

Resolution of this matter requires the Court to analyze three distinct statutory provisions; therefore, the Court will provide a brief overview of the relevant provisions. For a detailed explanation, see Mylan Labs., Inc. v. Thompson, 389 F.3d 1272 (D.C. Cir. 2004); Barr Labs., Inc. v. Thompson, 238 F. Supp. 2d 236 (D.D.C. 2002).

1. The Hatch-Waxman Amendments

21 U.S.C. § 355(j), a provision of the 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA"), "creates an approval shortcut for applicants seeking to market generic versions of approved drugs." Thompson, 389 F.3d at 1274-75. Section 355(j) permits a generic applicant to file an abbreviated new drug application ("ANDA") with the U.S. Food and Drug Administration ("FDA") certifying that the generic version is bioequivalent to an approved drug, and thus avoid having to conduct its own clinical trials. Id. at 1275. The ANDA must include "a certification, that for each of the patents applicable to the pioneer drug, the proposed generic drug would not infringe the patent because (I) the patent information has not been filed; (II) the patent has expired; (III) the patent will expire on a stated date; or (IV) the patent is invalid or will not be infringed by the manufacture, use or sale of the drug for which the abbreviated application applicant seeks approval." 21 U.S.C. § 355(j)(2)(A)(viii), cited in Mylan

Labs., Inc. V. Leavitt, No. 07-579, 2007 WL 1241884, at *2 (D.D.C. Apr. 30, 2007). These certifications are referred to as Paragraphs I, II, III, and IV, respectively.

35 U.S.C. § 271(e)(2), a patent statute, also enacted in the Hatch-Waxman Amendments, creates a cause of action for patent infringement based solely upon the filing of an ANDA containing a Paragraph IV certification. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990). Section 271(e)(4) sets out the exclusive remedies available in a patent infringement action under § 271(e)(2):

For an act of infringement described in paragraph (2)-
(A) the court shall order the effective date of any approval of the drug or veterinary biological product in the infringement to be a date which is not earlier than the date of expiration of the patent which has been infringed,
(B) 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, and
(C) damages or other monetary relief may be awarded against an infringer only if there has been 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.

35 U.S.C. § 271(e)(4).

2. The Period of Market Exclusivity

In 1997, in an effort to encourage the pediatric testing of drugs, Congress passed the Food and Drug Administration Modernization Act, Pub. L. No. 105-115, 111 Stat. 2296 (1997),

which grants manufacturers of drugs that agree to conduct pediatric studies, six months of market exclusivity for their products. Ass'n of Am. Physicians & Surgeons, Inc. v. U.S.F.D.A., 226 F. Supp. 2d 204, 206 (D.D.C. 2002). 21 U.S.C. § 355a, the "pediatric exclusivity" provision, authorizes a patent holder to receive a six-month period of market exclusivity beyond the patent's expiration date, if the patent holder "has satisfactorily conducted pediatric testing of its drug upon the FDA's request." Thompson, 389 F.3d at 1275. This provision serves as an incentive for a drug patent holder to conduct expensive and difficult pediatric studies of a drug that the FDA believes may have a beneficial pediatric use. Thompson, 389 F.3d at 1276; cf. Ass'n of Am. Physicians & Surgeons, 226 F. Supp. 2d at 206 (noting that "[b]ecause of the expense and difficulty in finding substantial pediatric populations to undergo tests, along with the ethical complications associated with testing new drugs on children, many drugs are tested for safety and effectiveness in adults only").

"If the FDA makes a request and the NDA holder satisfies that request's requirement, pediatric exclusivity provides for a six-month delay in the effective date of the pending ANDAs." Barr Labs., 238 F. Supp. 2d at 241. The effect of the grant of pediatric exclusivity depends on the type of certification included in the ANDA. If the drug is the subject of a Paragraph

II or Paragraph III certification, "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 patent expires (including any patent extensions)." 21 U.S.C. § 355a(c)(2)(A). 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)." 21 U.S.C. § 355a(c)(2)(B).

