

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

No. 5:08-CV-00119-H

CELLECTIS S.A.,)
)
Plaintiff,)
)
v.)
)
PRECISION BIOSCIENCES, INC.,)
)
Defendant.)

ORDER

This matter is before the Court on Defendant's motion to stay proceedings pending final resolution of the reexamination of U.S. Patent Nos. 6,610,545 and 7,309,605 [DE-123]. The issues have been fully briefed by the parties, and the Court held a hearing on June 16, 2010, to further develop the record. The motion is now ripe for decision.

STATEMENT OF THE CASE

Plaintiff Collectis S.A. ("Collectis") initiated this action against Precision Biosciences, Inc. ("Precision") on March 13, 2008, alleging infringements of United States Patent No. 7,309,605 ("the '605 patent") and United States Patent No. 6,610,545 ("the '545 patent") (collectively, the "Patents-in-Suit") and seeking damages and injunctive relief under the Patent Laws of the United States, 35 U.S.C. §§ 281-285. Collectis subsequently filed a supplemental complaint alleging libel *per se* and unfair competition. Supplemental Compl. ¶¶ 37-42 [DE-87]. Precision has asserted defenses and counterclaims of non-infringement, invalidity, and inequitable conduct. Answer ¶¶ 9-33 [DE-12]. On October 10, 2009, Precision filed a Motion to Dismiss for lack of standing and failure to join indispensable parties, asserting that Collectis, a licensee, did not have standing to bring suit without joining the patent holders and that the patent

holders are required parties. [DE-22.] The Court denied the motion to dismiss [DE-109], reasoning (1) that Collectis possessed “all substantial rights” under the Patents-in-Suit and, therefore, could bring suit without joining the patent holders, and (2) that the patent holders were not required parties because complete relief to the existing parties could be granted without joining the patent holders. On February 23, 2010, Precision filed the present motion to stay. Dispositive motions have not yet been filed. Significant discovery has occurred, but some fact discovery and expert discovery remain to be completed. Claim construction motions have been filed [DE-88 & 91], but a hearing has not yet been scheduled by the Court.

STATEMENT OF THE FACTS

Collectis is a French company headquartered in Paris. Precision is a Delaware corporation with its principal place of business in Durham, North Carolina. The original patent holders are two French non-profit, research-oriented organizations: the Institut Pasteur (“Pasteur”) and the Universite Pierre et Marie Curie (“the Universite”) (collectively, the “Patent Holders”). Collectis licenses the Patents-in-Suit from the Patent Holders. The Patents-in-Suit, called “Nucleotide Sequence Encoding the Enzyme I-SceI and the Uses Thereof,” deal with a scientific method called homologous recombination. During this process, a “homing endonuclease” such as I-SceI locates a specific target in a DNA strand and creates a break in the strand. A scientist injects different genes into the strand, the strand is “recombined,” with the end result being a genetically altered organism relevant to areas such as gene therapy and the creation of transgenic plants. Collectis designs and makes certain homing endonucleases used in this process. Collectis alleges that Precision makes its own endonucleases for methods that infringe the claims of the Patents-in-Suit. The ‘545 and ‘605 patents were issued in 2003 and 2007, respectively, upon continuation applications of United States Patent Application Serial No. 07/879,689. Collectis claims that there are no foreign equivalents to

the Patents-in-Suit, and while there are eleven other U.S. patents in the same family, none of those are at issue in this suit.

