IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ALCON, INC. and ALCON RESEARCH, LTD.,	)	
Plaintiffs,	)	
v.	)	Civ. No. 06-234-SLR
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this 5th day of August, 2010, having reviewed plaintiff's motion for an amended judgment order (D.I. 126) and the papers submitted in connection therewith;

IT IS ORDERED that plaintiff's motion is granted in part and denied in part, as follows:

1. **Background**. The present motion arises out of a patent infringement action involving U.S. Patent No. 6,716,830 ("the '830 patent"), belonging to plaintiffs Alcon, Inc. and Alcon Research, Ltd. (collectively, "Alcon"). The '830 patent issued from PCT application US 99/22622, which was filed on September 29, 1999. (D.I. 79, ex. 1 at ¶ 17) Alcon brought its suit against Teva on April 5, 2006, alleging infringement pursuant to 35 U.S.C. § 271(e)(2)(A).[1] (D.I. 1) Alcon asserted that Teva's Abbreviated New Drug Application ("ANDA") No. 78-073, filed on or about December 25, 2005 (D.I. 79, ex. 1 at

[1]"(2) It shall be an act of infringement to submit – (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent[.]"

¶ 30), infringed the '830 patent, which covers a topical ophthalmic solution comprised of the active ingredient moxifloxacin hydrochloride. (D.I. 1, Ex. C)

2. In an opinion dated October 19, 2009, the court found that claim 1 of the '830 patent was valid and infringed. (D.I. 122) In its October 19, 2009 order (D.I. 12), the court instructed the Clerk of Court to enter final judgment in favor of Alcon, but did not order injunctive relief or an FDA approval date for Teva's ANDA. Presently before the court is Alcon's motion to amend the judgment (D.I. 126) pursuant to Federal Rule of Civil Procedure 60(a),[2] requesting a declaration of the effective date of ANDA No. 78-073 under 35 U.S.C. § 271(e)(4)(A) and the entry of a permanent injunction under 35 U.S.C. § 271(e)(4)(B).

3. **Effective Date**. As a preliminary matter, Alcon is entitled to a declaration that the Food and Drug Administration ("FDA") may not approve Teva's ANDA prior to March 30, 2020. Under section 271(e)(4)(A) of Title 35, when the filing of an ANDA is found to be an infringing act, "the court **shall** order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." (emphasis added) The '830 patent expires twenty years after the September 29, 1999 filing date of its parent

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[2]Corrections Based on Clerical Mistakes; Oversights and Omissions. The court may correct a clerical mistake or a mistake arising from oversight or omission whenever one is found in a judgment, order, or other part of the record. The court may do so on motion or on its own, with or without notice. But after an appeal has been docketed in the appellate court and while it is pending, such a mistake may be corrected only with the appellate court's leave.

Fed. R. Civ. P. 60(a).

application. (D.I. 79, ex. 1 at ¶ 17); 35 U.S.C. § 154. Thus, the court must order that the FDA not approve Teva's ANDA prior to the September 29, 2019 expiration date of the '830 patent. In addition, Alcon was granted a pediatric exclusivity period for six months following expiration of the '830 patent. 21 U.S.C. § 355a(c)(1)(B)(ii); *see AstraZeneca AB v. Impax Laboratories, Inc.*, 490 F. Supp. 2d 368, 371 (S.D.N.Y. 2007) (describing the requirements for receiving market exclusivity for pediatric testing). "If the drug is the subject of a Paragraph IV certification 'and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under [21 U.S.C. § 355(j)(5)(B)] shall be extended by a period of six months after the date the patent expires (including any patent extensions).'" *Id.* at 372 (citing 21 U.S.C. § 355a(c)(2)(B)). Accordingly, it is appropriate for the court to order that the FDA not approve ANDA No. 78-073 until March 30, 2020.

4. **Injunctive Relief**. Alcon asserts that it is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B), which states, "injunctive relief **may** be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product" (emphasis added); *see Voda v. Cordis Corp.*, 536 F.3d 1311, 1329 (Fed. Cir. 2008) (affirming the denial of a permanent injunction where generic drug manufacturer lost infringement decision). In order to establish that an injunction is warranted, a plaintiff must demonstrate: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the

plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). "The decision to grant or deny permanent injunctive relief is an act of equitable discretion by the district court, reviewable on appeal for abuse of discretion." *Id.* (citing *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311-13 (1982)). In the case at bar, the court must determine whether to enjoin Teva from the "commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of" the moxifloxacin opthalmic solution covered by the '830 patent. 35 U.S.C. § 271(e)(4)(B).

