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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF UTAH, NORTHERN DIVISION

JASSEN BIOTECH, INC. a Pennsylvania corporation, Plaintiff, v. HYCLONE LABORATORIES, INC., a Utah corporation. Defendant.	**HYCLONE'S MOTION FOR INJUNCTIVE RELIEF, TO DISMISS, AND TO STAY** Case No. 1:16-cv-00071-JNP-EJF Judge Jill N. Parrish Magistrate Judge Evelyn J. Furse

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RELIEF SOUGHT

Defendant HyClone Laboratories, Inc. ("HyClone"), by and through counsel, hereby moves for an injunction prohibiting Janssen Biotech, Inc. ("Janssen") from prosecuting this action in contravention of its agreement not to use HyClone's confidential information for that purpose. In addition, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, HyClone moves to dismiss Janssen's Complaint for failure to state a claim upon which relief can be granted. Specifically, Janssen has not plausibly pleaded a cognizable claim for infringement under the "doctrine of equivalents." Absent an order enjoining or dismissing this action, HyClone moves for a stay pending resolution of litigation brought by Janssen in the District of Massachusetts against Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc. (collectively, "Celltrion").

This motion is based on the arguments and authorities set forth below, the declaration of David A. Caine filed concurrently herewith ("Caine Decl."), as well as on any further materials, evidence, or arguments to be presented either at or before the hearing on this motion, and any other materials or evidence the Court deems proper.

INTRODUCTION

Biological drugs are complex biological molecules that are grown in living cultures, unlike traditional pharmaceutical drugs, which are chemically synthesized. This litigation involves the cell culture media used to grow such biological drugs ("biologics"). Janssen makes Remicade, its version of a biologic drug called infliximab. Celltrion makes a biosimilar version of infliximab and, having obtained approval from the FDA, intends to sell its biosimilar in the U.S. market in competition with Janssen. Based on the framework provided by the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Janssen filed a number of patent lawsuits to block Celltrion's entry into the market so as to maintain Janssen's monopoly position. Two such actions are currently pending in the District of Massachusetts, where Janssen alleges, *inter alia*, that the cell culture media HyClone supplies Celltrion to grow its biosimilar infringes one of Janssen's patents.

After filing the first of its two actions against Celltrion in the District of Massachusetts, Janssen approached HyClone requesting expedited production of HyClone's proprietary, highly confidential cell culture media formulation. HyClone promptly responded that it would consider Janssen's request, and asked Janssen to propose an appropriate protocol for the protection of HyClone's highly confidential information. After a period of negotiation, Janssen and HyClone agreed on a framework for HyClone's voluntary production that incorporated terms of a draft protective order. Thus, Janssen and HyClone agreed that Janssen could use HyClone's confidential information "solely for purposes of this litigation" and not "as evidence or supporting materials in disputes or petitions to any regulatory agencies or courts in any jurisdiction or forum, regardless of country (other than this present litigation) . . . ."

Notwithstanding its express agreement to the contrary, Janssen filed the instant Complaint based on the very same highly confidential formulation information HyClone voluntarily provided. Since Janssen filed the Complaint in breach of its agreement and because no available legal remedy would adequately compensate HyClone for Janssen's breach, the Court should enjoin Janssen from prosecuting the instant action based on its use of HyClone confidential information.

Independent of the preceding, Janssen's Complaint should be dismissed for failure to state a claim. As Janssen concedes in the Complaint, it cannot prove that HyClone's cell culture media literally infringes any claim of U.S. Patent No. 7,598,083 (the "'083 patent") because many of the components in HyClone's accused cell culture media are not identical to the recited limitations of the claims of the '083 patent. Janssen thus relies on the "doctrine of equivalents," which permits a narrow extension of the scope of a patent claim to "prevent[ ] an accused infringer from avoiding liability for infringement by changing only minor or insubstantial details of a claimed invention while retaining the invention's essential identity." *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1424 (Fed. Cir. 1997). "[T]he doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." *Warner-Jenkinson*, 520 U.S. 17, 29 (1997). Yet, the Complaint does not address any specific non-identical component in detail, but rather pleads that the accused media is equivalent because the product obtained from using the accused media is not substantially different. This is insufficient to state a claim for infringement under the doctrine of equivalents.

Finally, even if not enjoined or dismissed, this case should be stayed until the termination of the Massachusetts actions. A stay would promote judicial economy because this litigation involves the same patent and the same accused product that are now at issue in Janssen's

Massachusetts actions. Furthermore, the first-filed Massachusetts action is much more advanced than the instant action. Fact discovery will soon close, and a trial is scheduled for the first half of 2017. A stay will also avoid the possibility of inconsistent rulings, and none of the parties would be unfairly prejudiced. Accordingly, HyClone respectfully requests that the Court stay this action in deference to Janssen's Massachusetts actions.

