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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF UTAH, NORTHERN DISTRICT

JANSSEN BIOTECH, INC., a Pennsylvania corporation, Plaintiff, v. HYCLONE LABORATORIES, INC., a Utah corporation, Defendant.	**COMPLAINT AND JURY DEMAND** Civil No. 1:16-cv-00071-BCW The Honorable Brooke C. Wells

Plaintiff Janssen Biotech, Inc. ("Janssen") for its Complaint against Defendant HyClone Laboratories, Inc. ("HyClone") alleges as follows.

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 7,598,083 ("the 083 patent") under 35 U.S.C. § 271(a).

2. HyClone, a General Electric company, makes and supplies cell culture media used to grow medicine-producing living cells, including media custom made to the specifications of a particular maker of a biological medicine. Pursuant to the Biologics Price Competition and Innovation Act ("BPCIA"), which was enacted in 2010 as part of the Patient Protection and Affordable Care Act, Celltrion Healthcare Co., Ltd. and Celltrion, Inc. (together, "Celltrion"), and Hospira, Inc. ("Hospira") submitted an abbreviated Biologic License Application ("aBLA") seeking permission to market a biosimilar version of Janssen's revolutionary biological medicine Remicade® (infliximab). HyClone, Celltrion's agent and supplier, makes cell culture media to grow the living cells that produce Celltrion's and Hospira's infliximab biosimilar product.

3. In a case currently pending in the United States District Court for the District of Massachusetts, Janssen is asserting claims against Celltrion and Hospira for technical acts of infringement of Janssen's 083 patent under the BPCIA. In particular, Janssen is asserting claims under 35 U.S.C. § 271(e)(2)(C)(ii) based on Celltrion's and Hospira's failure to provide manufacturing information as required by the BPCIA and on Janssen's analysis of the limited information provided by Celltrion and Hospira prior to the lawsuit. In that action, Janssen is seeking an injunction to bar the launch of Celltrion's and Hospira's infliximab biosimilar. *See Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd.*, No. 15-cv-10698 (D. Mass. filed Mar. 6, 2015).

4. The 083 patent includes claims that cover particular compositions of cell culture media, the important material that is used to grow the living cells that produce biologic medicines such as infliximab.

5. Since the filing of Case No. 15-cv-10698, Janssen has received information about the cell culture media custom made by HyClone for Celltrion's use in the manufacture of the infliximab biosimilar sold by Celltrion and Hospira. This information shows that Celltrion has caused HyClone, Celltrion's agent and supplier, to develop and manufacture in the United States (Logan, Utah) cell culture media ("Celltrion media" or "Celltrion custom-made media") that infringe claims of Janssen's 083 patent. Celltrion has already used these infringing media in the manufacture of large quantities of infliximab biosimilar that have been sold, and are currently being sold, outside the United States and intends to use the infringing media in the manufacture of infliximab product for sale in the United States. Celltrion's and Hospira's infliximab product, as manufactured using the infringing media made by HyClone, was recently approved by the FDA as a biosimilar of Janssen's Remicade®. Celltrion controlled the development of the infringing media, directing details of its composition and instructing HyClone to use the combinations of ingredients that together infringe the claims of the 083 patent.

6. Based on this information, Janssen asserts this Complaint seeking damages for past and current infringement of the 083 patent by HyClone under 35 U.S.C. § 271(a) and injunctive relief to prevent future infringement.

PARTIES, JURISDICTION AND VENUE

7. Janssen Biotech, Inc. is a company organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business in Horsham, Pennsylvania.

8. Upon information and belief, HyClone Laboratories, Inc. is a company organized and existing under the laws of the State of Utah, with a principal place of business in Logan, Utah. HyClone, a General Electric company, makes and supplies cell culture media to grow medicine-producing living cells, including media custom made to the specifications of a particular maker of a biological medicine.

9. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

10. HyClone is subject to personal jurisdiction in this judicial district because it is a domestic Utah corporation and has its principal place of business in Utah. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

GENERAL ALLEGATIONS

The 083 Patent.

11. Janssen owns U.S. Patent No. 7,598,083 (the "083 patent"), which covers cell culture media for use in growing antibody-producing cells.

12. On October 6, 2009, the PTO duly and properly issued the 083 patent, entitled "Chemically Defined Media Compositions." A true and correct copy of the 083 patent is attached as Exhibit A.

13. The cell culture media covered by the 083 patent comprise 61 ingredients at various concentration ranges and were developed through the intensive efforts of the inventors.

14. The 083 patent will expire on February 7, 2027.

Remicade® (Infliximab).