5. Alcon's assertion that it is entitled to a permanent injunction is seriously undermined by its failure to prove that it has suffered irreparable harm. Alcon's sole argument in this respect is that any deprivation of its right to exclude others constitutes irreparable harm to the monopoly granted by the '830 patent. This argument is unavailing. *See eBay*, 547 U.S. at 392 (holding that a patentee's "statutory right to exclude alone [does not justify] [a] general rule in favor of permanent injunctive relief," and that "injunctive relief 'may' issue only 'in accordance with the principles of equity.'") (citations omitted). Alcon cites two cases to support its irreparable harm argument. Both are inapposite. In *Martek Biosciences Corporation v. Nutrinova Incorporated*, 520 F. Supp. 2d 537 (D. Del. 2007), *aff'd in part*, 579 F.3d 1363 (Fed. Cir. 2009), the court found irreparable harm where the patentee spent $60 million to acquire the patents-in-suit, lost market share to the defendant, and attributed a commercial value to the right to exclude within the food and beverage industry. 520 F. Supp. 2d at 558. In a pre-*eBay* decision, *Honeywell International, Incorporated v. Universal Avionics Systems*

Corporation, 397 F. Supp. 2d 537 (D. Del. 2005), the court presumed irreparable harm based on the infringement of a direct competitor. 397 F. Supp. 2d at 545. Neither case supports Alcon's argument with respect to irreparable harm. Because of the relief requested under 35 U.S.C. § 271(e)(4)(A), *supra*, Teva will not be able to market its proposed moxifloxacin opthalmic product prior to the day six months after the expiration of the '830 patent, which necessarily prevents Teva from usurping any market share or goodwill from Alcon. Further, any use of the patented drug by Teva must be private and non-commercial and, therefore, cannot irreparably harm Alcon's "full enjoyment and protection of [its] patent rights." *Id.* Accordingly, Alcon cannot establish irreparable harm sufficient to satisfy the first permanent injunction factor.

6. Similarly, Alcon cannot prove that remedies available at law are inadequate to compensate for Teva's infringement. Again, Alcon rests solely on the argument that an injunction is required to repair the harm caused by the deprivation of its right to exclude. As discussed above, a remedy exists under 35 U.S.C. § 271(e)(4)(A) which prevents the FDA from approving Teva's ANDA until March 30, 2020. This effectively precludes practice of the '830 patent outside of the context of experimentation by any person or entity except for Alcon until after the patent's expiration. *See Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1133 n.2 (Fed. Cir. 1995) (referring to pediatric exclusivity period as "statutory bar" against FDA approval of ANDA). Once the '830 patent has expired, Teva may practice the invention, but will still have to wait six months before it can bring a product to market. 35 U.S.C. § 271(e)(4)(A). Without more, Alcon cannot prove that an adequate remedy at law does not exist.

7. Alcon has not met its burden in establishing that the balance of hardships tips

in its favor if injunctive relief is denied. Alcon merely asserts that the entry of an injunction maintains the status quo because the pediatric exclusivity period prevents Teva from marketing its drug until six months after the expiration of the '830 patent. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361-63 (Fed. Cir. 2008). Alcon does not assert that it will experience any hardship beyond the deprivation of its right to exclude Teva from experimental use of the '830 patent. At most, this factor is neutral to both parties.

8. Finally, Alcon cannot show that the public interest will suffer if a permanent injunction is not entered. Although there is a "significant public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents," *id.*, enjoining Teva from use of the '830 patent does not "promote the Progress of . . . useful Arts." U.S. CONST. art. I, § 8, cl. 8. On the contrary, because Teva cannot market its drug during the term of the patent, the only effect of an injunction would be to deprive the public of the benefit of Teva's developmental efforts. Because Alcon has not shown irreparable harm, the incentives provided "to inventors to risk the often enormous costs in terms of time, research, and development," are not implicated here. *Abbott Labs.*, 544 F.3d at 1363. Accordingly, the equities weigh in favor of Teva.

9. **Conclusion**. In view of the foregoing, Alcon's request for a permanent injunction is denied. An amended order shall issue.

United States District Judge