As an initial matter, the Court notes that AstraZeneca is entitled to a six-month period of pediatric exclusivity under 21 U.S.C. § 355a(c)(2)(B). This period of pediatric exclusivity is set to expire on October 20, 2007.

B. The Present Case

In April 2000, Impax sent Astra notice that it had submitted an abbreviated new drug application ("ANDA") to the FDA seeking approval to engage in the commercial manufacture, use, or sale of its 10-mg and 20-mg omeprazole products, called "Omeprazole Delayed Release Capsules 10 and 20 mg," as generic versions of Astra's Prilosec® product. As part of its ANDA, Impax included a Paragraph IV Certification, as described in 21

U.S.C. § 355(j)(2)(A)(vii)(IV), stating that the '505 and '230 patents "[are] invalid or will not be infringed by the manufacture, use, or sale of the new drug." (Second Am. Compl. Against Impax (hereinafter "Second Am. Compl.") ¶¶ 12, 24.)

On May 15, 2000, Plaintiffs filed their initial Complaint alleging that Impax committed an act of infringement under 35 U.S.C. § 271(e)(2) with respect to the '505 and '230 patents, by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of its 10- and 20-mg Omeprazole Delayed Release Capsules, prior to the expiration of the '505 and '230 patents. (Second Am. Compl. ¶¶ 11, 16, 28.)

On January 8, 2002, Impax sent Astra notice that it had "submitted an amendment to ANDA 75-785, providing for the addition of a 40mg strength" Omeprazole Delayed Release Capsule. (Trial Ex. 1128.)

On November 8, 2002, Impax obtained final approval of its ANDAs and in September 2004, began to market and sell its generic products. (Impax's Mem. of Law in Supp. of its Mot. to Dismiss Under Rule 12(b)(1) for Lack of Subject Matter Jurisdiction (hereinafter "Def.'s Motion") at 2.) With leave of Court, Plaintiffs filed a Second Amended Complaint on March 1, 2005, adding allegations of direct, contributory, and inducing infringement under 35 U.S.C. § 271(a), (b), and (c), respectively, and a demand for damages. (Second Am. Compl. ¶¶

19a-20, 31a-32.) On February 14, 2005, Impax filed its Answer and Counterclaims to Plaintiffs' Second Amended Complaint. Impax asserted counterclaims of invalidity and non-infringement, and demanded a jury trial on Plaintiffs' infringement claims and its counterclaims. (Impax Answer & Countercls. ¶ 235.) In order to include Impax in the consolidated Second Wave Bench Trial,¹ Plaintiffs agreed to dismiss with prejudice their claims for damages under § 271(a)-(c). In January 2006, the Court severed and stayed Impax's antitrust counterclaims pending the resolution of the patent infringement action, and ordered Plaintiffs to submit a voluntary dismissal of the damages claims.² (Order Denying Impax's Claim to Jury Trial, Jan. 13, 2006.)

The case was tried to the Court sitting without a jury for 42 trial days, starting April 3, 2006 and ending June 14, 2006. Post-trial findings of fact and conclusions of law were fully submitted on August 1, 2006. The '505 and '230 patents expired on April 20, 2007, while a final decision was sub judice.

¹ The Second Wave Trial included the following defendant pharmaceutical corporations: Mylan Laboratories Inc., Mylan Pharmaceuticals Inc., Esteve Quimica, S.A., Laboratorios Dr. Esteve, S.A., Apotex Corp., Apotex Inc., Torpharm Inc., Lek Pharmaceutical and Chemical Company D.D., Lek USA, Inc., and Impax Laboratories, Inc.

² In addition, the Court ordered that, upon entry of Astra's dismissal, Impax's jury demand would be struck. (Jan. 13, 2006 Order at 9.) On February 26, 2006, this Court denied Impax's motion for reconsideration. On March 2, 2006, the Federal Circuit denied Impax's petition for a writ of mandamus. Impax has filed a petition for certiorari in the Supreme Court of the United States.

