UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DEFENDANTS' RESPONSE TO PLAINTIFFS' RULE 56.1 STATEMENT OF MATERIAL FACTS; AND DEFENDANTS' RULE 56.1 STATEMENT OF MATERIAL FACTS

DEFENDANTS' RESPONSE TO PLAINTIFFS' RULE 56.1 STATEMENT OF MATERIAL FACTS

Pursuant to Local Civil Rule 56.1, Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., (together, "Celltrion") and Hospira, Inc. ("Hospira") submit the following response to Plaintiffs' Rule 56.1 Statement of Material Facts Not In Dispute, which supports Plaintiffs' Motion for Partial Summary Judgment ("Motion"). The parties have not yet engaged in discovery. Thus, to the extent Defendants do not dispute facts for purposes of the Motion, they reserve the right to do so in a future proceeding.

Remicade® and the Proposed Biosimilar of Remicade®

1. Remicade® is a biologic drug whose active ingredient is infliximab, a monoclonal antibody that binds to and neutralizes a substance in our bodies called TNFa which, if over-produced, can lead to chronic disease. Carey Decl. ¶ 4.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent a response is required, Defendants do not dispute the allegations of paragraph 1 solely for the purposes of responding to Plaintiffs' Motion.

2. The infliximab antibody was first developed by scientists from New York University ("NYU") and Centocor, Inc., the predecessor of Janssen Biotech, Inc. ("Janssen"), in the early 1990s. *Id.*

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of these allegations. If this Court decides these allegations are material, Defendants request time to take discovery relative to them. At present, Defendants do not dispute these allegations solely for the purposes of responding to Plaintiffs' Motion.

3. Remicade was first approved for the U.S. market in 1998, nearly a decade after it was first discovered in the lab. The first indication, or use, for which Remicade® was approved was the treatment of Crohn's disease, an inflammatory bowel disease that causes inflammation of the lining of the digestive tract. Remicade® was the first biological therapy approved for Crohn's disease in the United States. *Id.* ¶ 5.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent a response is required, Defendants do not dispute that Remicade® was first approved by the Food and Drug Administration ("FDA") in 1998 for the treatment of Crohn's disease. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations. If this Court decides these allegations are material, Defendants request time to take discovery relative to them. At present, Defendants do not dispute these allegations solely for the purposes of responding to Plaintiffs' Motion.

4. Subsequently, extensive additional pre-clinical and clinical development efforts led to FDA approval of Remicade® for additional indications, including rheumatoid arthritis (1999), ankylosing spondylitis, a chronic inflammatory disease of the axial skeleton (2004), psoriatic arthritis (2005), and ulcerative colitis, an inflammatory bowel disease (2006). *Id.* ¶ 6.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent a response is required, Defendants do not dispute that Remicade® was approved by the FDA for use in the treatment of rheumatoid arthritis (1999), ankylosing spondylitis (2004), psoriatic arthritis (2005), and ulcerative colitis (2006). Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations. If this Court decides these allegations are material, Defendants request time to take

discovery relative to them. At present, Defendants do not dispute these allegations solely for the purposes of responding to Plaintiffs' Motion.

5. In the course of developing Remicade®, Janssen has obtained or exclusively licensed a number of patents related to infliximab, its uses in treating disease, and the processes for manufacturing infliximab. Plaintiffs assert six of these patents in this action. *Id.* ¶¶15-16.

RESPONSE: Defendants do not dispute that Plaintiffs have asserted six patents in this action. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations. If this Court decides these allegations are material, Defendants request time to take discovery relative to them. At present, Defendants do not dispute these allegations solely for the purposes of responding to Plaintiffs' Motion.

6. Celltrion Healthcare Co., Inc. and Celltrion, Inc. (together "Celltrion") have undertaken the development of a proposed biosimilar to Janssen's Remicade® infliximab product. Hospira Inc. will market the proposed biosimilar product in the United States (Celltrion and Hospira together "Defendants"). *Id.* ¶ 8.

RESPONSE: Defendants do not dispute the allegations of paragraph 6 solely for the purposes of responding to Plaintiffs' Motion.

Proceedings Under the BPCIA

7. Pursuant to the Biologics Price Competition and Innovation Act ("BPCIA"), Defendants submitted an abbreviated Biologic License Application ("aBLA") on or around August 8, 2014 seeking permission to market a proposed biosimilar version of Janssen's revolutionary biological medicine Remicade® (infliximab). *Id.*

RESPONSE: Defendants do not dispute that, pursuant to the BPCIA, Celltrion, Inc. submitted an aBLA on or around August 8, 2014, seeking permission to market a proposed

biosimilar version of Janssen's drug branded as Remicade® (infliximab). *See* Hoang Ex. 1. Defendants dispute the remaining allegations in paragraph 7, which are not supported by evidence.

8. Defendants' aBLA was accepted for review by the Food and Drug Administration ("FDA") in October 2014, but FDA has not yet approved the application or given any indication whether it will be approved, when it will be approved, or what the scope of any approval will be. *Id.* ¶ 9.

