IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO STAY

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I. INTRODUCTION

Plaintiffs Janssen Biotech, Inc. and New York University (collectively "Janssen" or "Plaintiffs") hereby move this Court to stay proceedings in this case relating to United States Patent No. 6,284,471 (the "471 Patent") (Ex. 1)[1] pending the final outcome of the reexamination of that patent by the United States Patent and Trademark Office ("PTO").

The 471 Patent is one of six patents forming the basis of Janssen's lawsuit against Defendants—Celltrion Healthcare Co., Ltd., Celltrion, Inc. (collectively "Celltrion") and Hospira, Inc. (collectively "Defendants"). This motion seeks to stay proceedings only with respect to the 471 Patent.

The 471 Patent is undergoing reexamination at the PTO in a proceeding initiated by a third party, believed to be one or more of the Defendants. The 471 Patent claims currently stand finally rejected as invalid for obviousness-type double patenting. Janssen will submit its response to that rejection shortly.

The outcome of the reexamination will invariably impact the issues in this case. If the 471 Patent claims are ultimately cancelled, then all claims based on that patent here will be moot. If the 471 Patent emerges from reexamination, it will emerge with a meaningfully amended specification—an amendment that will not be effective outside of the PTO proceedings until the reexamination is concluded, but that is important to these proceedings because it is relevant to the framework for analyzing validity challenges Defendants will likely raise. Accordingly, any time, money or other resources spent litigating this patent now, in its current, unamended form, will be wasted.

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[1] Exhibits 1-12 are attached to the Declaration of Alison Casey in Support of Plaintiffs' Motion to Stay being filed herewith.

Because this litigation is in the early stages, Defendants will not be unduly prejudiced by a stay. Further, the issues in this case will necessarily be simplified by allowing the reexamination to conclude before proceeding with litigation over the 471 Patent. A stay of proceedings relative to that patent, pending final outcome of the reexamination, will obviate potentially unnecessary or wasteful litigation and reduce the burden on the Court and the parties.

II. FACTUAL BACKGROUND

A. Janssen

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. Remicade® is a monoclonal antibody that binds to and neutralizes a substance in our bodies called TNFα. TNFα plays an important role in our immune system but, if it is over-produced, it can lead to chronic disease. Scientists at NYU worked with scientists at Janssen Biotech, Inc.'s predecessor Centocor, Inc. ("Centocor") to develop the Remicade® infliximab product.

In recognition of the Centocor and NYU inventions stemming from this research, the PTO issued several patents—jointly assigned to Centocor (now Janssen) and NYU—relating to anti-TNFα antibodies and their uses. Two of those patents are a subject of the present litigation—the 471 Patent, directed to the composition of a specific anti-TNFα antibody; and U.S. Patent 7,223,396 (the "396 Patent") (Ex. 2), directed to a method of treatment of a specific type of Crohn's disease with an anti-TNFα antibody.

The 471 Patent is currently involved in a PTO reexamination proceeding that commenced almost two years ago. On information and belief, one or both of the Defendants, or their affiliates, initiated the reexamination. On February 12, 2015, the PTO issued a "final rejection" of the 471 Patent claims as invalid on grounds of obviousness-type double patenting. *See* PTO,

Office Action, Reexamination Control No. 90/012,851 at 9-26 (Feb. 12, 2015) ("Final Rejection") (Ex. 3). Pursuant to standard PTO procedure, Janssen is permitted to and will file its response shortly.

During the course of the reexamination proceedings, the PTO entered an amendment of the 471 Patent, clarifying its designation as a "divisional" application. *Id.* at 2, 12-13; PTO, Amended Specification, Reexamination Control No. 90/012,851 (Oct. 10, 2014) ("Amended Specification") (Ex. 4); PTO, Arguments/Remarks made in an Amendment, Reexamination Control No. 90/012,851 (Oct. 10, 2014) ("Applicant Argument") (Ex. 5). The fact that an application is a divisional application is relevant to any double patenting analysis. However, although the amendment is effective in the PTO proceedings, it will not take effect outside of the PTO until the reexamination proceedings are complete. 37 C.F.R. § 1.530(k).