Discussion

On April 23, 2007, Impax filed a Motion to Dismiss for Lack of Subject Matter Jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1). Impax asserts that upon the expiration of the '505 and '230 patents on April 20, 2007, the Court was divested of jurisdiction over Plaintiffs' claims for patent infringement under 35 U.S.C. § 271(a)-(c) and § 271(e)(2).

A. Legal Standard for Dismissal

A motion to dismiss for lack of subject matter jurisdiction presents only a procedural question, and does not raise issues unique to patent law. Toxgon Corp. v. BNFL, Inc., 312 F.3d 1379, 1380-81 (Fed. Cir. 2002). Accordingly, the Court must apply regional circuit law, in this case Second Circuit law, in resolving Impax's motion to dismiss. Id. Federal Rule of Civil Procedure 12(b)(1) provides for dismissal of a claim when the court "lacks . . . jurisdiction over the subject matter." F. R. Civ. P. 12(b)(1). "A case is properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it." Makarova v. United States, 201 F.3d 110, 113 (2d Cir. 2000). Plaintiffs bear the burden of establishing by a preponderance of the evidence that subject matter jurisdiction exists. Makarova, 201 F.3d at 113; Faggionato v. Lerner, No. 06 CV 2614, 2007 WL 959102, at *5 (S.D.N.Y. Mar. 30, 2007).

"Jurisdictional allegations must be shown affirmatively and may not be inferred favorably to the party asserting them."

Faggianato, 2007 WL 959102 at *5. In resolving a motion to dismiss for lack of subject matter jurisdiction, the Court may refer to evidence outside the pleadings. Makarova, 201 F.3d at 113.

B. Expiration of the '230 and '505 Patents Does Not Render Astra's Claims Moot

In support of its motion to dismiss, Impax argues that the Court lacks jurisdiction over the present controversy because "Astra has no remaining claim for relief against Impax." (See Def.'s Motion at 3.) Impax's argument can be summarized as follows. Under the Patent Act, Plaintiffs are entitled to only two remedies for infringement of the '505 and '230 patents: damages under 35 U.S.C. § 284, or an injunction under 35 U.S.C. § 283. Because Astra dismissed with prejudice all of its claims for damages, the only remedy available to Astra was an injunction under 35 U.S.C. § 283. Upon expiration of the patents, Astra is no longer entitled to injunctive relief under § 283, and Astra's claims for infringement under 35 U.S.C. § 271(e)(2) "expired." Thus, Impax asserts that Astra's claims for patent infringement are now moot and the Court's subject

matter jurisdiction over the claims has "dissolve[d]." (Def.'s Motion at 3).³

The Court disagrees. Mootness "refers to "[t]he requisite personal interest that must exist at the commencement of the litigation (standing) [and] continue throughout [the] existence" of the litigation.⁴ U.S. Parole Comm'n v. Geraghty, 445 U.S. 388, 396-97 (1980) (quoting Henry Paul Monaghan, *Constitutional Adjudication: The Who and When*, 82 Yale L.J. 1363, 1384 (1973)). "[A] case is moot when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." Powell v. McCormack 395 U.S. 486, 496-97 (1969) (citation omitted).

The Plaintiffs here have a legally cognizable interest, or "personal stake," in this litigation. See U.S. Parole Comm'n v. Geraghty, 445 U.S. at 396-96. So we are concerned only with whether the issues before the court are still "live." The "central question . . . is whether a change in the circumstances

³ In addition, Impax contends the Pennsylvania District Court's decision in Pfizer, Inc. v. Mylan Pharm., Inc., No.02 CV 1628, 2006 WL 2990398 (W.D. Pa. Oct. 18, 2006), dictates dismissal of Astra's claims against Impax. This Court disagrees. Pfizer v. Mylan is not binding precedent on this Court. Nor does it consider the detailed statutory analysis, upon which this Court relies.

