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' OPPOSITION TO PLAINTIFFS' MOTION TO STAY

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Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. (together, "Celltrion") and Hospira, Inc. oppose the motion to stay proceedings relating to U.S. Patent No. 6,284,471 ("the '471 patent") filed by Plaintiffs Janssen Biotech, Inc. and New York University.

I. INTRODUCTION

Celltrion has filed an application with the Food and Drug Administration ("FDA") seeking approval for Hospira to sell a less-expensive, "biosimilar" version of Janssen's multi-billion dollar drug Remicade® (containing the active ingredient infliximab). In response, Plaintiffs sued for patent infringement under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which established a statutory pathway to resolve patent disputes related to biosimilar drug products. *See* 42 U.S.C. § 262(k), (l). Less than two weeks later, however, Plaintiffs took the unusual step of moving for an indefinite stay of their own lawsuit as to the most important patent asserted in the case—the '471 patent, which they assert covers the infliximab antibody. That motion seeks to turn the BPCIA on its head and, therefore, should be denied.

Congress enacted the patent-resolution procedures of the BPCIA to "ensure that litigation surrounding relevant patents will be resolved ***expeditiously*** and ***prior to the launch of the biosimilar product***." (Ex. 1, *Biologics and Biosimilars: Balancing Incentives for Innovation*, Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary, 111th Cong. at 9 (2009) (Testimony of Representative Anna G. Eshoo) (emphasis added).)[1] To that end, the BPCIA requires the branded drug company—known as the reference product sponsor (here, Janssen)—to disclose to the biosimilar applicant all patents for which it "believes a claim of patent infringement could reasonably be asserted." 42 U.S.C.

[1] "Ex. [ ]" refers to exhibits attached to the Declaration of Dan H. Hoang in Support of Defendants' Opposition to Plaintiffs' Motion to Stay, filed concurrently herewith.

§ 262(l)(3)(A)(i). Where, as here, the parties "agree on which, if any, patents . . . shall be the subject of an action for patent infringement[,]" the statute encourages expedited patent litigation by presenting the brand with two options:

- ***Option 1:*** File suit within 30 days and prosecute the case to judgment in good faith, thus allowing the patentee to seek lost profits if the biosimilar launch were not enjoined; or
- ***Option 2:*** Delay suing for infringement, but in that case the "sole and exclusive remedy . . . shall be a reasonable royalty."

Id. § 262(l)(6)(A); 35 U.S.C. § 271(e)(4), (6).

The BPCIA thus penalizes patentees who opt to delay litigation by limiting the remedy to a reasonable royalty. The statutory rationale is straightforward: biosimilar applicants will generally seek patent certainty before launching a less-expensive, biosimilar product. Absent such patent certainty, the applicant must decide whether to launch the product "at risk"—meaning the applicant ultimately could face a substantial lost-profits damages award, perhaps exceeding the expected profits on the biosimilar product. Patentees like Janssen are fully aware that the mere possibility of an enormous lost-profits award, even if the patent is very weak, could discourage a biosimilar launch. Congress thus worded the BPCIA to bar patentees from delaying competition by forestalling patent certainty while reserving the right to seek lost profits at a later date.

Plaintiffs are engaging in the precise type of gamesmanship the BPCIA was designed to prevent. The U.S. Patent and Trademark Office ("PTO") is reexamining the '471 patent and, as Plaintiffs concede, all claims of this patent "currently stand finally rejected as invalid for obviousness-type double patenting." (Pls' Br., Dkt. 9, at 1.) The PTO's decision, however, is not yet final—meaning the patent is still technically enforceable until all appeals are resolved (which could take years). While Plaintiffs do not argue that the patent is valid in its current

form, they speculate that it may "emerge[] from reexamination . . . with a meaningfully amended specification—an amendment that will not be effective outside of the PTO proceedings until the reexamination is concluded[.]" (*Id.*) In other words, Plaintiffs currently have no valid basis to assert the '471 patent. But had they opted to delay suing on that patent in the hope that it ultimately will emerge from reexamination later as a stronger patent, their remedy would have been limited to a reasonable royalty.

