IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER INTELLECTUAL PROPERTY GMBH, and BAYER HEALTHCARE PHARMACEUTICALS INC.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 12-1726-LPS
WATSON LABORATORIES, INC.,	:	
Defendant.	:	

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MEMORANDUM OPINION

December 28, 2016
Wilmington, Delaware

STARK, U.S. District Judge:

In this patent litigation brought by Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. ("Bayer" or "Plaintiffs") pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(j), the Court held a bench trial, thereafter ruling that the generic drug product[1] proposed to be marketed by Defendant Watson Laboratories, Inc. ("Watson" or "Defendant") would infringe Bayer's valid U.S. Patent No. 8,071,577 ("the '577 patent"). (*See* D.I. 153, 154) After issuing an extensive post-trial Opinion, the Court directed the parties to file a proposed final judgment order. (D.I. 154) In response, the parties advised the Court that they disagreed as to whether the relief the Court would be awarding Plaintiffs should include a permanent injunction against Defendant and its employees making, selling, using, or offering for sale its generic product. (*See* D.I. 156) Thereafter, the Court ordered (*see* D.I. 157, 159) and received additional briefing directed to this dispute. (*See* D.I. 160, 161, 162, 163) Having reviewed the parties' submissions, the Court has determined that Plaintiffs have failed to show that the requested permanent injunction is warranted.

The parties agree that (in light of the Court's Opinion) the Court must enter judgment for Plaintiffs and against Defendant. The parties further agree that the relief the Court provides Plaintiffs must include an order that the United States Food and Drug Administration ("FDA") reset the approval date of Defendant's Abbreviated New Drug Application ("ANDA") until after the expiration of the '577 patent.[2] *See* 35 U.S.C. § 271(e)(4)(A). The parties disagree as to

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[1]Watson's proposed generic drug product is a generic version of Plaintiffs' Natazia®, a comprehensive oral contraceptive.

[2]The parties "agreements" that are noted in this paragraph are without prejudice to the parties' rights to appeal the Court's rulings.

whether the Court should additionally enter an order enjoining Defendant from infringing the patent-in-suit before it expires. *See* 35 U.S.C. § 271(e)(4)(B).[3]

Plaintiffs seek the additional injunctive relief against Defendant "because otherwise there is no Court Order preventing [Defendant] from infringing the [patent-in-suit] before it expires." (D.I. 156 at 1) In the absence of an injunction, Plaintiffs fear they may "have to undertake additional, duplicative infringement litigation in order to enforce a patent that has already been found valid and infringed" by Defendant's generic product. (*Id.*)

Defendant counters that an injunction is discretionary, not mandatory, and that Plaintiffs have failed to meet their burden to show it should be imposed here. (*See id.* at 2) Defendant further asserts that an injunction would be redundant, as it would not preclude any commercial activity that is not otherwise already precluded by the agreed-upon order the Court will direct to the FDA. (*See* D.I. 163 at 3)

Effectively, the parties' dispute seems to be whether to limit Defendant solely to research activities that are within the Hatch-Waxman Act's "safe harbor," 35 U.S.C. § 271(e)(1), or

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[3]The specific additional remedial language proposed by Bayer and opposed by Watson is as follows:

> Pursuant to 35 U.S.C. § 271(e)(4)(B), Watson and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby permanently enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Watson's proposed generic version of Bayer HealthCare's Natazia® combined oral contraceptive that is the subject of Watson's ANDA No. 202349 during the term of the '577 patent.

(D.I. 156 Ex. A at ¶ 4)

whether instead to allow Defendant to engage in all research and pre-commercialization activity that could precede a launch of a generic product. While there may be valid reasons to limit Defendant's activities to the extent Plaintiffs request, here Plaintiffs have failed to create a record which would justify such relief.

In order to obtain a permanent injunction, a party with a valid and infringed patent must show that the following factors favor the requested relief: (i) the patent holder has suffered or will suffer irreparable injury or harm, (ii) legal remedies are inadequate to compensate that injury, (iii) balance of hardships, and (iv) the public interest. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006); *see also Alcon, Inc. v. Teva Pharm. USA, Inc.*, 2010 WL 3081327, at *2 (D. Del. Aug. 5, 2010) (explaining that prevailing patentee in ANDA case is not automatically entitled to § 271(e)(4)(B) injunction but, instead, must demonstrate that *eBay* factors warrant such relief and persuade Court to exercise discretion to grant it).

Bayer has failed to show that it will suffer irreparable harm in the absence of its requested additional injunctive relief. Bayer's position largely relies on a series of speculations as to "illegal activity" Watson might undertake if the Court does not grant Bayer its full requested relief, such as "manufacture, importation, offers to sell, or the use of its generic ANDA product" and "working with and licensing with a third party for purposes of facilitating a second ANDA filing behind the veil of the third party company." (D.I. 160 at 3) Bayer further speculates that to detect and deter such "illegal activity" it will be forced to undertake "extensive monitoring" and "future litigation to relitigate issues already decided." (*Id.*) Plaintiffs also submit that they have already suffered irreparable harm because, "as a direct consequence of Watson's ANDA filing, it became economically irrational for Bayer to promote Natazia." (D.I. 162 at 2) The Court is not

persuaded.