⁴ "The rule that [courts] lack jurisdiction to consider the merits of a moot case is a branch of the constitutional command that the judicial power extends only to cases or controversies." Powell v. McCormack 395 U.S. 486, 497 (1969) (citing Sibron v. New York, 392 U.S. 40, 57 (1968)). But see Honig v. Doe, 484 U.S. 305, 330 (1988) (Rehnquist, C.J., concurring) (arguing that mootness doctrine is primarily prudential and not constitutionally based), cited in Erwin Chemersinky, Federal Jurisdiction § 2.5 (4th Ed. 2003).

that prevailed at the beginning of the litigation have forestalled any occasion for meaningful relief." 13A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 3553.3 (2d ed. 1984). In other words, whether the expiration of the '505 and '230 patents has rendered Plaintiff's claims moot depends on the availability of any judicial relief. See Earth Island Inst. v. United States Forest Serv., 442 F.3d 1147, 1157 (9th Cir. 2006) (In deciding whether a case is moot, "[t]he question is not whether the precise relief sought at the time of the application for an injunction was filed is still available. The question is whether there can be any effective relief.").

No one disputes that if the patent holder is seeking damages, it may maintain a cause of action past the expiration of the patents. See Clark v. Wooster, 119 U.S. 322, 325 (1886) (expiration of the patents does not deprive the court of jurisdiction to grant monetary relief). But if the patent holder is seeking an injunction under § 283 "to prevent the violation of any right secured by patent," 35 U.S.C. § 283, the patent must still be in effect in order for the court to grant relief because upon the expiration of the patent, the right to exclude others from practicing the claimed invention also expires. Kearns v. Chrysler Corp., 32 F.3d 1541, 1550 (Fed. Cir. 1994) ("Thus, when the rights secured by a patent are no longer protectable by virtue of expiration or unenforceability,

entitlement to injunctive relief becomes moot because such relief is no longer available."); see also Sears, Roebuck & Co. v. Stiffel, Co., 376 U.S. 225, 230 (1964); Lans v. Digital Equip. Corp., 252 F.3d 1320, 1328 (Fed Cir. 2001) ("The District Court cannot enjoin the Computer Companies from infringing an expired patent."). Because the '505 and '230 patents have expired, Astra is no longer entitled to an injunction under § 283.

However, the unavailability of money damages or an injunction under § 283 does not automatically render the entire controversy before the Court "moot." For the reasons set forth below, the Court finds that because Plaintiffs are entitled to judicial relief -- either under the Court's equitable power or 35 U.S.C. § 271(e)(4)(A) -- the case is not moot, and the Court has jurisdiction over Plaintiffs' claims for patent infringement.

1. Equitable Relief

In Roche Prods., Inc. v. Bolar Pharm. Co. Inc., 733 F.2d 858 (1984), cert denied, 469 U.S. 856 (1984), the Federal Circuit held that the expiration of the patents did not render the case before it moot, nor did it deprive the court of the power to grant alternative forms of equitable relief. In Roche, the plaintiff requested a permanent injunction against infringement by Bolar, the defendant. Id. at 865. After the

motion was fully briefed, but prior to oral argument, the patent at issue expired. Id. The Court held that the case was not moot "because although the initially requested order [was] no longer . . . necessary, other remedies can be fashioned to give Roche relief against Bolar's past infringement," such as "an order to confiscate and destroy the data which Bolar . . . generated during its infringing activity." Id. (citation omitted). In accordance with Roche, the Court finds that although the expiration of the '505 and '230 patents precludes it from granting Astra an injunction under § 283, the expiration of the patents has not divested the Court of the power to issue other forms of equitable relief.⁵

Contrary to Impax's assertion, Kearns does not dictate a different result. In analyzing its previous decision in Roche, the Federal Circuit in Kearns found that "[t]he post-expiration relief discussed in Roche was intended to return the parties to the status quo before infringement (e.g. destruction of data obtained as a result of infringement) and was not intended to

