

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

GENZYME CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 10-CV-00112
	)	
COBREK PHARMACEUTICALS, INC.,	)	Judge Robert M. Dow, Jr.
	)	
Defendant.	)	

**MEMORANDUM OPINION AND ORDER**

This matter is before the Court on Plaintiff Genzyme Corporation’s motion for a stay pending reexamination of U.S. Patent No. 7,148,211 by the U.S. Patent and Trademark Office [55]. Defendant Cobrek Pharmaceuticals opposes the motion. For the reasons stated below, the Court grants Plaintiff’s motion and stays this action.<sup>1</sup> In view of the stay, the Court also grants Plaintiff’s motions for an extension of time for service of final contentions [72] and to postpone service of final contentions [82].

**I. Background**

Plaintiff Genzyme Corporation (“Plaintiff”) is the owner of U.S. Patent Nos. 7,148,211 (“the ‘211 patent’) and 5,602,116 (“the ‘116 patent’”) for the pharmaceutical drug Hectorol. Defendant Cobrek Pharmaceuticals (“Defendant”) seeks to release a generic version of Hectorol. Accordingly, Defendant filed an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (“FDA”), which included assertions that the ‘211 and ‘116 patents are

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<sup>1</sup> The Court requests that the parties advise the Court promptly as additional developments in the reexamination proceedings take place.

invalid. Such assertions are considered to be acts of infringement (see 35 U.S.C. § 271(e)(2)). The FDA has not yet approved Defendant's ANDA, and the ANDA remains pending.

On October 13, 2009, Defendant filed with the U.S. Patent and Trademark Office ("PTO") a request for reexamination of the '211 patent, seeking a decision by the PTO invalidating the claims in the '211 patent. On November 25, 2009, the PTO issued a communication finding *all* of the claims in the '211 patent to be invalid. Plaintiff has filed amendments seeking to overcome the PTO's rejection of the claims. The reexamination process remains pending. Ultimately, the reexamination will result in cancellation, amendment, or affirmance of the claims.

## **II. Legal Standard**

A district court has "inherent power to manage [its] 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) (citing *Landis v. North Am. Co.*, 299 U.S. 248, 254 (1936)). In deciding a stay motion, courts consider whether a stay will (1) unduly prejudice or tactically disadvantage the non-moving party, (2) simplify the issues in question and streamline the trial, and (3) reduce the burden of litigation on the parties and on the court. See *Tap Pharm. Prods., Inc. v. Atrix Labs., Inc.*, 2004 WL 422697, at \*1 (N.D. Ill. Mar. 3, 2004).

## **III. Analysis**

Sections 302 and 303 of Title 35 of the U.S. Code permit any person to request that the PTO reexamine the validity of an unexpired U.S. patent when prior art patents or publications raise "a substantial new question of patentability." See 35 U.S.C. §§ 302-303. Once the PTO grants the reexamination request, a patent examiner must conduct the reexamination "with special dispatch." 37 C.F.R. §§ 1.525, 1.550(a). The Federal Circuit has explained that "special

dispatch' envisions some type of unique, extraordinary, or accelerated movement." *Ethicon*, 849 F.2d at 1428. A party may appeal the PTO's determination of validity to the Board of Patent Appeals and Interferences.

In enacting the reexamination procedure, Congress sought to create an inexpensive, expedient means of determining patent validity to which courts could defer in patent infringement cases.<sup>2</sup> See H.R. Rep. 96-1307(I) (Sept. 9, 1980); see also *Ingro v. Tyco Indust., Inc.*, 227 U.S.P.Q. 69, 70 (N.D. Ill. 1985). Courts have cautioned that parties may not "abuse the process by applying for reexamination after protracted, expensive discovery or trial preparation." *Ingro*, 227 U.S.P.Q. at 70 (quoting *Digital Magenetic Sys., Inc. v. Ansley*, 213 U.S.P.Q. (BNA) 290 (W.D. Okla. 1982)). However, when a case has not proceeded past the initial stages of litigation, "the reexamination procedure should be utilized." *Id.* Indeed, the reexamination procedure may be beneficial to both the parties and the court in a patent infringement dispute, as "[o]ne purpose of the reexamination procedure is to eliminate trial of that issue (when the claim is canceled) or facilitate trial of that issue by providing the district court with the expert view of