RESPONSE: Defendants do not dispute that Celltrion, Inc.'s aBLA was accepted for review by the FDA in October 2014 and that the FDA has not yet approved that application. *See* Hoang Decl. Ex. 1. While FDA has not said whether or when the aBLA will be approved, or what the scope of any approval will be, [redacted]. *Id*. Defendants dispute the remaining allegations in paragraph 8, which are not supported by evidence.

9. Shortly after their aBLA was accepted for review by FDA, Defendants provided a copy of their aBLA to Plaintiffs pursuant to the BPCIA's confidentiality restrictions. *Id.* ¶ 10.

RESPONSE: Defendants do not dispute that within 20 days after receiving notification that its aBLA was accepted for review by FDA, Celltrion, Inc. provided a copy of its aBLA to Janssen pursuant to the BPCIA's confidentiality restrictions. Defendants dispute the remaining allegations of paragraph 9, which are not supported by evidence.

10. Although Defendants provided their aBLA, they 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 they were required to do under the statute. 42 U.S.C. § 262(1)(2)(A). Carey Decl. ¶ 11; *see also id.* Exs. A & B.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent a response is required, Defendants dispute the allegation that they did not provide "information that describes the process or processed used to manufacture the biological product that is the subject of" Celltrion's application. As Defendants explained in their March 4, 2015 letter, on October 27, 2014, Celltrion, Inc. provided Janssen a copy of its aBLA 125544, including information that describes the processes used to manufacture Celltrion's infliximab biologic product. Carey Decl. Ex. D. at 3. Moreover, Defendants had no right nor obligation to produce proprietary third-party manufacturing information to Plaintiffs. *See, e.g.*, 42 U.S.C. 262(*l*)(1)(E) (referring to "confidential information disclosed" under the BPCIA as "the property of the subsection (k) applicant").

11. Based on the information that Defendants provided in their aBLA and Defendants' refusal to provide the required manufacturing information, on December 26, 2014, Plaintiffs provided Defendants a list of six patents for which a claim of infringement could reasonably be asserted. Carey Decl. ¶ 15.

RESPONSE: Defendants do not dispute that on December 26, 2014, Janssen (but not NYU) provided Celltrion a list of six patents for which Janssen purports a claim of infringement could reasonably be asserted. *See* Hoang Decl. Ex. 2. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations. If this Court decides these allegations are material, Defendants request time to take discovery relative to them. At present, Defendants do not dispute these allegations solely for the purposes of responding to Plaintiffs' Motion.

12. On February 5, 2015, Defendants provided a statement of defenses pursuant to 42 U.S.C. § 262(1)(3)(B). *Id.* ¶ 16.

RESPONSE: Defendants do not dispute the allegations of paragraph 12 solely for the purposes of responding to Plaintiffs' Motion.

13. In connection with their statement of defenses, Defendants asserted that they did not seek to limit the patents to be litigated, and that as a result, the remaining BPCIA's pre-litigation procedures, 42 U.S.C. § 262(1)(3)-(1)(5), were moot. *Id.* ¶ 25.

RESPONSE: Defendants dispute this characterization of the statement under 42 U.S.C. § 262(1)(3)(B), but do not dispute that this statement says, among other things, the following:

Carey Decl. Ex. E at 2.

14. Defendants further asserted that Janssen was required to file a lawsuit on all six listed patents within thirty days of Defendants' statement, i.e., by March 7, 2015, rather than within thirty days after the completion of the statutory pre-litigation procedures, as the BPCIA requires. *Id.* ¶ 26.

RESPONSE: Defendants dispute this characterization of the statement under 42 U.S.C. § 262(1)(3)(B), but do not dispute that this statement says, among other things, the following:

Carey Decl. Ex. E at 2.

15. On March 6, 2015, Plaintiffs filed this action. Dkt. No. 1.

RESPONSE: Undisputed.

Defendants' Premature "Notice of Commercial Marketing"

16. On February 5, 2015, the same day they provided their statement of defenses to Plaintiffs, Defendants sent Plaintiffs a letter that they called a "notice of commercial marketing," purportedly pursuant to 42 U.S.C. § 262(1)(8)(A). Carey Decl. ¶ 30; *see also id.* Ex. F.

RESPONSE: Undisputed.

17. In their letter, Defendants asserted that they would begin commercial marketing of their proposed biosimilar product "as early as 180 days from the date of this notice," i.e., August 4, 2015. Defendants also asserted that the BPCIA "prescribes no form or content for the required notice, nor does it include a condition precedent to providing notice." Carey Decl. ¶ 31.

RESPONSE: Defendants do not dispute the allegations of paragraph 17, which selectively quotes the notice of commercial marketing, solely for the purposes of responding to Plaintiffs' Motion. *See* Hoang Decl. Ex. 4.

18. At the time of their purported "notice of commercial marketing," Defendants' proposed biosimilar product was not licensed. *Id.* ¶¶ 34-35.

RESPONSE: Undisputed.