BACKGROUND

A. Cell Culture Media is the Material Used to Support the Growth of Microorganisms or Cells.

Biological medicines, or biologics, are large, complex biological molecules that are manufactured in a living system, such as animal cells, rather than being synthetized chemically. Compl. ¶¶ 25, 41. Specifically, biologics are produced in and by genetically-modified cells that are grown in cell culture media. *Id*. ¶ 43. The cell culture media contains components that allow the cells to grow and produce the desired biological product. *Id.* ¶¶ 44, 45. As 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. *Id*. ¶ 25.

B. The Parties.

1. Janssen and the '083 Patent.

Janssen contends that it is the owner of the '083 patent, which covers cell culture media for use in growing antibody-producing cells. Compl. ¶¶ 11-12 & Ex. A. According to Janssen, the inventors of the '083 patent (employees of Janssen's predecessor, Centocor) developed a 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. *Id.* ¶ 46. That formulation includes a sizeable number of components, sixty-one (61) of which are recited

in independent claim 1 of the '083 patent. *Id.* Ex. A. In claim 1, each of these sixty-one components has a required concentration range expressed in milligrams per Liter (mg/L). *Id.* ¶¶ 13, 46 & Ex. A. Of these sixty-one components, fifty-two (52) are required, in that they must be present in a concentration greater than 0 mg/L. *Id.* Nine (9) other components are optional because the low end of the concentration range is 0 mg/L. *Id.*

2. HyClone the Celltrion Media.

HyClone makes and supplies cell culture media used to grow medicine-producing living cells, including media custom made for particular makers of biological medicine. Compl. ¶¶ 2, 8. Janssen alleges that, in 2003, HyClone began working with Celltrion on the development of cell culture media to be used to manufacture Celltrion's products. *Id.* ¶ 51. According to Janssen, Celltrion directed HyClone's development of custom-made cell culture media for the specific purpose of manufacturing a biosimilar version of Remicade. *Id.* ¶ 54. Janssen asserts that Celltrion's personnel, who had years of experience in the development and optimization of cell culture media for antibody production, exercised control over the formulation of the media and instructed HyClone on what combinations of ingredients to use and in what concentrations. *Id.* Throughout the process, Celltrion's scientists allegedly analyzed and tested various iterations of media provided by HyClone and instructed HyClone to make specific adjustments to the media, such as adding, removing, or changing the concentrations of certain ingredients. *Id.* ¶ 55. Per the Complaint, HyClone merely followed Celltrion's instructions "[a]t every step of the way." *Id.* Relevant here are two cell culture media custom made by HyClone for Celltrion: the Celltrion Growth Media ("CGM") and the Celltrion Production Media ("CPM") (collectively,

the "Celltrion Media"), both of which are used in the production of Celltrion's biosimilar product and alleged to infringe the '083 patent, albeit only under the doctrine of equivalents. *Id.* ¶ 53.

C. The Massachusetts Litigation.

Janssen filed suit against Celltrion in the United States District Court for the District of Massachusetts in March 2015[1] alleging technical acts of infringement of the '083 patent under the BPCIA. Compl. ¶ 3. Specifically, Janssen asserts that Celltrion violated 35 U.S.C. § 271(e)(2)(C)(ii) by failing to provide manufacturing information relating to the Celltrion Media and its biosimilar as required. *Id.* HyClone is not a party to the Massachusetts Litigation.

In April 2015, not long after filing the Massachusetts Litigation, Janssen approached HyClone requesting access to HyClone's proprietary, highly confidential cell culture media formulations to evaluate Celltrion's alleged infringement. *See* Declaration of David A. Caine ("Caine Decl.") Ex. 1 at 9; Compl. ¶ 37. Instead of serving a subpoena, Janssen asked HyClone to respond to its requests voluntarily and "expeditiously." Caine Decl. Ex. 1 at 9. HyClone responded the same day, noting that "the information in question is highly sensitive" and asking for an outline of an appropriate review protocol. *Id.* at 8.

Thereafter, the parties negotiated a private production agreement whereby HyClone would provide Janssen with the details of its proprietary cell culture media formulations based on Janssen's agreement to use the information "solely for purposes of this litigation," *i.e.*, the Massachusetts Litigation, and not "as evidence or supporting materials in disputes or petitions to any regulatory agencies or courts in any jurisdiction or forum, regardless of country (other than

[1] *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-cv-10698 (D. Mass. Mar. 6, 2015) (the "Massachusetts Litigation").

this present litigation) …." *Id.* at 20-21. Janssen and HyClone incorporated this language into their private agreement as part of a draft protective order that Janssen and Celltrion were separately negotiating for use in the Massachusetts Litigation. *Id.*; Caine Decl., Ex. 3.[2]

Subsequent to Janssen and HyClone agreeing on terms for HyClone's production of highly confidential information to Janssen, Janssen and Celltrion finalized a protective order and submitted it to the District of Massachusetts. Caine Decl. Ex. 4. HyClone was not involved in that process. *Id*. Later still, Janssen filed a motion requesting modification of the protective order in the Massachusetts Litigation so that Janssen could use confidential information obtained in that action in other actions. HyClone was not a party to the proceedings on Janssen's motion. On May 19, 2016, the District of Massachusetts granted Janssen's motion, but without mentioning the private agreement between Janssen and HyClone governing the use of HyClone's confidential information. Caine Decl. Ex. 3. Janssen filed the instant Complaint shortly thereafter based on the confidential information Janssen obtained from HyClone in the Massachusetts Litigation. *See, e.g.*, Compl. ¶¶ 37-40. According to Janssen, "[t]he information provided by HyClone demonstrated that Janssen now had a basis upon which to claim actual infringement" of the '083 patent. *Id.* ¶ 37. Janssen also filed a second action in Massachusetts against Celltrion alleging that the Celltrion Media infringes the '083 patent.[3]

