UNITED STATES DISTRICT COURT
District of New Jersey

CHAMBERS OF
JOSE L. LINARES
JUDGE

MARTIN LUTHER KING JR.
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NOT FOR PUBLICATION

LETTER OPINION

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Re: Everett Laboratories, Inc. v. River's Edge Pharmaceuticals, LLC
Civil Action No. 09-3458 (JLL)

Dear Counsel:

This matter comes before the Court by way of: (1) Plaintiff's motion for a preliminary injunction as to its patent infringement claim [CM/ECF Docket Entry No. 14], and (2) Defendant's motion to stay the matter pending reexamination of the patent-in-suit [CM/ECF Docket Entry No. 74]. The Court has considered the submissions made in support of and in opposition to the instant motions.[1] The Court held oral argument on Plaintiff's motion for a preliminary injunction on Monday, November 2, 2009. Based on the reasons that follow, Defendant's motion to stay the matter pending reexamination of the patent-in-suit is granted in part. Plaintiff's motion for a preliminary injunction as to its patent infringement claim will be held in abeyance pending such reexamination.[2]

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[1] The Court notes that Everett has also filed an informal application to strike the Declaration of Robert DiSilvestro which was attached to Defendant's reply brief. See CM/ECF Docket Entry No. 84. River's Edge has opposed Everett's request in this regard. Because the Court has not relied on the DiSilvestro Declaration in reaching its decision, Everett's informal application is denied as moot.

[2] The Court recognizes that such could be construed as a denial of Everett's preliminary injunction application. See, e.g., Proctor & Gamble Co. v. Kraft Foods Global, Inc., 549 F.3d 842,

BACKGROUND

Plaintiff Everett Laboratories, Inc. ("Everett") sued Defendant River's Edge Pharmaceuticals, LLC ("River's Edge") for, inter alia, infringement of claims 1 through 6 of U.S. Patent No. 7,560,123 ("the '123 Patent"). Claims of the '123 Patent cover Everett's Select-OB® prescription prenatal multivitamin product. Everett seeks to preliminarily enjoin River's Edge, a manufacturer of low cost multivitamins and nutritional supplements, from continuing to market and sell Edge OB – a product which Everett contends is an "identical lower cost" version of Everett's established and patented Select-OB® brand product.

In response, River's Edge has asserted an invalidity defense based largely on Everett's alleged failure to disclose several prior art references – including one of its own products, Vitafol®PN – to the Patent and Trademark Office ("PTO") during the prosecution of the '123 Patent. According to River's Edge, claims of '123 Patent are rendered obvious by such prior art references. As a result, River's Edge filed a request for reexamination of the '123 Patent with the PTO in September 2009. In doing so, River's Edge asked the PTO to reexamine the patent-in-suit in light of Vitafol®PN, either alone or in combination with several other prior art references.

On October 26, 2009, while Everett's application for a preliminary injunction was pending before the Court, and on the eve of this Court's previously scheduled oral argument, the PTO granted River's Edge's request for reexamination of the '123 Patent, finding that "[a] substantial new question of patentability (SNQ) affecting claims 1-6 of . . . [the '123 Patent] is raised by the request for ex parte reexamination." (Tropper Decl., Ex. 1). In particular, the PTO found that "[t]here is a substantial likelihood that a reasonable examiner would consider the Vitafol disclosure important in determining whether claims 1-6 [of the '123 Patent] are patentable." (Id.). In light of this development, River's Edge now seeks a stay of the entire litigation – including Everett's motion for a preliminary injunction – pending reexamination of the patent-in-suit.

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846 (Fed. Cir. 2008) (concluding that stay order "can be deemed to have denied P&G's motion for a preliminary injunction"). Although the Court declines to render a final decision on Everett's preliminary injunction application at this time, to the extent this decision is nevertheless construed as a denial of such application, the Court notes that it would be improper to grant a preliminary injunction at this stage given that a substantial issue of patent validity has been raised by River's Edge. In other words, Everett would be unable to establish a reasonable likelihood of success on the merits at this time. See, e.g., Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001) ("[A] movant cannot be granted a preliminary injunction unless it establishes both of the first two factors, i.e., likelihood of success on the merits and irreparable harm.").

DISCUSSION

The decision of whether or not to stay a patent case during reexamination is discretionary. See Viskase Corp. v. Am. Nat'l Can Co., 261 F.3d 1316, 1328 (Fed. Cir. 2001); Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988). In deciding whether to stay a matter pending reexamination, courts have developed a three-part test: "(1) whether a stay would unduly prejudice or present a clear tactical disadvantage 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." Xerox Corp. v. 3Com Corp., 69 F. Supp. 2d 404, 406 (W.D.N.Y. 1999). Having considered the arguments made in support of and in opposition to Defendant's request for a stay, the Court finds that a stay of all claims and counterclaims related to Everett's Select-OB® brand product is appropriate under the circumstances.[3] This includes: claim 1 (patent infringement); claim 2 (federal unfair competition); claim 3 (copyright infringement); and claim 4 (state law unfair competition).