15. Janssen is a pioneer and leader in the development of biologic drugs. Janssen's biologic drug Remicade® was one of the first drugs of its kind sold in the United States for treatment of a chronic disease.

16. Remicade® is a monoclonal antibody that binds to and neutralizes a substance in our bodies called tumor necrosis factor alpha ("TNFα"). TNFα is an important player in our immune systems but, if it is over-produced, it can lead to chronic disease.

17. Scientists at New York University worked with scientists at Janssen's predecessor Centocor to develop the infliximab monoclonal antibody, also known as the "cA2" antibody.

18. Although the cA2 antibody had promising in vitro properties, given its complex structure and mechanism of operation it required extensive pre-clinical and clinical development before it could become a useful medicine for human beings.

19. From the time the infliximab antibody was first discovered, it took nearly a decade for Remicade® to be approved for sale in the United States. During that time, Centocor conducted dozens of clinical trials and spent tens of millions of dollars, with no guarantee of success.

20. Remicade® was first approved for the U.S. market in 1998. 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.

21. After Remicade® entered the market, Janssen continued to pursue extensive clinical development efforts for the drug. These efforts led to the discovery that Remicade® is safe and effective for a number of additional diseases and indications other than Crohn's disease.

22. Janssen's extensive development efforts have led to 16 FDA approvals for Remicade®, including indications for use in the treatment of Crohn's disease (1998), 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). Remicade® has changed the standard of care for the treatment of these diseases.

23. In total, Janssen has sponsored more than 170 clinical trials for Remicade®. Janssen has spent hundreds of millions of dollars in research and development of the drug.

24. Remicade® had been used to treat and improve the lives of more than 2.2 million patients suffering from chronic disease.

Celltrion's and Hospira's Biosimilar Product.

25. Biological medicines, or biologics, are complex biological molecules that need to be grown in living cultures rather than chemically synthesized, as are the more familiar pharmaceutical products known as chemical or small-molecule drugs. Because the biologic manufacturing process is complex and uses living organisms, the structural features of a biologic drug can vary based on the precise manner in which the biologic is made. Unlike small-molecule drugs, moreover, biological molecules generally cannot be completely characterized.

26. Because of the differences between biological and small-molecule drugs, biological and small-molecule pharmaceutical products are approved for sale in the United States through different regulatory pathways. Whereas small-molecule drugs are approved based on the submission of a New Drug Application ("NDA") (*see* 21 U.S.C. § 355), biological products are assessed pursuant to a Biological License Application ("BLA") (*see* 42 U.S.C. § 262(a)).

27. Although Congress created an abbreviated regulatory pathway for the approval of generic small-molecule drugs in the Hatch-Waxman Act of 1984, no abbreviated pathway for

approval of follow-on biologics products existed until the enactment of the BPCIA, as part of the Patient Protection and Affordable Care Act, in 2010. Before the enactment of the BPCIA, the only way to obtain U.S. approval of a biological product was through an original BLA supported by a full complement of pre-clinical and clinical data.

28. The BPCIA creates an abbreviated approval pathway (beginning with an aBLA) for FDA licensure of biological products upon a determination that the biological product is "biosimilar" to a previously licensed "reference product." 42 U.S.C. § 262(k). The BPCIA defines a "biosimilar" as a biological product that is (1) "highly similar to the reference product notwithstanding minor differences in clinically inactive components"; and (2) has "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. §§ 262(i)(2)(A), (B). The BPCIA defines a "reference product" to be a "single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." 42 U.S.C. § 262(i)(4).

29. Under the BPCIA, biosimilar applicants are permitted to make use of FDA's prior determinations as to the safety, purity, and potency of the reference product that was already approved by FDA. In particular, a biosimilar applicant must identify a single reference product that has already been approved by FDA and submit to FDA "publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii)(I). Consequently, the § 262(k) pathway created by the BPCIA allows the biosimilar applicant, taking advantage of the prior efforts and investments of the reference product's developer, to reduce the time, expense, and risks of research and development and the full complement of pre-clinical and clinical testing, and to gain licensure to

commercialize its biological product in the market as a biosimilar sooner and more cheaply than it could have done had it been required to submit an original BLA, as the reference product's developer did.

30. Celltrion and Hospira submitted an Investigational New Drug ("IND") application for their proposed biosimilar to Janssen's infliximab product under section 505(i) of the Federal Food, Drug, and Cosmetic Act on October 2, 2013, and the FDA accepted the IND on November 18, 2013. The IND permitted Celltrion and Hospira to conduct studies of their proposed infliximab biosimilar for use in an application for regulatory approval in the United States.