[2] The HyClone-Janssen agreement included certain additional restrictions ensuring that the confidential information only be used to review for purposes, such as the requirement that "Janssen will ensure said document(s) provided by HyClone are destroyed promptly upon completion of the review process." Caine Decl. Ex. 3, at 2.

[3] *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 16-cv-11117 (D. Mass. June 14, 2016).

D. This Lawsuit.

In the instant Complaint, Janssen alleges that the Celltrion Media infringes claims 1 and 2 of the '083 patent under the doctrine of equivalents. Compl. ¶¶ 5, 37, 38. With respect to the many components of the Celltrion Media that do not have concentrations identical to those recited in the asserted claims, Janssen contends that they "are not substantially outside the claimed ranges." *Id*. ¶¶ 65, 66. Janssen thus alleges that the non-identical components in the Celltrion Media are "equivalent to the ingredients at the claimed concentrations" because they allegedly "perform substantially the same function, in substantially the same way, with substantially the same results, as the ingredients at the claimed concentrations." *Id*. The Complaint does not specify how far outside the claimed ranges the various ingredients fall, nor does it allege what functions are performed by each non-identical ingredient, in what way, and to achieve what results.

Janssen pleads equivalence based on the results of experiments it conducted to determine whether the differences between the accused and claimed media are insubstantial.[4] *Id.* ¶ 67. In these experiments, Janssen's expert cultured the cell line used in the examples of the '083 patent in a series of cell culture media: replicas of the Celltrion Media (both CGM and CPM); variants of the Celltrion Media, each modified so that one element whose concentration in the Celltrion Media was outside the claimed range was adjusted to fall within the claimed range; variants of the Celltrion Media modified so that the concentration of all ingredients fall within the claimed ranges; and two negative control media, one devoid of the nutrients necessary for the cells'

[4] Janssen neglected to attach a copy of any report detailing its experiments, thereby preventing HyClone and the Court from identifying other deficiencies in Janssen's experimental method and results. For example, Janssen gives no indication of how (or if) the experiments controlled for components in the Celltrion Media that are not recited by the claims of the '083 patent.

survival and growth, and one with all of the nutrients provided by the Celltrion Media but at one-fifth the concentration. *Id*. ¶ 67.

Over the course of the culture, Janssen's experts measured three variables: 1) viable cell density ("VCD"), *i.e.*, the concentration of living cells in the culture; 2) viability, *i.e.*, the proportion of those cells that remained alive; and 3) titer, *i.e.*, the amount of antibody produced by the cells. *Id*. ¶ 68. Based on the results of those experiments, Janssen concludes that the discrepancy between the concentrations of the components in the Celltrion Media and the claimed ranges for the components in the '083 patent did not substantially impact the three measured metrics (VCD, viability, and titer) and, thus, the differences are purportedly insubstantial. *Id*. ¶¶ 68-74. Accordingly, Janssen alleges that the Celltrion Media infringes claim 1 of the '083 patent under the doctrine of equivalents. *Id*. ¶ 76.

ARGUMENT

I. JANSSEN SHOULD BE ENJOINED FROM IMPROPERLY USING HYCLONE'S CONFIDENTIAL INFORMATION TO INITIATE AND PROSECUTE AN ACTION AGAINST HYCLONE IN UTAH

Private parties enjoy considerable freedom in entering into voluntary agreements, even when those agreements impose substantial limitations on their respective rights. Courts, for example, routinely enforce covenants not to sue voluntarily undertaken. *See, e.g.*, *Simpson v. Townsley*, 283 F.2d 743, 748 (10th Cir. 1960) (holding that "covenant not to sue and agreement to hold harmless constituted a complete exoneration of Smith and removed any foundation upon which to impute negligence to Smith's employers"); *Lifetime Products, Inc. v. Correll, Inc.*, 323 F. Supp. 2d 1129, 1151 (D. Utah 2004) (dismissing claims covered by covenant not to sue). Here, Janssen and HyClone entered into a voluntarily, private agreement for the expeditious

production of HyClone's proprietary cell culture formulation details for Janssen's use in the Massachusetts Litigation. Caine Decl. Exs. 1, 2. HyClone, on the one hand, committed to provide Janssen with prompt discovery of highly confidential information. *Id.* Janssen, on the other, committed to maintain the confidentiality of that information and not to use it in any proceeding other than the Massachusetts Litigation, including to initiate or prosecute a lawsuit against HyClone. *Id.* HyClone did not require, and Janssen did not agree to, a covenant not to sue. Rather, HyClone required and Janssen agreed only that Janssen would not bring suit based on the proprietary formulation information that HyClone had agreed to provide.