19. Defendants previously asserted that a different document, provided before Defendants filed their aBLA, constituted a notice of commercial marketing under the BPCIA. In

briefing in an unsuccessful declaratory judgment action, Hospira asserted that an earlier declaratory judgment complaint by Celltrion alleging that it intended to sell its proposed biosimilar infliximab product in the United States "should satisfy the Act's notice provision, which does not prescribe any particular form." *See Hospira, Inc. v. Janssen Biotech, Inc.*, No. 14-cv-7059 (S.D.N.Y. Oct. 16, 2014) (Dkt. No. 42 at 22). Carey Decl. Ex. G.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion, which addresses the propriety of Defendants' February 5, 2015 notice of commercial marketing under 42 U.S.C. § 262(l)(8)(A). To the extent a response is required, Defendants do not dispute that, in a response to a motion to dismiss in the action, *Hospira, Inc. v. Janssen Biotech, Inc.*, No. 14-cv-7059 (S.D.N.Y. Oct. 16, 2014), Hospira stated as follows:

> In fact, Celltrion has arguably already given its notice of commercial marketing by filing its Massachusetts complaint—thus defeating Janssen's main argument for declining to hear this suit. (Mot. 19.) In that complaint, Celltrion told Janssen that Celltrion was "poised to introduce Remsima® into the U.S. market immediately upon the FDA's approval of Celltrion's BLA" and that "*[t]he Remsima® product Celltrion will market in the United States* is fixed and definite." (Celltrion Compl. ¶¶ 61, 62.) These statements should satisfy the Act's notice provision, which does not prescribe any particular form. Even if they do not, Celltrion still has time to provide notice that, under Janssen's proxy theory, would constitute adequate notice from Hospira too. (Mot. 19-20.)

Carey Decl. Ex. G at 22. Defendants dispute the remaining allegations of paragraph 19, which are not supported by evidence.

20. Thus, Defendants contend that a notice of commercial marketing may be provided at any time, including before the submission of an aBLA. Carey Decl. ¶ 33.

RESPONSE: Defendants object to Plaintiffs' allegations as immaterial to Plaintiffs' Motion, because Defendants provided their notice of commercial after submission of Celltrion's aBLA. Defendants further object to Plaintiffs' allegations as asserting a legal

conclusion to which no response is required. Defendants' position on this legal issue is set forth in their brief.

The Prematurity of a Motion for a Preliminary Injunction on Plaintiffs' Patents

21. As far as Plaintiffs are aware, serious questions remain about whether Defendants' proposed biosimilar product will be licensed, when it will be licensed, and what the scope of any license might be. Because of these uncertainties, it is premature to bring a motion for a preliminary injunction on all the patents Plaintiffs has asserted in this action. Carey Decl. ¶ 35.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion and as asserting a legal conclusion. To the extent a response is required, the notice of commercial marketing allows the sponsor at least 180 days to "*seek* a preliminary injunction" solely "with respect to any [non-listed] patent"—that is the patents included in the initial lists provided by the sponsor and applicant (42 U.S.C. § 262(*l*)(8)(B)(i)), but not included among the final list of patents subject to immediate litigation (*id.* § 262(*l*)(8)(B)(ii)). *Id.* § 262(*l*)(8)(B) (emphasis added). Indeed, by Plaintiffs' own admission, after a biosimilar applicant "provides a 180-day notice of commercial marketing, the innovator may assert *the patents that were not selected for immediate litigation* and may bring a motion for preliminary injunction to enforce its patents. 42 U.S.C. § 262(l)(8)." *See* Pls.' Br. at 5 (emphasis added). Nothing in the statute prevents the sponsor from seeking a preliminary injunction on any litigated patents at any time after the lawsuit begins.

After the parties reached agreement on which patents will be subject to patent litigation, Plaintiffs filed suit alleging infringement of the six patents asserted in this action. *See* Pls.' Compl. at Counts 3-8. The notice of commercial marketing does not affect Plaintiffs' right to assert any of these patents, including any right to seek a preliminary injunction on these patents.

Yet, as Mr. Carey declared, "Plaintiffs have not moved for a preliminary injunction on any of their six asserted patents at this time[.]" Carey Decl. ¶ 36; *see also* Dkt. 8 (Plaintiffs' motion to stay as to the '471 patent). Defendants dispute the remaining allegations in paragraph 21, which are not supported by evidence.

The 396 Patent

22. Plaintiffs' patent number U.S. 7,223,396 ("the 396 patent") covers specific methods of using infliximab to treat fistulas — abnormal connections between organs — in patients with Crohn's disease. Because the 396 patent is limited to these particular methods of use, Defendants' proposed biosimilar product will infringe the patent only if it is approved for use in treating fistulizing Crohn's disease. *Id.* ¶ 37.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion and as asserting a legal conclusion. To the extent a response is required, Defendants do not dispute that the '396 patent is directed to "[a] method of inhibiting TNFα in a human patient, wherein said human patient has fistulas in Crohn's disease." *See* '396 patent, Dkt. 1-2, at Claim 1. Defendants also do not dispute that their biosimilar will not infringe the '396 patent if it were not approved for use in treating fistulizing Crohn's disease.