31. Celltrion and Hospira submitted an aBLA (No. 125544) for this proposed biosimilar product on or about August 8, 2014 and the FDA accepted that application for review on or about October 7, 2014. The aBLA is an application to market Celltrion's and Hospira's proposed biosimilar infliximab product in the United States. Celltrion and Hospira received approval from the FDA on April 5, 2016 to sell biosimilar infliximab in the United States.

32. In 2009, Hospira entered into an agreement with Celltrion, pursuant to which Hospira obtained the rights to co-exclusively market biosimilar infliximab in the United States. Under the terms of the same agreement, Hospira obtained the rights to co-exclusively market biosimilar infliximab in, among other places, Europe and Canada. In 2014, the agreement was amended to grant Hospira the exclusive right to commercialize the product in certain countries, including the United States. The trade name for the infliximab product marketed by Hospira is Inflectra. Pursuant to Celltrion's agreement with Hospira, Hospira purchases infliximab from Celltrion and sells it in the markets in which it has distribution rights.

33. Celltrion and Hospira have sold and continue to sell biosimilar infliximab in more than 30 countries worldwide.

34. For example, Celltrion's and Hospira's biosimilar infliximab products have been sold in South Korea since the fourth quarter of 2012; in Finland, Norway, Czech Republic, and Portugal since the fourth quarter of 2013; in Ireland and Poland since the first quarter of 2014; in Japan since the fourth quarter of 2014; in Austria, Belgium, Canada, Denmark, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Spain, Sweden, and the UK since the first quarter of 2015; and in Venezuela since the second quarter of 2015. Furthermore, Celltrion's and Hospira's biosimilar infliximab was recently approved for sale in Brazil.

Background to the Present Action.

35. On March 6, 2015, Janssen initiated litigation in the District of Massachusetts, Case No. 15-cv-10698 ("the Celltrion Action"), as a result of Celltrion's and Hospira's failure to provide information regarding the manufacturing process for their infliximab biosimilar as required by the BPCIA, including the composition of the cell culture media used for the production of their biosimilar product. In particular, Janssen asserted claims under 35 U.S.C. § 271(e)(2)(C)(ii) for technical infringement of the 083 patent based on Celltrion's and Hospira's failure to provide manufacturing information as required by the BPCIA and on Janssen's analysis of the limited information provided by Celltrion and Hospira prior to the lawsuit. Celltrion and Hospira refused to participate in and sought to avoid patent dispute resolution procedures of the BPCIA, which would have revealed that their infliximab biosimilar product was made using cell culture media claimed in the 083 patent.

36. Celltrion and Hospira for a time were able to shroud their and HyClone's infringement of the 083 patent by refusing to provide Janssen with information necessary to investigate and evaluate potential claims. Despite having the information and relying on it to contest infringement of the 083 patent, Celltrion and Hospira refused for months to disclose the

composition of the cell culture media used to manufacture their infliximab biosimilar and the location where the media are made. Throughout Janssen's efforts to obtain this information from Celltrion and Hospira, they asserted that any infringing manufacturing conduct took place outside of the United States and therefore outside the reach of U.S. patents (and, thus, that the information was irrelevant). Celltrion and Hospira also pointed to differences in the concentration of certain claimed media ingredients without revealing the composition of the media. Celltrion and Hospira refused to provide any further information outside the context of litigation and insisted that Janssen file suit for technical infringement of the 083 patent under the BPCIA.

37. Even after the Celltrion Action began, Celltrion and Hospira refused to provide information about the composition of the cell culture media used to make their biosimilar product and where the media was made. Nonetheless, HyClone (a non-party to the Celltrion Action) eventually disclosed the composition of the media and that it was custom made for Celltrion in Logan, Utah.

38. Having learned their compositions, Janssen was then able to confirm that the custom-made Celltrion media infringe the 083 patent under the doctrine of equivalents, as described more fully below. The information provided by HyClone demonstrated that Janssen now had a basis upon which to claim actual infringement as opposed to "technical" acts thereof under the BPCIA.

39. After Janssen informed Celltrion and Hospira that it intended to sue for their actual infringement of the 083 patent, Celltrion and Hospira objected to any amendment of Janssen's existing complaint or to a separate complaint for actual infringement under 35 U.S.C. § 271(a) and (b). Despite clear 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, Celltrion and Hospira objected to modification of the protective order and to Janssen's use of the information it learned in an amended complaint or a new suit.