1. Prejudice and/or Tactical Disadvantage

First, Everett argues that it will be unduly prejudiced if the Court stays its patent infringement claim because Everett has already demonstrated that it will suffer irreparable harm in the absence of a preliminary injunction. However, Everett recognizes that: (a) it ultimately bears the burden of demonstrating that the injunction it seeks should issue,[4] (b) in order to establish likelihood of success

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[3] The Court declines to stay those claims which relate to Everett's Vitafol®PN product. This includes: claim 5 (federal trademark); claim 6 (federal unfair competition); and claim 7 (state law unfair competition). Defendant has given the Court no reasonable basis on which to stay such claims – which have no direct bearing Everett's patented Select-OB® brand product – at this time.

[4] See Abbott Labs. v. Andrx Pharm., Inc., 452 F.3d 1331, 1334 (Fed. Cir. 2006). In determining whether injunctive relief should be granted, the Court examines the following four factors:

> (1) whether the movant has shown a reasonable likelihood of success on the merits;
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> (2) whether the movant will be irreparably harmed by denial of the injunctive relief sought;
>
> (3) whether the injury to the movant in the absence of injunctive relief outweighs the possible harm to the non-movant if the injunction is granted; and
>
> (4) the impact of a preliminary injunction on the public interest.

on the merits at the preliminary injunction stage, it must show, among other things, that it will likely withstand any challenges to the validity of the '123 Patent,[5] and (c) because River's Edge, the alleged infringer, has responded to Everett's motion by attacking the validity of the patent, Everett, in turn, must show that such an invalidity defense lacks substantial merit.[6] In other words, Everett does not dispute that if River's Edge raises a substantial question of invalidity, Plaintiff is not entitled to a preliminary injunction. See Amazon.com, 239 F.3d at 1350-51 (stating that if the alleged infringer "raises a substantial question concerning either infringement or validity, i.e., asserts an infringement or invalidity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary injunction should not issue").

Although Everett urges the Court to give great weight to the irreparable harm it has alleged in the context of its preliminary injunction application, the Court has made no findings on the existence of such irreparable harm. That being said, the Court recognizes that River's Edge does not dispute infringement of the '123 Patent. The Court likewise recognizes that River's Edge's continued infringement *could* result in a loss of market share which may be difficult to quantify,[7] and that loss of such market share *could* constitute irreparable harm.[8] In any event, even if the Court *had* found the existence of irreparable harm in connection with Everett's preliminary injunction application, such a finding would be meaningless unless Everett can also demonstrate a reasonable likelihood of success on the merits, that is, that the invalidity defense raised by River's Edge lacks substantial merit. See Amazon.com,, 239 F.3d at 1350 ("[A] movant cannot be granted a preliminary injunction unless it establishes both of the first two factors, i.e., likelihood of success on the merits and irreparable harm."). Thus, in assessing whether a stay would unduly prejudice or present a clear tactical disadvantage to Everett, the Court cannot, on the one hand, give substantial weight to claims of irreparable harm which were raised in connection with Everett's preliminary injunction application, while at the same time ignore the potential implications of the PTO's decision to

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Id.

[5] See Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1376 (Fed. Cir. 2009).

[6] See Abbott Labs., 452 F.3d at 1335.

[7] See Everett Labs., Inc. v. Breckenridge Pharm., Inc., 573 F. Supp. 2d 855, 868 (D.N.J. 2008) (Linares, J.) (finding that "in the context of this product and the marketing strategies involved it will be impossible to measure the amount of lost market share due to the presence of other competitive products on the market, i.e., Everett will not be able to know how much of the market share it lost due to the presence of a Vitafol-OB 'generic' versus how much it lost to other prescription prenatal nutritional supplements and multivitamins – its competitors.").

[8] See Everett Labs., 573 F. Supp.2d at 868 ("Thus, Everett must decide between indirectly promoting Multifol Plus or ceasing all promotion and marketing of its own [patented] product. The Court agrees that loss of market share is difficult to quantify in this context and thus, constitutes irreparable harm.").

reexamine the patent-in-suit on said application. It is the Court's view that, in the context of this particular case, these two factors, as they relate to the prejudice prong of the stay analysis, go hand-in-hand.

While the PTO's decision to reexamine the '123 Patent in light of Vitafol®PN is not dispositive on the issue of its validity,[9] certainly the PTO's decision in this regard is relevant to whether a substantial question of invalidity has been raised.[10] This is particularly so in this case given that River's Edge has based its invalidity defense on Everett's failure to disclose its own Vitafol®PN product as a prior art reference during the prosecution of the '123 Patent.[11] This is the very issue which is now the subject of reexamination.[12] In particular, the PTO has now found a substantial likelihood that a reasonable examiner *would have* considered the Vitafol®PN disclosure significant in determining whether claims of the '123 Patent were patentable. Although the Court reiterates that this factor is not dispositive, Everett has offered no explanation, whatsoever, behind its decision *not* to disclose Vitafol®PN to the PTO during the prosecution of the '123 Patent. Thus, any added delay (or resulting prejudice) now caused by the reexamination of the patent-in-suit in light of Vitafol®PN could, arguably, have been prevented by Everett.

