

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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

MEMORANDUM

Plaintiffs Par Pharmaceutical, Inc. and Alkermes Pharma Ireland Limited (collectively, “Par”) filed suit in September 2011 against TWi Pharmaceuticals, Inc. (“TWi”) alleging infringement of U.S. Patent 7,101,576 (“the ‘576 patent”). After a bench trial, the court ruled on February 21, 2014, that the ‘576 patent was invalid as obvious. Par requested, and this court granted, an injunction pending resolution of the case on appeal. On August 12, 2014, the court ordered Par to post a \$10 million bond as security against any losses TWi might suffer over a six-month period. (Memorandum & Order, ECF Nos. 257, 258.) The FDA granted final approval to TWi’s generic on August 28, 2014. On appeal, the Federal Circuit vacated this court’s judgment and remanded the case “for further analysis of the food effect limitation consistent with [the Federal Circuit’s] precedent on inherency.” *Par Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1200 (Fed. Cir. 2014). On March 9, 2015, this court granted another injunction while it considered the case on remand, and ordered Par to post an additional \$6 million bond. (Memorandum & Order, ECF Nos. 279, 280.) On remand, and after oral argument, the court ruled (again) on July 28, 2015, that the ‘576 patent was invalid as obvious, and also ruled that it was invalid for lack of enablement. (Memorandum & Order, ECF Nos. 304, 305.) That same day, Par noted an appeal to the Federal Circuit and moved for an injunction

pending appeal. The court denied Par's motion, and the Federal Circuit affirmed this court's decision on December 15, 2015. *Par Pharm., Inc. v. TWi Pharms., Inc.*, 624 Fed. App'x 756 (Fed. Cir. 2015) (mem.). The matter presently before the court is TWi's motion to execute the injunction bonds (ECF No. 320).¹ For the reasons that follow, TWi may recover \$10 million on the first bond; \$2,720,966 on the second bond; and post-judgment interest as applicable.

Legal Standard

Federal Rule of Civil Procedure 65(c) authorizes a court to "issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." When a party is found to have been wrongfully enjoined, that party may recover proven damages, up to the full amount of the bond, that naturally and proximately resulted from the wrongful injunction. *See Glaxo Grp. Ltd. v. Leavitt*, 481 F. Supp. 2d 434, 437 (D. Md. 2007). Recoverable damages are those that were suffered during the period in which the bond was in effect, and those damages must be proven by a reasonable certainty. *Id.* (quoting 11A Wright & Miller, Federal Practice & Procedure § 2973 and *Univ. Lite Dist., Inc. v. Northwest Indus., Inc.*, 602 F.2d 1173, 1175 (4th Cir. 1979)).

Analysis

TWi seeks to recover the full \$16 million from both bonds, plus interest, claiming its proven damages far exceed this amount. Par disputes the assumptions and calculations underlying TWi's damages estimate, asserting that TWi is entitled to recover no more than \$3,787,759. While the parties dispute a number of factors in calculating their damage estimates, two primary points of contention emerge: (1) whether Par would have launched its authorized

¹ The court also has considered the associated motions to seal (ECF Nos. 322, 342, and 348), which are unopposed and will be granted.

generic if its injunction requests had been denied and TWi had proceeded with an at-risk launch, and (2) the size of the market had TWi been able to launch its generic at the time of the courts' injunctions. The court also must evaluate what price, costs per unit produced, and market share TWi has established by a reasonable certainty.

Par's Authorized Generic

As to the first point of dispute, TWi offers a damages estimate that assumes it would have been the only generic player in the market during the pendency of the injunction period.² Par vigorously disputes this point, arguing that it certainly would have launched its authorized generic in 2014 had TWi proceeded with its at-risk launch. In support of its position, Par points to the fact that it did indeed launch an authorized generic on July 28, 2015, the same day TWi launched its generic product after this court issued a second opinion finding the '576 patent invalid. Additionally, it points to contemporaneous documents showing that Par had the capability of launching an authorized generic in September 2014, and it offers affidavits from Par personnel stating that it would have launched the authorized generic had TWi proceeded with its launch.