40. Janssen also notified HyClone of its intention to file suit against HyClone, provided HyClone with a draft complaint, and asked HyClone if it had any objection to modification of the protective order to permit suit. Although HyClone did not object to Janssen filing suit against it, in light of Celltrion's and Hospira's objection, Janssen was unable to proceed with this lawsuit until the court in Massachusetts ruled on Janssen's motion to modify the protective order. On May 19, 2016, the court in the Celltrion Action granted Janssen's motion to modify the protective order to permit the present action.

The Importance of Cell Culture Media.

41. Biologics like Remicade® and Celltrion's and Hospira's infliximab product are made from living cells rather than synthesized chemically. In general, biological medicines are significantly larger than chemical or "small-molecule" drugs and their mechanisms of action are more complex and often incompletely understood.

42. The three-dimensional structure of biologics, as well as the pattern of sugar molecules attached to them (*i.e.*, the glycosylation pattern) are difficult or impossible to characterize fully. And, because biological medicines are made in living cells rather than synthesized from chemical components, their three-dimensional structure and glycosylation pattern is affected by the manufacturing process, including the cell culture media that is used.

43. Biological products are produced in and by genetically-modified cells. These medicine-producing cells are grown in cell culture media.

44. An appropriate cell culture media contains ingredients that allow cells to grow and produce the desired biological product. The cell culture media in which a biological product is manufactured is critical to the manufacturing process and the resulting biological product.

45. Changes in the cell culture media being used to manufacture a biological product can change the nature of the biological product, including its efficacy and safety. Accordingly, a change in the cell culture media used to manufacture an approved biological product will require significant validation before being acceptable to regulatory authorities.

Janssen's Development of the 083 Patent and Work with Hyclone.

46. Through expensive and painstaking efforts, the inventors of the 083 patent, who were employees of Centocor (Janssen's predecessor), developed a novel cell culture media formulation that could sustain high levels of cell growth and promote the production by those cells of high levels of the active ingredient in biological medicine. The formulation, reflected in Janssen's 083 patent, calls for 52 required ingredients and 9 optional ingredients.

47. Beginning in 2003, Centocor retained HyClone to manufacture this new cell culture medium on a large scale for testing for biopharmaceutical production. HyClone, which is now an indirect subsidiary of General Electric Company, is based in Logan, Utah.

48. Centocor's work with HyClone began before the October 29, 2004 priority application for the 083 patent was filed and was subject to an April 2003 confidentiality agreement between the two companies. Under the protection of that agreement, in December 2003, Centocor gave HyClone Centocor's confidential formulation for a cell culture medium later claimed in the 083 patent.

49. HyClone was informed that the 083 media, manufactured according to the recipe Centocor provided to HyClone, worked well for large scale biopharmaceutical production. HyClone congratulated Centocor on Centocor's successful design of the 083 media.

50. HyClone sought to be Centocor's manufacturer for the 083 media. HyClone also sought to become Centocor's supplier for the media already approved to manufacture Remicade®. However, Centocor decided not to use HyClone as its supplier for cell culture media for Remicade®. HyClone is now Celltrion's supplier for cell culture media for Celltrion's and Hospira's biosimilar version of Remicade®.

Development of Celltrion's Infringing Media.

51. In late 2003, Celltrion and HyClone began working together in the development of cell culture media to be used to manufacture Celltrion's products. Celltrion and HyClone entered into a non-disclosure and confidentiality agreement on December 3, 2003 and since that date have entered into a variety of supply agreements for the production and sale to Celltrion of media custom-made for Celltrion for manufacturing infliximab.

52. Celltrion's first confidentiality agreement with HyClone was executed a number of months after Centocor had retained HyClone, and less than one month before Centocor provided HyClone the formulation of the 083 media under a confidentiality agreement, as discussed above. At least four of the same HyClone employees that worked on the cell culture media project for Centocor also worked on the development of Celltrion's cell culture media. HyClone did not disclose to Centocor that it was collaborating with Celltrion or that its employees who worked on Centocor's media were helping to develop media for Celltrion.

53. As described below, at least two of the cell culture media custom made by HyClone for Celltrion ("Celltrion Growth Media," or "CGM," and "Celltrion Production

Media," or "CPM") infringe the 083 patent. Both media are used in the production of Celltrion's and Hospira's biosimilar product. These cell culture media infringe claims 1-2 of the 083 patent under the doctrine of equivalents.

54. Celltrion directed HyClone's development of custom-made cell culture media for the specific purpose of manufacturing a biosimilar version of Remicade®. Although Celltrion lacked the facilities to manufacture media on a large scale, its personnel had years of experience in the development and optimization of cell culture media for antibody production. Relying on that expertise, Celltrion exercised control over the formulation of the media, instructing HyClone on what combinations of ingredients to use and in what concentrations. Celltrion also tested antibodies made using the cell culture media to ensure that it resulted in a biosimilar product.

