UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

BRAINTREE LABORATORIES, INC.,

Plaintiff,

Civil Action No. 3:13-cv-00389-TJC- MCR

v.

GATOR PHARMACEUTICALS, INC.;
KVK-TECH, Inc.

Defendants.

PLAINTIFF BRAINTREE LABORATORIES, INC.'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' AMENDED MOTION TO STAY

Plaintiff, Braintree Laboratories, Inc. ("Braintree"), respectfully submits this Memorandum in opposition to the Amended Motion to Stay of Gator Pharmaceuticals, Inc. ("Gator") and KVK-TECH, Inc. ("KVK") (collectively "Defendants") (Dkt. 36) ("Def. Br.").

I. INTRODUCTION

This Court should deny Defendants' Amended Motion to Stay because: (1) Braintree's proposed Case Management Report (Dkt. 33) provides an efficient plan for this litigation pursuant to the Local Rules of this District; (2) a stay of this litigation could unduly prejudice Braintree and frustrate the policy behind the Hatch-Waxman Act; and (3) a stay may not meaningfully simplify the issues in this case.

II. BACKGROUND

A. Braintree and its Patented Invention

Braintree is a small, privately-held pharmaceutical company based in Braintree, Massachusetts. Since its founding in 1982, Braintree has been an innovator in developing,

manufacturing, and selling prescription pharmaceutical products, primarily in the gastrointestinal field.

Braintree is the assignee of U.S. Patent 6,946,149 ("the '149 patent"), which names Dr. Mark Cleveland of Braintree and Dr. John Fordtran of the Baylor University Medical Center as inventors. The '149 patent will expire no earlier than March 7, 2023.[1] The patent claims compositions and methods for safely and effectively purging fecal matter from a patient's colon. These compositions and methods are useful to prepare a patient for a colonoscopy, a procedure for early detection of polyps that form inside the colon. Early detection is important because polyps can become cancerous or malignant. Colon cancer is the third most commonly diagnosed cancer in the United States. Once it is in its final stages, the survival rate is only 6%.

Through several years and millions of dollars of research, development, and animal and human clinical trials, Braintree developed a commercial embodiment of the '149 patent invention, called SUPREP® Bowel Prep Kit ("SUPREP"). On July 1, 2008, Braintree filed a New Drug Application ("NDA") for SUPREP, which the U.S. Food and Drug Administration ("FDA") approved on August 5, 2010. Since its commercial launch in September 2010, SUPREP has been a successful product in the market for prescription colonoscopy preparations.

B. The Hatch-Waxman Act

This patent infringement lawsuit arises under the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the "Hatch-Waxman" Act). Under the Hatch-Waxman Act, a generic drug manufacturer wishing to make and sell a generic version of an innovator's drug may submit to FDA a 505(b)(2) New Drug Application ("a 505(b)(2) NDA") or an Abbreviated New Drug Application ("ANDA"), relying on the innovator's data from clinical trials to demonstrate that the proposed generic drug is safe and effective. *See* 21 U.S.C.

[1] Braintree has applied for a patent term extension until August 5, 2024.

§ 355(b)(2); 21 U.S.C. § 355(j). In response, the innovator may bring suit for patent infringement. *See* 21 U.S.C. § 355(c)(3)(C); 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2). If the patent owner initiates suit, the FDA may not issue a final approval for the generic's 505(b)(2) NDA or ANDA until the expiration of a 30-month stay, which dates from the patent owner's receipt of a so-called "Paragraph IV" letter from the generic company. *See* 21 U.S.C. § 355(c)(3)(C); 21 U.S.C. § 355(j)(5)(B)(iii); *see also Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 557 F.3d 1346, 1348 (Fed. Cir. 2009) (describing Hatch-Waxman statutory scheme).

Through this framework, Congress has struck a careful balance between pioneering new drug developers and generic manufacturers seeking to produce low-cost copies of those drugs. *See Eli Lilly v. Teva*, 557 F.3d at 1348. To streamline the entry of inexpensive generics into the market, the Act permits would-be generic manufacturers to obtain expedited regulatory approval by "allowing the generic to piggy-back" on the clinical data obtained by the pioneering drug developer. *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013). In exchange, Congress granted branded drug developers an expedited patent infringement remedy, as well as the 30-month stay, which "allows the patent holder to assert its patent rights before the generic competitor is permitted to enter the market." 21 U.S.C. § 355(c)(3)(C); *see Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-77 (1990); *Mylan Pharms., Inc. v. Sebelius*, 856 F. Supp. 2d 196, 201 (D.D.C. 2012).