HyClone complied with its agreement by voluntarily providing Janssen with copies of its proprietary cell culture media formulations. Caine Decl. Ex. 3. Having secured HyClone's cooperation, however, Janssen reneged on its agreement, filing the present suit admittedly based on the confidential materials that HyClone had provided. *See* Compl. ¶¶ 37-40. HyClone respectfully requests that the Court enjoin Janssen's suit because it constitutes a breach of the parties' private agreement.

A. Legal Standard.

The Tenth Circuit holds that to obtain injunctive relief, a moving party must establish that: (1) it has a substantial likelihood of prevailing on the merits; (2) it will suffer irreparable harm unless the preliminary injunction is issued; (3) the threatened injury outweighs the harm the preliminary injunction might cause the opposing party; and (4) the preliminary injunction, if issued, will not adversely affect the public interest. *Prairie Band of Potawatomi Indians v. Pierce*, 253 F.3d 1234, 1246 (10th Cir.2001). Here, these factors weigh in favor of granting an injunction.

B. HyClone has a Substantial Likelihood of Prevailing on the Merits.

Janssen has plainly breached its agreement with HyClone restricting Janssen's use of HyClone's confidential information to the Massachusetts Litigation. The relevant facts are straightforward. Janssen asked HyClone, a non-party to the Massachusetts Litigation, to voluntarily and expeditiously produce the proprietary, confidential formulations of the Celltrion Media, among other things. Caine Decl. Ex. 1. Janssen said that expedient production was important because it was purportedly in a race against the clock in its efforts to impede Celltrion's entry into the U.S. market. Caine Decl. Ex. 7 at 2. HyClone agreed to the production, but only based on Janssen's agreement to use HyClone's confidential information "solely for purposes of this litigation" and not "as evidence or supporting materials in disputes or petitions to any regulatory agencies or courts in any jurisdiction or forum, regardless of country (other than this present litigation) . . . ." *See* Caine Decl. Ex. 1. Janssen accepted. *See* Caine Decl. Ex. 2. HyClone performed. *See* Caine Decl. Ex. 3. Yet, despite having received the benefit of its bargain, Janssen turned around and sued HyClone, basing its allegations on the proprietary Celltrion Media formulations that HyClone had voluntarily provided pursuant to its agreement. Janssen's filing constitutes a breach.

Janssen, however, contends that it did not engage in any wrongful conduct when it sued HyClone based on its review and analysis of HyClone's proprietary Celltrion Media formulations based on events that unfolded in the Massachusetts Litigation. Janssen's argument is a red herring. Subsequent to the negotiations between HyClone and Janssen for a confidentiality agreement, the parties to the Massachusetts Litigation (Janssen and Celltrion) finalized the terms of a protective order to govern the production of confidential information in

that case. Caine Decl. Ex. 4. HyClone was not involved. Caine Decl. Ex 2. The District of Massachusetts entered the protective order that Janssen and Celltrion had requested. Caine Decl. *Id*.

When Janssen later informed Celltrion that it intended to file suit for actual (as opposed to technical) infringement of the ’083 patent based on its review of HyClone’s confidential information, Celltrion objected that the filing would violate the parties’ protective order. Caine Decl. Ex. 6. Janssen then moved the District Court to modify the protective order to eliminate from that order the restriction on use of confidential materials for purposes other than the litigation for which they had been obtained. *Id*. The District of Massachusetts granted Janssen’s motion and modified the protective order. Caine Decl. Ex. 5. Janssen thus argues that its filing of the instant Complaint was permissible under the modified protective order.

Janssen’s argument is flawed because HyClone does not premise its argument on a violation of the protective order entered in the Massachusetts Litigation. HyClone is not a party to the Massachusetts Litigation, did not participate in the drafting or submission of the protective order in that case, and was not involved in the motion practice whereby Janssen obtained a modification of that order. The protective order and its subsequent modification are irrelevant. HyClone provided its proprietary formulation details to Janssen based on the private, voluntary agreement it negotiated with Janssen. Janssen entered into that agreement because it desired more expedient access to that information than it could have obtained through formal service of a subpoena. The *quid pro quo* was Janssen’s agreement to keep HyClone’s proprietary information confidential and not to use it for any purpose other than the Massachusetts Litigation. HyClone neither argues that Janssen violated the protective order entered in the

Massachusetts Litigation when it brought the instant suit against HyClone nor that Janssen is prohibited from bringing suit against HyClone. Rather, under the terms of the HyClone-Janssen agreement, Janssen could not sue HyClone using the confidential information that HyClone voluntarily provided. Since that is exactly what Janssen has done, this suit should be enjoined as a breach of that agreement.[5]