55. Throughout the process of developing the media for manufacture of its biosimilar infliximab, Celltrion's scientists analyzed and tested various iterations of media provided by HyClone and instructed HyClone to make specific adjustments to the media. Sometimes Celltrion instructed HyClone to add ingredients, sometimes to remove them, and sometimes to change their concentration. At every step of the way, HyClone followed Celltrion's instructions. HyClone also provided Celltrion with whatever information about the media formulations Celltrion needed to make specific adjustments.

56. HyClone and Celltrion thus understood that the custom-made media project was being conducted for Celltrion and under Celltrion's control. HyClone consistently sought approval from Celltrion for various versions of the media it produced on behalf of Celltrion because the media had to meet Celltrion's specifications.

57. Celltrion instructed HyClone to combine the ingredients that resulted in the infringing media at issue here. HyClone followed those instructions. By no later than December

2013, Celltrion, including its top executives, knew the precise formulations of the infringing media, which Celltrion has used and continues to use to manufacture infliximab sold throughout the world.

58. The development and optimization of the media was supervised by Celltrion. And because any change in the media could cause a change in the characteristics of the biosimilar product itself, Celltrion needed control over the compositions in case HyClone ever became unable to manufacture the media.

59. Celltrion and HyClone have had and continue to have a contractual relationship relating to the production of the infringing custom-made cell culture media for Celltrion. Pursuant to that relationship, the development and manufacture of media for Celltrion have been subject to Celltrion's control.

60. Since as early as 2010, HyClone has produced infringing custom-made cell culture media in Logan, Utah for use in the manufacture of Celltrion's and Hospira's infliximab product, and continues to do so.

61. Since as early as 2012, Celltrion and Hospira have sold, now in over 30 countries worldwide, biosimilar infliximab made using the infringing custom-made cell culture media.

62. The infringing custom-made cell culture media made in the United States are critical to Celltrion's and Hospira's infliximab product. The biosimilar infliximab product approved in the United States and worldwide is made using the infringing media custom-made for Celltrion in the United States.

63. Celltrion and Hospira are able to sell their approved infliximab product as a result of infringement of the 083 patent.

Hyclone's Infringement of the 083 Patent.

64. Claim 1 of the 083 patent claims "[a] soluble composition, suitable for producing a final volume of cell culture media, wherein the composition comprises the following components in the following amounts per liter of the final volume of cell culture media," followed by a list of 61 components, each with its own concentration range. For 9 of the listed components, the lower bound of the claimed concentration range is zero mg/L.

65. The cell culture media custom made for Celltrion by HyClone include all of the ingredients required by claim 1 of the 083 patent, in precisely the same chemical forms as claimed. Most of the ingredients are present in Celltrion's cell culture media in concentrations that are literally within the claimed ranges. The rest are present in Celltrion's media in concentrations that are not substantially outside of the claimed ranges.

66. The ingredients in the Celltrion media at these concentrations are insubstantially different from, and thus equivalent to, the ingredients at the claimed concentrations. Specifically, the ingredients at the concentrations in the custom media perform substantially the same function, in substantially the same way, with substantially the same results, as the ingredients at the claimed concentrations. This has been confirmed by testing performed by experts retained by Janssen prior to filing this complaint.

67. Janssen's experts performed a series of experiments to determine, on an ingredient-by-ingredient basis, what effect the literal differences from the claimed concentrations have on the performance of the Celltrion media in cell culture. Janssen's experts did this by culturing the cell line used in the examples of the 083 patent (C743B) in a series of cell culture media that the experts prepared. One of the tested media was a replica of Celltrion's media ("Celltrion Growth Media" in one experiment, and "Celltrion Production Media" in another).