C. SUPREP Hatch-Waxman Litigation

In 2010, Braintree initiated Hatch-Waxman litigation against Novel Laboratories, Inc. ("Novel") for infringement of the '149 patent, in the United States District Court for the District of New Jersey. *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, D.N.J., C.A. No. 11-1341. In that suit, U.S. District Judge Peter G. Sheridan construed four disputed claim terms in

the patent. *Id.*, Dkt. 130. At summary judgment, Judge Sheridan held that Novel's proposed generic version of SUPREP would infringe the '149 patent. *Id.*, Dkt. 261, 262. After a 6-day trial, Judge Sheridan found that Novel had failed to prove the '149 patent invalid by clear and convincing evidence. *Id.*, Dkt. 380, 381. On June 19, 2013, Novel appealed Judge Sheridan's construction of two of the disputed claim terms, and his findings of infringement and validity, to the United States Court of Appeals for the Federal Circuit, *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, Appeal No. 2013-1438 ("the Novel Appeal"). *Id.*, Dkt. 390.

On March 7, 2013, Braintree received a Paragraph IV letter from Gator notifying Braintree that Gator had submitted a 505(b)(2) NDA to FDA requesting approval to market a generic powder copy of SUPREP prior to the expiration of the '149 patent.[2] On April 15, 2013, Braintree filed the present suit against Gator and KVK for infringement of the '149 patent.[3] The 30-month Hatch-Waxman stay in this case expires on September 7, 2015. *See* 21 U.S.C. § 355(c)(3)(C).

III. ARGUMENT

A. Legal Standard

In determining whether a litigation stay is appropriate, a district court has broad discretion to assess and balance the "totality of the circumstances" of "each individual case." *See Automatic Mfg. Sys., Inc. v. Primera Tech., Inc.*, No. 6:12-CV-1727-ORL-37DAB, 2013 WL 6133763 at *2 (M.D. Fla. Nov. 21, 2013) (Dalton, U.S.D.J.). In exercising that discretion, courts frequently consider three factors: "(1) whether the stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in

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[2] In the Motion to Stay, Defendants refer to Gator's application as an ANDA. However, that application is a 505(b)(2) NDA.

[3] Braintree sued KVK as a co-defendant based on the information and belief that KVK participated and/or assisted in the drafting and filing of Gator's 505(b)(2) NDA. *See* Dkt. 1, ¶17. In their answer, Defendants admitted the same. *See* Dkt. 17, ¶17.

question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set." *Id.*; *see also eCOMSYSTEMS, Inc. v. Shared Mktg. Servs., Inc.*, No. 810-CV-1531-T-33AEP, 2011 WL 280942 at *2 (M.D. Fla. Jan. 26, 2011) (Covington, U.S.D.J.).[4] Balancing these factors, Defendants' Motion to Stay should be denied. *See eCOMSYSTEMS*, 2011 WL 280942 at *3-4.

B. Braintree's Proposed Case Management Plan Is the Most Efficient Way to Proceed

Under Braintree's proposed Case Management Report, which follows the Court's customary track for handling cases like this one, the parties will proceed with fact and expert discovery without the need for much, if any, intervention from this Court. *See* Dkt. 33; Dkt. 4 (Notice of Designation); L. Civ. R. 3.05. When the Federal Circuit rules in the Novel Appeal, discovery will be complete and the parties will be fully ready for claim construction briefing. *See* Dkt. 33. Thirty days after the Federal Circuit renders its decision (or on July 17, 2014, whichever is later), the parties will present any claim construction disputes to this Court with the benefit of the Federal Circuit's decision. *See id.*[5] This will allow the case to stay on track to reach final judgment before the 30-month stay ends. In contrast, under Defendants' proposed

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[4] Defendants misstate the applicable standard, as being whether a stay would present a clear tactical "*advantage* to the non-moving party." Def. Br. at 3 (emphasis added). To the extent that Defendants' motion relies on that incorrect standard, the Court should disregard it. *See Automatic Mfg.*, 2013 WL 6133763 at *2; *WABCO Holdings, Inc. v. Bendix Commercial Vehicle Sys., LLC*, No. CIV.A.09-3179DMC, 2010 WL 2628335 at *2 (D.N.J. June 28, 2010); *cf. U.S. Nutraceuticals, LLC v. Cyanotech Corp.*, No. 5:12-CV-366-OC-10PRL, 2013 WL 6050744 at *2, 3 (M.D. Fla. Nov. 15, 2013) (Lammens, U.S.M.J.) (citing *WABCO*, 2010 WL 2628335 at *2).

