UNITED STATES DISTRICT COURT

DISTRICT OF COLUMBIA

GlycoBioSciences, Inc.,	)	Civil Action No.: 1:12-cv-01901-RDM
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
Innocutis Holdings, LLC, *et al.*	)	
	)	
	)	
Defendants.	)	
	)	

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANTS' MOTION FOR STAY PENDING OUTCOME OF REEXAMINATION OF PATENT IN SUIT

Defendants Innocutis Holdings, LLC ("Innocutis"), DARA Biosciences, Inc. ("DARA") and Fidia Farmaceutici S.p.A. ("Fidia") move the Court to stay this litigation pending a final decision in the reexamination proceeding currently pending at the United States Patent and Trademark Office ("USPTO") concerning the patent involved in this litigation, namely U.S. Patent 6,387,407 ("the '407 patent").

A. Introduction

Plaintiff GlycoBioSciences, Inc. ("Plaintiff" or "Glyco") originally initiated this lawsuit in November 2012 with a Complaint for patent infringement of two patents, specifically U.S. Patent 6,120,804 ("the '804 patent") and U.S. Patent 6,723,345 ("the '345 patent"). The litigation was stayed pending reexaminations of the two patents, which reexaminations resulted in all of the asserted claims in the '345 patent being found not patentable over prior art and the only asserted claim in the '804 patent being amended to such an extent that Glyco could no longer assert the claim against the Defendants .

As a result, Glyco changed course and filed an amended complaint that asserted a new patent, the ‘407 patent, against the Defendants Innocutis and DARA. Glyco subsequently filed a complaint against Fidia that, in part, asserted infringement of the ‘407 patent.

A Request for *Ex Parte* Reexamination was filed against the ‘407 patent on December 21, 2015 and Reexamination of all of the claims of the ‘407 patent was ordered on February 25, 2016. The Reexamination Order stated that the Request had raised eight different prior art grounds and Reexamination was ordered with respect to all eight prior art grounds.

The most recent USPTO statistics on the results of *ex parte* reexamination indicate that only 22% of all patents survive intact from a reexamination. In the present case, the claims of the ‘407 patent cannot be amended in the reexamination since the patent has already expired.

Therefore, it is extremely likely that the patent claims asserted by Glyco in this case will be invalidated in the reexamination proceedings, thus rendering Glyco’s entire infringement allegation moot.

Neither the Court nor the Parties should be forced to engage in litigation efforts before conclusion of the reexamination proceedings.

For these reasons and the reasons set forth below, Defendants respectfully request that this litigation be stayed until conclusion of the reexamination proceeding against the ‘407 patent asserted by Plaintiff.

B. Statement of Facts

1. Glyco has asserted claims 1 – 3 of the ‘407 patent against Defendants Innocutis and DARA and has asserted claim 1 against Fidia.

2. A Request for *Ex Parte* Reexamination against all of claims 1 – 6 of the ‘407 patent was filed on December 21, 2015. (See Exhibit 1) That Request asserted that all of the claims of

the ‘407 patent were unpatentable over the prior art, either as being anticipated or obvious. Eight different combinations of prior art were asserted against the ‘407 patent.

3. The USPTO granted the Request for Reexamination and Ordered reexamination of the ‘407 patent on February 25, 2016. (See Exhibit 2) The USPTO Order found that all eight of the asserted combinations of prior art justified reexamination of the ‘407 patent claims.

C. Argument – The Court Should Stay This Litigation Pending Conclusion of the Reexamination of the ‘407 Patent

A district court’s inherent power to control and manage its docket includes the discretion to stay proceedings. *See Abbott Diabetes Care, Inc. v. DexCom, Inc.,* No. 06-514-GMS, 2007 U.S. Dist. LEXIS 73198, at *12-13 (D. Del. Sept. 30, 2007) (citing *Cost. Bros., Inc. v. Travelers Indem. Co.,* 760 F.2d 58, 60 (3d Cir. 1985)). It is well-established that the existence of a pending reexamination of a patent by the USPTO is a ground for a stay of litigation involving the patent under reexamination. *See Ethicon, Inc. v. Quigg,* 849 F.2d 1422, 1426-27 (Fed. Cir. 1988) (“Courts have inherent power to manage their dockets and stay proceedings, including the authority to order a stay pending conclusion of a PTO reexamination”).

