IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PAR PHARMACEUTICALS, INC. and ALKERMES PHARMA IRELAND LTD.	:	
v.	:	Civil No. CCB-11-2466
TWI PHARMACEUTICALS, INC.	:	

MEMORANDUM

Plaintiffs Par Pharmaceuticals, Inc. and Alkermes Pharma Ireland, Limited (collectively, "Par") filed this action against TWi Pharmaceuticals, Inc. ("TWi") alleging infringement of U.S. Patent 7,101,576 ("the '576 patent"). The patent relates to Par's Megace ES medication, a nanoparticulate formulation of megestrol acetate used to treat anorexia, cachexia, and unexplained weight loss in patients with HIV and AIDS. After the parties stipulated that TWi's generic version of Megace ES would infringe the asserted claims of the '576 patent, a five-day bench trial was held in October 2013 on TWi's invalidity defense and challenge to Par Pharmaceuticals Inc.'s standing. After trial, and prior to the issuance of the judgment, the parties stipulated to a preliminary injunction barring TWi from marketing or selling its generic version of Megace ES until the court issued its decision on the merits. The court ultimately concluded the '576 patent was invalid as obvious and issued its judgment on February 21, 2014. Par filed a notice of appeal to the Federal Circuit on March 18, 2014. Pursuant to Federal Rule of Civil Procedure 62(c), Par now moves for an injunction barring TWi from marketing or selling its generic version of Megace ES until the appeal is resolved. Its motion will be granted on the condition that it posts a bond and moves to expedite its appeal in the Federal Circuit.

STANDARD OF REVIEW

Rule 62(c) provides that "[w]hile an appeal is pending from an interlocutory order or final judgment that grants, dissolves, or denies an injunction, the court may suspend, modify, restore, or grant an injunction . . . ." Fed. R. Civ. P. 62(c). In determining whether to grant an injunction pending appeal, the court considers four factors: (1) whether the applicant has made a strong showing he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent an injunction; (3) whether an injunction will substantially injure the other party; and (4) the public interest. *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 513 (Fed. Cir. 1990).[1] "Each factor . . . need not be given equal weight." *Standard Havens*, 897 F.2d at 512. Instead, the court "assesses [the] movant's chances for success on appeal and weighs the equities as they affect the parties and the public." *Id.* at 513 (quoting *E.I. Dupont de Nemours & Co. v. Phillips Petroleum*, 835 F.2d 277, 278 (Fed. Cir. 1987)) (internal quotation marks omitted); *see also Hilton*, 481 U.S. at 777 ("[T]he traditional stay factors contemplate individualized judgments in each case, the formula cannot be reduced to a set of rigid rules."); *MicroStrategy, Inc. v. Business Objects, S.A.*, 661 F. Supp. 2d 548, 558 (E.D. Va. 2009) ("Many courts view the first two factors as a sliding scale, with the greater the harm to the movant requiring a lesser showing of the likelihood of success on appeal.").

[1] The court is unable to find clear authority on whether this court is bound by Fourth Circuit or Federal Circuit precedents in deciding the issues presented by Par's motion. It appears other courts in this circuit refer to Federal Circuit case law when deciding Rule 62(c) motions in patent cases. *See, e.g.*, *ePlus Inc. v. Lawson Software, Inc.*, 946 F. Supp. 2d 503, 507-08 (E.D. Va. 2013); *Johns Hopkins Univ. v. Datascope Corp.*, 2007 WL 2709986, at *1 (D. Md. Aug. 31, 2007). In any event, the two circuits apply the same test. *Compare Standard Havens*, 897 F.2d at 513, *with Long v. Robinson*, 432 F.2d 977, 979 (4th Cir. 1970).

ANALYSIS

I. Laches

As a preliminary matter, TWi claims Par should be barred from relief under the doctrine of laches. To succeed on the defense of laches, TWi must demonstrate that Par was not diligent in protecting its rights and that TWi was prejudiced by Par's delay in bringing the present motion. *See Costello v. United States*, 365 U.S. 265, 282 (1961).

TWi has failed to demonstrate that it was sufficiently prejudiced by any unjustified delay. In its July 24, 2014, letter to the court, TWi claims prejudice because it "invest[ed] millions of dollars in preparation for its ANDA launch" after the initial injunction expired in February of this year. (TWi Letter, ECF No. 237, at 2.) TWi offers no evidence of its investments. Further, as Par points out, TWi claimed in January that it was ready to launch its product as soon as it received FDA approval. The court then imposed an injunction pending its decision. With no evidence proffered, the court fails to understand, therefore, what additional investments TWi has made since January. In addition, any prejudice to TWi is somewhat of its own making as it apparently continued to prepare its product for launch despite the pending appeal in which the Federal Circuit may ultimately decide Par's patent is valid.