⁵ Having properly obtained jurisdiction over the present controversy, the Court is not automatically divested of it upon the expiration of the patents. See John R. Kennel, Luchas Martin, et al., Corpus Juris Secundum Patents § 434 ("Where jurisdiction is once acquired, it is not ousted by the expiration of the patent during the pendency of the suit, but continues for the purpose of an accounting." (citing Rice & Adams Corp. v. Lathrop, 278 U.S. 509 (1929)); see also Rice & Adams Corp., 278 U.S. at 514-15 ("Jurisdiction of the court sitting in equity, having been rightfully invoked, was not lost . . . by the expiration of the patent pending final decree. . . . [I]f the case was one for equitable relief when the suit was instituted, the mere fact that the ground for such relief expired by the expiration of the patent, would not take away jurisdiction, and preclude the court from proceeding to grant . . . incidental relief").

prohibit future use of the invention." Kearns, 32 F.3d at 1550. The court noted that "[i]mportantly, the relief was also considered in the context of harm to a patent owner that had been selling the patented product. Thus, deferral of competition by an infringer who had entered the market prematurely, i.e., before the patent expired, was considered as a means of equitably compensating the patent owner." Id. Similarly, in this case, were the Court to find the patents valid and infringed and issue an order pursuant to 35 U.S.C. § 271(e)(4)(A) directing Impax's ANDA to have a delayed effective date, such an order would have the effect of returning the parties to the status quo before infringement -- that is before Impax filed its ANDA with a Paragraph IV certification. As will be discussed in more detail below, an order directing withdrawal of final FDA approval of Impax's ANDA and delaying the effective date would require Impax to wait until the expiration of Astra's six-month period of pediatric exclusivity before it could re-enter the market to sell its generic products. This remedy would put the parties in the position they would have been in had the act of infringement never occurred: It would subject Impax to Astra's six-month period of pediatric exclusivity, as it would have been had it filed an ANDA with a Paragraph II or Paragraph III certification. Moreover, such an order would give effect to, and is in accordance with the goal of the statutory

scheme enacted by Congress when it authorized the grant of market exclusivity to patent holders who conduct pediatric studies. See Ass'n of Am. Physicians & Surgeons, 226 F. Supp. 2d at 206 (“[I]n an effort to encourage pediatric testing, Congress passed the Food and Drug Administration Modernization Act,” under which “[d]rug manufacturers that agreed to conduct these pediatric tests could receive six months of market exclusivity for their products.”).

2. Relief under 35 U.S.C. § 271(e)(4)(A)

In addition to the judicial relief available under the Court’s equitable power, 35 U.S.C. § 271(e)(4)(A) independently provides a remedy. Contrary to Impax’s assertion the expiration of the patents does not “eliminate[] any Section 271(e)(2) claim that may have existed.” (See Def.’s Motion at 3.) Section 271(e)(2) states that

it shall be an act of infringement to submit an application under 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, if the purpose of such submission is to obtain approval under such Act to engage in the commercial, use or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). Section 271(e)(2) creates “a new (and somewhat artificial) act of infringement” based solely upon the filing of an ANDA containing a Paragraph IV certification “that

is in error as to whether the commercial, manufacture, use, or sale of the new product (none of which has actually occurred) violates the relevant patent." Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676-79 (1990).

35 U.S.C. Section 271(e)(4) sets out the remedies that are available for an act of infringement under § 271(e)(2). In addition to injunctive relief under § 271(e)(4)(B), and damages or other monetary relief under § 271 (e)(4)(C), Section 271(e)(4)(A) provides an alternative form of relief to which Astra is still entitled. Section 271(e)(4)(A) states that upon finding an act of infringement, "the court shall order the effective date of any approval of the drug or veterinary biological product in the infringement to be a date which is not earlier than the date of expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A) (emphasis added).

Impax asserts that the remedy under 271(e)(4)(A) is only available prior to the expiration of the patents. In support, Impax cites a section of legislative history from 1984, prior to the enactment of the statutory provisions authorizing the grant of pediatric exclusivity, which states that:

If the infringing party has begun commercial marketing of the drug, damages, and other monetary relief and injunctive may be awarded for the infringement and to prevent further infringement. In addition, the FDA would be mandated to change the effective date of the approved ANDA to the expiration of the infringed patent.