One Congressional goal in establishing the reexamination process was to “shift the burden or reexamination of patent validity from the courts to the PTO.” *Nanometrics, Inc. v. Nova Measuring Instruments, LTD.*, No. C 06-2252 (SBA), 2007 U.S. Dist. LEXIS 18785, at *3 (N.D. Cal. Feb. 26, 2007) (citations and quotations omitted). Courts recognize that there is “a liberal policy in favor of granting motions to stay proceedings pending the outcome” of reexamination proceedings. *ASCII Corp. v. STD Entm’t USA, Inc.,* 844 F. Supp. 1378, 1381 (N.D. Cal. 1994) (citations omitted). This policy is especially employed “in cases that are still in the initial stages of litigation and where there has been little or no discovery.” *Nanometrics, Inc.*, 2007 U.S. Dist. LEXIS 18785 at *4.

In considering whether to stay an action, courts generally consider three factors:

(1) the stage of the litigation, including whether discovery is complete or nearly completed,

(2) whether a stay will simplify the issues in question and trial of the case, and

(3) whether a stay will cause undue prejudice or tactial disadvantage to the non-moving party.

Id; *See also, Aten Int'l Co. v. Emine Tech. Co.*, 2010 U.S. Dist. LEXIS 46226, at *20-21;

Applying these factors, the Court should find that a stay of this litigation with respect to the reexamined patent is appropriate for at least the following reasons:

1. Discovery is Not Nearly Complete

The facts and procedural history of this case justify a stay. Although some document production has occurred by both sides, Defendants have taken only one deposition and Plaintiff has not taken or noticed any depositions. Indeed, a hearing will be held before the court on April 4, 2016 to resolve several significant discovery disputes.

In addition, Defendants' Motion to Dismiss is still pending before the court, and the hearing on April 4th is also expected to determine when Plaintiff shall respond to Defendants' Motion for Summary Judgment filed on January 27, 2016. Actions by both the court and the parties on all of those matters could be postponed and perhaps may never be necessary if the court stays this litigation pending the outcome of the reexamination of the '407 patent. As noted above, based on the latest USPTO statistics, only 22% of patents survive reexamination with the claims intact. (See Exhibit 3, p. 2). Thus, there is a 78% chance that the claims of the '407 patent will not survive reexamination, so there is a 78% chance that the court and the parties would never need to take any further actions with regard to the patent infringement issues in this litigation.

3.2. The Reexamination Will Simplify and Alter, and May Moot, the Issues in This Case, Streamline Any Trial, and Conserve Judicial and Party Resources

Because the administrative proceedings before the PTO may moot or resolve issues presented in this case, the law firmly recommends entry of a stay pending conclusion of the PTO's review of the patents-in-suit. "One purpose of the reexamination procedure is to eliminate trial of [the infringement issue] (when the [patent] is canceled) 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)." *Gould v. Control Laser Corp.*, 705 F.2d 1340, 1342 (Fed. Cir. 1983). Congress specifically "instituted the reexamination process to shift the burden of reexamination or [*sic*] patent validity from the courts to the PTO." *Canady v. Erbe Elektromedizin GmbH*, 271 F. Supp. 2d 64, 78 (D.D.C. 2002). Given that a reexamination may "eliminate, narrow, or clarify key disputed issues" in the litigation, continued litigation in the face of a pending reexamination proceeding is fraught with the potential for the waste of judicial resources. *ICI Uniqema, Inc. v. Kobo Prods., Inc.*, 06 Civ. 2943, 2009 U.S. Dist. LEXIS 108421, at *5 (D.N.J. Nov. 20, 2009).