On March 18, 2009, Precision filed requests with the United States Patent & Trademark Office (the “PTO”) for *inter partes* reexamination of two patents, United States Patent No. 7,214,536 (“the ‘536 Patent”) and United States Patent No. 6,833,252 (“the ‘252 Patent”). These patents are in the same patent family as the Patents-in-Suit and are similar to the Patents-in-Suit in that they are directed to methods of using Group I intron-encoded endonucleases. However, the claims of these patents are different in scope than those of the Patents-in-Suit. On May 27, 2009, the PTO granted reexamination and issued first office actions initially rejecting all reexamined claims. On July 31, 2009, Precision filed requests with the PTO for *inter partes* reexamination of the Patents-in-Suit. On February 1, 2010, the PTO issued office actions closing prosecution for the ‘536 and ‘252 Patents and again rejecting all reexamined claims. On September 17, 2009, the PTO granted reexamination of the Patents-in-Suit and issued first office actions initially rejecting all reexamined claims. On February 18, 2010, the PTO issued an office action closing prosecution on the ‘545 Patent and on June 7, 2010, the PTO issued an office action closing prosecution on the ‘605 Patent, again rejecting all reexamined claims for both patents. None of these decisions are final decisions of the PTO, and Collectis has responded by amending certain claims. In the event the PTO ultimately issues final rejections, Collectis may appeal the PTO’s final rejection to the Board of Patent Appeals and Interferences (“BPAI”) and the BPAI’s decision is appealable to the Federal Circuit.

DISCUSSION

I. Standard of Review

“The determination of whether to grant a stay pending the outcome of the PTO’s reexamination is soundly within the court’s discretion.” *Cornerstone BioPharma, Inc. v. Vision Pharma, LLC*, No. 5:07-CV-00389-F, 2008 U.S. Dist. LEXIS 76374, at *3 (E.D.N.C. Feb. 15,

2008) (internal citations omitted). Commonly, courts consider the following factors to aid in their determinations: “(1) the stage of the litigation, including whether discovery is or will be almost completed and whether the matter has been scheduled for trial; (2) whether a stay will unduly prejudice or tactically disadvantage the nonmoving party; and, (3) whether a stay will simplify the issues in question and streamline the trial, thereby reducing the burden of litigation on the parties and on the court.” *Id.* “There is a liberal policy in favor of granting motions to stay proceedings pending the outcome of USPTO reexamination or reissuance proceedings.” *Id.* at *4.

As a general matter, there are benefits to staying litigation pending a reexamination proceeding:

- 1) all prior art presented to the Court will have been first considered by the PTO with its particular expertise;
- 2) many discovery problems relating to the prior art can be alleviated by the PTO examination;
- 3) in those cases resulting in effective invalidity of the patent, the suit will likely be dismissed;
- 4) the outcome of the reexamination may encourage a settlement without the further use of the Court;
- 5) the record of reexamination would likely be entered at trial, thereby reducing the complexity and length of the litigation;
- 6) issues, defenses and evidence will be effectively limited in pre-trial conferences after a reexamination; and
- 7) the cost of litigation will likely be reduced.

BarTex Research, LLC v. FedEx Corp., 611 F. Supp. 2d 647, 650 (E.D. Tex. 2009). These benefits must be weighed against the potential prejudice to the non-moving party. *Id.*

II. Analysis

a. Stage of the Litigation

The first factor to consider is the stage of the litigation, including whether discovery is or will be almost completed and whether the matter has been scheduled for trial. In support of a stay, Precision contends that despite the fact that discovery is nearly complete, much remains to

be done in this case, namely: (1) Precision seeks additional documents from Collectis not produced in response to Precision's previous document requests; (2) Discovery requested by Collectis from a third-party has not been completed; (3) Expert discovery is incomplete; (4) A claim construction hearing has not been scheduled; and (5) Summary judgment motions have not been filed. In opposing the stay, Collectis points to the substantial discovery that has occurred: (1) Nearly 500,000 documents have been produced; (2) Claim construction briefing is complete and claim construction experts have been deposed; (3) The majority of third-party discovery is complete; and (4) All fact discovery is nearly complete.