Notwithstanding the evidence offered by Par establishing its capability of launching an authorized generic in 2014, TWi has pointed to sufficient evidence to establish by a reasonable certainty that Par would not have launched an authorized generic in September 2014 had this court denied its request for injunctive relief pending appeal. First, Par represented in its briefing that, had the court denied its initial request for injunctive relief, "Par expects that the generic product will capture virtually the entire market for branded Megace® ES sales in a matter of days or weeks." (Mem. Supp. Mot. TRO 13, ECF No. 229.) Par made no mention of the

² TWi also argues that Par should be judicially estopped from claiming it would have launched its authorized generic after offering contradictory statements to this court during consideration of the initial injunction. It is not necessary to reach this question.

mitigating effects of launching an authorized generic in its arguments regarding irreparable harm. Further, Par offered the expert declaration of Dr. Walter Vandaele in support of its motion for a Temporary Restraining Order, in which Dr. Vandaele states that “the vast majority of Megace® ES sales would be lost to competition from TWi’s generic megestrol ES within a few months or even weeks of TWi’s market entry, and essentially all Megace® ES sales would be lost to the generic thereafter.” (Decl. Vandaele Supp. Mot. TRO 3, ECF No. 235.) Dr. Vandaele made no mention of an authorized generic when considering the impact of a “premature” TWi launch. Indeed, the only contemporaneous statement to the court acknowledging even the possibility of an authorized generic launch was contained in Par’s reply brief in support of its TRO motion, addressing the appropriate amount for an injunction bond: “Further, TWi’s bond calculations fail to address the economic reality that Par would need to compete on price to retain market share, including potentially by launching its own generic product through the normal generic channels of trade.” (Reply Supp. Mot. TRO 20, ECF No. 255.) The court sees no reason to credit this single, hedged statement over Par’s affirmative representations of what would happen in the case of a premature TWi launch. Finally, while these statements alone might not be sufficient to establish a reasonable certainty, the litigation posture in August 2014 was significantly different from July 2015, when Par actually launched its authorized generic. Namely, in August 2014, Par was appealing this court’s finding of invalidity, and expressed great certainty that it would prevail at the Federal Circuit: “Plaintiffs have a substantial chance of reversing this case on appeal Plaintiffs have shown that they are likely to succeed on the merits on appeal.” (Reply Supp. Mot. TRO 2, ECF No. 255.) Given this apparent certainty, it is not likely that Par would have launched its own generic and accepted the inevitable and irreversible price erosion that would follow. Taken together, Par’s contemporaneous statements

to this court establish by a reasonable certainty that it would not have launched an authorized generic while its appeal was pending.

A different scenario existed, however, at the time of the court's second injunction in March 2015. The Federal Circuit had remanded the case to this court, but only on one limited issue that did not portend the court reaching a new finding on the issue of invalidity. At this point, Par reasonably could have expected that TWi ultimately might succeed on its claims. Thus, Par's conduct in July 2015—launching its authorized generic alongside TWi's generic launch—is illustrative of the conduct Par likely would have taken had the court denied its second request for injunctive relief in light of its impending reconsideration of the case. Accordingly, while TWi has established by a reasonable certainty that it would have been the only generic player on the market from August 28, 2014, until March 9, 2015, there is a much higher likelihood that Par would have launched its authorized generic had the court denied its request for injunctive relief on March 9, 2015.

The “but for” market, then, for the purposes of calculating recoverable damages on the injunction bonds, contemplates TWi being the only generic on the market from August 28, 2014, until March 8, 2015, and Par launching its authorized generic on March 9, 2015 (at the start of the time period covered by the second bond).

Price, Market Share, and Costs per Unit

To calculate recoverable damages, the court must ascertain the price at which TWi could have sold its generic product, and the share of the market TWi would have enjoyed had the injunctions not been issued. TWi contends that it would have charged \$ [REDACTED] per unit, which is approximately [REDACTED] % of the \$777.51 sale price of Par's Megace® ES product. Par does not offer evidence to contradict that TWi would have charged this amount if it had offered the only

generic on the market, and that price is consistent with estimates of generic drug pricing provided by the Federal Trade Commission and cited by Par's expert, Dr. Vandaele. (Suppl. Decl. Vandaele Supp. Mot. TRO 4, ECF No. 277-1.) Accordingly, TWi has established by a reasonable certainty that it would have charged \$ [REDACTED] per unit during the pendency of the first injunctive bond. TWi's expert, Craig Elson, assumed TWi would capture 88% of the market upon entry, which is consistent both with Par's predictions in its request for injunctive relief and reflective of the combined market share actually garnered by TWi's generic and Par's authorized generic after launching last year. The court will accept Mr. Elson's calculations of market share for the period covered by the first injunctive bond.