B. Celltrion and Hospira

Defendant Celltrion has filed an application with the Food & Drug Administration ("FDA") seeking approval to sell a "biosimilar" version of Janssen's drug Remicade®. Janssen understands that Defendant Hospira, Inc. has obtained from Celltrion exclusive rights to market Celltrion's biosimilar drug candidate in the United States. The FDA has not yet approved Celltrion's application or given any indication whether it will be approved, when it will be approved, or what the scope of any approval will be. Potentially signaling problems with Celltrion's biosimilar drug application, the FDA recently postponed indefinitely an FDA Advisory Committee meeting scheduled to consider it. *See* FDA, POSTPONED: March 17, 2015: Arthritis Advisory Committee Meeting Announcement, http://www.fda.gov/advisorycommittees/ucm433919.htm (last visited March 15, 2015) ("FDA Announcement") (Ex. 6).

C. This Action

As set forth in Janssen's Complaint, Defendants have improperly attempted to circumvent statutory procedures for resolving patent disputes between patent-holders, such as Janssen, and parties seeking FDA approval to sell "biosimilars," such as Defendants. D.I. 1, Complaint ¶¶ 111-118 ("Compl."). Defendants' actions compelled Janssen to file this suit asserting patent infringement claims that might never have to be litigated, including its infringement claims under the 471 Patent, or potentially risk losing substantial rights under Defendants' flawed construction of the law. *Id*. ¶ 113.

III. RELEVANT LAW

District courts have the "inherent power to manage their dockets and stay proceedings, including the authority to order a stay pending conclusion of a PTO reexamination." *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988) (citation omitted). In appropriate circumstances, judicial economy strongly favors the grant of a stay. These include eliminating litigation over any patent claims that are ultimately cancelled by the PTO, simplification and limitation of issues before the court, and a reduction in complexity of the litigation. *See Datatreasury Corp. v Wells Fargo & Co.,* 490 F. Supp. 2d 749, 754 (E.D. Tex. 2006).

To determine whether a stay is appropriate, courts consider: (1) whether a stay would unduly prejudice or tactically disadvantage the non-movant; (2) whether a stay would simplify issues for trial; and (3) the stage of the litigation, particularly the stage of discovery and whether a trial date has been set. *Gryphon Networks Corp. v. Contact Ctr. Compliance Corp.*, 792 F. Supp. 2d 87, 90 (D. Mass. 2011). There is a liberal policy in favor of granting a stay pending the outcome of a reexamination, particularly in cases that are still in their early stages. *Boston Heart Diagnostics Corp. v. Health Diagnostics Lab., Inc.*, Civil No. 13-13111, 2014 U.S. Dist. LEXIS

67711, at *5-6 (D. Mass. May 16, 2014) (quoting *Tse v. Apple, Inc.*, No. C 06-06573, 2007 U.S. Dist. LEXIS 76521, at *4 (N.D. Cal. Oct. 4, 2007)) (Ex. 7).

IV. THE COURT SHOULD STAY LITIGATION OVER THE 471 PATENT

All of the relevant factors favor this Court exercising its discretion to stay proceedings directed to the 471 Patent.

First, the case is in its infancy, no deadlines have been set by the Court, and no discovery has yet been taken. Indeed, this case is premature under the relevant statutory framework and has been filed now—at Defendants' wrongful insistence—simply to preserve Plaintiffs' rights and to obtain Defendants' compliance with the law. Compl. ¶ 113.

Second, reexamination of the patent will simplify the issues for trial. Either the 471 Patent will emerge in a different form with a specification that has been amended in a significant way during the reexamination proceedings, or the PTO will confirm rejection of all pending 471 Patent claims and cancel those claims (thereby mooting the need for any trial of these claims). In either case, a stay will significantly simplify and/or clarify the issues for trial.

Finally, a stay will not unduly prejudice Defendants. At present, Celltrion does not have a license to sell its biosimilar product. It cannot be predicted whether, or when, Celltrion will ever receive FDA approval to sell its proposed biosimilar product. Accordingly, Defendants will not be unduly prejudiced by an immediate stay of proceedings relating to the 471 Patent, pending final conclusion of the reexamination proceedings.