The cases on which TWi relies to support its laches defense do not require a different conclusion. In both *Graceway* and *Uniroyal*, the defendants had already launched their allegedly infringing products when the patent holders first filed suit and first gave notice that they would bring any kind of legal action. *Graceway Pharm., LLC v. Perrigo Co.*, 697 F. Supp. 2d 600, 603 (D.N.J. 2010); *Uniroyal, Inc. v. Daly-Herring Co.*, 294 F. Supp. 754, 756, 759-60 (E.D.N.C. 1968). In *Graceway*, the delay put at risk the generic manufacturer's 180-day exclusivity period

because it had already started running. 697 F. Supp. 2d at 607. TWi has not demonstrated that it has suffered any kind of similar prejudice and Par is not barred from seeking an injunction pending appeal under the doctrine of laches. The court will thus turn to the four factors courts consider under Rule 62(c).

II. Likelihood of Success on the Merits

"Where [a party] establishes that it has a strong likelihood of success on appeal, or where, failing that, it can nonetheless demonstrate a substantial case on the merits," provided the other factors also militate in the applicant's favor, then an injunction pending appeal is appropriate. *Hilton*, 481 U.S. at 778. To succeed, Par thus does not need to demonstrate that it will certainly win on appeal or that there is a mathematical probability of success. *See Standard Havens*, 897 F.3d at 512-13. At a minimum, it must demonstrate a substantial case.[2]

Here, Par claims that it will succeed on the merits because this court erred in its application of the law with respect to motivations to combine the prior art and inherency.[3] (Pl.'s Mem., ECF No. 229, at 5-11.) Although the court stands by its judgment, it recognizes that the case presents a close call. Further, the Federal Circuit will conduct a *de novo* review of whether the '576 patent is obvious, including whether this court properly interpreted the law regarding motivation and inherency. *See Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1370 (Fed. Cir. 2000) (stating the standard of review). The court is not persuaded Par has demonstrated a "strong" likelihood of success on appeal—especially given that most of its dispute with this

[2] The court agrees with Par that the appropriate standard is likelihood of success on appeal, rather than likelihood of success in the entire course of the litigation.

[3] Specifically, the plaintiffs claim that the court incorrectly applied the rule that alternative motivations to combine the prior art must have been motivations to create the invention as claimed. Par also claims the court erred in determining the claimed pharmacokinetic properties were inherent because the court erroneously interpreted the Federal Circuit's requirement that a property be *necessarily* present in the prior art to be considered inherent.

court's earlier decision is only rehashing the legal arguments it has already made. Par has, however, made a showing of a substantial case. Because, as discussed below, the balance of hardships tips strongly in its favor as well, this showing is sufficient. *See Butamax Advanced Biofuels LLC v. Gevo, Inc.*, 2012 WL 2675232, at *2 & n.2 (D. Del. July 6, 2012) (finding that a strong showing of irreparable harm and the Federal Circuit's *de novo* review can merit a stay of a preliminary injunction pending appeal); *In re Cyclobenzaprine*, 2011 WL 1980610, at *3 (D. Del. May 20, 2011) (finding the likelihood of success factor to marginally support a temporary restraining order pending appeal of the court's invalidity finding where "plaintiffs' success on appeal is just as likely as not").

III. Irreparable Harm to Par

Before addressing the harm to Par, the court addresses TWi's claim that Par Pharmaceuticals, Inc. does not have standing. According to TWi, because Par Pharmaceuticals does not have standing, but is the only entity claiming harm, the plaintiffs have not met their burden. Par does have standing. A party that holds exclusionary rights to a patent, even if it does not hold all substantial rights, meets constitutional standing requirements to bring suit against an infringer and meets prudential standing requirements when it brings suit as a co-plaintiff with the patentee. *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1340 (Fed. Cir. 2007). Exclusionary rights are those that allow the holder to exclude others from making, using, or selling the invention.[4] *Id.*

Par Pharmaceutical's licensing agreement with Alkermes gives it the exclusive right to make, use, offer for sale, and sell liquid forms of megestrol acetate made using Alkermes'

[4] The court notes that the right to bring suit for infringement of the patent at issue is not sufficient to confer standing. *Ortho Pharm. Corp. v. Genetics Institute, Inc.*, 52 F.3d 1026, 1034 (Fed. Cir. 1995) ("[A] right to sue clause cannot negate the requirement that, for co-plaintiff standing, a licensee must have beneficial ownership of some of the patentee's proprietary rights.").

