UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

BRAINTREE LABORATORIES, INC.,	)	
	)	
Plaintiff,	)	
Counterclaim Defendant	)	
v.	)	Civil Action No. 3:13-cv-389-TJC-MCR
	)	
GATOR PHARMACEUTICALS, INC.;	)	
KVK-TECH, INC.	)	
	)	
Defendants,	)	
Counterclaim Plaintiffs.	)	
	)	
	)	

DEFENDANTS' JOINT MOTION FOR STAY

Table of Contents

I. INTRODUCTION 1

II. MEMORANDUM OF LAW 2

A. Introduction and Status of Proceeding 2

B. A Stay In This Case Is Warranted Pending The Outcome Of The Appeal 3

1. The Stay Would Simplify Issues For Trial or Eliminate The Need For Trial 4

2. The Stay Would Not Prejudice Plaintiff 5

3. The Procedural Posture Favors A Stay 6

III. CONCLUSION 7

IV. CERTIFICATION OF COUNSEL 7

Table of Authorities

CASES

Abbott Diabetes Care, Inc. v. Dexcom, Inc.,
2007 WL 2892707, at *4 (D. Del. Sept. 30, 2007) 3, 7
Allergan, Inc. v. Alcon Labs., Inc.,
324 F.3d 1322, 1337 n.5 (Fed. Cir. 2003) 6
Andrx Pharms., Inc. v. Biovail Corp.,
276 F.3d 1368, 1375-1376 (Fed. Cir. 2002) 6
ASCII Corp. v. STD Entm't USA, Inc,
844 F. Supp 1378, 1381 (N.D. Cal. 1994) 5
Automatic Mfg. Sys. v. Primera Tech., Inc.,
2013 U.S. Dist. LEXIS 165692 (M.D. Fla. 2013) 3
Braintree Laboratories, Inc. v. Novel Laboratories, Inc.,
Appeal No. 2013-1438 1
Cost Bros., Inc. v. Travelers Indem. Co.,
760 F.2d 58, 60 (3d Cir. 1985) 3
Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc.,
557 F.3d 1346, 1348 (Fed. Cir. 2009) 6
Glaxo, Inc. v. Geneva Pharm.,
1997 U.S. Dist. LEXIS 22132, at *6 n.2 (D. N.J. Aug. 6, 1997) 6
GPAC, Inc. v. D.W.W. Enter., Inc.,
144 F.R.D. 60, 64 (D. N.J. 1992) 7
I.A. Durbin, Inc. v. Jefferson Nat'l Bank,
793 F.2d 1541, 1551 (11th Cir. 1986) 3
I.A. Durbin, Inv. v. Jefferson Nat'l Bank,
793 F.2s 1541, 1551-1552 (11th Cir. 1986) 5
Joao Bock Transaction Sys., LLC v. USAmeriBank,
2013 U.S. Dist. LEXIS 129456, *8-9 (M.D. Fla) 3
KLA-Tencor v. Nanometrics, Inc.,
2006 WL 708661 at *3 (N.D. Cal. March 16, 2006) 5
Mylan Pharms., Inc. v. Thompson,
268 F.3d 1323, 1327 (Fed. Cir. 2001) 6
Pfizer Inc. v. Apotex Corp.,
640 F. Supp. 2d 1006, 1010 (N.D. Ill. 2009) 5
Playtex Products., Inc. v. Procter & Gamble Co.,
400 F.3d 901, 905-06 (Fed. Cir. 2005) 3
Schering Corp. v. Caraco Pharmaceutical Laboratories, Ltd.,
2007 U.S. Dist. LEXIS 41020, at *7-9 (E.D. Mich. June 6, 2007) 5
Southeastern Metals Mfg. Co. v. Millennium Metals, Inc.,
2012 U.S. Dist. LEXIS 39356, *4-5 (M.D. Fla. 2012) 6

Trujillo v. Conover & Co. Communs., Inc.,
221 F.3d 1262, 1264 (11th Cir. 2000) 3
U.S. Nutraceuticals LLC v. Cyanotech Corp.,
2013 U.S. Dist. LEXIS 163057, *4-5 (M.D. Fla. 2013) 3
Vehicle IP, LLC v. Wal-Mart Stores, Inc.,
2010 U.S. Dist. LEXIS 123493, *4 (D. Del. 2010) 6
WABCO Holdings v. Bendix Commercial Vehicle Sys.,
2010 U.S. Dist. LEXIS 64036, 2010 WL 2628335, at *2 (D.N.J. 2010)) 3

STATUTES

21 U.S.C. § 355(j)(5)(B) 6

I. INTRODUCTION

Defendants Gator Pharmaceuticals, Inc. and KVK-Tech, Inc. ("Defendants"), by and through undersigned counsel, jointly move the Court to stay this action until the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") rules on the appeal in *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, Appeal No. 2013-1438 ("Novel Appeal"), which includes claim construction issues that may be dispositive of the instant case. In support hereof, Defendants state:

1. The Novel Appeal involves re-examined U.S. Patent No. 6,946,149 ("the '149 patent") – the same patent asserted in the present case. The Novel Appeal includes several claim construction issues, the resolution of which may well impact this case and the resolution of at least one claim phrase, namely, "wherein the composition does not produce any clinically significant electrolyte shifts," may go a long way to resolving the present litigation.