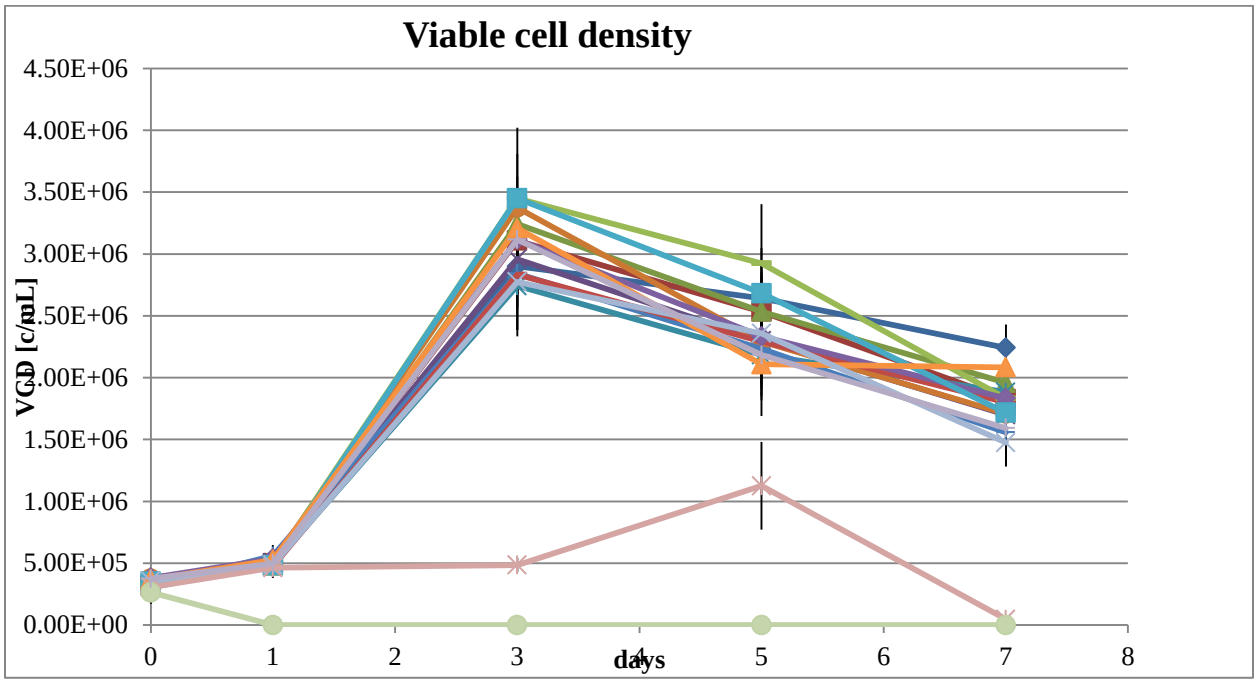
The other test media were variants of the replica, each one modified so that one of the elements (whose concentration in Celltrion's media was outside the claimed range) literally fell within the range identified in claim 1 of the 083 patent. Janssen's experts also prepared a test medium in which the concentrations of all ingredients whose concentration in Celltrion's media was outside the claimed range were modified to fall within the claimed range. Finally, Janssen's experts prepared two negative control media for each experiment. One negative control contained only phosphate buffered saline ("PBS"), a medium devoid of nutrients necessary for the cells' survival and growth. The second negative control was 80% PBS and 20% CGM or CPM. In other words, the second negative control contained all of the nutrients provided by Celltrion's media but at about one-fifth the concentration.

68. Over the course of a culture, Janssen's experts measured the concentration of living cells in the culture (the viable cell density, or "VCD"), the proportion of those cells that remained alive (the viability), and the amount of antibody produced by the cells (the titer). Each test condition was run in triplicate, and the results averaged.