A. The Early Stage Of This Litigation Favors A Stay

The fact that this case is in its infancy strongly favors a stay. *See Boston Heart Diagnostics*, 2014 U.S. Dist. LEXIS 67711, at *12 (explaining that courts routinely grant reexamination stays when sought during an early stage of the litigation, but often deny stays after significant litigation has occurred); *Kaz USA, Inc. v. E. Mishan & Sons, Inc.*, No. 13-40037, 2014

U.S. Dist. LEXIS 93149, at *15 (D. Mass. July 9, 2014) (recognizing that early stage of litigation weighed heavily in favor of a stay where parties had not yet exchanged claim construction positions and little discovery had taken place) (Ex. 8); *Progressive Cas. Ins. Co. v. Safeco Ins. Co.*, No. 10 CV 1370, 2010 U.S. Dist. LEXIS 120222, at *12-13 (N.D. Ohio Nov. 12, 2010) (recognizing that early stage of litigation favored a stay even before the PTO granted the reexamination request) (Ex. 9).

Indeed, this case could not be at an earlier stage of litigation. The Court has not yet entered a scheduling order, and the parties have not begun discovery or engaged in any claim construction efforts with respect to the 471 Patent. Indeed, this case is at a far earlier stage than most cases where the early stage-of-the-case has been found to favor a stay. *See, e.g.*, *Kaz USA, Inc.*, 2014 U.S. Dist. LEXIS 93149, at *15. Further, the initial issues to be addressed in this case will be Defendants failure to comply with the relevant statutory framework and the prematurity of any patent infringement claims Plaintiffs were compelled to file as a result of Defendants' conduct. In Plaintiffs' view, litigation of any of the six asserted patents at this time is premature.

The overwhelming majority of time and expense associated with litigating the 471 Patent is yet to come. The fact that Janssen is seeking a stay at the outset of the case, which is premature as to the patents in the first place, strongly favors granting a stay.

B. Reexamination Will Simplify This Litigation

A stay pending reexamination will simplify this litigation. The reexamination of the 471 Patent has been underway for nearly two years. Although Janssen is convinced of the validity of the patent claims and of the merits of its positions, the claims of the 471 Patent currently stand rejected by the PTO. *See* Final Rejection (Ex. 3). It is possible that Janssen may not ultimately prevail, and that any of its infringement claims under the 471 Patent will be moot at the conclusion of the reexamination. *See Englishtown, Inc. v. Rosetta Stone Inc.*, 962 F. Supp. 2d

355, 360 (D. Mass. 2013) (granting patentee's request for a stay at a time when all claims were rejected in reexamination).

But, importantly, if the 471 Patent emerges from reexamination, it will do so in a meaningfully different form. The PTO has entered an amendment to the 471 Patent that clarifies the designation of the patent as a "divisional" of its parent application, rather than a "continuation-in-part." *See* Amended Specification (Ex. 4); Applicant Argument (Ex. 5). That amendment is relevant to resolving double-patenting challenges to the validity of the 471 Patent that the Defendants previously alleged, and are likely to allege in this lawsuit. D.I. 1, Complaint, *Celltrion Healthcare Co. Ltd. v. Janssen Biotech, Inc.*, No. 14-cv-11613 (D. Mass. filed March 31, 2014) ¶¶ 87, 89 ("Celltrion DJ Complaint"); D.I. 1, Complaint, *Hospira, Inc. v. Janssen Biotech, Inc.*, No. 14-cv-7049 (S.D.N.Y. filed Aug. 29, 2014) ¶ 95 ("Hospira DJ Complaint").

Specifically, as Janssen has explained to the PTO in the reexamination proceeding, the amendment to expressly identify the 471 Patent as a "divisional" of its parent application reinforces Janssen's position that the 471 Patent is not invalid for double-patenting because the patent is entitled to the statutory safe harbor provision of 35 U.S.C. § 121. Applicant Argument at 127-35 (Ex. 5). If the PTO determines that a patent application is directed to multiple "distinct" inventions, the PTO can require the application to be restricted to one invention. The other inventions may be prosecuted through "divisional" applications. When this happens, and the patentee prosecutes these "distinct" inventions through divisional applications, the PTO cannot later reverse course and assert that the inventions are not patentably distinct by applying a double-patenting rejection. This "safe harbor" is codified in 35 U.S.C. § 121. *See Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1360-61 (Fed. Cir. 2008). The amendment entered by the PTO expressly designating the patent as a "divisional" reinforces Janssen's position that the

claims are valid in light of 35 U.S.C. § 121. *See id.* at 1359-62; *Amgen Inc. v. F. Hoffman-La Roche, Ltd.*, 580 F.3d 1340, 1352-53 (Fed. Cir. 2009); *see also* 35 U.S.C. § 121.