Plaintiffs' motion to stay is a litigation tactic designed to get the best of both worlds—that is, delay patent litigation indefinitely while, at the same time, reserving the right to recover lost profits for any "at risk" launch. The Court should prevent Plaintiffs from using the procedural vehicle of a litigation stay to circumvent the conditions and policy of the BPCIA. Plaintiffs should either (1) litigate their claim for infringement of the '471 patent now (and thus risk an adverse judgment that would constitute claim preclusion); or (2) dismiss that claim, thus reserving the right to sue on that patent later to seek the limited remedy of a reasonable royalty.

As shown below, neither fairness nor judicial efficiency supports Plaintiffs' motion for a stay that would not limit their remedy. Now that Plaintiffs opted to bring suit on the '471 patent, the Court should deny the requested stay and expeditiously adjudicate whether that patent is invalid for double patenting. Indeed, this Court has previously adopted a similar approach for expedited resolution of a double-patenting defense when denying a motion to stay. *See In re Columbia Univ. Patent Litig.*, 330 F. Supp. 2d 12, 18 (D. Mass. 2004) (Wolf, J.). Alternatively, if the Court were inclined to consider a stay, such a stay should be conditioned on a stipulation by Plaintiffs that they will be limited to the remedy of a reasonable royalty—thus ensuring that the stay would not contravene the BPCIA and, even worse, delay competition that will benefit consumers.

II. BACKGROUND

A. The BPCIA Encourages Early Resolution Of Patent Disputes.

In 2010, Congress enacted the BPCIA, which governs a new statutory framework for the regulatory approval, marketing, and sale of biological medicines known as "biosimilars." 42 U.S.C. § 262(k). A biosimilar is a biological product that is highly similar to an already approved biological product (referred to as the "reference product") such that pre-clinical and clinical studies demonstrate that there are no clinically meaningful differences in terms of its potency, purity, and safety. *Id.* § 262(i)(2).

The BPCIA established "a biosimilars pathway balancing innovation and consumer interests." Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010). This pathway permits a company (such as Celltrion) to rely on the FDA's prior approval of the reference product (here, Remicade®) to expedite approval of a less expensive, competing biosimilar product. The BPCIA also created patent dispute resolution procedures to begin shortly after the FDA's acceptance (which precedes approval) of the biosimilar application. *See* 42 U.S.C. § 262(l). As Congresswoman Anna Eshoo (a primary author of the BPCIA) testified to the Subcommittee on Courts and Competition Policy of the House Committee on the Judiciary, the purpose of these procedures is to resolve patent disputes "expeditiously and prior to the launch of the biosimilar product":

> In order to protect the rights of all parties and ensure that all patent disputes involving a biosimilar are resolved before, and I emphasize the word before, the expiration of the data-exclusivity period, H.R. 1548 also establishes a simple, streamlined patent resolution process. ***This process would take place within a short window of time, roughly 6 to 8 months after the biosimilars application has been filed with the FDA. It will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large.***

(*See* Ex. 1, *Biologics and Biosimilars* at 9 (emphasis added).)

Under the patent resolution procedures of the BPCIA, the reference product sponsor and biosimilar applicant must identify the patents that each "believes a claim of patent infringement could reasonably be asserted by the reference product sponsor." 42 U.S.C. § 262(l)(3)(A)(i), (B)(i). The BPCIA requires that, not later than 30 days after the parties reach agreement on which patents will be the subject of a patent infringement action, the reference product sponsor shall bring a patent infringement action with respect to those patents. *See id.* § 262(l)(6).

The BPCIA penalizes the reference product sponsor for delayed litigation. In particular, where the reference product sponsor has either brought an infringement action "after the expiration of the 30-day period," or brought a timely infringement action that "was dismissed without prejudice or was not prosecuted to judgment in good faith," the reference product sponsor is limited to "the sole and exclusive remedy" of a "reasonable royalty." *See* 35 U.S.C. § 271(e)(6)(A), (B). These procedures reinforce the expeditious resolution of patent disputes before FDA approval of the proposed biosimilar product—thus mitigating the possibility that delayed litigation will lead to delayed competition.