H.R. Rep. No. 98-857, pt. 1, at 46 (1984). However, this is not the language contained in the statute. The statute states that “the court shall order the effective date . . . to be a date which is not earlier than the date of the expiration of the patent which has been infringed.” 35 U.S.C. § 271(e)(4) (emphasis added). Had Congress intended to limit relief under 271(e)(4)(A) to an order mandating the effective date of the ANDA to be the date of the expiration of the patent, it could have written the provision to say that. But it did not. Rather, the clear and unambiguous language of the statute sets the date of the expiration of the patent only as the earliest effective date a court may order. The Court will not “accept [Impax’s] invitation to ignore [the] language which Congress saw fit to enact” and search the legislative history for a contrary meaning. United States v. McGoff, 831 F.2d 1071, 1080 & n.19 (D.C. Cir. 1987) (“Only the most extraordinary showing of contrary intentions in the legislative history will justify departure from the plain and unambiguous language of the statute.” (quoting United States v. Albertini, 472 U.S. 675, 680 (1985))).

The statutory language of 271(e)(4)(A) also fails to limit the Court’s power to issue a remedy to the term of the patent. Section 271(e)(4)(A) must be read in conjunction with 21 U.S.C.

§ 355a, the statutory provision governing the grant of a six-month period of market exclusivity to a patent holder who completes FDA-requested pediatric studies. 21 U.S.C. § 355a "authorizes an extra six-month 'pediatric exclusivity' period following expiration of a drug patent for a patent holder that has satisfactorily conducted pediatric testing of its drug upon the FDA's request." Mylan Labs., Inc. v. Thompson, 389 F.3d 1272, 1275 (D.C. Cir. 2004) (emphasis added). The statute provides that 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 1276. Nothing in the language of 21 U.S.C. § 355a(c)(2)(B) requires the Court to render its decision prior to the expiration of the patents.

Impax contends that "'pediatric exclusivity' does not rescue Astra's claims" because "pediatric exclusivity is a reward bestowed by the FDA on pharmaceutical companies for testing drug products on young patients[,] . . . [i]t does not, however, extend the terms of the patents." (Def's Motion at 4.) The Court agrees that the six-month period of pediatric

exclusivity does not extend the term of the patents, but it does grant the patent holder a period of market exclusivity, which this Court has the power to enforce. Accordingly, the Court finds that relief under § 271(e)(4)(A) does not become moot when the patents expire but the period of pediatric exclusivity is still in effect.

Such a result is in accordance with the Federal Circuit's decision in Alza Corp. v. Mylan Labs., Inc., 391 F.3d 1365 (Fed. Cir. 2004). In Alza, the patent was due to expire in July 2004. Id. at 1368. The Federal Circuit stated in a decision rendered on December 10, 2004 -- after the expiration of the patents -- that "following the Food and Drug Administration's approval of pediatric use of [the drug], the patent will now expire on January 23, 2005." Id. The parties conceded that the case would be moot after January 23, 2005. Id. at n.3. Although the Vermont District Court's decision in Alza was rendered prior to the expiration of the patents, the Federal Circuit did not find that the case became moot upon expiration of the patent, nor did it find that it lost jurisdiction over the appeal upon expiration of the patent. Instead, the court asserted jurisdiction over the appeal and affirmed the district court's decision that the patents were neither anticipated nor obvious, and that the patent was not unenforceable due to inequitable conduct. Id. at 1373.

In support of its motion to dismiss, Impax asserts that the Court is powerless to enforce the period of pediatric exclusivity because section 355a requires a "court determin[ation] that the patent is valid and would be infringed" in order for the ANDA with a Paragraph IV certification to be subject to the period of pediatric exclusivity. Thus Impax contends that because the patents expired while the determination of validity and infringement was sub judice, Astra has lost its right to its six-month period of pediatric exclusivity under 21 U.S.C. § 355a. The Court declines to reach such an anomalous result.