To the extent Everett argues that it will face additional prejudice – beyond the irreparable harm alleged in connection with its preliminary injunction application – based sheerly on the length of time that the PTO *may* take in conducting the reexamination, the Court notes that delay, alone, is not dispositive on the issue of prejudice, particularly given that such delay is common to all stayed cases.[13] Moreover, a delay in these proceedings serves the interests of correctness and finality by

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[9] See Proctor & Gamble, 549 F.3d at 848 (cautioning that "the PTO does not appear to equate the 'substantial new question of patentability' standard for whether reexamination should take place with the 'substantial question of validity' standard by which a defendant may prevent a patentee from demonstrating a likelihood of success on the merits") (internal citation omitted).

[10] See Amazon.com, 239 F.3d at 1350-51 (stating that if the alleged infringer "raises a substantial question concerning either infringement or validity, i.e., asserts an infringement or invalidity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary injunction should not issue").

[11] This argument relates to the obviousness defense, as well as claims that Everett engaged in inequitable conduct before the PTO, both of which were raised by River's Edge in opposition to Everett's motion for a preliminary injunction.

[12] See generally Proctor & Gamble, 549 F.3d at 849 ("[A] stay should ordinarily not be granted unless there is a substantial patentability issue raised in the inter partes reexamination proceeding.").

[13] See, e.g., Sorensen v. Black & Decker Corp., No. 06-1572, 2007 WL 2696590, at *4 (S.D.Cal. Sept. 10, 2007) (citing delay itself as insufficient rationale to deny stay).

assuring that any decision by the PTO as to the relevance of the Vitafol®PN prior art (as it relates to Defendants' obviousness defense) can be taken into account by this Court prior to its decision on Everett's application for a preliminary injunction. Finally, the Court notes – and Everett concedes[14] – that any such delay is not open-ended. Certainly, the reexamination process would not be indefinite enough to warrant denial of the stay on that basis.

In light of the foregoing, the Court finds that any prejudice Everett will suffer through delay or tactical advantage, while undeniably present, does not, under these circumstances, weigh heavily in the balancing of the stay factors. Xerox Corp., 69 F. Supp. 2d at 406.

2. Simplification of Issues

"A stay is particularly justified where the outcome of the reexamination would be likely to assist the court in determining patent validity and, if the claims were canceled in the reexamination, would eliminate the need to try the infringement issue." In re Cygnus Telecomm. Tech., LLC, Patent Litig., 385 F. Supp. 2d 1022, 1023 (N.D. Cal. 2005). Staying certain claims while the PTO reexamines the '123 Patent in light of Vitafol®PN would simplify the issues before this Court by ensuring that the crux of the prior art presented to the Court will have been first considered by the PTO. Given the present posture of this case, therefore, this Court finds that the simplification of issues factor weighs in favor of granting the stay.

3. Effect of the Stay on the Trial Schedule and Discovery

This case is undeniably in its early stages. "One of the most critical factors in determining whether to stay litigation pending the outcome of a reexamination proceeding is the stage of the litigation. Courts stress the importance of the stay being sought early in the litigation." Sabert Corp. v. Waddington N. Am., Inc., No. 06-5423, 2007 WL 2705157, at *7 (D.N.J. Sept. 14, 2007). The Complaint was filed this year. Motions to dismiss have only recently been fully briefed. Although the parties have engaged in limited disclosures, to date, no pretrial scheduling order has been entered in this case. Pausing for a stay at this juncture would allow the parties to curtail their discovery activities before full-blown discovery begins. Accordingly, this factor also weighs in favor of granting the stay.

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[14] See Tr. (Nov. 2, 2009) at 11:6-10 ("A typical ex parte reexam takes about two years. It will not take forever. It's not so open ended, but it takes a while . . .").

CONCLUSION

The Court finds that a stay of all claims and counterclaims related to Everett's patented Select-OB® product is appropriate.[15] Though this stay may prejudice Everett, such prejudice is outweighed by the benefits that may be gained by awaiting the determination of the reexamination. This is particularly so in this case given that River's Edge has based its invalidity defense on the fact that Everett did not disclose its own Vitafol®PN product as a prior art reference during the prosecution of the patent-in-suit; this is the very issue which is now the subject of reexamination by the PTO. The stay will, therefore, narrow and/or clarify the very issues which are currently before the Court. For these reasons, and those set forth above, Defendant's motion to stay is granted.

DATE: November 24, 2009

/s/ Jose L. Linares
Jose L. Linares
United States District Judge

[15] The Court recognizes that there are two motions to dismiss currently pending. See CM/ECF Docket Entry Nos. 36 (Defendant's motion to dismiss) and 49 (Plaintiff's motion to dismiss certain counterclaims). To the extent such motions pertain to claims related to Everett's patented Select-OB® product, such will remain stayed pending the PTO's reexamination. To the extent such motions pertain to claims which are unrelated to Everett's patented Select-OB® product, the Court will consider and render a decision on those aspects of the foregoing motions in due course.