23. Defendants have applied for such an indication but there is considerable doubt whether FDA will grant a license for fistulizing Crohn's disease. In Canada, where Defendants' proposed product has already been approved, the health authorities did not approve an indication for Crohn's disease (fistulizing or otherwise), concluding that Plaintiffs' Remicade data could not be extrapolated to Defendants' product. *Id.* ¶ 38 & Exhibit H.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent a response is required, Defendants do not dispute that the Canadian health authorities stated:

> The sponsor requested authorization for all of the indications and uses currently authorized to Remicade. Remicade is currently authorized for indications and uses in rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn's disease, and ulcerative colitis. . . . Scientific rationales submitted by the sponsor were found to be adequate to support extrapolation to the indications and uses pertaining to psoriatic arthritis and plaque psoriasis; however, extrapolation to indications and uses pertaining to Crohn's disease and ulcerative colitis could not be recommended due to differences between Remsima and the reference product, that could have an impact on the clinical safety and efficacy of these products in these indications.

See Carey Decl. Ex. H at 4. Defendants dispute the remaining speculation and allegations in paragraph 23 to the extent that they mischaracterize the statement by the Canadian health authorities, or otherwise are not supported by evidence.

24. If FDA were to take the same view as Health Canada, the 396 patent would not be infringed by Defendants' marketing of their proposed biosimilar product. Carey Decl. ¶ 40.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent a response is required, Defendants do not dispute that if FDA did not license Defendants biosimilar with an indication to treat Crohn's disease, Defendants' marketing of that biosimilar would not infringe the '396 patent.

25. Given the doubt whether FDA will license Defendants' product for Crohn's disease, a preliminary injunction motion on the 396 patent now would be a waste of time and resources. *Id.* ¶ 39.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent a response is required, Defendants dispute the allegations of paragraph 25. Courts have routinely entertained preliminary injunction motions even though the generic drug

manufacturer was merely *seeking* FDA approval that may or may not be granted in whole or in part. *See, e.g., Glaxo Group Ltd. v. Ranbaxy Pharms, Inc.*, 262 F.3d 1333, 1338 (Fed. Cir. 2001); *Apotex Inc. v. Eisai Inc.*, 2010 WL 3420470, at *4 (M.D.N.C. Aug. 27, 2010); *The Research Found. v. Mylan Pharm. Inc.*, 723 F. Supp. 2d 638, 644 (D. Del. 2010).

The 715 Patent (Functional Antibodies)

26. U.S. Patent No. 5,807,715 ("the 715 patent"), exclusively licensed by Janssen from Stanford University and Columbia University, covers methods of producing functional antibodies. It will expire on September 15, 2015 — less than 180 days from now. Carey Decl. ¶ 41.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent that a response is required, Defendants do not dispute that the '715 patent is directed to "a method for producing a functional immunoglobulin comprising a heavy chain and a light chain." *See* '715 patent, Dkt. 1-3, at Claim 1. Defendants further do not dispute that the '715 patent will expire on September 15, 2015.

27. Because of the indefinite adjournment of the advisory committee meeting on Defendants' product, it is highly unlikely that Defendants' product will be approved and ready to be marketed by September 15, 2015. *Id.*

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion, calling for speculation and unsupported by evidence. To the extent a response is required, Defendants dispute the allegations in paragraph 27, which are not supported by evidence.

28. Given the unlikelihood that Defendants will enter the market before the expiration of the 715 patent, it would be wasteful and premature for Plaintiffs to move for a preliminary injunction on this patent. *Id.* ¶ 42.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent a response is required, Defendants dispute the allegations in paragraph 28, which are not supported by evidence.

The 471 Patent (Infliximab Antibody)

29. Plaintiffs' patent number U.S. 6,284,471 ("the 471 patent"), covering the infliximab antibody, is in reexamination at the Patent and Trademark Office (apparently initiated by one or more of the Defendants) and its claims now stand rejected. The reexamination is ongoing. Carey Decl. ¶ 43.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent a response is required, Defendants do not dispute that the '471 patent is in reexamination before the Patent and Trademark Office and its claims now stand rejected. Defendants also do not dispute that reexamination of the '471 patent is ongoing.

30. In the reexamination, Plaintiffs have successfully amended the patent specification, but this amendment will not become effective until the reexamination proceeding is complete. *Id.*

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion and as asserting a legal conclusion. To the extent a response is required, Defendants do not dispute that the specification of the '471 patent has been amended during the reexamination but that amendment is not—and may never become—effective.

31. Until a reexamination certificate issues that sets out the 471 patent's newly amended form, Janssen will not be in a position to move for a preliminary injunction on the patent. *Id.* ¶ 44.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent a response is required, Defendants do not dispute the allegations of paragraph 31 solely for the purposes of responding to Plaintiffs' Motion.

32. By the time Defendants' product is actually approved, however, if it is, the 471 patent may have emerged from reexamination. If that occurs, Plaintiffs would then be able to seek a preliminary injunction on the 471 patent. *Id.* ¶ 45.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion and calling for speculation. To the extent a response is required, Defendants dispute the allegations of paragraph 32 for the reasons explained in their opposition to Plaintiffs' pending motion to stay. *See* Dkt. 41.

The Manufacturing Patents

33. Janssen has asserted three manufacturing patents: U.S. 7,598,083 ("the 083 patent"), U.S. 6,900,056 ("the 056 patent"), and U.S. 6,773,600 ("the 600 patent"). Carey Decl. ¶ 46.

RESPONSE: Undisputed.