As for the time period covered by the second bond, the best evidence of the price per unit is what actually happened after the simultaneous launch of TWi's generic and Par's authorized generic on July 28, 2015. Having to compete with Par's authorized generic on pricing, TWi only has been able to charge an average of \$ [REDACTED] per unit. Thus, for the time period covered by the second bond, TWi's damages will be calculated using a price of \$ [REDACTED] per unit. A closer question is what market share TWi would have enjoyed during the time period of the second bond in this but-for world. While TWi has enjoyed less than 40% of the market share since launching alongside Par's authorized generic, in the but-for world governing the court's analysis, TWi would have launched its product several months before Par launched its authorized generic. While TWi certainly would have lost market share due to competition from the authorized generic, the amount of that loss has not been considered or quantified by the parties' experts. Without expert testimony on this matter, the court cannot say with reasonable certainty that TWi would have maintained its 88% market share. Accordingly, the court will look to the best evidence in front of it, the market share split after the actual launch of the two generics.

Considering this split, and the benefits inherent in being the first generic to market, the court finds that TWi can establish by a reasonable certainty that it would have captured approximately 50% of the market share during the time period of the second bond, as that is approximately the amount Par maintained when it had the benefit of launching an authorized generic.

Finally, in order to calculate damages, the court must consider the costs per unit to TWi. TWi claims per-unit expenses of \$ [REDACTED] (Pallokat Decl. ¶ 19, ECF No. 321-2.) Par does not challenge this assertion, and it is accepted for the purposes of this damages analysis.

Market Expansion Effect

A more difficult question is whether, and to what degree, TWi's entry would have expanded the market in this but-for world. Both parties' experts opine on market growth, with Mr. Elson for TWi claiming a 56.4% anticipated expansion upon entrance of its generic product, and Dr. Vandaele offering a rebuttal affidavit claiming that TWi has not proven its market expansion estimate by a reasonable certainty.

Mr. Elson reaches his 56.4% rate by conducting a regression-based forecast developed from pre-generic introduction IMS data. Using his regression analysis for a continually declining sales rate, he calculates what the expected sales would have been for July–December 2015 had no generic entered the market. He compares these numbers to the actual combined sales following introduction of TWi and Par's competing generics into the marketplace in July 2015. (Elson Decl., Ex. 5, ECF No. 321-1.) From these numbers, he calculates an average 56.4% increase over the projected units sold during this time period. Dr. Vandaele offers a competing log-linear analysis to show a slower decline rate, resulting in only a 13.6% expansion during this post-introduction time period. For the reasons stated in Mr. Elson's reply declaration—namely, that Dr. Vandaele failed to implement his regression properly when

specifying the starting value for the first month of his regression set—the court finds Mr. Elson’s analysis more reliable and persuasive (but only for the time period covered by the second injunctive bond, for the reasons set forth below). (Elson Reply Decl. ¶ 33, ECF No. 347-1.)³

Dr. Vandaele claims Mr. Elson’s calculation ignores the offsetting contraction effect that would have accompanied Par’s withdrawal of promotion support for Megace® ES at the time TWi’s generic hit the market. While Par correctly notes that it still had funds and staff allocated to promoting the Megace® ES product in September 2014, its arguments on this front are insufficient to cast sufficient doubt on Mr. Elson’s estimates. Par offers an affidavit asserting that several million dollars were allocated for salesforce detailing and other promotional efforts for Megace® ES in FY 2014 and FY 2015, but cannot deny that in January 2013, Strativa (the branded unit responsible for promoting Megace® ES) reduced its sales force by over 50% in anticipation of entering into a settlement agreement with the U.S. Department of Justice over its marketing of Megace® ES, and that the remaining Strativa staff focused their marketing efforts principally on Nascobal®. Thus, it is perfectly reasonable for Mr. Elson’s estimate to treat marketing efforts by Par as having a negligible effect on the expansion rate of the market, particularly considering that the effect of this reduction in marketing efforts would have been more pronounced at the time of the real-world launch of the competing generics in 2015, the time period to which Mr. Elson looks in calculating his expansion rate.

Dr. Vandaele also criticizes Mr. Elson’s reliance on the real-world, post-generic introduction sales because any growth was likely attributable to one-time pipeline purchases to fill inventories. As explained in Mr. Elson’s reply declaration, any potential inventory is not

³ Additionally, as reflected in Mr. Elson’s reply declaration, when Dr. Vandaele’s analysis is adjusted to account for the correct starting value, the R2 statistics for the two models show that Mr. Elson’s linear trend is more reliable in explaining the movement observed in the historical data. (Elson Reply Decl. ¶ 37, ECF No. 347-1.)

captured in the IMS NSP data upon which Mr. Elson relied to calculate his 56.4% expansion rate. Par's criticisms of Mr. Elson's estimates do not hold water, and will not be credited in the court's damages analysis. Mr. Elson has employed statistically reliable methodology using the best available data to predict an expansion rate of 56.4% in a two-generic market.