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<sup>2</sup> The legislative history of the Patent Act of 1980 describes the reexamination process as follows:

Reexamination will permit efficient resolution of questions about the validity of issued patents without recourse to expensive and lengthy infringement litigation \* \* \*. A new patent reexamination procedure is needed to permit the owner of a patent to have the validity of his patent tested in the patent office where the most expert opinions exist and at a much reduced cost \* \* \*. The reexamination of issued patents could be conducted with a fraction of the time and cost of formal legal proceedings and would help restore confidence in the effectiveness of our patent system. The bill does not provide for a stay of court proceedings. It is believed by the committee that stay provisions are unnecessary in that such power already resides with the court to prevent costly pretrial maneuvering which attempts to circumvent the reexamination procedure. It is anticipated that these measures provide a useful and necessary alternative for challengers and for patent owners to test the validity of United States patents in an efficient and relatively inexpensive manner.

H.R. Rep. 96-1307(I) (Sept. 9, 1980).

the PTO (when a claim survives the reexamination proceedings).” *Gould v. Control Laser Corp.*, 705 F.2d 1340, 1342 (Fed. Cir. 1983).

When the PTO grants a request for reexamination, the PTO may not stay the reexamination pending the outcome of any parallel proceedings in federal court. See generally *Ethicon*, 849 F.2d 1422. However, a court, in the exercise of its discretion, may stay the litigation pending the outcome of the reexamination proceedings. Indeed, as noted above, Congress appears to have recognized that discretionary stays of litigation may be warranted to allow reexaminations to proceed as an “alternative for challengers and for patent owners to test the validity of United States patents in an efficient and relatively inexpensive manner.” H.R. Rep. 96-1307(I) (Sept. 9, 1980); see also *Emhart Indust., Inc. v. Sankyo Seiki Mfg. Co., Ltd.*, 1987 WL 6314, at \*1 (N.D. Ill. Feb. 2, 1987) (observing that “a stay operates to shift to the PTO a significant issue, patent claim validity, involved in the dispute before the Court”). With this in mind, the Court turns to the parties’ arguments concerning the request for a stay of this litigation.

#### **A. Length of Reexamination Proceedings**

Defendant argues that the request for stay should be denied because the reexamination proceedings may be quite lengthy and could exceed the time that it would take to resolve the litigation. Defendant relies upon a Delaware case for the proposition that when trial is likely to be completed before the reexamination proceedings, that factor weighs against granting a stay. See *Cognex Corp. v. Nat’l Instruments Corp.*, 2001 WL 34368283, at \*3 (D. Del. Jun. 29, 2001). The parties in *Cognex* had conducted extended discovery, scheduled experts, made trial support accommodations, and were scheduled to begin trial six months after the motion for stay was filed. *Id.* Here, by contrast, only limited discovery has been conducted, no depositions have

been taken, and no trial date has been set. Given that the litigation in *Cognex* had advanced much further than in this case, the Court finds *Cognex* readily distinguishable.

Moreover, although Defendant cites cases noting that the reexamination proceedings can last more than six years (see *Sunbeam Prods. v. Hamilton Beach Brands, Inc.*, 2010 WL 1946262, at \*3 (E.D. Va. May 10, 2010)), Plaintiff asserts, and Defendant does not dispute, that the median duration of a reexamination request is 32 months, including appeals to the Board of Patent Appeals and Interferences. This litigation may take at least as long (indeed, the parties' companion suit pertaining to the '116 patent has been pending for nearly three years). It may be shorter (especially if the disposition of the companion '116 litigation has any collateral effect on the claims asserted in the '211 litigation). At present, there is simply no reliable gauge of how long the respective proceedings are likely to last.

Finally, as Plaintiff observes, the fact that *Defendant* filed the request for reexamination in the first instance takes some of the bite out of Defendant's complaints regarding the length of that process. Any delay that inheres in the reexamination process does not by itself constitute undue prejudice. See *Sorensen v. Digital Networks v. North Am. Inc.*, 2008 WL 152179, at \*2 (N.D. Cal. Jan. 16, 2008). Given that Defendant (1) initiated the reexamination process and (2) appears to have succeeded (at least thus far) in convincing the PTO to invalidate the claims in the '211 patent across the board, the Court finds Defendant's argument concerning prejudice based on the length of the reexamination process less persuasive than it might otherwise have been.

