

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**BOSTON HEART DIAGNOSTICS
CORP.,**

Plaintiff,

v.

**HEALTH DIAGNOSTICS
LABORATORY, INC.,**

Defendant.

**Civil No.
13-13111-FDS**

**MEMORANDUM AND ORDER ON
DEFENDANT’S MOTION TO STAY**

SAYLOR, J.

This is a claim for patent infringement. Plaintiff Boston Heart Diagnostics Corp. (“BHDX”) is the exclusive licensee of a patent for a medical test that detects an individual’s susceptibility to statin-induced myopathy. BHDX contends that Health Diagnostics Laboratory, Inc. (“HDL”) is infringing that patent by offering a similar test.

Defendant has moved to stay the litigation pending the results of a reexamination of the patent by the U.S. Patent and Trademark Office (“PTO”), which defendant itself requested. For the reasons set forth below, the motion will be granted.

I. Background

BHDX is a Massachusetts healthcare company that specializes in treatments and technologies for cardiovascular diseases. Since November 2011, BHDX has been the exclusive licensee of U.S. Patent No. 8,455,194 (the “’194 Patent”), issued on June 4, 2013. The ’194 patent embodies diagnostic methods for detecting the susceptibility of an individual to statin-

induced myopathy—muscular pain or weakness caused by cholesterol medications—based on the association between that condition and a mutation at position 521 of the SLCO1B1 gene. One of the methods is the Boston Heart Statin-Induced Myopathy Genotype Test (the “SLCO1B1 Test”), which identifies patients who are at greater risk of developing severe myopathy as a result of statin drugs prescribed to reduce low-density lipoprotein cholesterol levels.

HDL, a Virginia corporation that works in the field of disease management and laboratory medicine, offers a test similar to the SLCO1B1 test. According to BHDx, HDL is a much larger company, with annual revenues of \$600 million compared to \$75 million for BHDx; the two are direct competitors. Other companies and organizations allegedly also offer SLCO1B1 tests. According to BHDx, it has taken actions against many of those entities short of filing suit, but asserts that HDL remains its primary competitor and the only one that commercially offers an infringing test at significant volumes.

On July 23, 2013, BHDx sent a letter to HDL stating that one of HDL’s products may infringe on the ’194 patent. HDL responded on August 9, requesting further detail about the allegations. BHDx did not respond. On November 22, 2013, HDL filed a request with the PTO for *ex parte* reexamination of claims 1-7 of the ’194 Patent (which has 14 claims in all), asserting in part that the patent is invalid because of anticipation by prior art.¹ On January 14, 2014, the

¹ *Ex parte* reexamination is a procedure by which any person may request that the PTO reevaluate the patentability of an issued and unexpired U.S. patent. 35 U.S.C. § 302. “Congress instituted the reexamination process to shift the burden of reexamination of patent validity from the courts to the PTO.” *Canady v. Erbe Elektromedizin GmbH*, 271 F. Supp. 2d 64, 78 (D.D.C. 2002). “The grant of a request for reexamination, although surely evidence that the criterion for reexamination has been met (*i.e.*, that a ‘substantial new question of patentability’ has been raised, 35 U.S.C. § 303), does not establish a likelihood of patent invalidity.” *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1584 (Fed. Cir. 1996).

The average pendency of an *ex parte* reexamination proceeding is 27.8 months. (Def. Mem., Ex. 8). The

PTO granted that request.

Meanwhile, on December 8, 2013, BHDX filed a complaint in this Court. On December 10, it filed an amended complaint, contending that HDL is willfully infringing the '194 Patent. On March 7, 2014, HDL moved to stay the litigation as to claims 1-7 pending the outcome of the reexamination proceedings.

II. Analysis

District courts have “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, 1426-1427 (Fed. Cir. 1988); *In re Columbia Univ. Patent Litig.*, 330 F. Supp. 2d 12, 15 (D. Mass. 2004). In determining whether a stay is appropriate, courts must consider the following factors: (1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay would simplify the issues in question and trial of the case; and (3) the stage of the litigation. *Cynosure, Inc. v. Cooltouch Inc.*, 2009 U.S. Dist. LEXIS 70493, at *5, 2009 WL 2462565 (D. Mass. Aug. 10, 2009) (internal quotations omitted); *see also Gryphon Networks Corp. v. Contact Ctr. Compliance Corp.*, 792 F. Supp. 2d 87, 90 (D. Mass. 2011) (citing the same factors, but referring to third factor as “whether discovery is complete and whether a trial date has been set”).

There is a “liberal policy in favor of granting motions to stay proceedings pending the outcome of reexamination, especially in cases that are still in the initial stages of litigation and where there has been little or no discovery.” *Tse v. Apple Inc.*, 2007 WL 2904279, at *1 (N.D. Cal. Oct. 4, 2007); *see also Spa Syspatronic, AG v. Verifone, Inc.*, 2008 WL 1886020, at *1

median period is 20.1 months. (*Id.*). Approximately 66% of these proceedings result in some change to the contested claims, and an additional 12% result in all claims being cancelled. (*Id.*).