Mr. Elson's consideration of sales data from a time period in which two generic drugs were on the market is not indicative, however, of what the damages would have been during the time period of the first injunctive bond. He does not explain why his estimate of market expansion would hold true if only TWi's product were on the market at a significantly higher price than that charged for the two competing generics in 2015. Accordingly, the court will not credit any market expansion (none having been proven by a reasonable certainty) for the duration of the first bond period, during which TWi would have charged \$ [REDACTED] per unit. The court will apply this expansion estimate, however, in calculating damages for the time period of the second bond, as the but-for market would then include both TWi and Par as generic competitors.

Amount of Damages

With the above issues resolved, the court must calculate the damages incurred during each of the two bond periods.⁴ The first bond covers a six-month period beginning on the date the FDA approved TWi's ANDA, August 28, 2014. For this time period, as explained above, the relevant assumptions are that TWi would receive \$ [REDACTED] in net revenue per unit and obtain 88% of the market share, with costs per unit of \$ [REDACTED] and no market expansion. Adjusting Mr. Elson's calculations, (Elson Decl., Ex. 1.6, ECF No. 321-1), based on these considerations, TWi's lost profits for this time period are as follows: \$2,257,401 for September 2014; \$2,033,642 for October 2014; \$1,841,297 for November 2014; \$2,228,404 for December 2014;

⁴ Notwithstanding TWi's arguments to the contrary, a party may recover only those damages incurred during the period of time in which the bond was in place. Thus, the court will not award damages for the time period following TWi's generic launch in July 2015.

\$1,804,568 for January 2015; and \$1,618,988 for February 2015. The sum of these monthly losses is \$11,784,300. Thus, TWi is entitled to recover the full \$10 million on the first bond. See *First-Citizens Bank & Trust v. Camp*, 432 F.2d 481, 484 (4th Cir. 1970).

The second bond covers a period from March 9, 2015, until July 28, 2015, the day the court reinstated its judgment finding the '576 patent invalid, and TWi and Par launched their competing generic products. For this time period, as explained above, the relevant assumptions are that TWi would receive \$ [REDACTED] net revenue per unit and obtain 50% of the market share, with costs of \$ [REDACTED] and a market expansion rate of 56.4%.⁵ Adjusting Mr. Elson's calculations, (Elson Decl., Ex. 1.1, ECF No. 321-1), based on these considerations, TWi's lost profits for this time period are as follows:⁶ \$586,168 for March 2015; \$541,365 for April 2015; \$540,951 for May 2015; \$701,378 for June 2015; and \$323,332 for July 2015. Thus, TWi is entitled to recover \$2,693,194 in damages on the second bond, plus pre-judgment interest as calculated below.

Lost Product Damages

Additionally, TWi seeks to recover damages for lost products—that is, product TWi had to destroy because it became unsaleable based on its reduced shelf life during the injunction period. TWi, however, offers only the declaration of Mr. Pallokat, with its conclusory assertions that certain amounts of product—manufactured while this litigation was ongoing—became “unsaleable based on its reduced shelf life.” (Pallokat Decl. ¶ 21, ECF No. 321-2.) Although

⁵ The court notes that Mr. Elson's calculations do not apply the 56.4% expansion rate to the month of July 2015, and thus the court will not apply it in its damages calculation.

⁶ To account for the fact that the bond period did not begin until March 9, 2015, and ended on July 28, 2015, the court must adjust the actual total units sold (the starting point for calculating lost profits) to reflect those days in March and July not covered by the bond period. The actual units sold in March 2015 was 4,894, thus, for the purposes of calculating damages during the first bond period, the court will deduct 1,264 units (an average of 157.87 units per day for 31 days = 4,894 units; eight days x 158 units = 1,264 units) for a starting point of 3,630 units in March 2015. The actual units sold in July 2015 was 4,119, thus, for the purposes of calculating damages during the second bond period, the court will deduct 532 units (an average of 132.87 units per day for 31 days = 4,119 units; four days x 133 units = 532 units) for a starting point of 3,587 in July 2015.