Both parties are correct in that much has been done, and yet there is much left to do. The fact that significant resources have been expended to date does not in and of itself justify continued expenditure of significant additional resources, and the preparation for and conducting of a claim construction hearing and trial will no doubt be costly endeavors for both sides. *See Insituform Technologies, Inc. v. Liqui-Force Services (USA), Inc.*, No. 08-11916, 2009 U.S. Dist. LEXIS 44116, at *9 (E.D. Mich. May 26, 2009) (“[T]he discovery costs incurred to date will not be recouped by denying a stay and proceeding to trial.”) (internal quotation omitted). Cutting off further, and potentially futile, expenditure of time and resources by both the parties and the Court weighs in favor of granting a stay even at this stage of the litigation. *See, e.g., Broadcast Innovation, L.L.C. v. Charter Commuc'ns, Inc.*, No. 03-cv-2223, 2006 U.S. Dist. LEXIS 46623, at *27-*28 (D. Colo. July 11, 2006) (granting stay after filing of dispositive motions and only three months prior to trial date; “For every court that yields to completed discovery and a looming trial date, another court finds these dates outweighed by other factors – be it the complexity of the suit, the value of PTO expertise, simplification of the issues, lack of hardship to the nonmovant, or the overall burden of duplicitous litigation on the parties and the court.”)

This matter was filed on March 13, 2008, and one year later Precision filed its request for re-examination of the '536 and '252 Patents. Four months later, sixteen months after this action was initiated, Precision sought reexamination of the Patents-in-Suit. Precision then waited an additional six months, almost two years after this action was initiated, to file its motion to stay. Precision argued at the hearing on this motion that it did not request reexamination at the outset of this litigation because it thought that the litigation would proceed faster than the reexamination process, but later altered its strategy when it became clear that this initial assumption was false. Collectis suggests alternate motives for delay: perhaps Precision was testing the reexamination waters with its related patents to avoid an adverse outcome in the PTO that could negatively impact this litigation. It is undisputed that only after the PTO initially rejected the claims of the '536 and '252 Patents, based on much the same invalidity arguments Precision asserted against the claims of the Patents-in-Suit in this case, did Precision seek reexamination of the Patents-in-Suit. Further, Precision has made no showing that it was in any way precluded from filing its reexamination request or motion to stay this case earlier in this proceeding. The Court is troubled by Precision's delay and acknowledges that other courts have denied requests to stay cases where the movant did not exercise the "requisite diligence." *E.g.*, *BarTex*, 611 F. Supp. 2d at 654 (E.D. Tex. 2009). Nevertheless, without some evidence of bad faith on the part of Precision, the Court declines to attribute a nefarious motive to Precision's tactical decision to delay its requests for reexamination and stay and is not inclined to weigh this factor heavily against granting a stay given the potential savings of additional resources yet to be expended to move this case to trial.

b. Undue Prejudice or Tactical Disadvantage to Collectis

The next factor is whether a stay will unduly prejudice or tactically disadvantage the nonmoving party. Collectis contends that if the Court stays this case it will be unduly prejudiced by delay and effectively deprived of its right to injunctive relief, i.e., the right to exclude Precision from the market. The Court has addressed the timing of Precision's motion, *supra*, and will not revisit that discussion, except to add that delay is inherent in the reexamination process and "does not constitute, by itself, undue prejudice," *Cornerstone BioPharma*, 2008 U.S. Dist. LEXIS 76374, at *5 (citation omitted). The Court cannot conclude on the record before it that Precision has engaged in dilatory motives or tactics that would create undue prejudice based on delay.

More persuasive is Collectis's contention that a stay will result in undue prejudice by effectively depriving it of its right to injunctive relief. The Court recognizes that an infringer can cause substantial and long-lasting damage to a patentee's position in the commercial marketplace by luring existing and new customers or inducing others to infringe. This damage cannot always be remedied with money damages alone, and Collectis thus has sought injunctive relief in this case, albeit not in the form of a preliminary injunction. *See Insituform*, 2009 U.S. Dist. LEXIS 44116, at *7 (plaintiff's failure to move for TRO or preliminary injunction suggests that stay would not be unduly prejudicial). Precision, alternatively, contends that there can be no prejudice to Collectis because (1) the amendment of the asserted claims of the '605 patent precludes Collectis from receiving an injunction with respect to those claims until they issue following reexamination and appeal to the BPAI, and (2) damage from infringement of the '545 patent is fully compensable with money damages. Def.'s Reply Br. at 7 [DE-128].