2. Oral argument is scheduled in the Novel Appeal for February 4, 2014 and the Federal Circuit is expected to issue a ruling in the Novel Appeal near June, 2014.

3. Plaintiff Braintree will not be unduly prejudiced by the delay, which is expected to be only a few months.

4. The stay will, at the least, simplify the issues for trial and provide guidance from the Federal Circuit on claim construction issues relevant to this case and, moreover, may well dispose of the case in its entirety. Plaintiff acknowledges, in a statement to the Court in the proposed Case Management Report filed December 23, 2013 that the Federal Circuit's ruling on the Novel Appeal will be relevant to the claims and defenses in this litigation. [D.I. 33, at page 11].

5. The instant proceeding has not progressed past the pleading stage, there are no outstanding discovery requests that have been issued or served and no trial date set, all of which favor granting a brief stay.

II. MEMORANDUM OF LAW

A. Introduction and Status of Proceeding

Plaintiff Braintree asserts that Defendants infringed the '149 patent by submitting an Abbreviated New Drug Application ("ANDA") seeking approval from the U.S. Food and Drug Administration ("FDA") for a generic version of the reference drug SUPREP® Bowel Prep Kit. [D.I. 1, Complaint]. Defendants filed an Answer and Counterclaims denying the allegations. [D.I. 17]. Discovery has not yet been initiated.

Braintree asserted the '149 patent-in-suit against Novel in the United States District Court for the District of New Jersey. This case is currently on appeal to the Federal Circuit and one of the issues before the Federal Circuit, relating to claim construction, may well dispose of this entire case but, at the very least, will narrow the issues for trial. The Novel Appeal is fully briefed and oral argument is scheduled for February 4, 2014. A decision on this appeal is expected in a few months, likely in or before mid-2014.

Specifically, one of the issues in the Novel Appeal involves a question of claim construction of the '149 patent-in-suit, which is relevant to Defendants' non-infringement defense. If the Federal Circuit adopts the construction proposed by Novel, then Defendants' ANDA should be determined not to infringe the '149 patent (for the same reason the Novel ANDA would be deemed to not infringe the '149 patent) and the present case should therefore also be terminated with a judgment of non-infringement entered in favor of Defendants. At the very least, the Federal Circuit's claim construction determination of the claim terms in the '149 patent will significantly reduce the issues before this Court relating to claim construction, which is a necessary step before determining both infringement and

validity. *See Playtex Products., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 905-06 (Fed. Cir. 2005)("A determination of patent infringement consists of two steps: (1) the court must first interpret the claim, and (2) it must then compare the properly construed claims to the allegedly infringing device.)(other citations omitted).

B. A Stay In This Case Is Warranted Pending The Outcome Of The Appeal

"The decision to stay a case is firmly within the discretion of the Court." *Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, 2007 WL 2892707, at *4 (D. Del. Sept. 30, 2007) (citing *Cost Bros., Inc. v. Travelers Indem. Co.*, 760 F.2d 58, 60 (3d Cir. 1985)); *see also Trujillo v. Conover & Co. Communs., Inc.*, 221 F.3d 1262, 1264 (11th Cir. 2000). "A stay is particularly appropriate where the resolution of one of the related matters will be dispositive of the other, such that duplicative and unnecessary litigation is avoided." *Joao Bock Transaction Sys., LLC v. USAmeriBank*, 2013 U.S. Dist. LEXIS 129456, *8-9 (M.D. Fla) (citing *I.A. Durbin, Inc. v. Jefferson Nat'l Bank*, 793 F.2d 1541, 1551 (11th Cir. 1986).

"In deciding whether to stay a given action, courts frequently consider three factors: (1) whether the stay would unduly prejudice or present a clear tactical advantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set." *U.S. Nutraceuticals LLC v. Cyanotech Corp.*, 2013 U.S. Dist. LEXIS 163057, *4-5 (M.D. Fla. 2013)(citing *WABCO Holdings v. Bendix Commercial Vehicle Sys.*, 2010 U.S. Dist. LEXIS 64036, 2010 WL 2628335, at *2 (D.N.J. 2010)); *See also Automatic Mfg. Sys. v. Primera Tech., Inc.*, 2013 U.S. Dist. LEXIS 165692 (M.D. Fla. 2013).