Although the PTO will treat the amendment to the 471 Patent as entered for the purpose of the remaining proceedings before it, the amendment will not take effect outside of the PTO until conclusion of the reexamination proceedings, *i.e.*, when a reexamination certificate is issued. 37 C.F.R. § 1.530(k). In other words, at this time, the 471 Patent would be presented to the Court in its unamended form, not in the amended form that ultimately will issue after a successful resolution of the reexamination proceedings.

The amendment of the 471 Patent favors a stay. The Court should adjudicate the 471 Patent in the form it will have when it ultimately emerges from the reexamination proceedings. It would be wasteful for the Court to adjudicate the patent without the benefit of the PTO's completed reexamination record. Courts have routinely explained that, where the PTO is likely to modify the patent during a co-pending reexamination, staying the case conserves the parties' and the court's resources. *See, e.g.*, *ICI Uniqema, Inc. v. Kobo Prods., Inc.*, Civil Action No. 06-2943, 2009 U.S. Dist. LEXIS 108421, at *5 (D.N.J. Nov. 20, 2009) ("A stay would prevent resources from being expended on invalid or amended claims.") (Ex. 10); s*ee also Indus. Tech. Research Inst. v. LG Elecs. Inc.*, Civil Action No. 12-949, 2013 U.S. Dist. LEXIS 130918, at *23 (D.N.J. Sept. 12, 2013) (finding that a stay would simplify litigation where "[c]laim amendment isn't merely possible; it is guaranteed") (Ex. 11). Here it is not merely possible that the 471 Patent will emerge—if at all—in an amended form; it is guaranteed.

Under these circumstances, it would be futile to direct pretrial activities toward the 471 Patent as it currently exists. It would also unnecessarily complicate the proceedings to begin litigation of the 471 Patent in its current form, only to change directions after the PTO completes

reexamination of the patent. Indeed, absent a stay, the Court and the parties risk expending substantial resources litigating issues that *will* be affected by the reexamination proceedings. And, to the extent this Court resolves the issues before the PTO completes reexamination, any appeal of this Court's decision would either be moot (if the claims are finally cancelled), or based on an incomplete record (if the PTO confirms the claims in light of the changed specification).

Finally, if the 471 Patent emerges from the reexamination, this Court will be able to consider the PTO's complete analysis when ruling on any similar issues in this litigation. *Ethicon v. Quigg*, 849 F.2d at 1428; *Gould v. Control Laser Corp.*, 705 F.2d 1340, 1342 (Fed. Cir. 1983) ("One purpose of the reexamination procedure is to eliminate trial of that issue (when the claim is cancelled) or to facilitate trial of that issue by providing the district court with the expert view of the PTO (when a claim survives the reexamination proceeding).").

Because a stay pending reexamination would significantly simplify issues relating to the 471 Patent in this litigation and avoid wasteful litigation, this Court should grant Janssen's motion to stay.

C. A Stay Will Not Unduly Prejudice Defendants

Defendants will not be unduly prejudiced by a stay. "Mere delay, without more, does not constitute undue prejudice." *See Body Sci. LLC v. Phillips Elec. N. Am. Corp.*, No. 12-md-2375, 2012 U.S. Dist. LEXIS 158835, at *14 (D. Mass. Nov. 2, 2012) (Ex. 12). To determine whether a reexamination stay would unduly prejudice the non-movant, courts routinely consider whether the parties are direct competitors. *See Boston Heart Diagnostics*, 2014 U.S. Dist. LEXIS 67711, at *7 (collecting cases). Where parties are not direct competitors, delay caused by a stay is generally not unduly prejudicial. *Body Sci. LLC*, 2012 U.S. Dist. LEXIS 158835, at *14.

Defendants will not be unduly prejudiced by a stay of the proceedings with respect to the

471 Patent because they do not currently compete with Janssen. They do not have approval from the FDA to sell any biosimilar product. Neither Defendant can lose market share during a stay because they have no market share to lose. And, although Celltrion has submitted its application to the FDA requesting approval to sell its biosimilar product, there is no certainty whether, or when, the FDA will approve that application.