The Patents-in-Suit will expire in May of 2012. Pl.'s Opp'n Br. at 10 [DE-125]. The average pendency for an *inter partes* reexamination was 35.9 months as of June 30, 2010. *Inter*

Partes Reexamination Filing Data – June 30, 2010, U.S. Patent & Trademark Office, http://www.uspto.gov/patents/stats/Reexamination_Information.jsp (follow “Inter partes reexamination historical statistics” hyperlink). It has been nearly one year since Precision filed its request for reexamination. Accordingly, it is uncertain whether the PTO’s reexamination will be completed before the patents expire and highly unlikely that any appeal of the PTO’s decision will be resolved prior to the expiration of the patents. The Court can say, however, with certainty, that the life of the patents will be significantly diminished before Collectis could receive a judgment and injunctive relief in this case. *See Insituform*, U.S. Dist. LEXIS 44116, at *7 (concluding no undue prejudice where stay would likely outlast life of patent because, among other things, “culmination of [the] matter in trial would significantly decrease the time remaining before the patents expire.”) As previously noted, this case is not ready for trial and, in fact, will not be ready for trial until sometime next year; some fact discovery, a claim construction hearing and decision by the Court, expert discovery and reports, preparation and filing of dispositive motions and decision by the Court, pretrial conference, any pretrial motions, and ultimately the trial of this case remain to be completed.

The Court concludes that the undue prejudice/tactical disadvantage factor ultimately weighs against granting the stay of this case, but its weight is lessened by the fact that the life of the Patents-in-Suit will be significantly diminished by the time this case could be tried to a judgment.

c. Simplification of Issues/Burden on Parties and Court

The final factor is whether a stay will simplify the issues in question and streamline the trial, thereby reducing the burden of litigation on the parties and on the court. Collectis contends that reexamination “offers limited potential to narrow issues in the case.” Pl.’s Opp’n Br. at 14

(citing *TouchTunes Music Corp. v. Rowe Int'l Corp.*, 676 F. Supp. 2d 169, 178 (S.D.N.Y. 2009)). In addition to Collectis's claims for infringement, it seeks to recover for libel *per se*, unfair competition, and Lanham Act violations. Precision has asserted counter claims of patent invalidity and unenforceability based on prior art and inequitable conduct. Collectis concludes that "at most" the reexamination proceedings might narrow issues related only to patent infringement and validity. Pl.'s Opp'n Br. at 14. Yet, the issues of infringement and validity are not insignificant in this case, the Patents-in-Suit are technical and complex, and prior art references are key to the issues of infringement and validity. *See Broadcast Innovation*, 2006 U.S. Dist. LEXIS 46623, at *14-*15 (noting the increased utility of PTO expertise based on the technical nature of the patent and significance of prior art references). Resolution or narrowing of these issues through conclusion of the reexamination process would be of great value to the parties and to the Court relative to claim construction and the trial of these issues and, not inconsequentially, in potential settlement of this case. *Id.* at *14-*25 (granting stay with detailed discussion of how reexamination benefits the parties and the court through simplification of issues); *see also Gould v. Control Laser Corp.*, 705 F.2d 1340, 1342 (Fed. Cir. 1983) (recognizing benefit of stay pending reexamination both where claims are canceled and where claims survive). The Court further notes that the claims of libel *per se*, unfair competition, and Lanham Act violations were the result of a Precision press release directly related to Precision's characterization of the reexamination proceeding. Accordingly, it appears the only claim that would not be impacted by the reexamination proceeding is Precision's inequitable conduct counter-claim.

To date, the PTO has issued initial rejections of all asserted claims of the Patents-in Suit, followed by actions closing prosecution that again rejected all asserted claims. Additionally,

Collectis amended certain claims in an attempt to overcome the PTO's rejections, but argued at the hearing that these amendments were not substantial, which Precision disputes. According to PTO statistics, of the 167 *inter partes* reexamination certificates issued since 1999, 49% issued with all claims canceled or disclaimed and 43% issued with claims changes; only 8% issued with all claims confirmed. *Inter Partes* Reexamination Filing Data – June 30, 2010, U.S. Patent & Trademark Office, http://www.uspto.gov/patents/stats/Reexamination_Information.jsp (follow "*Inter partes* reexamination historical statistics" hyperlink).