Any claims rejected upon reexamination "will not need to be litigated and, further, it is possible that any claims surviving reexamination may be amended." *Id.* In such cases, stays prevent valuable resources "from being expended on invalid or amended claims." *Id.* Thus courts regularly stay cases pending the completion of reexamination proceedings "to wait for reexamination results that will simplify litigation by eliminating, clarifying, or limiting the claims." *Canady*, 271 F. Supp. 2d at 68 (citing *Ethicon*, 849 F.2d at 1428); *see also Abbott Diabetes Care*, 2007 U.S. Dist. LEXIS 73198, at *15 (finding that a stay will "save time and judicial resources" "where the court has not yet conducted a Rule 16(b)(2) scheduling

conference, no scheduling Order is in place, no discovery has taken place, and little time has yet to be invested in the litigation.")

The benefit of a stay is that the result of the reexamination could invalidate one or more claims and, thus, eliminate trial on those claims and, perhaps, on the issue of infringement. If the PTO invalidates one or more claims, then issues at trial will be simplified. Even if the claims are reconfirmed, this court would benefit from the PTO's expertise: "if the reexamination proceeding reaffirms all the claims as issued, the Court will then have the benefit of the PTO expert analysis of the prior art that allegedly invalidates or limits the claims." *Softview Computer Prods. Corp.*, 56 U.S.P.Q. 2d 1633, 1636 (S.D.N.Y. 2000). Judicial economy would be promoted by a stay, since neither the Court, nor the parties would expend resources on invalid claims. *Id.*

See, In re Ether, 756 F.2d 852, 857 (Fed. Cir. 1985). ("When the patent is concurrently involved in litigation, an auxiliary function [of reexamination] is to free the court from any need to consider prior art without the benefit of the PTO's initial consideration."); *Brown v. Shimano American Corp.*, 18 U.S.P.Q. 2d 1496 (C.D. Cal. 1991) ("[R]eexamination by the PTO when issues relevant to prior art are involved is especially helpful given the PTO's expertise."). This factor weighs heavily in favor of granting a stay.

There are usually three possible outcomes of a reexamination: the PTO may cancel, amend or confirm the issued claims. But in the present case, the '407 patent has already expired, so the claims of the patent cannot be amended (see ¶ 16 of the USPTO Order dated February 25, 2016). If the PTO cancels all the asserted claims, then Glyco no longer has patent claims on which it may proceed against Defendants. If that occurs, and this Court does not stay this case, then all of the time and cost expended by the Court and the parties will have been wasted. Indeed, the most recent USPTO statistics on ex parte reexamination indicate that 78%

of patents under reexamination have all claims canceled or the claims must be amended to survive. But since the claims of the ‘407 patent cannot be amended, there is only a 22% chance that the claims of the ‘407 patent will survive.

Plaintiff Glyco has asserted some non-patent infringement issues in this case, namely alleged trade secret violations and false patent marking. But a stay of the litigation pending reexamination of the ‘407 patent is still warranted.

First of all, only patent infringement allegations have been asserted against Defendants Innocutis and DARA. Thus, if the claims of the ‘407 patent do not survive reexamination, then all allegations against Innocutis and DARA would be moot.

Secondly, if the claims of the ‘407 patent do not survive reexamination, any future actions in this case will be greatly simplified by elimination of the patent infringement allegations.

Indeed, Defendant Fidia believes that the non-patent infringement issues in this case could be rather easily disposed of either now or after conclusion of the ‘407 patent reexamination by (a) consideration of Fidia’s Motion to Dismiss the trade secret-related Counts based on forum selection clauses in the underlying confidentiality agreements that has been fully briefed by the parties, and (b) consideration of Fidia’s Motion for Summary Judgment with respect to the false patent marking allegations.