NanoCrystal Technology. (DTX 248 at Cl. 2.1.0-2.1.1.) The licensing agreement also gives Par Pharmaceuticals the right to grant sublicenses to make, use or sell the formulation as long it obtains prior written consent from Alkermes. (*Id.* at Cl. 2.2.1.) Par has, therefore, exclusionary rights in the patent. *See Morrow*, 499 F.3d at 1341 (noting that the grant of an exclusive license to make, use or sell a patented invention along with the grant of a right to sublicense "constituted a transfer of exclusionary rights to the patent"); *Evident Corp. v. Church & Dwight Co., Inc.*, 399 F.3d 1310, 1313-14 (Fed. Cir. 2005) (finding "there can be no dispute" that a licensee had standing where it had the right to make, use, and sell the patented composition and to grant sublicenses); *Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA*, 944 F.2d 870, 875 (Fed. Cir. 1991) (noting that a "sublicensing veto was a minor derogation" of the grant of rights under a licensing agreement and "did not substantially interfere with the full use . . . of the exclusive rights under the patent"). TWi's reliance on *Mitutoyo* for a different conclusion is misplaced, as *Mitutoyo* addressed whether a party with a distributorship agreement had prudential standing, a situation not at issue here. *Mitutoyo Corp. v. Central Purchasing, LLC*, 499 F.3d 1284, 1291 (Fed. Cir. 2007).

Having established Par Pharmaceuticals' standing, Par also has demonstrated that it will suffer irreparable harm should TWi launch before the Federal Circuit issues a decision. Although those harms that can be compensated by money damages are not irreparable, *see Graceway*, 687 F. Supp. 2d at 608, Par has presented evidence that it would suffer more than just lost revenue. Par has also demonstrated that the lost revenue will likely force its entire branded division, Strativa, to shut down. (John Ameres Decl., ECF No. 233, ¶¶ 16, 17 (stating that sales of Megace ES constitute at least 50 percent of total revenue for Strativa); Walter Vandaele Decl.,

ECF No. 235, ¶ 11 (citing research demonstrating brand drug sales drop more than 75 percent within three months after entry of a generic).) TWi claims this does not demonstrate irreparable harm because Strativa is a small portion of Par's overall business and most of Strativa's sales force is focused on its other branded drug, Nascobal. (*See* Form 10-Q for Quarter Ending March 31, 2014, Sholar Decl. Ex. C, ECF No. 245-1, at 36-37 (listing revenue from Strativa and the rest of Par and stating that, in January 2013, Par restructured Strativa, reducing the workforce by over half and refocusing the remaining sales force on sales of Nascobal).) TWi points to no authority for the position that harm is not irreparable where it only destroys a division of a company instead of the entire entity. Further, the 10-Q TWi cites indicates that sales of Megace ES make up over 50 percent of Strativa's total revenue. (*Id.* at 36.) In his declaration, John Ameres, the Vice President of Marketing and Business Analytics for Par, states that revenue from Megace ES goes back into funding Strativa's operations. (Ameres Dec. ¶ 17.) Given that generic drugs quickly overtake the relevant market, the court finds it likely that, should TWi launch its product, Strativa would quickly lose an essential part of its funding and likely be forced to close. This kind of harm is irreparable.[5] *See Standard Havens*, 897 F.2d at 515 (determining that "employee layoffs, immediate insolvency, and possible extinction" constituted irreparable harm to a company).

In addition, there is evidence that were TWi to enter the market only to be required to exit again, the price erosion and revenue losses Megace ES would suffer would be impossible to reverse completely. In his declaration, Ameres described the formulary system for ranking drugs for the purpose of calculating co-pays and how, once a generic is introduced, Megace ES could be dropped to a tier in which the co-pay is higher or even dropped from the formulary entirely so

[5] TWi claims in its opposition memorandum that Strativa is "already failing." The court finds no evidence of this in the record.

that insurance companies will not reimburse patients using the branded drug. (Ameres Decl. ¶¶ 8-12; *see also* Vandaele Decl. ¶¶ 12-13.) According to Ameres, even if TWi's generic were eventually pulled from the market again, Par would have to negotiate with the third-party payers to restore Megace ES's position on the formularies, which likely would require it to agree to discounted prices.[6] (Ameres Decl. ¶ 13.) In addition, Par would lose goodwill among patients who had begun purchasing the lower-priced generics prior to their removal. (*Id.* ¶ 14.) Although some of these harms might be compensable, as TWi claims,[7] it appears it would make the revival of Strativa impossible.