For the reasons set forth below, Defendants respectfully submit that a stay is appropriate, because each of the foregoing factors, taken separately or together, weigh heavily in favor of granting a stay.

1. The Stay Would Simplify Issues For Trial or Eliminate The Need For Trial

Staying the case pending the Federal Circuit's ruling on claim construction in the Novel appeal is the most efficient course of action for the present case. One of the claim construction issues before the Federal Circuit may well be case-dispositive and, even if not case dispositive, will, in any event, provide significant guidance from the Federal Circuit with respect to claim construction issues relating to the '149 patent-in-suit. This will, at the very least, narrow the issues for the case and for trial.

At issue in the Novel Appeal is the meaning of the patent claim phrase "wherein the composition does not produce any clinically significant electrolyte shifts." This claim phrase appears in both of the independent claims of the '149 patent asserted in the present case. The Federal Circuit's construction of this term may be dispositive in this case. The defendant in the Novel Appeal has proffered a claim construction of the phrase in question that, if accepted by the Federal Circuit, should result in a finding of non-infringement in the present case for the same reasons proffered by the defendant in the Novel Appeal.

Plaintiff Braintree concedes that the claim construction ruling in the Novel Appeal will impact this case and may, in fact, be case-dispositive. For example, Plaintiff, in the proposed Case Management Report submitted to the Court on December 23, 2013, has proposed that opening claim construction briefs should not be submitted until 30 days after the Federal Circuit rules on the Novel Appeal and further concedes that the Federal Circuit's ruling on the Novel Appeal will be relevant to the claims and defenses in this litigation. [D.I. 33, at pages 6 and 10-11].

Given that the Federal Circuit's ruling will almost certainly impact the present case at least by focusing the issues, and may well dispose of the case in its entirety, it is most cost-effective for the parties to move forward in the present case (including discovery) only *after* the Federal Circuit makes its ruling. This will avoid wasteful and unnecessary litigation

costs incurred by the parties, as well as preserve the Court's resources and is consistent with the general principle of avoiding duplicative litigation. *See I.A. Durbin, Inv. v. Jefferson Nat'l Bank*, 793 F.2s 1541, 1551-1552 (11th Cir. 1986).

2. The Stay Would Not Prejudice Plaintiff

Given that the Federal Circuit's ruling is expected by June, 2014, the slight delay will not adversely impact any of the parties and certainly does not prejudice the Plaintiff. "Granting a stay does not cause the nonmoving party undue prejudice when that party has not invested substantial expense and time in the litigation." *KLA-Tencor v. Nanometrics, Inc.*, 2006 WL 708661 at *3 (N.D. Cal. March 16, 2006). Of course, by definition, a stay will result in an initial delay of this matter. Delay alone, however, is not prejudicial for purposes of a motion to stay. For example, where co-pending reexamination proceedings are involved, courts have adopted a liberal policy of granting stays because the issues will largely be narrowed for trial –if the case is not altogether moot. *See e.g., ASCII Corp. v. STD Entm't USA, Inc.* 844 F. Supp 1378, 1381 (N.D. Cal. 1994).

Awaiting the Federal Circuit's decision evokes similar considerations here. Waiting for a few months will most certainly provide the parties and the Court with insight regarding the scope of the claims (which impacts the scope of discovery), and may, as discussed above, dispose of the case altogether.

"T]he mere fact that this case arises under the Hatch-Waxman Act" does not provide a sufficient basis to refuse to enter a stay. *Pfizer Inc. v. Apotex Corp.*, 640 F. Supp. 2d 1006, 1010 (N.D. Ill. 2009); *see also Schering Corp. v. Caraco Pharmaceutical Laboratories, Ltd.*, 2007 U.S. Dist. LEXIS 41020, at *7-9 (E.D. Mich. June 6, 2007) (staying Hatch-Waxman case despite defendant's claim of prejudice resulting from delay in ANDA approval). Indeed, courts have granted stays pending other proceedings in the Hatch-Waxman context where doing so could serve to hone and narrow the issues. *See, e.g., Glaxo, Inc. v. Geneva Pharm.*, 1997 U.S. Dist.

LEXIS 22132, at *6 n.2 (D. N.J. Aug. 6, 1997) (noting case had been stayed pending outcome of Federal Circuit decision).

Here, the proposed stay is short, only a few months, and will not prejudice or disadvantage Plaintiff. Further, all of the litigants will benefit equally from cost-savings, and the Court will avoid unnecessary proceedings.