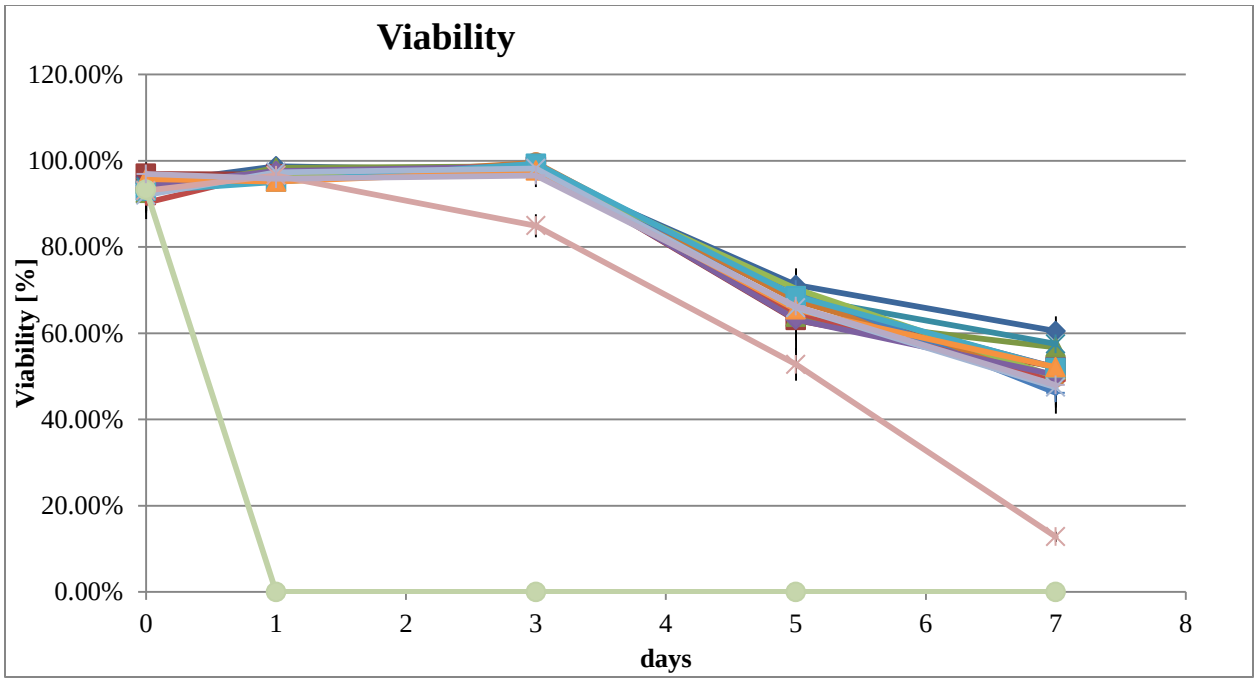
69. The results of the experiments demonstrated that, with respect to each ingredient whose concentration in Celltrion's media was outside the claimed range, on an element by element basis, the difference had no substantial effect on the performance of the media in cell culture. Nor did the all of the concentration differences together have any substantial effect on the performance of the media in cell culture.

70. The figure below shows, for each of the tested media in the CGM experiment, the viable cell density (in millions of cells per mL) of the culture as a function of the number of days of the culture. This is a measure of the ability of the tested media to promote cell growth. As is evident from the graph, all of the tested media (except for the negative controls, represented by

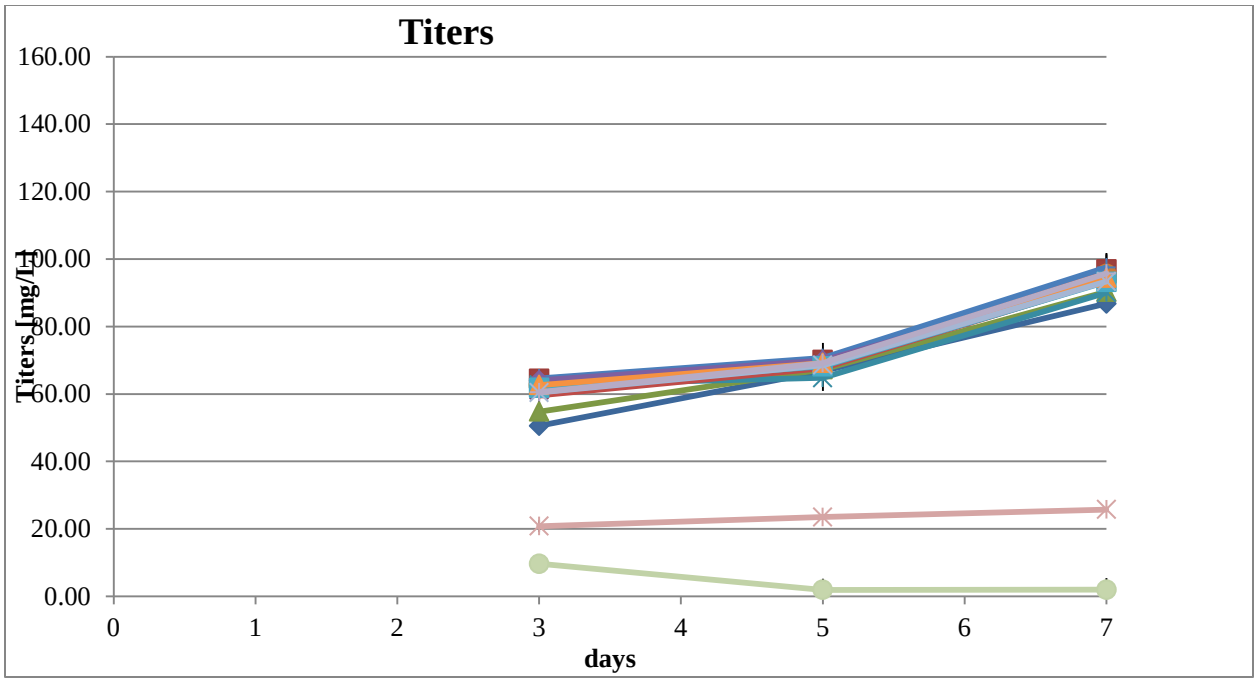
the two lines at the bottom) exhibited substantially similar performance in this regard. (Identifying information is omitted from the graphs to protect the confidentiality of Celltrion's formula.)