TWi claims that Par's delay in seeking this injunction demonstrates that any harm it would suffer is not in fact irreparable. Otherwise, according to TWi, Par would have sought an injunction sooner. (TWi Letter at 3-4.) Although TWi is correct that a delay in filing for an injunction militates against finding irreparable harm, the court is not persuaded that it overwhelms the evidence presented by Par here. Par did not wait until TWi actually launched its product. Further, TWi's predictions as to when it would obtain FDA approval to launch its generic have not been entirely accurate at other stages in this litigation such that Par's delay is necessarily unjustified. That Par waited, but acted before the harm was inflicted, is insufficient to undermine its showing of irreparable injury.

The court is persuaded that Par would suffer irreparable harm should TWi launch its

[6] TWi's expert, Harry Boghigian, states in his declaration that, despite already discounting Megace ES to get it on a formulary in the first place, Par would likely have to accept further discounts to get it back on after TWi's generic was pulled from the market. (Boghigian Decl., ECF No. 247, ¶¶ 18, 22.)

[7] TWi also claims that the experiences of other pharmaceuticals demonstrate that Par's claims of harm are baseless. The court does not find TWi's examples persuasive. As Par points out in its reply, Tylenol's reduction on the market was due to poisoned bottles, (*see* Boghigian Decl. ¶ 13), a circumstance completely different from that presented here. Although the Plavix example is closer to being on point because it involves the entry onto the market of a generic, it appears the drug held a completely different position in the market such that it is hard to draw comparisons to Megace ES. (*See id.* ¶ 14.)

product before the Federal Circuit has decided the appeal. *See, e.g., Standard Havens*, 897 F.2d at 515; *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382-83 (Fed. Cir. 2006) (finding the district court did not abuse its discretion in concluding that the producer of a branded drug would suffer irreparable price erosion from the presence of generics due to the tiered pricing system for pharmaceuticals); *Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 846, 854 (N.D. Ill. 2007) (finding irreparable injury where lost revenue and market share would result in lost good will and sales representatives)

IV. Injury to TWi and the Balance of Hardships

TWi claims it will be harmed by an injunction in four ways: 1) the launch of its product will be delayed, 2) the Megace ES market is eroding such that TWi will have an even smaller market within which to sell its generic after a delay, 3) a delay will cause TWi to lose expected funding for its research of new drugs, and 4) TWi will suffer reputational harm because it has already made public statements that a launch is imminent.

Should TWi ultimately prevail, when it does enter the market it will still have a 180-day exclusivity period. Thus, any revenue from that period is only time-shifted by the imposition of an injunction.[8] It claims, however, that it would lose a further exclusivity-like period because, as it estimates, another generic seeking to enter the market is about two years behind in receiving FDA approval. Even this type of harm, however, is easily remedied with damages. *See The Research Foundation of SUNY v. Mylan Pharm. Inc.*, 723 F. Supp. 2d 638, 661-62 (D. Del. 2010) (refusing to give much weight to any lost exclusivity beyond the statutorily guaranteed 180 days because any further time was not contemplated or guaranteed by the Hatch-Waxman scheme). The same is true of the allegedly eroding Megace ES market. Any erosion appears to

[8] The court notes that the length of delay is somewhat speculative as TWi has not yet obtained FDA approval for its ANDA.

be easily traceable, as TWi's expert has done, (*see* Trial Tr., ECF No. 195, at 65:19-67:25), and thus compensable.

Similarly, it appears funding for TWi's research arm would also only be delayed, not destroyed, by an injunction. Calvin Chen, TWi's President, states in his declaration that TWi's growth will slow or stop without the funding for research. (Chen Decl., ECF No. 246, ¶ 18.) Any slowing or halting, however, would only be temporary given that, should TWi ultimately prevail, it would still launch its product and receive the expected funding.

Finally, any reputational harm TWi will suffer from having already announced that its generic will launch soon appears to be somewhat of TWi's own making. It knew when it announced the impending launch that it was still involved in this litigation and that the Federal Circuit would be reviewing this court's earlier judgment that the '576 patent was invalid. TWi thus took a known risk in making the announcement and the court does not find any harm it may suffer from doing so particularly compelling for the purposes of this analysis.