34. Janssen asserted these patents under 35 U.S.C. § 271(e)(2)(C)(ii) to preserve its rights after Defendants refused to provide the manufacturing information required by the BPCIA. Instead, Defendants insisted that they would provide such information only if they were sued on these patents. *Id.* ¶ 47.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. Defendants further object to the allegations in the first sentence of paragraph 34 as a recitation of Plaintiffs' subjective beliefs rather than a statement of material fact. Defendants dispute the allegations in the second sentence of paragraph 34 as a mischaracterization of Defendants' prior statements. *See* Carey Ex. D at 2-3.

35. Plaintiffs have now instituted suit, and have renewed their requests for manufacturing information. To date, however, Janssen has still not received the manufacturing information that should have been provided in October 2014. *Id.* ¶ 48.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent a response is required, Defendants dispute the allegation that Plaintiffs "should have been provided" additional manufacturing information "in October 2014." As Defendants explained in their March 4, 2015 letter, on October 27, 2014, Celltrion, Inc. provided Janssen a copy of its aBLA 125544, including information that describes the processes used to manufacture Celltrion's infliximab biologic product. Carey Decl. Ex. D. at 3 Ex. E, at 36-47. Moreover, Defendants had no right nor obligation to produce proprietary third-party manufacturing information to Plaintiffs. *See*, *e.g.*, 42 U.S.C. 262(*l*)(1)(E) (referring to "confidential information disclosed" under the BPCIA as "the property of the subsection (k) applicant").

36. Without complete manufacturing information, Janssen does not know for certain whether Defendants infringe the manufacturing patents. In light of this uncertainty, a motion for a preliminary injunction on Plaintiffs' manufacturing patents is premature. *Id.* ¶ 49.

RESPONSE: Defendants object to these allegations as immaterial to Plaintiffs' Motion. To the extent a response is required, Defendants object to the allegations in the first

sentence of paragraph 36 as a recitation of Plaintiffs' subjective beliefs rather than a statement of material fact. Defendants dispute the allegation that Plaintiffs "should have been provided" additional manufacturing information "in October 2014." As Defendants explained in their March 4, 2015 letter, on October 27, 2014, Celltrion, Inc. provided Janssen a copy of its aBLA 125544, including information that describes the processes used to manufacture Celltrion's infliximab biologic product. Carey Decl. Ex. D. at 3 Ex. E, at 36-47. Moreover, Defendants had no right nor obligation to produce proprietary third-party manufacturing information to Plaintiffs. *See*, *e.g.*, 42 U.S.C. 262(*l*)(1)(E) (referring to "confidential information disclosed" under the BPCIA as "the property of the subsection (k) applicant").

DEFENDANTS' RULE 56.1 STATEMENT OF MATERIAL FACTS

Pursuant to Local Civil Rule 56.1, Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., (together, "Celltrion") and Hospira, Inc. ("Hospira") submit their Rule 56.1 Statement of Material Facts in Support of Defendants' Cross-Motion for Partial Summary Judgment on Count 2 of the Compliant filed by Plaintiffs Janssen Biotech, Inc. and New York University.

Janssen's Remicade Product and Period of Non-Patent Exclusivity

1. Janssen's biologic drug Remicade® was first approved for the U.S. market in 1998. *See* Pls.' Compl. at ¶ 35; Carey Decl. ¶ 5.

2. As Plaintiffs concede, the Biologics Price Competition and Innovation Act ("BPCIA") "provides no non-patent exclusivity" that would delay marketing of a biosimilar of Remicade®. *See* Pls.' Br. at 5.

Defendants' Biosimilar Infliximab Product

3. Celltrion and Hospira seek to introduce in the United States a biosimilar of Remicade at an affordable cost to patients suffering from debilitating and potentially life-threatening diseases. *See* Park Decl. ¶ 14; Meerdervoort Decl. ¶ 2.

4. In 2008, Celltrion began developing a biosimilar version of Remicade, referred to under the trade name Remsima®. Park Decl. ¶¶ 3, 5. Throughout this process, Celltrion has invested more than $112 million in out-of-pocket external costs, in addition to significant internal manpower and other corporate resources, in developing Remsima® and bringing it to market. *Id.* ¶ 5.

5. Beginning in March 2010, Celltrion conducted global clinical trials involving more than 1,400 patients in 20 countries. *Id.* ¶ 7. Phase I and III clinical trials were completed by July 2013. *Id.*

6. In July 2012, Celltrion received regulatory approval for Remsima® from Korea's Ministry of Food and Drug Safety. *Id.* ¶ 9. This marked the first instance of regulatory approval under internationally-accepted guidelines for a biosimilar monoclonal antibody product.

7. In September 2013, Celltrion received approval for Remsima® from the European Medicines Agency. *Id.* ¶ 11. Through this approval, Celltrion obtained marketing authorization from 28 European Union countries and three European Economic Area countries. *Id.*

8. As of April 2015, more than fifty nations, such as the European nations, Canada, and Japan, have approved Remsima® as a biosimilar version of Remicade®. *Id.* ¶ 12.

9. Pursuant to the BPCIA, on August 8, 2014, Celltrion, Inc. submitted an abbreviated Biologic License Application ("aBLA") No. 125544 to the U.S. Food and Drug Administration ("FDA") seeking permission for Celltrion and/or Hospira to market a biosimilar version of Remicade® in the United States. *Id.* ¶ 17.