71. The figure below shows, for each of the tested media in the CGM experiment, the proportion of viable (living) cells (expressed as a percentage of all cells) in the culture as a function of the number of days of the culture. This is a measure of the ability of the tested media to sustain cell life. As is evident from the graph, all of the tested media (except for the negative controls, again represented by the two lines at the bottom) exhibited substantially similar performance in this regard.



72. Finally, the figure below shows, for each of the tested media in the CGM experiment, the titer (i.e., amount of antibody produced in culture, measured in mg/L) as a function of the number of days of the culture. This is a measure of the ability of the tested media to support the cells' production of antibody. As is evident from the graph, all of the tested media (except for the negative controls, again represented by the two lines at the bottom) exhibited substantially similar performance in this regard.



73. The results of the CPM experiment were similar to those of the CGM experiment.

74. The substantially similar performance of the tested media in the experiments confirms that the differences in concentrations of the ingredients in Celltrion's media are insubstantial, and do not yield substantially different results in terms of cell culture.

75. Celltrion's media also meet all the additional claim limitations of claim 2 of the 083 patent, including a buffering molecule with a pKa between 5.9 and 7.8 and a cell protectant.

76. Thus, the critically important cell culture media that Celltrion has HyClone custom-make in the United States to support its and Hospira's sales of biosimilar infliximab products worldwide meet all of the claim limitations of claims 1-2 of the 083 patent. All the ingredients are present literally and so are the concentrations for most of them. For the remaining ingredients, the concentration limitations are met under the doctrine of equivalents. The further claim limitations of claim 2 are all literally met.

FIRST CAUSE OF ACTION

(Infringement of the 083 Patent Under 35 U.S.C. § 271(a))

77. Janssen incorporates by reference paragraphs 1-76 as if fully set forth herein.

78. At Celltrion's direction and under Celltrion's control, and acting as Celltrion's agent, HyClone developed custom-made cell culture media in the United States that infringe claims 1-2 of the 083 patent under the doctrine of equivalents.

79. Under contract with Celltrion, HyClone has manufactured and continues to manufacture the infringing custom-made media in the United States for Celltrion's use in the manufacture and sale of a biological product that has been and continues to be sold by Celltrion and Hospira outside of the United States under the trade names Remsima and Inflectra respectively and that Hospira intends to sell in the United States under the trade name Inflectra.

80. HyClone had actual knowledge, or was willfully blind to the fact that, Celltrion's custom-made media infringe claims 1-2 of the 083 patent.

81. Upon information and belief, HyClone's past and current infringement of the claims of the 083 patent were and are intentional, willful, and knowing, and/or objectively or subjectively reckless. HyClone's wrongful conduct makes this case exceptional and entitles Janssen to attorneys' fees and increased damages.

82. HyClone's conduct has harmed and continues to harm Janssen, including by preventing it from enjoying the exclusive rights granted by the 083 patent; by causing Janssen to lose market share for and profits from Remicade® in the markets in which Celltrion's and Hospira's biosimilar product is marketed; and by causing Janssen's licensee for the distribution of Remicade® to lose market share for and profits from Remicade® in markets in which Celltrion's and Hospira's biosimilar product is marketed.

83. Unless HyClone is enjoined from infringing the 083 patent, Janssen will continue to suffer irreparable loss, injury, and damages.

PRAYER FOR RELIEF

WHEREFORE, Janssen respectfully requests that this Court enter judgment in its favor against HyClone and grant the following relief:

(a) a judgment that HyClone has infringed and continues to infringe the 083 patent under 35 U.S.C. § 271(a);

(b) preliminary and/or permanent equitable relief, including but not limited to a preliminary and/or permanent injunction that enjoins HyClone, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns, from making, using, importing, offering for sale or selling the Celltrion custom-made media and from otherwise infringing the 083 patent;

(c) damages caused by the infringement of the 083 patent, with interest and trebled, pursuant to 35 U.S.C. § 284;

(d) a declaration that this is an exceptional case and an award to Janssen of its attorneys' fees, costs and expenses pursuant to 35 U.S.C. § 285; and

(e) such other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Janssen demands a jury trial as to all issues triable by a jury.

DATED: June 14, 2016.

STOEL RIVES LLP

/s/ Timothy K. Conde _____
Timothy K. Conde
Andrew T. Wojciechowski

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