Collectis urges that, due to the recent inception of *inter partes* reexamination, this case should not be "generically cast within the statistics," Pl.'s Opp'n Br. at 17-18, and emphasizes that the PTO's decisions are not yet final. Collectis directs the Court to the *BarTex* case, where the court gave little weight to the simplification of issues factor based in part on its inability to "determine the statistical significance of the PTO's initial rejection of all claims." 611 F. Supp. 2d at 653. However, *BarTex* is distinguishable in two important ways. First, the PTO data before the *BarTex* court was based on a much smaller sample: only 44 reexamination certificates had issued at the time of *BarTex* as compared to the 167 reexamination certificates that have issued through June 30, 2010. It is understandable that the *BarTex* court would find statistics based on such a relatively small sample to be "of limited value." *Id.* Second, the reexamination proceeding in *BarTex* occurred at an earlier stage than the reexamination proceeding in this case. The motion to stay in *BarTex* was filed shortly after the PTO's initial office action issued, *id.* at 649, whereas in the present case the PTO has twice rejected all asserted claims and issued actions closing prosecution. Additionally, Collectis has amended certain claims. Accordingly, the Court finds that under the facts and circumstances of this case, as compared to those of *BarTex*, it is more likely that the claims of the Patents-in-Suit will ultimately be cancelled or

modified. *Id.* at 653. While the Court does not find the PTO statistics dispositive of the question, they are worth consideration as they provide insight as to the historical outcomes of the reexamination process. Further, even if the PTO ultimately reverses itself, the Court and the parties will benefit from the PTO's expert evaluation of the Patents-in-Suit. *Broadcast Innovation*, 2006 U.S. Dist. LEXIS 46623, at *17.

The Court concludes that granting the stay would result in simplification of the issues and would lessen the burden on the parties and the Court in the event this case is ultimately tried. The Court draws its conclusion from the actions of the PTO to date in twice rejecting Collectis's claims, the significance of the infringement and invalidity issues in relation to the other claims asserted, and the apparent likelihood that the claims emerging from the reexamination will be at best amended from their present form. The substantial expenditure of the parties' and the Court's resources in conducting a claim construction hearing and trial on claims that may ultimately be invalidated and likely altered from their present form weighs heavily in favor of granting the stay.

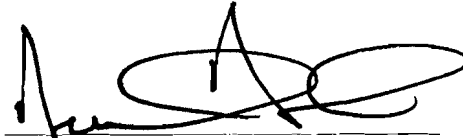
Therefore, having considered the facts and circumstances of the present case and the able arguments of the parties, while the Court finds this a close decision, it will in its discretion grant Precision's motion to stay proceedings pending final resolution of the reexamination of U.S. Patent Nos. 6,610,545 and 7,309,605. The Court finds (1) that the timing of the requests for reexamination and stay and the potential prejudice to Collectis if the Patents-in-Suit expire prior to resolution of the reexamination do not outweigh the potential benefits from staying the case pending resolution of the reexamination, (2) that the reexamination has proceeded in an expeditious manner thus far, (3) that the conclusion of that proceeding will likely narrow and potentially obviate the infringement and invalidity claims, thus simplifying the issues and

reducing the burden on the Court and the parties, and (4) that the decision of the PTO will be of substantial value to the Court and the parties should this case ultimately proceed.

CONCLUSION

Defendant's motion to stay proceedings pending final resolution of the reexamination of U.S. Patent Nos. 6,610,545 and 7,309,605 [DE-123] is **GRANTED**. Each party is **ORDERED** to file a status report as to the progress of the PTO's reexamination with the Court on a quarterly basis beginning November 1, 2010, and to notify the Court forthwith upon any final decision from the PTO regarding the '545 or '605 patent. Nothing in this order precludes either party from requesting the stay be lifted should circumstances that may impact the Court's decision materially change. Finally, the pending cross-motions for claim construction [DE-88 & 91] are summarily **DENIED WITHOUT PREJUDICE** to refile in the event the stay is lifted.

This the 31st day of August, 2010.



DAVID W. DANIEL
United States Magistrate Judge