10. FDA accepted Celltrion's aBLA No. 125544 for review on October 7, 2014. *Id.* ¶ 18; Hoang Decl. Ex. 1.

11. [redacted]. *Id.*

BPCIA Patent Dispute Resolution Procedures

12. On October 27, 2014, Celltrion timely produced to Janssen its aBLA No. 125544 under the BPCIA. Carey Decl. ¶ 10.

13. On December 26, 2014, Janssen provided its list of patents pursuant to 42 U.S.C. § 262(l)(3)(A). Hoang Decl. Ex. 2; *see* Carey Decl. ¶ 15. Janssen identified six patents—U.S. Patent Nos. 6,284,471; 7,223,396; 5,807,715; 6,773,600; 6,900,056; and 7,598,083—that it believed could reasonably be asserted against Defendants. Hoang Decl. Ex. 2.

14. On February 5, 2015, Celltrion informed Plaintiffs that they are not listing any patents pursuant to 42 U.S.C. § 262(l)(3)(B)(i). Hoang Decl. Ex. 3 at 1. Celltrion further informed Plaintiffs that it "consent[ed] to—i.e., does not seek to restrict or expand—Janssen's list of patents for which Janssen believes a claim of patent infringement could reasonably be asserted":

Id. at 2. Defendants further provided their factual and legal contentions that each of the patents listed is invalid, unenforceable, or will not be infringed. *Id.* at 4-53.

15. On February 5, 2015, having consented to Janssen's list of patents, Celltrion served its notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A). Hoang Decl. Ex. 4. Specifically, Celltrion gave notice that: [redacted] *Id.*

16. At the time that Celltrion served its notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A), Celltrion's aBLA No. 125544 was not approved by the FDA. *Compare id.*; *with* Park Decl. ¶ 18.

Present Litigation

17. On March 6, 2015, Plaintiffs filed this present suit. *See generally* Pls.' Compl., Dkt. 1.

18. In their complaint, Plaintiffs allege a violation of the patent dispute resolution procedures under 42 U.S.C. § 262(*l*) and a violation of the notice of commercial marketing provision under 42 U.S.C. § 262(*l*)(8)(A). *See* Pls.' Compl., Dkt. 1, at Counts 1-2.

19. In their complaint, Plaintiffs also allege patent infringement of the six patents Janssen identified during the BPCIA patent exchange: U.S. Patent Nos. 6,284,471; 7,223,396; 5,807,715; 6,773,600; 6,900,056; and 7,598,083. *See* Pls.' Compl., Dkt. 1, at Counts 3-8.

20. Plaintiffs have thus filed suit on all of the patents identified in Janssen's December 26, 2014 patent list pursuant to 42 U.S.C. § 262(l)(3)(A) and in Celltrion's February 5, 2015 patent list pursuant to 42 U.S.C. § 262(l)(3)(B)(ii). *Compare* Pls.' Compl., Dkt. 1, at Counts 3-8; *with* Hoang Decl. Ex. 2; Hoang Decl. Ex. 3 at 1.

21. There are no patents included in the patent lists provided by Janssen or Celltrion that have not been asserted in the present litigation. *Id*.

Pertinent Legislative History of the BPCIA

22. On July 14, 2009, the Subcommittee on Courts and Competition Policy of the Committee on the Judiciary from the House of Representatives held a hearing, entitled "Biologics and Biosimilars: Balancing Incentives for Innovation," to discuss creation of a pathway for the regulatory approval of biosimilar drugs. Hoang Ex. 5 at 1.

23. Mr. Jeffrey P. Kushan testified before the House the Subcommittee on Courts and Competition Policy on behalf of the Biotechnology Industry Organization (BIO). *Id.* at 38. In his testimony, Mr. Kushan expressed BIO's support for "fair and balanced patent review procedures that will precede approval of a biosimilar":

> BIO strongly supports the data exclusivity provisions of H.R. 1548, introduced by Representative Eshoo. We believe that it provides the appropriate balance. It also incorporates fair and balanced patent review procedures that will precede approval of a biosimilar, and importantly includes regulatory linkage.

Id. at 39.

24. In his prepared statement, Mr. Kushan summarized how "nearly all stakeholders in the biosimilar debates support inclusion of procedures to identify and resolve patent issues before a biosimilar is approved and placed on the market":

> Nearly all stakeholders in the biosimilar debates support inclusion of procedures to identify and resolve patent issues before a biosimilar is approved and placed on the market. The reasons are simple; patent litigation commenced only after the biosimilar product is launched will lead to a longer period of uncertainty about patents and will cause greater market disruptions concerning the biosimilar product. Providing a way to start patent litigation before the biosimilar product is on the market (i.e., during the data exclusivity period of the innovator and while the biosimilar product cannot be marketed because it is undergoing review by the FDA) will benefit patients, physicians, insurers, follow-on manufacturers and innovators alike. Indeed, without such a mechanism, follow-on products will enter the market under a cloud of patent uncertainty, and, once on the market, patent disputes over such products will not allow patients, physicians, and insurers to assume there will be long-term availability of the biosimilar product.