B. Defendants Expended Significant Resources To Bring Their Proposed Biosimilar Infliximab Product To Market.

Celltrion has, as its mission, pursued ways of supplying innovative monoclonal antibodies and other biopharmaceutical medicines at an affordable cost to patients suffering from life-threatening and debilitating diseases. To provide more affordable and accessible drugs for these patients, in 2008, Celltrion began development of a biosimilar version of Remicade® (infliximab). (*See* Ex. 2, *Celltrion Healthcare Co., Ltd. v. Janssen Biotech, Inc.*, C.A. 1:14-cv-11613-MLW (D. Mass.) (Compl., Dkt. 1, at ¶ 23).) Celltrion expended significant resources, totaling over $110 million in out-of-pocket external costs in addition to significant internal

manpower and corporate resources, in the research and development of its proposed biosimilar infliximab product. (*Id.*)

In 2012, Celltrion became the first company to successfully create and obtain regulatory approval under internationally-accepted guidelines for a biosimilar monoclonal antibody product. (*Id.* ¶ 3.) Celltrion conducted global clinical trials involving over 1,400 patients in 20 countries. (*Id.* ¶ 30.) These clinical trials established that Defendants' proposed biosimilar infliximab product was comparable in safety and efficacy to Remicade® sufficient to secure regulatory approval in over 50 countries worldwide, including from regulatory agencies in Europe, Japan, and Canada. (*See* Ex. 3, Press Release, Celltrion, Inc., Celltrion Files for US FDA Approval of Remsima® (August 11, 2014).)

On August 8, 2014, Celltrion submitted to the FDA its aBLA 1255444 seeking approval to market its proposed biosimilar infliximab product, which the FDA accepted for review on October 7, 2014. (*See* Compl., Dkt. 1, at ¶ 89.) Based on Celltrion's prior successes internationally, Defendants reasonably expect that the FDA will approve Celltrion's aBLA this year.

Hospira is Celltrion's U.S. marketing partner with the exclusive rights to market Celltrion's proposed biosimilar infliximab product in the United States. (*Id.* at ¶ 88.) Following FDA approval of Celltrion's aBLA (which Defendants expect to receive in 2015), Hospira intends to enter the U.S. market with an affordable biosimilar infliximab product that will compete with Remicade® providing significant savings for consumers. (*See* Ex. 4, Kim J et al., *5 Year Budget Impact Analysis of CT-P13 (Infliximab) for the Treatment of Crohn's Disease in UK, Italy and France*, J. Crohns Colitis, 9 Suppl 1:S144-5, S145 (2015) ("The introduction of the CT-P13 (infliximab) as a treatment option for patients with Crohn's disease could achieve

substantial cost savings. In the scenarios tested, the total 5 year saving across UK, Italy and France ranged from 76 million to 336 million euros.").)

C. Plaintiffs Sued On The '471 Patent To Frustrate Defendants' Ability To Market Their Proposed Biosimilar Infliximab Product.

Plaintiffs filed the present suit to prevent Defendants from marketing their proposed biosimilar infliximab product in the United States until at least the expiration of six patents, including the '471 patent. (*See* Compl., Dkt. 1, at Counts 3-8.) The '471 patent issued on September 4, 2001, from U.S. Patent Application No. 08/192,093. (*See* Ex. 5, '471 patent, at cover page.) Plaintiffs purport that the '471 patent claims chimeric anti-TNFα antibodies, including infliximab. (*See* Compl., Dkt. 1, at ¶ 41.)

On April 29, 2013, the PTO received a request for *ex parte* reexamination of the '471 patent, which the PTO granted on June 13, 2013. (*See* Ex. 6, Request for *Ex Parte* Reexamination, Reexam. No. 90/012,851; Ex. 7, Reexamination Order, Reexam. No. 90/012,851.) The PTO has three times rejected the claims of the '471 patent for obviousness-type double patenting.[2] (*See* Ex. 11, Non-Final Office Action, Reexam. No. 90/012,851, at 5-7; Ex. 12, First Final Office Action, Reexam. No. 90/012,851, at 6-8; Ex. 13, Second Final Office Action, Reexam. No. 90/012,851, at 5-9.) Even Plaintiffs do not believe that the '471 patent is valid: in response to the PTO's "final" rejection, they have taken extreme measures—revising the specification, drawings, and abstract of the '471 patent and seeking to redraw its lineage to its