#### **B. Impact of Reexamination on Litigation Issues**

Plaintiff contends in its motion that the reexamination is likely to significantly simplify issues in this litigation should the PTO cancel or amend some (or all) of the claims in the '211 patent. Even if the PTO affirms rather than cancelling or amending the claims, Plaintiff submits

that the litigation will be streamlined because Defendant will not be able to re-litigate an issue that it “raised or could have raised during the *inter partes* reexamination proceedings.” 35 U.S.C. § 315(c).

Defendant counters that simplification of the issues before this Court is not an inevitable result of the reexamination process, as the PTO will not consider all, but only some, of the defenses during the reexamination. Defendant further notes that the ultimate issue of validity still may be challenged in this Court even after resolution of the reexamination process.

Although the Court acknowledges that certain issues may remain in dispute even upon conclusion of the reexamination proceedings, it also is cognizant of the many advantages to which courts have pointed that often merit a stay:

1. All prior art presented to the Court will have been first considered by an expert PTO examiner;
2. The reexamination may alleviate discovery problems relating to the prior art;
3. The suit will likely be dismissed if the reexamination results in effective invalidity of the patent;
4. The outcome of the reexamination may encourage settlement;
5. The record of the reexamination would likely be entered at trial and thus reduce the complexity and length of the litigation;
6. The reexamination will facilitate limitation of issues, defenses, and evidence in pre-trial conferences;
7. Litigation costs to the parties and the Court will likely be reduced.

*Emhart Indust.*, 1987 WL 6314, at \*2; see also *Tap Pharm. Prods.*, 2004 WL 422697, at \*1 (granting stay in part because “[t]here is a significant chance that the PTO will either invalidate this patent or drastically decrease its scope [as a result of the reexamination] \* \* \* [creating] a very real possibility that the parties will waste their resources litigating over issues that will ultimately be rendered moot by the PTO’s findings”).

At this point, the PTO has rejected *all* of the claims in the ‘211 patent. Even if the amendments that Plaintiff filed with the PTO succeed in overcoming some or all of the

rejections, the form and substance of the '211 patent are likely to change, perhaps significantly. In view of those considerations, there appears to be a strong likelihood that both the parties and the Court would be spared considerable time and expense by staying lengthy and complex parallel proceedings – including claim construction proceedings – during the reexamination process.

### **C. Potential Harm to the Defendant**

Finally, Defendant opposes a stay on the ground that it will suffer harm if the litigation is put on hold. First, Defendant contends that investors and strategic partners would be unlikely to invest in the company before the litigation is resolved. However, as Plaintiff points out, Defendant has been involved in litigation over this ANDA since 2008, when the companion '116 litigation concerning Hecetrol commenced before this Court. The companion litigation is still pending. Any additional effect on investments that may result from the “cloud of litigation” that Defendant fears this suit will create is negligible at best – especially in view of the PTO rulings to date that have found all of the claims in the '211 patent invalid, and thus presumably should buoy Defendant’s investors.

Second, Defendant contends that Plaintiff delayed unnecessarily in filing its request for a stay and that the motion should be denied on that ground as well. The Court concludes that the eight-month delay between the filing of the complaint and the filing of the motion for stay does not weigh significantly against granting a stay. No trial date has been set, expert discovery has not yet commenced, no depositions have been taken, and the Court has not conducted claim construction or any pre-trial proceedings. *Cf. Cognex Corp.*, 2001 WL 3436828, at \*3 (denying stay where trial was imminent); *Agar Corp., Inc. v. Multi-Fluid, Inc.*, 983 F. Supp. 1126, 1128 (S.D. Tex. 1997) (holding that “courts are inclined to deny a stay when the case is set for trial

and the discovery phase has almost been completed”). The Court is sensitive to the fact that Defendant already has expended some resources litigating this matter, *e.g.*, filing a summary judgment motion. On balance, however, the Court concludes that the lag in filing the instant motion was not unreasonable and any prejudice that it caused is substantially outweighed by the competing concerns identified above. If anything, far more resources of both parties likely would be squandered by denying the stay and embarking further in parallel proceedings.