[5] Defendants' claim that inefficiency would result from the current litigation schedule rings hollow. Def. Br. 4-5. When Gator submitted its 505(b)(2) NDA, it was fully aware of the pending Novel litigation and of a possible appeal to the Federal Circuit. Gator nonetheless chose to initiate this proceeding by sending Braintree its Paragraph IV letter on March 7, 2013. By statute, Braintree had only 45 days from receipt of that letter to file suit. 21 U.S.C. § 355(c)(3)(C); *F.T.C. v. Actavis*, 133 S. Ct. at 2228.

stay, fact and expert discovery would have ***to begin*** after the Federal Circuit rules, unnecessarily delaying this litigation to Braintree's detriment.[6]

C. Staying This Litigation Would Unduly Prejudice and Clearly Disadvantage Braintree

A stay would unduly prejudice Braintree because it may delay adjudication of the issues of patent infringement and validity by this Court until after Gator is permitted to launch its proposed product. Because Braintree brought the present suit for patent infringement within 45 days of receiving Gator's Paragraph IV letter, the FDA may not issue a final approval for Gator's 505(b)(2) NDA until the expiration of the 30-month stay on September 7, 2015. *See* 21 U.S.C. § 355(c)(3)(C). Upon such approval, Gator could launch its generic product even if proceedings before this Court have not yet been completed – a much more likely possibility if Defendants' proposed stay is granted.

Defendants state that they "expect" that the Federal Circuit will render its decision in the Novel Appeal within 6 months. But in fact, neither Braintree nor Gator can say with any certainty when the decision will come down, and the Federal Circuit may have the appeal under advisement for a longer period of time. If this case is stayed and the Federal Circuit decision is delayed beyond current expectations, the parties and the Court may be unable to adjudicate the issues of infringement and validity before the expiration of the 30-month stay. Not only would this prejudice Braintree, but it would also undermine the policy underlying the Hatch-Waxman Act: to "simplify and expedite the process by which generic drugs are brought to market" through orderly and prompt adjudication of patent disputes. *See Mylan*, 856 F. Supp. 2d at 200.

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[6] This litigation was already significantly delayed to accommodate Defendants and avoid burdening the Court when, at Defendants' request, Braintree agreed to wait a lengthy period to serve Defendants with the complaint while the parties discussed settlement options. No further delays are necessary.

If Gator launched its proposed generic product before the issues of patent infringement and validity are adjudicated by this Court, Gator would have obtained the benefit of using Braintree's clinical data to gain FDA approval for its generic product. Meanwhile, Braintree would not receive the corresponding benefit of having the patent infringement litigation completed before the generic product is permitted to enter the market. 21 U.S.C. § 355(c)(3)(C); *Eli Lilly v. Medtronic*, 496 U.S. at 678; *Mylan*, 856 F. Supp. 2d at 201. And far from receiving any benefit, Braintree would be disadvantaged by having to move this Court for a preliminary injunction, and later file suit against Gator for damages if this Court found the '149 patent valid and infringed.

D. The Requested Stay Will Not Significantly Simplify the Case

Staying this litigation may not meaningfully simplify the issues before this Court. While the Federal Circuit's decision on claim construction and patent validity is relevant here, Braintree's proposed schedule takes that factor into account by providing that the *Markman* proceedings not take place until after the Federal Circuit renders its decision in the Novel Appeal. *See* Dkt. 33. Thus, Braintree's proposed schedule maintains the efficiency benefits that may stem from the Federal Circuit's decision, but provides for the parties to put discovery behind them before that time.

Defendants suggest that a holding for Novel by the Federal Circuit on claim construction would result in an automatic finding of no infringement in this litigation. *See* Def. Br. 4. That is simply not correct since any ruling by the Federal Circuit would have to be applied to the facts of this case.

In fact, a stay could complicate this litigation if Defendants launch their generic product before this Court has ruled on the issues of infringement and validity. In such a situation, this Court may need to decide infringement and validity *and* a motion for an injunction. These

unnecessary complexities would be avoided if the litigation were to proceed without a stay, and in accordance with the schedule in the Case Management Report.[7] *See* Dkt. 33.

IV. CONCLUSION

For the reasons stated above, Braintree respectfully requests that this Court deny Defendants' Motion to Stay.

Dated: January 6, 2014

Respectfully submitted,

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[7] As to the third factor that courts may consider in determining whether a stay should be granted – the status of the litigation – this case is at an early stage and discovery has not yet begun. However, the other two factors – undue prejudice and no simplification of the issues – strongly outweigh the early stage of the litigation. *See eCOMSYSTEMS*, 2011 WL 280942 at *2, 5 (finding, on balance, that factors weigh in favor of denying stay despite being in initial stages of lawsuit, before discovery).

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 6, 2014, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system. I also certify that the foregoing document is also being furnished to counsel of record as identified below, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive Notices of Electronic Filing via the CM/ECF system:

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