C. HyClone will Suffer Irreparable Harm Absent an Injunction

A finding of irreparable harm may be based on factors such as the "difficulty in calculating damages ... and [the] existence of intangible harms such as loss of goodwill or competitive market position." *Dominion Video Satellite, Inc. v. Echostar Satellite Corp*., 356 F.3d 1256, 1262 (10th Cir.2004). Absent an injunction, Janssen will be permitted to continue to rely on HyClone's confidential information to prosecute this litigation in direct contravention of its agreement. Furthermore, Janssen's prosecution of this lawsuit will expose HyClone to the countless burdens necessitated in defending a lawsuit for patent infringement, such as litigation expense, management distraction, the loss of goodwill, and potential setbacks in its production and sales of cell culture media. All of these harms would not occur but for Janssen's breach and most could not be compensated with money damages after the fact. Moreover, the Utah Supreme Court recently held that breach of a confidentiality agreement creates a rebuttable presumption of irreparable harm. *InnoSys Inc. v. Mercer*, 364 P.3d 1013, 1020, 1025 (Utah 2015). Accordingly, Janssen's maintenance of the present suit in breach of its agreement threatens HyClone with irreparable harm.

[5] Should this litigation proceed, HyClone will file a counterclaim against Janssen for breach of its agreement not to use HyClone's confidential information outside of the Massachusetts Litigation in which it was produced.

D. The Threatened Injury to HyClone Outweighs Any Harm to Janssen

As detailed immediately above, the harm to HyClone from Janssen's continued misuse of HyClone's confidential information is great. In sharp contrast, Janssen will suffer no harm if it is unable to use HyClone's confidential information outside of the Massachusetts Litigation absent a ruling to the contrary. HyClone does not contend that it is immune from suit based on its agreement with Janssen concerning the production of its proprietary cell formulation information. Rather, to the extent Janssen seeks to sue HyClone, it must do so without using that confidential information, or any analysis thereof, as the basis for the allegations of it complaint. Consequently, Janssen will suffer no harm from being required to comply with the terms of the private agreement it voluntarily undertook.

E. Grant of an Injunction will Serve the Public Interest

"Granting equitable relief such as a preliminary injunction may serve the public interest if it will 'discourage . . . the wrongful use of confidential information and . . . the disavowal of freely contracted obligations.'" *Fisher Bioservices, Inc. v. Bilcare, Inc.*, No. Civ. A. 06–567, 2006 WL 1517382, at *21 (E.D. Pa. May 31, 2006) (*quoting Nat'l Bus. Servs., Inc. v. Wright*, 2 F. Supp. 2d 701, 709 (E.D. Pa.1998)). Here, both purposes will be served by an order enjoining suit. Janssen will be held to its "freely contracted obligation," and the Court will have prevented Janssen from wrongfully using HyClone's confidential information to file suit. An order enjoining Janssen's suit will thus serve the public interest, and this factor thus weighs in favor of granting an injunction.

As each of the factors weigh in favor of granting HyClone an injunction preventing Janssen from using HyClone's confidential information outside of the Massachusetts Litigation, HyClone respectfully submits that its request for injunctive relief should be granted.

II. THE COMPLAINT FAILS TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED

A. Janssen Must Plead Facts Sufficient to State a Plausible Claim.

As clarified by the Supreme Court, to withstand a motion to dismiss under Rule 12(b)(6), "'a complaint must contain enough allegations of fact, taken as true, to state a claim to relief that is plausible on its face.'" *Al–Owhali v. Holder*, 687 F.3d 1236, 1239 (10th Cir. 2012)[6] (*quoting Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).[7] Although the complaint must contain a "short and plain statement of the claim," the rules require a "showing," not simply a "blanket assertion," of why relief is due. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 n.3 (2007). Thus, "a plaintiff must offer sufficient factual allegations to 'raise a right to relief above the speculative level.'" *Kansas Penn Gaming, LLC v. Collins*, 656 F.3d 1210, 1214 (10th Cir. 2011) (quoting *Twombly*, 550 U.S. at 555). Since a plaintiff is required to plead "more than a sheer possibility that a defendant has acted unlawfully," it follows that if the "complaint pleads facts that are 'merely

[6] "In patent cases, the standards applicable to motions under Rule 12(b)(6) are those articulated by the regional Court of Appeals rather than any uniform standard set by the Federal Circuit." *Atlas IP, LLC v. Exelon Corp*., Case No. 15 C 10746, 2016 WL 2866134, at *1 (N.D. Ill. May 17, 2016). *See also In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1331 (Fed. Cir. 2012)).

[7] Complaints filed since the December 1, 2015, amendments to the Federal Rules of Civil Procedure abrogating both Rule 84 and Form 18 are subject to the same standard as other causes of action. *See* Order Amending Fed. R. Civ. P. (U.S. Apr. 29, 2015). Consequently, district courts must now assess patent infringement claims under the *Twombly-Iqbal* standard and have dismissed claims that do not sufficiently allege facts giving rise to a plausible inference of liability. *See, e.g., Atlas*, 2016 WL 2866134, at *1, *5 ("[F]actual allegations that do not permit a court to infer that the accused product infringes each element of at least one claim are not suggestive of infringement—they are merely compatible with infringement.").

consistent with' a defendant's liability it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556); *see also, e.g.*, *Williams v. Wilkinson*, No. 15-7022, 2016 WL 1459529, at *13 (10th Cir. Apr. 14, 2016) (affirming dismissal where complaint pleaded facts merely consistent with, but not plausibly suggesting, liability).