Third, Defendant argues that the nature of ANDA litigation militates against a stay. Specifically, Defendant contends that a stay would permit Plaintiff to extend its “monopoly” on the Hectorol market: if the ANDA is approved while the litigation is stayed, Defendant will be forced either to launch-at-risk its proposed generic product (leaving it vulnerable to treble damages in a potential liability suit) or refrain from marketing the generic product (causing it to lose its 180-day marketing exclusivity rights to which it is entitled as the first ANDA filer under 21 U.S.C. § 355(j)(5)(B)(iv)).

The risk of prejudice to Defendant rests on a number of potentialities. To begin with, the outcome of the parties’ companion litigation before this Court concerning the ‘116 patent may significantly affect the timing of Defendant’s launch of its generic product. For example, if the Court denied the stay, Defendant would not be able to market its generic until the ‘116 patent expires three years from now if the Court deems that patent valid in the companion litigation. Alternatively, if the Court grants the stay, the reexamination may so simplify the issues in this case that the litigation would progress far more rapidly upon its resumption, making up (at least in part) for any delay caused by the interim stay. As such, the Court concludes that the likely potential outcomes set in motion by the stay are too speculative to support a finding of undue prejudice to Defendant.



Finally, Defendant argues that Plaintiff has failed repeatedly to disclose prior art to the PTO and that it should not benefit from its nondisclosure by means of obtaining this stay while the prior art is considered during the reexamination proceedings. This argument goes to the merits of the case (and the reexamination proceedings), and the Court declines to consider it at this juncture.

**D. Hardship to Plaintiff**

The parties dispute whether Plaintiff must make a showing of hardship to obtain a stay. In general, “the suppliant for a stay must make out a clear case of hardship or inequity in being required to go forward if there is even a fair possibility that the stay for which he prays will work damage to some one else.” *Landis*, 299 U.S. at 255. However, Plaintiff argues that a showing of hardship pursuant to *Landis* is inapplicable “when a parallel proceeding serves as the basis for a stay and the only potential ‘damage worked’ is to parties to both proceedings.” *SanDisk Corp. v. Phison Electronics Corp.*, 538 F. Supp. 2d 1060, 1066 (W.D. Wis. 2008).

The dispute over applicability of *Landis* ultimately is of no consequence, as the Court concludes that Plaintiff has adequately shown that it would suffer hardship should the stay be denied given (1) the complexity of the claims now at issue before both the PTO and this Court, (2) the expertise that the PTO will bring to bear in determining the outcome of those claims, (3) the likelihood that the litigation will be streamlined as a result of the determination, and (4) the fact that it was Defendant that first sought reexamination of the claims.

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In sum, the Court finds that factors weigh in favor of granting a stay of these proceedings. It is unclear whether the stay will significantly delay resolution of this case, which still is in its early stages. Even if it does, it is fairly likely that the reexamination will streamline or, at a

minimum, alter the issues for trial given that the PTO has rejected all of the claims in the '211 patent and Plaintiff has filed amendments seeking to overcome those rejections. Furthermore, this litigation would materially benefit from whatever findings the PTO makes given the agency's expertise. And, although the Court is mindful of the potential prejudice to Defendant as a result of the stay, the degree of any such prejudice is somewhat speculative, and the other factors weigh strongly in favor of a stay while the validity of the patent claims at issue in this litigation are under consideration in the PTO reexamination proceedings. Finally, Defendant affirmatively sought reexamination of the '211 patent's validity and thus far successfully has pursued its objectives with the PTO.

#### **IV. Conclusion**

For the reasons above, the Court grants Defendant's motion for a stay of this litigation [55]. The Court also grants Plaintiff's motions for an extension of time for service of final contentions [72] and to postpone service of final contentions [82], and all further proceedings and deadlines in this matter are deferred until further order of the Court.<sup>3</sup>



Dated: February 17, 2011

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Robert M. Dow, Jr.  
United States District Judge

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<sup>3</sup> The parties of course remain free to request that the stay be lifted based on new developments, including but not limited to rulings in the reexamination proceedings.