[2] The doctrine of obviousness-type double patenting "is a judicially created doctrine adopted to prevent claims in separate applications or patents that . . . claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." *Amgen v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1352 (Fed. Cir. 2009). That is exactly what the patentees have done in prosecuting the '471 patent and its progeny. Although the '471 patent is directed to chimeric anti-TNFα antibodies which Plaintiffs assert include infliximab, the patents claiming infliximab and its use to treat rheumatoid arthritis and Crohn's disease have expired. (*See* Ex. 8, U.S. Patent No. 6,790,444; Ex. 9, U.S. Patent No. 5,698,195; Ex. 10, U.S. Patent No. 5,656,272.) Plaintiffs have improperly extended the life of patent protection for an obvious variation of the same invention through the later-expiring '471 patent.

parent applications—in an attempt at resurrection. (*See, e.g.*, Ex. 14, Amendment After Final Rejection, Reexam. No. 90/012,851 at 103.) Despite their efforts, Plaintiffs have yet to amend any of the pending claims at any time during reexamination. (*Id.*) Rather, Plaintiffs have revised nearly every other aspect of the '471 patent in an effort to overcome the PTO's double patenting rejection through a narrow safe harbor provided in 35 U.S.C. § 121—a refuge that has been rejected by the PTO even after these amendments. (Ex. 13, Second Final Office Action, Reexam. No. 90/012,851, at 5-9.)

As Plaintiffs admit, presently all claims of the '471 patent stand finally rejected as invalid for obviousness-type double patenting. (*See* Pls' Br., Dkt. 9, at 1.) Plaintiffs nonetheless brought suit on this patent, presumably to reserve their right to seek lost profits if Defendants were to launch their biosimilar product "at risk" and the patent ultimately were to emerge from reexamination. But this reexamination process, including all appeals, could take years. *See Columbia Univ. Patent Litig.*, 330 F. Supp. 2d at 16 (Wolf, J.) ("[I]f [the patentee] is dissatisfied with the results of the proceedings, the process may take significantly longer as [the patentee] appeals to the Board of Patent Appeals and Interference and then to the Court of Appeals for the Federal Circuit.").

III. ARGUMENT

A stay is discretionary and, therefore, the Court "is not required to stay judicial resolution in view of the reexaminations." *Viskase Corp. v. Am. Nat. Can. Co.*, 261 F.3d 1316, 1328 (Fed. Cir. 2001). "Congress declined to include an automatic stay provision in the patent reexamination statutes and instead left the matter within the sound discretion of the courts." *ADA Solutions, Inc. v. Engineered Plastics, Inc.*, 826 F. Supp. 2d 348, 350 (D. Mass. 2011). In deciding whether to stay litigation pending patent reexamination, courts consider three factors: "1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-

moving party; 2) whether a stay will simplify the issues in question and trial of the case; and 3) whether discovery is complete and whether a trial date has been set." *Id.* Application of these factors strongly weigh against a stay pending reexamination here.[3]

A. A Stay Would Unduly Prejudice Defendants And Present Them With A Clear Tactical Disadvantage.

In this district, "[t]he first and arguably ***most important factor*** is whether and to what extent a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party." *Id.* (emphasis added). "The moving party bears the burden of showing that the non-moving party will not be prejudiced by a stay." *Id.* "[I]f there is a danger that the stay will damage the [non-moving] party," then "[t]o be entitled to a stay, [Plaintiffs] must demonstrate a ***clear case of hardship***." *Saint-Gobain Performance Plastics Corp. v. Advanced Flexible Composites, Inc.*, 436 F. Supp. 2d 252, 253 (D. Mass. 2006) (emphasis added). Plaintiffs have not met their burden: they significantly understate the prejudice and tactical disadvantage Defendants would face from the requested stay, and they fail to make any clear case of hardship to themselves.

1. The Requested Stay Would Unduly Prejudice Defendants By Delaying Patent Litigation Without Limiting Plaintiffs' Remedy.