Id. at 77.

25. Attached to his prepared statement, Mr. Kushan provided BIO's comments in response to questions by the Federal Trade Commission regarding developing a regulatory approval pathway for biosimilar products. *Id.* at 87. In BIO's comments, it emphasized the importance of "resolv[ing] patent disputes concurrently with the approval process" with "[s]ufficient time for resolution of patent disputes prior to follow-on biologic approval":

> *B1. Would it be important to have the litigation of any patent disputes proceed concurrently with the abbreviated FDA approval process for follow-on biologics? Why or why not? What has been learned from the experience under Hatch-Waxman about the incentives necessary to encourage early resolution of patent issues?*
>
> It would be important to resolve patent disputes concurrently with the approval process, and prior to launch of, a follow-on biologic, because premature launches

> of such products carry numerous risks that significantly impact the public as well as the private interests of the parties. A judicial determination of patent infringement for a prematurely-launched FOB product would raise significant concerns about therapeutic disruption for patients. In fact, consistency of product availability is of great importance to patient health and physician prescribing practices and such consistency would be jeopardized by a premature launch without patent resolution.
>
> . . .
>
> Sufficient time for resolution of patent disputes prior to follow-on biologic approval must therefore be provided. Ideally, patent disputes would be resolved by the time the innovator statutory exclusivity period expires. This way, the patent resolution could take place without the need for special stays pending litigation during a time when the FOB product could otherwise be launched. Such timing of patent resolution would provide business certainty that a risk-tree FOB launch could occur at a fixed point in time. Timing of patent resolution prior to the expiration of the innovator's statutory exclusivity period would also encourage full resolution of patent validity questions on the merits, rather than through settlement, thus providing more patent certainty for subsequent FOB applicants.

Id. at 105-6.

26. Ms. Teresa Stanek Rea testified before the House the Subcommittee on Courts and Competition Policy on behalf of the American Intellectual Property Law Association (AIPLA). *Id.* at 196. In her prepared statement, Ms. Rea testified that the patent enforcement mechanism should include "a streamlined, efficient litigation scheme that encourages resolution of patent infringement claims by the reference product holder as well as by third-party patent holders before FDA approval of the follow-on product":

> AIPLA believes that, should Congress create an abbreviated regulatory approval process for a "follow-on" biological product, it is essential that such a process contain a patent enforcement mechanism that preserves the value of intellectual property. Such a regime should include:
>
> 1. a timely and confidential information exchange sufficient to allow the reference product holder and third-party patent holders to determine whether they have a good faith basis to assert a patent infringement claim;
>
> 2. a streamlined, efficient litigation scheme that encourages resolution of patent infringement claims by the reference product holder as well as by third-party patent holders before FDA approval of the follow-on product;

> 3. a corresponding opportunity for a follow-on product applicant to seek a declaratory judgment of non-infringement, invalidity or unenforceability as to patents that it believes in good faith may be asserted against the follow-on product, if the patent holder does not bring a timely infringement action before product launch;
>
> 4. procedures that apply the existing law of venue; and
>
> 5. all available remedies, including damages and injunctive relief, should patent infringement be found

Id. at 200.

27. In her prepared statement, Ms. Rea further explained that "the primary concern of the AIPLA" is "that the patent dispute resolution mechanism should operate prior to FDA approval of the biosimilar product and should not unduly create additional rules that increase the cost and complexity of litigation or otherwise undermine the value of valid patent rights in biotechnology inventions." *Id.*

Dated: April 29, 2015

Respectfully submitted,

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

By their attorneys,

/s/Andrea L. Martin

Dennis J. Kelly (BBO # 266340)
dkelly@burnslev.com
Andrea L. Martin (BBO #666117)
amartin@burnslev.com
BURNS & LEVINSON LLP
125 Summer Street
Boston, MA 02110-1624
Telephone: 617-345-3000
Facsimile: 617-345-3299

Of Counsel:

WINSTON & STRAWN LLP

Charles B. Klein, *admitted pro hac vice*
1700 K Street NW
Washington, DC 20006
Phone: (202) 282-5000
cklein@winston.com

Peter E. Perkowski, *admitted pro hac vice*
333 S Grand Ave, Suite 3800
Los Angeles, CA 90071
Phone: (213) 615-1700
pperkowski@winston.com

Samuel S. Park, *admitted pro hac vice*
Dan H. Hoang, *admitted pro hac vice*
35 West Wacker Drive
Chicago, Illinois 60601-9703
Phone: (312) 558-5600
spark@winston.com
dhoang@winston.com

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

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 April 29, 2015.

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

4828-6240-6179.1

[redacted]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DECLARATION OF JAEHWEE PARK IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

I, JaeHwee Park, declare as follows:

1. I am the Head of Corporate Regulatory Affairs at Celltrion, Inc. I have a bachelor's and master's degree in biotechnology from Yeonsei University and Seoul National University, respectively.

2. I have worked at Celltrion since 2006. During that time, I have participated in the development of Remsima®, a biosimilar monoclonal antibody product, beginning in its early stages.

3. Remsima® is a biosimilar of the antibody drug Infliximab, which Janssen Biotech, Inc. ("Janssen") distributes under the trade name Remicade®.