TWi is correct that Par previously stated it was “prepared to compensate TWi’s actual expenditures on any existing launch stock that drops below 15 months of shelf life during the injunction,” (Reply Supp. Mot. Inj. Bonds 18, ECF No. 347 (citing Reply Supp. Mot. TRO 9-10, ECF No. 255)), TWi should have offered more than Mr. Pallokát’s unsupported declaration to establish its entitlement to these damages by a reasonable certainty. Accordingly, no damages will be awarded for any lost product.

Pre-Judgment and Post-Judgment Interest

Finally, the parties dispute the rate and time period for awarding pre-judgment interest in this case. As an initial matter, pre-judgment interest would run from the issuance of each bond through the date of judgment. Because TWi’s proven damages for the first bond period exceed the amount of the bond, however, the court will not award pre-judgment interest on the first bond. *See First-Citizens Bank & Trust v. Camp*, 432 F.2d 481, 484 (4th Cir. 1970); *Sprint Comms. Co. L.P. v. CAT Comms. Int’l, Inc.*, 335 F.3d 235, 240-41 (3d Cir. 2003) (reasoning that an injunctive bond “limits liability at the amount posted when the applicant accepted the preliminary injunction”). Regarding judgment, the opinion issued on July 28, 2015, establishes TWi’s right to recover on the bonds and thus is the appropriate “judgment” by which to delineate pre- and post-judgment interest. *Cf. Mathis v. Spears*, 857 F.2d 749, 760 (Fed. Cir. 1988) (“[Post-judgment] [i]nterest on an attorney fee award thus runs from the date of the judgment establishing the right to the award, not the date of the judgment establishing its quantum.”).

TWi will be awarded pre-judgment interest on the second bond period at Maryland’s simple (not compounded) statutory rate of 6%. “Generally, ‘the interest rate prescribed for post-judgment interest under 28 U.S.C. § 1961 is appropriate for fixing the rate of pre-judgment interest unless the trial judge finds, on substantial evidence, that the equities of a particular case

require a different rate.” *Feldman’s Med. Ctr. Pharmacy, Inc. v. CareFirst, Inc.*, 823 F. Supp. 2d 307, 326 (D. Md. 2011) (quoting *Blankenship v. Liberty Life Assurance Co. of Boston*, 486 F.3d 620, 628 (9th Cir. 2007)). “The essential rationale for awarding prejudgment interest is to ensure that an injured party is fully compensated for its loss.” *City of Milwaukee v. Cement Div., Nat’l Gypsum Co.*, 515 U.S. 189, 195 (1995). The equities in this case favor a higher pre-judgment interest rate than that provided in § 1961 for post-judgment remedies. In particular, TWi suffers from ongoing losses due to its delayed entry into the market—losses that it will not recover because they occurred after the pendency of the bond period. Maryland’s statutory rate of 6% is reasonable, *see Beckman Instruments Inc. v. LKB Produkter AB*, No. R-85-3133, 1990 WL 10072480, at *11 (D. Md. Aug. 9, 1990) (applying Maryland’s then-statutory rate of 10% for pre-judgment interest and noting “a number of other courts have looked to the state statutory rate of interest when awarding prejudgment interest in patent cases”),⁷ and will ensure TWi is compensated for its losses. Adjusting Mr. Elson’s calculations, (Elson Decl., Ex. 10.0, ECF No. 321-1), based on the damages specified above, TWi is entitled to pre-judgment interest as follows for the second bond period: \$11,466 for March 2015; \$7,920 for April 2015; \$5,158 for May 2015; and \$3,228 for June 2015. Accordingly, TWi will be awarded a total of \$27,772 in pre-judgment interest on the second bond. TWi also will be entitled to post-judgment interest at the rate dictated by § 28 U.S.C. 1961.⁸

⁷ Unpublished cases are cited for the soundness of their reasoning, not for any precedential value.

⁸ The parties have stipulated that, “[i]n the event that there is a final order in this case requiring Par to pay post-judgment interest for the period following expiration of the injunction, and if such ordered amount of post-judgment interest exceeds the amount of any applicable bond, Par will pay the amount of such interest.” (Stip. ¶ 6, ECF No. 316.)

CONCLUSION

In accordance with this opinion, TWi may recover a total of \$10 million on the first bond, \$2,720,996 on the second bond, and post-judgment interest as applicable.

A separate order follows.

9/27/16
Date

/s/
Catherine C. Blake
United States District Judge