The requested stay would unduly prejudice Defendants by allowing Plaintiffs to circumvent the statutory limitation on recovery when litigation is delayed. The BPCIA requires that the reference product sponsor either ***file now*** a meritorious suit that is prosecuted to

[3] Courts in this district have repeatedly denied motions to stay pending patent reexamination or reissuance. *See, e.g.*, *Columbia Univ. Patent Litig.*, 330 F. Supp. 2d at 18 (Wolf, J.); *ADA Solutions*, 826 F. Supp. 2d at 352 (Gorton, J.); *Saint-Gobain Performance*, 436 F. Supp. 2d at 253 (Saylor, J.); *Nuance Commc'ns, Inc. v. Vlingo Corp.*, C.A. No. 09-11414-RWZ, 2011 WL 1366862, at *1 (D. Mass. Apr. 12, 2011) (Zobel, J.); *Cynosure, Inc. v. Cooltouch Inc.*, C.A. No. 08-10026-NMG, 2009 WL 2462565, at *3 (D. Mass. Aug. 10, 2009) (Gorton, J.); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, C.A. No. 02-11280-RWZ, 2005 WL 1342721, at *1 (D. Mass. Jun. 6, 2005) (Zobel, J.).

judgment in good faith, or ***file later*** with a penalty of limited recovery. *See* 42 U.S.C. § 262(l)(6)(A); 35 U.S.C. § 271(e)(6)(B). As the BPCIA makes clear, efforts to frustrate expedited patent litigation result in a remedy limited to "a reasonable royalty":

> In an action for infringement of a patent described in subparagraph (A) [i.e., a lawsuit brought more than 30 days after agreement on the patent list, or a patent claim that "was dismissed without prejudice or was not prosecuted to judgment in good faith"], ***the sole and exclusive remedy that may be granted by a court***, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, ***shall be a reasonable royalty***.

35 U.S.C. § 271(e)(6)(B) (emphasis added). This statutory carrot and stick furthers the goal of the BPCIA to "ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product." (Ex. 1, *Biologics and Biosimilars*, at 9.)[4]

Plaintiffs chose to file a timely suit, setting the '471 patent on a pathway to swift resolution. But Plaintiffs' motion to stay reveals their true intent not to "prosecute[] to judgment" their claim based on the '471 patent. Indeed, judgment is the precise result that Plaintiffs seek to avoid. After all, Plaintiffs have not disputed in their motion that, as the PTO has found, the '471 patent is invalid. (*See, e.g.,* Ex. 11, Non-Final Office Action, Reexam. No. 90/012,851, at 5-7; Ex. 12, First Final Office Action, Reexam. No. 90/012,851, at 6-8; Pls' Br., Dkt. 9, at 6 ("[T]he claims of the 471 Patent currently stand rejected by the PTO.").) While during reexamination Plaintiffs have substantially amended the patent specification (but not the pending claims) and altered the patent in an attempt to make it a divisional of its parent application in an effort to save the patent—an effort the PTO has already rejected (*see* Ex. 14, Amendment After Final Rejection, Reexam. No. 90/012,851 at 103; Ex. 13, Second Final Office

[4] Plaintiffs speculate that "one or more of the Defendants" initiated the reexamination proceedings at the PTO. (Pls' Br., Dkt. 9, at 1.) Even if true, this fact would not allow Plaintiffs to circumvent the statutory requirement that they either litigate the validity of the '471 patent now, or seek a remedy limited to a reasonable royalty.

Action, Reexam. No. 90/012,851, at 9, 11)—the patent on which Plaintiffs have brought suit does not include those amendments.

So why would Plaintiffs bring suit on an invalid patent and immediately move to stay their own lawsuit for an indefinite period? The answer is simple: Plaintiffs hope to circumvent the statutory provision that limits their remedy to a reasonable royalty. Indeed, they have been upfront about this intent, alleging in their complaint that they brought suit precisely to preserve their "right to injunctive relief or lost profits." (Compl., Dkt. 1, ¶¶ 114, 148.) But under the BPCIA, Plaintiffs have no such right unless they actually "prosecute[] to judgment" their claim for infringement of the '471 patent "in good faith." 35 U.S.C. § 271(e)(6)(A)(ii)(II), (e)(6)(B). Allowing Plaintiffs to circumvent this statutory limitation on damages through a litigation stay would not only unduly prejudice Defendants, it would gut a key provision of the BPCIA that expressly prevents brands like Janssen from delaying patent judgments while preserving the right to seek lost profits damages.