The requisite plausibility must be evident from the face of the complaint, as "it is no answer to say that a claim just shy of a plausible entitlement to relief can, if groundless, be weeded out early in the discovery process . . . ." *Twombly*, 550 U.S. at 559; *Iqbal*, 566 U.S. at 678-79 (noting that Rule 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions"). "'A claim has facial plausibility when the [pleaded] factual content . . . allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Rosenfield v. HSBC Bank, USA*, 681 F.3d 1172, 1178 (10th Cir. 2012). "Thus, in ruling on a motion to dismiss, a court should disregard all conclusory statements of law and consider whether the remaining specific factual allegations, if assumed to be true, plausibly suggest the defendant is liable." *Kansas Penn Gaming*, 656 F.3d at 1214.

B. The Doctrine of Equivalents Requires an Element-By-Element Analysis of Equivalence.

To succeed in proving infringement, a patent holder must show that an accused product contains every element of the claim literally or, if not literally present, under the doctrine of equivalents. *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1322 (Fed. Cir. 2001). Literal infringement requires the patentee to show that each limitation of the claim is identically present in the accused product. *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). "[A] device that does not infringe a patent claim literally may still infringe the very same

claim under the doctrine of equivalents if every limitation of the claim is literally or equivalently present in the accused device. For a claim limitation to be 'equivalently present' in an accused device, there must be only 'insubstantial differences' between the missing claim limitation and corresponding aspects of the accused device." *Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc.*, 206 F.3d 1408, 1415 (Fed. Cir. 2000).

The doctrine of equivalents, however, must be narrowly construed. Applied too broadly, it "conflicts with the definitional and public-notice functions of the statutory claiming requirement." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. at 29. As such, the doctrine of equivalents cannot be used to erase "meaningful structural and functional limitations of the claim on which the public is entitled to rely in avoiding infringement." *Pennwalt Corp. v. Durand–Wayland, Inc.*, 833 F.2d 931, 935 (Fed. Cir. 1987) (*en banc*) (*quoting Perkin–Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532 (Fed.Cir.1987)).

To that end, the "[i]nfringement analysis under the doctrine of equivalents proceeds element-by-element; a generalized showing of equivalency between the claim as a whole and the allegedly infringing product or process is not sufficient to show infringement." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1296 (Fed. Cir. 2009); *see also Warner-Jenkinson*, 520 U.S. at 29 ("[T]he doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole."). "Equivalency may be found if the differences between that which is claimed and its embodiment in the accused composition are insubstantial. The usual test of the substantiality of the differences is whether the element in the accused composition performs substantially the same function in substantially the same way to obtain substantially the same result as the claimed element." *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1309 (Fed.

Cir. 2000). The "focus on individual limitations, rather than on the accused device as a whole, aids the court in being specially vigilant against allowing the concept of equivalence to eliminate any claim limitations completely." *Allen Eng'g Corp. v. Bartell Indus., Inc*., 299 F.3d 1336, 1345 (Fed. Cir. 2002).

As the Supreme Court summarized, "[a]n analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element." *Warner-Jenkinson Co.*, 520 U.S. at 40. Thus, to establish equivalence, Janssen needs to show, with respect to each component of the Celltrion Media with a concentration outside of the range claimed in the '083 patent, that the component is either insubstantially different or performs substantially the same function in substantially the same way to achieve substantially the same result as the recited component within the claimed concentration range.

C. Janssen Has Failed To Adequately Plead Infringement Under the Doctrine of Equivalents.

The Complaint fails to state a claim for infringement under the doctrine of equivalent because its purported experiments show, at most, only that the differences between the concentrations of the components of the Celltrion Media and the concentrations recited in claim 1 of the '083 patent "had no substantial effect on the performance of the media in cell culture." Compl. ¶ 69. This analysis is irrelevant. The question is not whether the Celltrion Media achieves the same result as the cell culture recited in claim 1, but whether individual non-identical components of the Celltrion Media are equivalent to individual limitations of claim 1. *See Abbott Labs*., 566 F.3d at 1296 ("Infringement analysis under the doctrine of equivalents

proceeds element-by-element; a generalized showing of equivalency between the claim as a whole and the allegedly infringing product or process is not sufficient to show infringement."); *Upjohn Co*., 225 F.3d at 1309 ("The usual test of the substantiality of the differences is whether the element in the accused composition performs substantially the same function in substantially the same way to obtain substantially the same result as the claimed element.").

Having alleged equivalence of the Celltrion Media as a whole, the Complaint ***fails to even mention the function*** of any of the non-identical components, let alone allege that the different concentrations of each non-identical component has an insubstantial effect on the ***way*** that the component's (unspecified) ***function*** achieves the component's (unspecified) ***result***. In other words, Janssen does not allege that component X has function Y, that varying the concentration of component X between the claimed range and the concentration present in the Celltrion Media had no significant impact on function Y, the way function Y was performed or the result that component X was intended to achieve. To plausibly plead infringement under the doctrine of equivalents, Janssen would have had to make such factual allegations for ***all*** components of the Celltrion Media that are not identical to the elements of the claim. As pleaded, the Complaint lacks sufficient factual allegations for ***any*** non-identical component.

