production process. (*Id.* ¶ 204.)

105. As I described above, the invention of the '083 patent was a breakthrough that addressed these long-felt needs. The examples in the patent show that a claimed cell culture medium allowed for the growth of an antibody-producing cell line to quite high sustained viable cell densities in a perfusion bioreactor setting (in the range of 10-20 million cells/mL over several week). And the antibody yield in this bioreactor was also quite significant. That the inventors were able to demonstrate such results with a chemically-defined medium at the time of the invention in the early 2000s, and publish both the results and the medium formulation in a patent, was a breakthrough that satisfied the long-felt need.

VIII. Indefiniteness Analysis

106. Dr. Glacken opines that the claims would be indefinite if they are found to cover the accused products. (*Id.* ¶ 264.) The claims are not indefinite.

107. As I described in my Opening Infringement Report, the asserted claims cover soluble compositions used to make cell culture media, the scope of which is defined by a list of 61 specific defined ingredients in 61 specific concentration ranges. (Wurm Report ¶¶ 16-17.) Each ingredient and corresponding concentration range is recited with certainty. A POSA would understand the scope of the claims with reasonable certainty, and therefore the '083 patent claims are not indefinite.

108. Dr. Glacken appears to opine that the claims are indefinite because infringement is asserted under the doctrine of equivalents, which provides that a product that falls outside the literal scope of a claim may nevertheless be found to infringe if the differences between the product and the claim scope are insubstantial. As I understand it, every patent claim has a potential range of equivalents that extends beyond its literal scope. Since the doctrine of equivalents is a general principle of patent law, whether a claim of infringement is being asserted under the doctrine of equivalents has no relationship to whether a patent claim is indefinite.

109. Indeed, as I discussed above, a POSA would understand the scope of the claims—defined by a list of specific ingredients with specific concentration ranges—with reasonable certainty. That a product that falls outside the literal scope of the claims may nonetheless infringe under the doctrine of equivalents does not affect the fact that a POSA would understand the scope of the claims with reasonable certainty. A POSA reading the claims would recognize that literal differences between the claim and a product may turn out to be insubstantial.

110. Thus, claims 1 and 2 of the '083 patent are not indefinite.

XIV. Signature

Dated: October 14, 2016

Professor Florian M. Wurm, Dr. rer. nat.

Defendants' Motion *in Limine* No. 1
Exhibit 10
(Filed Under Seal)