In fact, the pattern of delays attendant to Celltrion's request for FDA approval for its biosimilar product suggests problems with the approval process and the possibility that approval may never be forthcoming. Almost a year ago, on March 31, 2014, Celltrion filed a declaratory judgment action against Janssen in this Court, alleging that it expected to file its application for FDA approval during the first half of 2014 and that it expected to receive the FDA's approval by "early 2015." Celltrion DJ Complaint ¶ 6. But Celltrion did not file its FDA application until August, 2014. Then, by the time its marketing partner Hospira filed its own declaratory judgment case against Janssen at the end of August, the projected date for approval had slipped to sometime "[in] 2015." Hospira DJ Complaint ¶ 7 (alteration in original). But, for the reasons below, even that date now looks unrealistic.

The FDA initially provided public notice that it planned to consider Celltrion's proposed biosimilar product in a full-day meeting of its Arthritis Advisory Committee on March 17, 2015. *See* FDA Announcement (Ex. 6). But on February 25, 2015, the FDA indefinitely postponed that meeting. The FDA's postponement announcement states:

> The Food and Drug Administration (FDA) is postponing the meeting of the Arthritis Advisory Committee scheduled for March 17, 2015. The postponement is due to information requests pending with the sponsor of the application. A future meeting date will be announced in the Federal Register.

Id. The FDA's action underscores the uncertainty about whether, and when, Defendants' biosimilar product might ever be approved by the FDA and be brought to market. Thus it is

uncertain whether or when Defendants and Janssen will be direct competitors, and certainly whether they will be so before the PTO resolves the validity of the 471 Patent in the reexamination, or before the patent's term expires.

The circumstances here differ from the usual circumstances in which a party requests a stay of litigation pending conclusion of a reexamination. More commonly, it is defendants/accused infringers, who have sought concurrent PTO review of an asserted patent, who move to stay the litigation against them while the PTO completes a co-pending reexamination. In contrast, here it is the patentee, Janssen, seeking the stay. But that distinction does not make Janssen's motion any less appropriate or compelling. Courts have considered the propriety of a plaintiff's motion to stay its own case. *See Englishtown*, 962 F. Supp. 2d 355; *In re Laughlin Prods., Inc.*, 265 F. Supp. 2d 525 (E.D. Pa. 2003); *Wayne Automation Corp. v. R.A. Pearson Co.*, 782 F. Supp. 516 (E.D. Wash. 1991). In those cases, the patentee's motivation for requesting the stay, combined with the stage of the litigation, weighed heavily in the court's decision. *Compare Laughlin*, 265 F. Supp. 2d at 532 ("Nevertheless, this is not a case where the party seeking a stay delayed filing its reexamination request with the PTO until the litigation had progressed well into discovery. Rather, the MDL is still in its infancy.") *with Wayne Automation*, 782 F. Supp. at 519 ("The court is satisfied that it would not be fair to allow plaintiff to institute this action, agree to cutoff dates, have defendant conduct extensive discovery and then allow plaintiff to file for reexamination of the patent and stay this action."). Those factors here strongly favor granting Janssen's motion to stay.

As explained above, this litigation is in its infancy. Janssen did not precipitate the events that underlie its request for a stay. It did not initiate the reexamination of its 471 Patent at the PTO; on information and belief, *Defendants* or one of their affiliates did so. Compl. ¶ 47.

Accordingly, Janssen cannot be accused of filing the present stay motion as a dilatory tactic, and Defendants cannot reasonably complain about allowing the PTO proceeding *they* initiated to run to completion before they challenge the patent's validity in District Court.

V. CONCLUSION

This case is in its early stages. The claims of the 471 Patent currently stand rejected in PTO reexamination proceedings. When the patent emerges from the PTO proceedings, it will have been amended in a way that is meaningful to the validity challenges that Defendants are likely to bring in this lawsuit. Or, it is possible the patent may not survive the reexamination proceedings at all. A stay pending completion of the reexamination will simplify the issues for this Court. There is no undue prejudice to Defendants as the parties do not currently compete with each other, and there is no certainty as to whether or when that will ever happen. Janssen has not brought this motion to stay in an effort to unfairly delay the case. This Court should stay the case with respect to the 471 Patent.

Dated: March 16, 2015

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CERTIFICATE OF SERVICE

I certify that on March 16, 2015, this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing and if not so registered, that copies will be electronically mailed to such parties or their counsel.

/s/ Heather B. Repicky
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