This statutory provision serves an important purpose—it bars brands like Janssen from perpetuating a cloud of patent uncertainty that could delay competition for an indefinite period. As Congresswoman Anna Eshoo explained, the BPCIA created a "streamlined patent resolution process" to "help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product." (*See* Ex. 1, *Biologics and Biosimilars* at 9.) And this process was designed to further the important goal of "providing certainty to the applicant, the reference product manufacturer, and the public at large." (*Id.*)

If granted, the requested stay—with no limitation on damages—would prejudice Defendants by forcing them to decide, in light of the slim chance that Plaintiffs would prevail on any patent that may emerge from reexamination, whether to launch their product despite the

underlying risk of lost profits damages. Indeed, if Defendants were to decide not to take that risk, Plaintiffs could delay competition for years by taking unilateral steps to forestall resolution of the reexamination, e.g., by reopening the proceedings with the Patent Examiner even after a "final" office action, appealing the Patent Examiner's decision to the Patent Trial and Appeal Board, and appealing the Board's decision to the Federal Circuit.

This Court and other courts have repeatedly recognized the prejudice to alleged infringers (as well as to the public at large) that would result from such a delay in competition. *See Columbia Univ. Patent Litig.*, 330 F. Supp. 2d at 17 (Wolf, J.) ("While any stay is in effect, the drug companies' potential damages will mount. The uncertainty over whether they owe Columbia royalties on their products might create difficulties in pricing those products. It may also cause the drug companies to delay introduction of new products or needlessly invest money in efforts to design around an invalid patent."); *In re Brimonidine Patent Litigation*, MDL No. 07-md-1866-GMS, 2008 WL 4809037, at *2 (D. Del. Nov. 3, 2008) ("[T]he court agrees that staying this action against Exela will delay market entry of any Exela generic product covered by the [application] at issue in this litigation. In the court's view, these potential consequences for Exela are not insignificant."); *Akzenta Paneele + Profile GmbH v. Unilin Flooring N.C. LLC*, 464 F. Supp. 2d 481, 485 (D. Md. 2006) (In light of the uncertainty from "not knowing whether [the alleged infringers'] activities will subject them to liability for patent infringement," "[t]he Court declines to leave the infringement suit hanging over [the alleged infringer's] operations.").

Based on this undue prejudice alone, the requested stay should be denied. If Plaintiffs do not wish to prosecute their patent, they should be required to dismiss that claim—thus limiting any future claim for damages based on that patent to "a reasonable royalty." 35 U.S.C. § 271(e)(6)(B).

2. A Stay Also Would Place Defendants At A Clear Tactical Disadvantage By Avoiding A Dismissal With Prejudice.

The requested stay also would place Defendants at a clear tactical disadvantage by allowing Plaintiffs to avoid a dismissal of the ’471 patent infringement claim with prejudice. Plaintiffs opted to bring suit on the ’471 patent in its current form, thus exposing it to the scrutiny of litigation. In response, Defendants intend to seek a schedule to address expeditiously whether the ’471 patent is invalid for obviousness-type double patenting—for the reasons raised by the PTO and for others yet to be asserted there. This dispute addresses a clear issue of law that can be resolved by a pre-trial, dispositive motion.

Under similar circumstances, this Court has allowed the issue of obviousness-type double patenting to continue under an expedited schedule, instead of staying the action pending patent reexamination. *See Columbia Univ. Patent Litig.*, 330 F. Supp. 2d at 18 (Wolf, J.). There, this Court denied a motion to stay, noting that “at the June 22, 2004 hearing the court identified the contention that the ’275 patent is invalid under the doctrine of non-statutory double patenting as one that should be able to be quickly developed and decided in 2004, either on a motion for summary judgment or at a trial to be conducted in December 2004.” *Id.*