Not only does Janssen fail to plead element-by-element equivalence, its factual averments concerning experimentation cannot support an inference of element-by-element equivalence. Janssen's experiments track only three metrics: VCD, viability, and titer. Compl. ¶¶ 67-74. But nowhere does Janssen allege that the role of ***any*** of the non-identical components—let alone ***all*** of them—is to impact VCD, viability or titer. Each of those components could have been included in the claimed formulation to affect other, equally important metrics, and any change in

concentration outside the claimed range could have a dramatic impact on those metrics. For example, the '083 patent explains that its cell media is designed to satisfy certain criteria for optimal production of biopharmaceuticals, such as antibodies. *See* Compl. Ex. A, at 1:50-67. "First, such compositions must limit eukaryotic cell damage resulting from shear forces and other cell-damaging processes that occur in the bioreactor vessels typically used for biopharmaceutical production." *Id*. at 1:52-55. Another important criteria is that "such compositions must limit the production of lactic acid by cultured eukaryotic cells to permit the most efficient cellular use of glucose." *Id*. at 1:61-65. The Complaint, however, does not indicate whether any of the non-identical components impact the occurrence of eukaryotic cell damage or the production of lactic acid, nor does the Complaint allege that a change in the concentration of any of those components would not affect those or other metrics. By focusing only on certain characteristics of the experimental media as a whole (VCD, viability, and titer), Janssen's allegations amount to a *non sequitur* with respect to the necessary plausible pleading of element-by-element equivalence.

A hypothetical confirms this fallacy. Janssen's patent claim can be analogized to a claim covering the batter for making a cake. Suppose the claimed batter requires, among other things, a pinch of salt and a cup of sugar. The allegedly infringing batter contains all of the same ingredients as the claimed batter, but instead of a pinch of salt, it calls for a cup, and instead of a cup of sugar, it calls for a pinch. In an attempt to demonstrate equivalency, the patentee conducted experiments in which it baked multiple cakes: some using the claimed batter, some using the purportedly infringing batter, some using salt at the claimed concentration (a pinch), and some using sugar at the claimed concentration (a cup). Over the course of the experiments,

the patentee tracked three key metrics of the cakes produced with the various batters: color, volume, and consistency. Based on the experiments, the patentee proudly concluded that any difference between the concentrations of sugar and salt in the various batters were insubstantial: all of the cakes were golden brown, of similar volume, and were soft and spongy. The flaw in this reasoning, however, is evident from the first bite. The function of the salt in the recipe is not to affect the color, volume, or consistency of the cake, and the same is true for sugar. Without identifying the ***functions*** of each relevant non-identical ingredient, the ***ways*** in which those ingredients perform their respective functions and the ***results*** achieved, the experiments say nothing about whether the differences between the concentrations of each non-identical ingredient in the claimed and accused batter are insubstantial.

Janssen's Complaint is also implausible because it does not contain any facts explaining how far outside of the claimed ranges the concentrations of the non-identical components fall or why those significant differences are, in fact, insignificant. Where the concentrations of components in the accused product fall far outside of the numeric ranges recited in the claim, the patentee faces a particularly difficult challenge in plausibly pleading that the differences between the elements of the claimed and accused media are insubstantial. *See Warner–Jenkinson*, 520 U.S. at 29 ("It is important to ensure that the application of the doctrine of equivalents, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.").

For example, in *Minnesota Mining and Mfg. Co., Inc. v. Beautone Specialties Co., Ltd.*, 117 F. Supp. 2d 72 (D. Mass. 1999), the court found that stabilizers used in the defendant's adhesive product did not have an equivalent "interfacial tension" as the stabilizers recited in the

claim because of the substantial numerical difference between the accused and recited tensions. *Id*. at 90. The patent claimed an interfacial tension of "at least about 15 dynes per centimeter." *Id.* The interfacial tensions of Beautone's stabilizers, however, were 9.0 and 13.0 dynes per centimeter with a combined tension of 11.0, "in each case is significantly less than 15.0 dynes per centimeter." *Id.* "Therefore, when compared to the interfacial tensions of the exemplary stabilizers in the specification which range from 15.4 to 21.2, the difference between the interfacial tensions of Beautone's associated in situ stabilizer and the claimed stabilizers cannot be said to be 'insubstantial.'" *Id*. To hold otherwise and conclude that they are equivalents "would 'effectively eliminate the [lower limit numerical limitation] of the claim in its entirety.'" *Id*. (quoting *Warner–Jenkinson*, 520 U.S. at 29); *see also Conopco, Inc. v. May Dept. Stores Co.*, 46 F.3d 1556, 1562 (Fed. Cir. 1994) ("A conclusion that the 162.9:1 formulation infringes [a limitation calling for 'about 40:1'] under the doctrine of equivalents would eviscerate the plain meaning of that limitation."); *Talbert Fuel Sys. Patents Co. v. Unocal Corp*., 347 F.3d 1355, 1360 (Fed. Cir. 2003) ("[T]he classical principles of the doctrine of equivalents preclude a finding of equivalency, for such finding requires only insubstantial differences between the invention as claimed and the alleged equivalent . . . [and] no reasonable trier of fact could find only insubstantial differences between fuels having an endpoint of 345°F and fuels with the endpoints [ranging from 373.8°F to 472.9°F].").