4. I am familiar with and participated in Celltrion's successful efforts at obtaining regulatory approval in multiple jurisdictions (including Europe and Korea), as well as its ongoing work to obtain approval of Remsima® for sale in the United States.

[redacted]

5. Celltrion began developing Remsima® in 2008. The process of developing and marketing a biosimilar like Remsima® is complex, requiring a significant investment in research, bioengineering, and clinical development. Celltrion has invested more than $ 112 million in out-of-pocket external costs, as well as significant internal manpower and other corporate resources, in developing Remsima® and bringing it to market.

6. Celltrion began applying for approval of Remsima® as a biosimilar in multiple countries in 2011.

7. Beginning in March 2010, Celltrion conducted global clinical trials involving more than 1,400 patients in 20 countries. Phase I and Phase III clinical trials were completed by July 2013.

8. The results of the clinical trials to date established that Remsima® was comparable in safety and efficacy to Remicade® when used to treat rheumatoid arthritis in combination with methotrexate.[1]

9. In July 2012, Korea's Ministry of Food and Drug Safety became the first national body to approve the marketing of Remsima®. To the best of my knowledge, Remsima® is the first biosimilar monoclonal antibody product to receive regulatory approval under internationally-accepted guidelines. Celltrion has been marketing Remsima® in Korea for over two years.

10. In March 2012, Celltrion submitted its Marketing Authorization Application to the European Medicines Agency ("EMA"). On June 28, 2013, the EMA's Committee for Medicinal Products for Human Use issued a positive opinion for the approval of Remsima® in the European Union.

[1] www.clinicaltrials.gov; trial NCT01571219.

[redacted]

11. After the EMA announced its approval of the marketing of Remsima® in September 2013, Celltrion obtained marketing authorization from 28 European Union countries and three European Economic Area countries.

12. More than fifty nations, including countries with some of the most rigorous regulatory authorities, such as the European nations, Canada, and Japan, have approved the marketing of Remsima®.

13. [redacted] Remsima® is currently sold in more than fifty countries.

14. Celltrion, in conjunction with Hospira, Inc., seeks to introduce a biosimilar of Remicade® to patients in the United States suffering from debilitating and potentially life-threatening diseases.

[redacted]

16. Celltrion followed the FDA's recommendations and subsequently submitted its IND application for Remsima® to the FDA on October 2, 2013. The FDA accepted Celltrion's IND on November 18, 2013, without finding any defects in Celltrion's application.

[redacted]

17. On August 8, 2014, Celltrion submitted to the FDA its application for licensure of Remsima® as a biosimilar.

18. On October 7, 2014, Celltrion's BLA was accepted by the FDA for review without requests for supplemental information. [redacted]

19. The introduction of Remsima® into the United States market, among the largest in the world, would present a substantial opportunity for Celltrion to grow its business.

20. In anticipation of FDA approval, Celltrion is working with Hospira to prepare a distribution network that will allow Celltrion and/or Hospira to sell the biosimilar product in the United States shortly after FDA approves Celltrion's application.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on April 29, 2015.

JaeHwee Park

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DECLARATION OF ANTOINE POMPE VAN MEERDERVOORT IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

I, Antoine Pompe van Meerdervoort, declare as follows:

1. I am the Lead Director of Autoimmune Biologics at Hospira, Inc.

2. I am familiar with and have participated in Hospira's plans to introduce into the United States a biosimilar version of Janssen's biologic drug Remicade® (infliximab).

3. In this venture, Hospira has collaborated with Celltrion, Inc. Celltrion has obtained regulatory approval in multiple countries, including the European Union nations, Canada, and Japan for its biosimilar version of Remicade® that Celltrion distributes internationally under the trade name Remsima®.

4. Hospira has acquired the rights to market Celltrion's product in many countries including the exclusive right to market Celltrion's product in the United States . Hospira currently markets this product in Europe and Canada under a different trade name, Inflectra™.

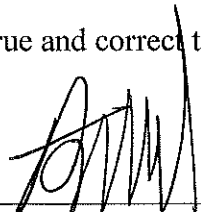
In other words, Remsima® and Inflectra™ are trade names for the same product depending on whether Celltrion or Hospira, respectively, markets the product.

5. Celltrion has filed an application for approval from the United States Food and Drug Administration ("FDA") to market its biosimilar infliximab product in the United States. FDA has accepted that application for review and approval is pending.

6. In anticipation of FDA approval, Hospira, in coordination with Celltrion, is preparing a distribution network that will allow Hospira and/or Celltrion to sell the biosimilar product in the United States as soon as they can after FDA approves Celltrion's application.

7. The introduction of Inflectra™ into the United States market, among the largest in the world, would present a substantial opportunity for Hospira to grow its business. Inflectra™ will be Hospira's first biosimilar, and among the first biosimilars, to be marketed in this country. Hospira's marketing of Inflectra™ following FDA approval thus will help establish Hospira as a pioneer and leader of the biosimilar industry in the United States. The industry has been following Hospira's impending biosimilar launch and, therefore, any injunction delaying that launch would significantly harm its reputation.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed on April 29, 2015.



Antoine Pompe van Meerdervoort