A similar expedited schedule is warranted here to address the clear (and possibly undisputed) invalidity of the ’471 patent. Critically, a dismissal with prejudice of the ’471 patent infringement claim would not only remove from the public domain an invalid patent, it would preclude Plaintiffs from later asserting that patent against Defendants—even if the patent were to emerge from patent reexamination. *See Senju Pharm. Co. v. Apotex Inc.*, 746 F.3d 1344, 1353 (Fed. Cir. 2014) (A patentee cannot “use reexamination to obtain a second bite at the apple, to assert its patent against the same party . . . and the same product . . . . [T]hat is exactly what claim preclusion was designed to prevent.”); *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672

F.3d 1335, 1341 (Fed. Cir. 2012) ("[T]here is no force to [the patentee's] argument that the reexamination of the '545 patent created entirely new causes of action on which [the patentee] could freely sue, even though it had previously had an opportunity to sue on the corresponding original claims of the '545 patent. . . . [This] is forbidden by the principles of res judicata."). Plaintiffs have no right to assert an invalid patent. They elected to bring suit on that patent now, instead of waiting to see if it emerges from reexamination, and they should be held to that decision. Indeed, deciding the issue of double patenting here could result in a decision by this Court that moots any patent that may emerge from reexamination.

In short, a dismissal with prejudice—on the patent Plaintiffs opted to assert—would grant Defendants the form of pre-launch patent certainty contemplated by Congress when it passed the BPCIA. Allowing Plaintiffs to avoid this result would place Defendants at a clear tactical disadvantage, thus independently cutting against the requested litigation stay.[5]

Against this substantial danger that the requested stay will unduly prejudice Defendants and present them with a clear tactical disadvantage, Plaintiffs have not demonstrated a clear case of hardship—or even articulated any hardship—if a stay did not issue. *See Saint-Gobain Performance*, 436 F. Supp. 2d at 253 ("To be entitled to a stay, a party must demonstrate a clear case of hardship if there is a danger that the stay will damage the other party."). Indeed, there would be no hardship to Plaintiffs. Absent a stay, Plaintiffs would be required to litigate the

[5] According to Plaintiffs, "[t]here is no undue prejudice to Defendants as the parties do not currently compete. . . ." (Pls' Br., Dkt. 9, at 12.) This misses the point. As discussed, Defendants would be unduly prejudiced as future competitors unless they received patent certainty, or at least a limitation on Plaintiffs' remedy, before FDA approval. Plaintiffs' cases merely found that the prejudice from preventing *patentees* from "vindicating their patent rights for an extended period of time . . . is heightened when parties to litigation are direct competitors." *ADA Solutions*, 826 F. Supp. 2d at 351. This principle has no application here, where the patentees are seeking to stay their own litigation.

patent that they themselves put in issue and, presumably, sought to litigate in the first place. The balance of equities strongly weighs against granting a stay.

B. A Stay Would Not Simplify The Issues For Litigation.

The second factor—whether a stay would simplify the issues in question and trial of the case—also cuts against the requested stay. As it stands, the litigation with regard to the '471 patent is very simple, i.e., whether that patent is invalid on double-patenting grounds, just as the PTO has found. This is a straightforward legal issue that can be addressed expeditiously. Because the requested stay would not stay the entire case but affect only one aspect of this six-patent litigation, the requested stay would cause significant case management inefficiencies ignored by Plaintiffs.

For example, Plaintiffs do not seek to stay the litigation with respect to a related patent—U.S. Patent No. 7,223,396 ("the '396 patent"). The '471 patent is directed to chimeric anti-TNFα antibodies, and the '396 patent is directed to the use of those antibodies to treat Crohn's disease. (Ex. 5, '471 patent at claims 1, 3; Ex. 15, '396 patent at claims 5, 7.) Importantly, the '471 patent and the '396 patent share a common lineage. Both patents belong to the same patent family (the '471 patent is the great-great-great-grandparent of the '396 patent) and list the same six named inventors.

There can be no question, therefore, that the '471 and '396 patents present overlapping issues for fact and expert discovery, as well as for summary judgment or trial. Given the common history and overlapping subject matter of these patents, at least the following discovery will take place even if the requested stay were granted as to the '471 patent: (1) Plaintiffs' development of chimeric anti-TNFα antibodies, (2) the prior art disclosure of chimeric anti-TNFα antibodies and their expected use for treating diseases, and (3) depositions of the same named inventors. There also could be related issues of claim construction.