Absent any allegations of how far outside the claimed ranges the concentrations of the non-identical ingredients of the Celltrion Media fall, or any facts regarding the function, way, and result of using the specific, non-identical ingredients, Janssen has fallen far short of its

burden to plead facts sufficient to state a plausible claim of infringement under the doctrine of equivalents. Accordingly, the Complaint should be dismissed.

III. A STAY IS APPROPRIATE

This litigation should be stayed pending the resolution of the litigation currently pending in the District of Massachusetts. "The Court has inherent power to grant a stay pending the result of other proceedings." *Gale v. Brinker Int'l Payroll Co., L.P.*, No. 1:09-CV-129 TS, 2010 WL 3835215, at *1 (D. Utah Sept. 29, 2010) (citing *Nederlandse Erts–Tankersmaatschappij, N.V. v. Isbrandtsen Co.*, 339 F.2d 440, 441 (2d Cir.1964)). Indeed, the Tenth Circuit has recognized that "sound judicial administration" at times requires that a court "decline consideration of [an] action" until related proceedings are completed. *Pet Milk Co. v. Ritter*, 323 F.2d 586, 588 (10th Cir.1963) (quoting *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936)). The Supreme Court has described this power as being "incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis*, 299 U.S. at 254. "Based on these principles, this Court may stay a case pending the completion of related federal proceedings." *Alter v. F.D.I.C.*, 57 F. Supp. 3d 1325, 1334 (D. Utah. 2014). The following factors are relevant to the court's decision: (1) whether a stay would promote judicial economy, (2) whether a stay would avoid confusion and inconsistent results, and (3) whether a stay would unduly prejudice the parties or create undue hardship. *Alter v. F.D.I.C.*, No. 2:13-CV-456 TS, 2014 WL 4257768, at *1 (D. Utah Feb. 27, 2014). Here, the balance of these factors weigh heavily in favor of a stay.

A stay would promote judicial economy. Janssen's allegations that the Celltrion Media infringe the '083 patent have been pending in the Massachusetts Litigation since March 2015.

Compl. ¶ 35. Although that case involves claims of technical infringement (*id.*), Janssen has recently filed suit against Celltrion asserting claims of actual infringement of the '083 patent that mirror the claims here. The (first-filed) Massachusetts Litigation is at an advanced stage. According to Janssen, discovery is well underway, and Janssen has sought to expedite trial to February 2017. Caine Decl. Ex. 7, at 2. A stay here would greatly promote judicial economy because the litigation pending in Massachusetts will cover the same ground as Janssen's claims here.

A stay will also avoid confusion and inconsistent results. Since the cases pending in Massachusetts involve the same patent and same accused product, the significant overlap between those cases and the instant litigation opens the door to the potential of inconsistent rulings. A stay in deference to the Massachusetts cases would avoid any inconsistent rulings, as the Court's rulings here could be made with the knowledge of how the Massachusetts district court has already ruled.

Finally, a stay here would not unduly prejudice Janssen or create any undue hardship. Janssen's claims, both here and in Massachusetts, are primarily directed against Celltrion. Here, although HyClone is the named defendant, much of the Complaint is devoted to allegations that HyClone was merely acting at Celltrion's behest to make cell culture media sufficient to allow Celltrion to produce its biosimilar. *See* Compl. ¶¶ 51- 63. A stay here will not impede Janssen's efforts to purportedly vindicate its rights against Celltrion in Massachusetts. Indeed, if Janssen prevails there, it is likely the instant litigation will be of minimal, if any, importance to Janssen given the relief Janssen seeks against Celltrion in Massachusetts. Conversely, if Celltrion prevails in Massachusetts, either with respect to noninfringement or invalidity of the '083 patent,

those determinations would collaterally estop Janssen's re-litigation of its claims in this case. Accordingly, a stay is appropriate.

CONCLUSION

For the foregoing reasons, HyClone respectfully requests that this Court enjoin Janssen from using HyClone's confidential information in violation of the parties' agreement. HyClone further respectfully requests that the Court dismiss the Complaint in its entirety. Absent injunction or dismissal, HyClone respectfully requests that the Court stay this action pending resolution of the actions pending in the District of Massachusetts.

Dated this 5th day of August, 2016.

RAY QUINNEY & NEBEKER P.C.

/s/ Samuel C. Straight
Samuel C. Straight

Attorneys for Non-Party HyClone Laboratories, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of August, 2016, I electronically filed the foregoing **HYCLONE'S MOTION FOR INJUNCTIVE RELEIF, TO DISMISS, AND TO STAY** with the Clerk of Court using the CM/ECF system, and notification of such filing was sent electronically to the following:

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