(E.D. Tex. Apr. 25, 2008). That policy gives full effect to a process that was intended to “settle validity disputes more quickly and less expensively” than litigation, and to “allow courts to refer patent validity questions to the expertise of the [PTO].” *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 602 (Fed. Cir. 1985).

A. Undue Prejudice

The first factor is whether the stay would unduly prejudice, or present a clear tactical disadvantage to, the plaintiff. “The moving party bears the burden of showing that the non-moving party will not be prejudiced by a stay.” *ADA Solutions, Inc. v. Engineered Plastics, Inc.*, 826 F. Supp. 2d 348, 350 (D. Mass. 2011).

Plaintiff contends that it will be unduly prejudiced because defendant is its direct competitor and would be permitted to continue to sell the allegedly infringing product while the case is stayed. The harm is compounded, plaintiff argues, because the patent was issued less than one year ago and it has a right to operate exclusively in a relatively nascent market. According to plaintiff, the injury from defendant’s competition could irreparably and irremediably change the market. Defendant, in turn, points out that other competitors exist in the market whom plaintiff has not sued, and contends that plaintiff’s failure to seek a preliminary injunction against them implies that money damages could compensate any harm, if proved.

There is reason to believe that plaintiff would suffer some harm because of defendant’s direct competition, which weighs in favor of denying a stay. *See ADA Solutions, Inc. v. Engineered Plastics, Inc.*, 826 F. Supp. 2d 348, 350-51 (D. Mass. 2011) (“[P]rejudice is heightened when parties to litigation are direct competitors; in such cases, courts presume that a stay will prejudice the non-movant.”); *Tric Tools, Inc. v. TT Technologies, Inc.*, 2012 WL

5289409, at *2 (N.D. Cal. Oct. 25, 2012) (considering direct competition as a factor); *El Du Pont De Nemours & Co. v. MacDermid Printing Solutions LLC*, 2012 WL 2995182, at *3 (D.N.J. July 23, 2012) (same); *Sunbeam Products, Inc. v. Hamilton Beach Brands, Inc.*, 2010 WL 1946262, at *4 (E.D. Va. May 10, 2010) (same); *Nat'l Oilwell Varco, L.P. v. Auto-Dril, Inc.*, 2010 WL 8923337, at *1 (E.D. Tex. Jan. 5, 2010) (same).

Furthermore, no adverse inference may be drawn where a patent holder has not sued all of the alleged infringers at once, unless there is evidence of unreasonable delay, willingness to accept royalty-type damages instead of market exclusivity, or indifference to enforcement of the patent. *Polymer Technologies, Inc. v. Bridwell*, 103 F.3d 970, 976 (Fed. Cir. 1996); *see also A.C. Aukerman Co. v. Miller Formless Co., Inc.*, 693 F.2d 697, 700 (7th Cir. 1982) (“Patentees have no obligation to sue all alleged infringers at the same time . . .”). None of those factors exist here. In particular, as plaintiff points out, courts are generally reluctant to enjoin the sale of allegedly infringing medicines and medical devices because of the public’s interest in having access to medical treatment. *Cordis Corp. v. Boston Scientific Corp.*, 99 F. App’x 928, 935-36 (Fed. Cir. 2004); *Smith & Nephew, Inc. v. Interlace Med., Inc.*, 955 F. Supp. 2d 69, 80 (D. Mass. 2013) (“Given the importance of optimal patient care, the public interest weighs against granting a permanent injunction here.”). Plaintiff’s failure to seek a preliminary injunction does not, therefore, necessarily weigh in favor of a stay.²

On the other hand, any undue harm to plaintiff could be substantially mitigated, if not entirely addressed, by an award of money damages, including a payment of a reasonable royalty. Indeed, the reluctance of courts to issue injunctions restraining the sale of medicines and medical

² Plaintiff reportedly is in discussions with the other competitors concerning their alleged infringement.

devices is something of a double-edged sword: even if plaintiff ultimately prevails in this litigation, it is likely to be awarded only money damages, and defendant may still wind up competing in the market (although it would have to pay a reasonable royalty).

Furthermore, the fact that defendant filed an application for reexamination prior to the filing of the complaint also supports a stay; it is some evidence that defendant did not request a reexamination in order to seek a tactical advantage in the litigation. *See Vehicle IP, LLC v. Wal-Mart Stores, Inc.*, 2010 WL 4823393, at *2 (D. Del. Nov. 22, 2010).