As a matter of judicial economy, it makes sense to litigate both patents simultaneously. This would provide the Court with the opportunity to decide all of the asserted patents with a fuller understanding of infliximab and its therapeutic effect. By contrast, the requested stay, if granted, would result in inefficiencies and complexities—such as multiple document productions, witnesses being deposed twice, multiple claim construction hearings, and possibly even multiple summary judgment hearings or trials. Undertaking these duplicative efforts would significantly increase litigation expenses for all parties and unnecessarily take up more of the Court's time. In short, the requested stay would make this litigation unduly complex, not simplify it.

C. The Early Stage Of This Case Does Not Outweigh The Prejudicial Nature And Complexity Of The Requested Stay.

The final factor—whether discovery is complete and whether a trial date has been set—does not outweigh the prejudicial effects and complexities of the requested stay discussed above.

While the Court may consider the early stage of the case in connection with a motion to stay, that factor "does not, of course, warrant the stay of every case in its early stages." *See ADA Solutions*, 826 F. Supp. 2d at 352. Nor does the early stage of the case even create an inference in favor of a stay: "[J]ust as the absence of a negative inference does not create a positive inference, so also the lesser cost of granting a stay early in the litigation process does not equate to a factor favoring a stay." *Id.* (quoting *Sunbeam Prods., Inc. v. Hamilton Beach Brands, Inc.*, C.A. No. 3:09cv791, 2010 WL 1946262, at *3 (E.D. Va. May 10, 2010)). Indeed, as one court explained, there is "a growing concern" that litigation stays "even in its early stages" have "not led to the just, speedy, and efficient management of the litigation":

> [T]here appears to be a growing concern among at least some judges . . . that, on balance, staying a case even in its early stages pending reexamination has not led to the just, speedy, and efficient management of the litigation, but instead has tended to prolong it without achieving sufficient benefits in simplification to

> justify the delay. This concern stems in part from the unpredictable but often lengthy duration of the stay due to the length of PTO reexamination proceedings . . . in contrast to the salutary effect of firm deadlines on efficient case management.

Network Appliance Inc. v. Sun Microsystems Inc., C.A. No. C-007-06053-EDL, 2008 WL 2168917, at *3 (N.D. Cal. May 23, 2008).

For the reasons discussed above, the prejudice to Defendants and the high likelihood that a stay will not facilitate resolution of the remaining factual and legal issues in dispute strongly outweigh the fact that this case is in an early stage.

D. Alternatively, Any Stay Should Be Conditioned On A Stipulation That The Remedy For Any Infringement of the ’471 Patent Be Limited To A Reasonable Royalty.

As discussed above, Plaintiffs have thus far avoided the statutory limitation on a remedy by filing a timely suit asserting infringement of the ’471 patent. But as their motion makes clear, Plaintiffs have no intention to prosecute their suit based on the ’471 patent to judgment in good faith. Instead, Plaintiffs hope to delay litigation while reserving their right to seek a lost-profits or injunction remedy at some unknown date in the distant future if the patent ultimately were to emerge from reexamination.

Plaintiffs cannot have it both ways. Consistent with the objective of the BPCIA, if the Court were inclined to stay this case as to the ’471 patent, such a stay should be conditioned on a stipulation by Plaintiffs that their sole and exclusive remedy based on that patent shall be limited to a reasonably royalty. *See* 35 U.S.C. § 271(e)(6)(B). Any stay without that condition would circumvent congressional intent and possibly delay competition—thus harming consumers awaiting a less-expensive, biosimilar version of Janssen’s Remicade® product.

IV. CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court deny Plaintiffs' motion to stay the proceedings in this case relating to the '471 patent pending patent reexamination at the PTO. Alternatively, if a stay were ordered, this Court should limit Plaintiffs to the sole and exclusive remedy of a reasonable royalty for any infringement of that patent.

Dated: April 9, 2015

Respectfully,

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

By their attorneys,

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CERTIFICATION 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 the following non-registered participants on April 9, 2015:

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