In any event, if the claims of the ‘407 patent are found not patentable in the reexamination proceeding, any remaining issues in this case will (a) not involve Innocutis and DARA and (b) will be greatly simplified for the parties and the court.

3.3. A Stay Will Cause No Prejudice Or Disadvantage to Plaintiff Glyco

A stay pending the reexamination would not prejudice Glyco, which has not sought a preliminary injunction. Thus, if Glyco were to ultimately prevail on liability, it can pursue its

claim for money damages, which, if warranted, can easily be awarded after a stay. *See DataQuill Limited*, 2009 U.S. Dist. LEXIS 42178, at *8; *SKF Condition Monitoring Inc. v. SAT Corp.*, No. 07 CV 1116 (BTM), 2008 U.S. Dist. LEXIS 24310, at *19 (S.D. Cal. Feb. 26, 2008) ("Where Plaintiffs have an adequate remedy at law, there is no undue prejudice.") (internal quotations and citations omitted); *Speedtrack, Inc. v. Wal-Mart.com USA, LLC*, No. C 06-7336 (PJH), 2009 U.S. Dist. LEXIS 8564, at *6 (N.D. Cal. Feb. 5, 2009) (court finds that money damages would adequately compensate plaintiff in the event that the PTO finds the relevant claims valid over the prior art references).

Obviously, a stay would delay any future actions in this case, but courts recognize that mere delay in the litigation is insufficient to defeat a stay request, as some delay is a feature common to all stayed cases. *Research in Motion, Ltd. v. Visto Corp.*, 545 F. Supp. 2d 1011, 1012 (N.D. Cal. 2008). As a consequence, the inherent delay due to the reexamination process does not constitute undue prejudice. *Sorensen*, 2007 U.S. Dist. LEXIS 66712, at *14 ("Protracted delay is always a risk inherent in granting a stay, yet courts continue to stay actions pending reexamination. The general prejudice of having to wait for resolution is not a persuasive reason to deny the motion for stay."). Further, in this case, all of the claims asserted in the Complaint have been ordered by the USPTO to be reexamined. Thus, "[s]ome delay is more than off-set by increased certainty of whether these patents will survive re-examination and whether there will be any need for litigation." *Nanometrics, Inc.*, 2007 U.S. Dist. LEXIS 18785, at *10.

Failing to enter a stay could potentially prejudice Defendants. During the patent reexamination process, the PTO is not bound by any determinations of this Court. *Sorensen*, 2007 U.S. Dist. LEXIS 66712, at *14-15. Thus, Defendants and Glyco could litigate Glyco's infringement claims and the PTO could later determine the patent to be invalid. This creates a

prejudice to Defendants, not to Glyco. *Id.* ("Because [the PTO is not bound in its reexamination by determinations of the Court], the Court finds that not only is Plaintiff unlikely to be prejudiced in these proceedings by a stay pending the PTO reexamination, but Defendants would potentially be prejudiced by *failing* to enter a stay.") (emphasis in original).

A stay would not put GlycoBioSciences at any disadvantage, let alone a clear tactical disadvantage discussed in the relevant case law. Once the reexamination is concluded, the parties should be able to efficiently proceed with the litigation, if it is not otherwise mooted by the outcome of the reexamination.

The efficiencies in staying this matter to allow the PTO to resolve the reexamination far outweigh any disadvantage to Glyco.

5. Conclusion

In summary, Defendants submit that a stay of this litigation pending reexamination of the '407 patent promotes judicial economy, avoids potentially unnecessary expenses for both parties, and would not prejudice any of the parties. For these reasons, Defendants respectfully request this Court to enter an Order staying further litigation regarding the '407 patent now under reexamination until the reexamination proceedings before the USPTO is complete.

DATED: April 1, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on April 1, 2016, I electronically transmitted the foregoing to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to the following CM/ECF registrants:

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