It is true, as Bayer contends, that Watson seeks to be a direct competitor of Bayer in the market for Natazia® and has committed an "act of infringement" (albeit an "artificial" act) by filing an ANDA. (D.I. 162 at 1-2) But these facts alone are insufficient to establish irreparable harm in all ANDA cases. *See generally Alcon*, 2010 WL 3081327, at *2. Bayer presents little evidence to support its claim that it will be irreparably harmed in the absence of an injunction. As Watson correctly observes, "Bayer does not submit any data to explain the general magnitude of potential lost revenues or establish any harm to itself as a company." (D.I. 161 at 4) Although Bayer suggests that it has already been harmed due to changing its marketing plans for Natazia®, Bayer has not proven that Watson's ANDA filing caused those changes. *See Apple Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1363 (Fed. Cir. 2013) ("[T]he purpose of the causal nexus requirement is to show that the patentee is irreparably harmed by the infringement."). Indeed, the testimony Bayer relies on suggests that other factors, such as the timing of FDA approval of indications, played a significant role in Bayer's marketing decisions. (*See* D.I. 160 Ex. A at 337) While Defendant's launch of a generic product during the life of the patent is the type of activity that could result in irreparable harm to Bayer, Plaintiffs' speculation that Defendant will risk criminal sanctions by launching its generic product into the market without FDA approval strikes the Court as entirely unfounded, and FDA approval will not happen until after the expiration of the patent. Moreover, the possible necessity of future litigation with Defendants is slight, and litigation costs cannot support a finding of irreparable harm. *See ActiveVideo Networks, Inc. v. Verizon Comm., Inc.*, 694 F.3d 1312, 1337 (Fed. Cir. 2012) ("Reliance on litigation costs to support a determination of irreparable harm [is] legal error."). Further support for the conclusion

that Bayer has failed to prove irreparable harm is the evidence of the relatively small sales of Natazia®, and the drug's seemingly close-to-inconsequential place in Bayer's overall portfolio of corporate activities. (*See generally id.* at 1-2) (summarizing evidence) Generally, the record lacks evidence of irreparable harm.[4]

Bayer has also failed to show that the remedies available to it at law are inadequate. The costs of litigation, including any future litigation, are quantifiable and can be compensated by money damages. As with the irreparable harm factor, Bayer hypothesizes there could be "a premature product launch," by which Watson would "flood the market with lower priced generics" before FDA approval. (D.I. 160 at 3) However, as Bayer acknowledges, this would subject Watson "to significant penalties." (*Id.* at 3 n.1) Watson contends, without contradiction, that such penalties would be both civil and ***criminal***. (D.I. 161 at 3) It seems unlikely that if Watson – which is in the business of developing and marketing drug products in the United States, all of which require FDA approval – proves willing to risk its relationship with the FDA in order to prematurely and unlawfully launch its generic version of this one product, Natazia®, that an additional order from this Court would prove to be the dispositive deterrent to such unlawful conduct. Thus, Plaintiffs have not demonstrated that legal remedies are inadequate. *See also Alcon*, 2010 WL 3081327, at *3 (explaining that § 271(e)(4)(A) relief, delaying FDA approval of ANDA, "effectively precludes practice of the [patent-in-suit] outside the context of experimentation . . . until after the patent's expiration," supporting a finding that adequate legal remedies for harm to patentee do exist).

[4]It is notable that Bayer, after failing to make a record of irreparable harm at trial, also chose not to take advantage of the additional opportunity the Court provided the parties – after issuing its Opinion – to present additional evidence. (*See* D.I. 157, 159)

Bayer has succeeded in showing that the balance of hardships favors its requested additional injunctive relief. Bayer stands to lose some of the value of its patent if "infringing activity" is permitted to occur during the life of the patent. By contrast, there would be little, if any, harm to Watson were the Court to grant Bayer's requested injunction. Watson suggests that the requested injunction would "prevent[] Watson from making or using or experimenting with its ANDA product," which could "chill further experimentation on the product." (D.I. 161 at 4-5) But Watson does not address whether some of these activities would fall within the safe harbor of § 271(e)(1). Also, the record contains no evidence as to how much more quickly, if at all, Watson could launch its proposed generic product (following FDA approval) without the injunction as compared to with the injunction in place. Thus, while there is little evidence of harm on either side of the balance, the Court concludes from the record that the balance of hardships slightly favors Bayer.

Finally, the public interest also appears, slightly, to favor Bayer. Here, the public has an interest in having what could be a somewhat earlier launch of a generic drug, which favors Watson, but the public also has an interest in protecting valid patents and encouraging investment in new pharmaceutical products. Neither side presented evidence on these points. However, given that the FDA already must delay approval of the product until after the expiration of the patent, the Court finds that the public interest would not be disserved by an additional injunction of equal duration being directed to Watson.

In sum, Bayer has failed to show irreparable harm or that the remedies available at law are inadequate, although Bayer has succeeded in showing that the balance of harms and the public interest do support the additional requested injunction. Weighing all of the pertinent

considerations, the Court has determined that the most reasonable exercise of its discretion is to deny the requested permanent injunction.

Accordingly, the Court will sign and docket the final judgment order proposed by Watson.