3. The Procedural Posture Favors A Stay

In the present action, the litigation has not advanced beyond the pleading stage, no discovery is underway and the case has not yet been scheduled for trial, all of which favor a stay. *Southeastern Metals Mfg. Co. v. Millennium Metals, Inc.*, 2012 U.S. Dist. LEXIS 39356, *4-5 (M.D. Fla. 2012) (granting stay where case was in early stages and neither party had served or exchanged discovery); *Vehicle IP, LLC v. Wal-Mart Stores, Inc.*, 2010 U.S. Dist. LEXIS 123493, *4 (D. Del. 2010) (granting stay where case is in its "infancy"); *see also Juniper*, 2010 U.S. Dist. LEXIS 136503, at *6 (granting stay where, *inter alia*, "no scheduling conference has been held, and no scheduling order has even been proposed").

This case is just beginning, and if ever there were a time to grant a stay, it is now[1]. Indeed, "most often, cases have been denied a stay due to the late stage of the litigation, the fact that discovery was or would be almost completed, or the matter had been marked for trial." *GPAC, Inc. v. D.W.W. Enter., Inc.*, 144 F.R.D. 60, 64 (D. N.J. 1992)); *see also, Abbott Diabetes Care, Inc.*, 2007 WL 2892707, at *5; *Alloc*, 2003 WL 21640372, at *3 (granting stay, stating:

[1] There is no basis or reason to extend the automatic 30-month stay of FDA approval granted by the Hatch-Waxman act in view of this brief stay requested by Defendants. Here, the FDA stay of approval expires on September 7, 2015. Under 21 U.S.C. § 355(j)(5)(B), courts may either shorten or lengthen the 30-month period, but only if "either party to the action failed to reasonably cooperate in expediting the action." *Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc.*, 557 F.3d 1346, 1348 (Fed. Cir. 2009); *see also Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1327 (Fed. Cir. 2001); *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1337 n.5 (Fed. Cir. 2003) (Schall, J., concurring). The present situation does not lend itself to extending the FDA stay. *See Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1375-1376 (Fed. Cir. 2002).

"Finally, the court notes that discovery in this case has not yet begun, nor has a discovery schedule been entered at this time. Likewise the court has not yet set a trial date.").

Given the foregoing, this factor, as well as the other two factors to be considered by the Court, overwhelmingly favor a stay of this litigation pending the outcome of the Novel Appeal, which is expected to be resolved within the next few months.

III. CONCLUSION

Based on the foregoing, Defendants submit that the requested stay of the case should be granted until the Federal Circuit issues its decision in the Novel Appeal.

IV. CERTIFICATION OF COUNSEL

The undersigned counsel certifies that he has conferred with Counsel for Plaintiff regarding the relief sought in this motion. Counsel for Braintree has advised that Plaintiff opposes the relief sought in this motion.

/s/ John P. Marino
John P. Marino, Trial Counsel
Florida Bar No.: 814539
FOWLER WHITE BOGGS P.A.
50 North Laura Street, Suite 2800
Jacksonville, FL 32202
Phone: (904) 598-3120
Fax: (904) 598-3131
jmarino@fowlerwhite.com

John J. Regan (*admitted pro hac vice*)
Jennifer Brown (*admitted pro hac vice*)
WILMER CUTLER PICKERING
HALE and DORR LLP
60 State Street
Boston, MA 02109
Telephone: (617) 526-6000
Facsimile: (617) 526-5000
Email: john.regan@wilmerhale.com
Email: jennifer.brown@wilmerhale.com

/s/ Christopher J. Mueller
Christopher J. Mueller, Esq.
Florida Bar No.: 0015536
TAYLOR, DAY, GRIMM & BOYD
cjm@taylordaylaw.com
50 North Laura Street, Suite 3500
Jacksonville, FL 32202
(904)356-0700
Fax-(904)356-3224

Neil F. Greenblum (*admitted pro hac vice*)
Paul A. Braier, Ph.D.
P. Branko Pejic (*admitted pro hac vice*)
GREENBLUM & BERNSTEIN P.L.C.
1950 Roland Clarke Place
Reston, Virginia 20191
703-716-1191

Attorneys for Defendants Gator Pharmaceuticals, Inc. and KVK-Tech, Inc.

Christopher R. Noyes (*admitted pro hac vice*)
WILMER CUTLER PICKERING
HALE and DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
Telephone: (212) 230-8800
Facsimile: (212) 230-8888
Email: christopher.noyes@wilmerhale.com

Attorneys for Plaintiff
Braintree Laboratories, Inc.

Dated: December 23, 2013