In sum, TWi would not face the same kind of structural harm if the status quo is maintained that Par would suffer if it is not. Instead, it will suffer delayed revenue that it can recover through damages. Further, some of its harms are self-inflicted. Accordingly, the balance of the harms weighs in favor of granting a stay. *See, e.g.*, *Impax Labs., Inc. v. Aventis Pharm., Inc.*, 235 F. Supp. 2d 390, 396 (D. Del. 2002) (finding minimal hardship for an alleged infringer where it had not yet entered the market and a preliminary injunction would merely maintain the status quo for the duration of the litigation).

V. The Public Interest

The court recognizes that the public is served by the availability of low-cost generic

medications, especially where an invalid patent has previously barred their entry into the market. *See Abbott Labs.*, 500 F. Supp. 2d at 855. On the other hand, the public also has an interest in the protection of valid patents because it promotes innovation. *Id.*; *see also Biotechnology Indus. Org. v. Dist. of Columbia*, 505 F.3d 1343, 1347 (Fed. Cir. 2007) (recognizing the tension between the need for affordable drugs and promoting innovation with the availability of patents). This factor, therefore, is neutral. *See Standard Havens*, 897 F.2d at 516 (granting a motion for a stay pending appeal despite the fact that the public interest factor favored neither party); *In re Cyclobenzaprine*, 2011 WL 1980610, at *4 (same).

VI. Bond

Evaluating the four factors above, the court determines that an injunction pending appeal is proper. Further, the court will require Par to post a bond as a security against any losses TWi may suffer should it ultimately prevail on appeal. The parties disagree over the appropriate amount of the bond. It seems clear, however, that any bond should only cover losses TWi may suffer while the injunction is in place. Given that the median disposition time for appeals to the Federal Circuit is eleven months or less, (*see* Chart: Median Disposition Time for Cases Decided by Merits Panels, Fiscal Years 2004-2013[9]), and the fact that five months have already passed since Par filed its appeal of this court's judgment, the bond should cover potential losses over a six-month period.

According to TWi's expert's estimate of annual profits, TWi seeks $16.85 million to cover lost profits over six months.[10] (Boghigian Decl., ECF No. 247, ¶ 40.) This number is

[9] Available at http://www.cafc.uscourts.gov/images/stories/Statistics/med%20disp%20time%20merits_chart.pdf (last visited August 11, 2014).

[10] TWi also claims $2 million in lost inventory, but the court is unable to find any evidence that the inventory in which it has invested would be lost. (*See* Chen Decl. ¶ 15 (stating that upon learning it was likely to receive FDA approval , TWi invested $1.8 million in launch quantities of its drug).) In any event, any loss would seem to be

based on an average of Par's gross sales revenue over seventeen months ending with May 2014, TWi's expert's conclusion that TWi would be able to match the current price at which Par sells the branded version, and an assumption of a ninety-one percent gross margin. (*Id.* ¶¶ 37-41.) The court is persuaded that this number is too high, as it does not appear generics can often garner a price that matches the branded drug—in fact, such a result would seem to run counter to the entire branded/generic scheme—and because, as TWi claims, the market for the drug is eroding such that the sales data from the past year and a half would not be entirely indicative of the market over the next six months. Par claims the bond should only be $4.6 million, the amount an independent analyst estimated TWi would earn in the first 180 days of exclusivity for sales of its generic. (*See* Koh Decl. Ex. 3, ECF No. 231-3, at 8.)

Par's expert, on the other hand, estimates that Par will lose $20 million in annual operating profits should a generic enter the market. (Vandaele Decl. ¶ 11; *see also* Vandaele Reply Decl., ECF No. 255-2, ¶ 10 (stating the branded drug, Megace ES, generates $20 million in profits annually).) Seemingly, therefore, those operating profits would shift to TWi upon its entry. The court will thus impose a bond of $10 million, six months of Par's estimated operating profits. Although TWi will likely earn less in operating profits because it will be selling a generic, not a branded drug, the court finds that $10 million is a reasonable estimate of not only TWi's loss of potential revenue, but also its loss of some of its head start against other generic producers and the uncertainty around the Federal Circuit's timeline in rendering a decision.

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somewhat of TWi's own doing given that it knew this litigation was still ongoing and that the district court's judgment may be reversed on appeal.

CONCLUSION

Par's motion for a stay of this court's judgment pending appeal will be granted. The court grants the motion, however, on the condition that Par posts a bond in the amount of $10 million and that it moves to expedite its appeal in the Federal Circuit. A separate order follows.

August 12, 2014
Date

/S/
Catherine C. Blake
United States District Judge