The parties' remaining arguments as to this factor are essentially neutral. The length of time required for (and delay inherent in) reexamination, the costs associated with litigation, and the risk of inconsistent judgments between the PTO and the court, without more, generally do not constitute undue prejudice. *See SenoRx, Inc. v. Hologic, Inc.*, 2013 WL 144255, at *7 (D. Del. Jan. 11, 2013) ("Potential delay from reexamination does not, by itself, amount to undue prejudice." (internal quotation and citation omitted)); *In re Body Sci. LLC Patent Litig.*, 2012 WL 5449667, at *4 (D. Mass. Nov. 2, 2012) ("Mere delay, without more, does not constitute undue prejudice."); *id.* ("Additional costs to the plaintiff that may result from reexamination will not create undue prejudice."); *Sunbeam Products, Inc. v. Hamilton Beach Brands, Inc.*, 2010 WL 1946262, at *4 (E.D. Va. May 10, 2010) ("The mere fact that this action will go forward, and that litigating it will cost money, is an insufficient reason to warrant a stay.").

In sum, the question of undue prejudice to plaintiff weighs against a stay, but there are countervailing issues suggesting the contrary.

B. Efficiency and Simplification of Issues

Plaintiff's case involves fourteen claims, seven of which are under reexamination.

Statistically, it is likely that the reexamination will result in the modification or cancellation of some of those claims, given that the PTO changes at least one claim in approximately 66% of all *ex parte* reexaminations and cancels all claims in 12% of all *ex parte* reexaminations. After reexamination, the Court undoubtedly would benefit from any analysis conducted by the PTO. *See SenoRx, Inc. v. Hologic, Inc.*, 2013 WL 144255, at *3 (D. Del. Jan. 11, 2013) (“[E]ven if certain (or all) of the claims are ultimately confirmed, the Court will likely benefit, inter alia, from the PTO’s analysis of prior art that is later presented to the Court.”). Those factors are, to be sure, present in all cases. Indeed, “[i]t is little more than a tautology to state that reexamination will simplify the matters at issue.” *Sunbeam Products, Inc. v. Hamilton Beach Brands, Inc.*, 2010 WL 1946262, at *3 (E.D. Va. May 10, 2010). But that simplification does weigh in favor of a stay to some extent.

On the other hand, the case will not be totally resolved. Litigation as to claims 8-14 of the patent would have to go forward even if all claims under reexamination were cancelled, despite defendant’s assertion that those claims cannot reasonably asserted against it.

In any event, and considered as a whole, the efficiency factor weighs somewhat in favor of a stay.

C. Stage of the Litigation

This case is at an early stage. Defendant filed for reexamination prior to the filing of the complaint, and moved for a stay three months later. The Court has not even held a scheduling conference. Nor, for that matter, have parties engage in discovery or set dates for a *Markman* hearing or trial.

“Stays pending reexamination are routinely granted for cases in the initial stages of

litigation.” *Implicit Networks, Inc. V. Advanced Micro Devices, Inc.*, 2009 WL 357902, at *3 (W.D. Wash. Feb.9, 2009). In contrast, stays are often denied when the motion to stay is filed after significant litigation has occurred. *See, e.g., Cynosure, Inc. v. Cooltouch Inc.*, 2009 WL 2462565 (D. Mass. Aug.10, 2009) (stay denied where defendant did not inform the court that it was pursuing a request for reexamination until the *Markman* hearing, after the close of all fact discovery and only two days before the close of expert discovery); *Oracle Corp. v. Parallel Networks, LLP*, 2010 WL 3613851 (D. Del. Sept. 8, 2010) (stay denied where fact and expert discovery had both been completed two years earlier); *Nidec Corp. v. LG Innotek Co., Ltd.*, 2009 WL 3673433, at *7 (E.D. Tex. Apr. 3, 2009) (“This case was filed on March 6, 2007. On October 3, 2008—almost nineteen months later—defendants filed the request for reexamination. Defendants filed the present motion on January 19, 2009—over twenty-two months after the complaint was filed.”).³

Here, the fact that this case is at a very early stage is a factor that weighs in favor of a stay.

IV. Conclusion

Whether to order a stay is, at best, a very close call, and there are factors weighing in both directions. On balance, and under the circumstances, the Court finds that there is sufficient cause to stay this case until the PTO has reexamined the patent-in-suit.

Accordingly, and for the foregoing reasons, defendant’s motion to stay pending

³ One court in this district has concluded that “just 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; the lower cost simply indicates the best time to grant a stay is in the early stages of litigation.” *ADA Solutions, Inc. v. Engineered Plastics, Inc.*, 826 F. Supp. 2d 348, 352 (D. Mass. 2011). *But see Tric Tools, Inc. v. TT Technologies, Inc.*, 2012 WL 5289409, at *2 (N.D. Cal. Oct. 25, 2012) (“A stay sought in the early stage of the litigation generally *weighs in favor of* granting a stay pending reexamination.” (emphasis added)).

reexamination is GRANTED.

So Ordered.

Dated: May 16, 2014

/s/ F. Dennis Saylor
F. Dennis Saylor IV
United States District Judge