Had Impax filed a Paragraph II or Paragraph III certification, it would have been automatically subject to Astra's six-month period of pediatric exclusivity prior to receiving final approval of its ANDA. See 21 U.S.C. § 355a(c)(2)(B). Instead, Impax filed a Paragraph IV certification, and while the patent litigation was pending, it obtained final approval of its ANDAs and began to manufacture and sell its generic products. Simply because the statutory provisions do not address the specific fact pattern before us does not mean that Astra is not entitled to the six-month period of market exclusivity that it earned by conducting the requested pediatric studies.

In this regard Ranbaxy Labs. Lim. V. United States Food & Drug Admin., 307 F. Supp. 2d 15 (D.D.C. 2004), is instructive. In Ranbaxy, the generic drug manufacturer, Ranbaxy Labs., received tentative approval of its ANDAs during the course of litigation. Id. at 18. "After the summary judgment decision, . . . the court indicated to Ranbaxy and Pfizer [the patent holder], that the court's schedule would not allow for a trial until after the January 29, 2004, expiration of the '216 patent." Id. at 17. In response the parties entered into a stipulation of dismissal providing that because the '216 was set to expire before the court could accommodate a trial, the "actions would be dismissed as moot upon the . . . expiration of the '216 patent." Id. at 17.

Ranbaxy sought confirmation from the FDA that it would receive final approval of its ANDA upon expiration of the patent, irrespective of Pfizer's period of pediatric exclusivity. Id. at 18. Ranbaxy argued that because it had received tentative approval of its ANDAs, upon expiration of the patents the ANDAs "automatically gained or were entitled to gain, immediate effective approval . . . because the patent litigation became moot at the very instant the patents expired." Id. at 19. In addition, Ranbaxy asserted a similar argument to that made by Impax in support of the present motion: Ranbaxy argued "that the preconditions for delaying an ANDA on the basis

of pediatric exclusivity provided for in Section 505(a)(c)(2)(B) [and 21 U.S.C. § 355a(b)(2)(b)] (governing Paragraph IV submissions) could not be satisfied unless Pfizer obtained a ruling that the [relevant] patent was valid and would be infringed, which it was unlikely to do in view of the district court's schedule." Id. at 18.

By letter dated January 28, 2004, "the FDA issued an administrative decision indicating that Ranbaxy's ANDA would not be approved until after the expiration of Pfizer's pediatric exclusivity on July 29, 2004." Id. "The FDA concluded that an ANDA applicant will be subject to any pediatric exclusivity that attaches to a patent where the ANDA applicant has filed a paragraph IV certification, was sued by the NDA holder or patent owner within 45 days, and the litigation is unresolved on the merits and the 30-month stay has not run when the patent expires." Id. at 18 (citation omitted).

Although the facts of Ranbaxy differ from the case before us, the Court finds that the FDA's reasoning is equally applicable to the case at bar. In Ranbaxy, "the FDA concluded that the absence of a [statutory] provision addressing unresolved patent litigations in the Paragraph IV certification context did not mean that Congress intended to exclude such circumstances from the pediatric exclusivity provision." Ranbaxy, 307 F. Supp. 2d at 19. According to the FDA, Ranbaxy's

"alternative reading . . . would undercut the purpose of the pediatric exclusivity and invite anomalies and manipulation of the statute." Id. Similarly, the Court finds that Impax's interpretation of the statutory provisions would create an anomalous result that is at odds with Congress's goal in enacting § 355a.

Accordingly, the Court concludes that if it determines that the '505 and '230 patents are valid and infringed, it may issue an order pursuant to 35 U.S.C. § 271(e)(4)(A) recognizing Astra's six-month period of pediatric exclusivity under 21 U.S.C. § 355a(c)(2)(B), and mandating that the effective date of approval of Impax's ANDA is no earlier than the date on which the pediatric exclusivity ends -- that is October 20, 2007. Such an order does not extend the term of the patents, but instead gives effect to a period of market exclusivity which Congress has bestowed upon brand manufacturers who incur the costly task of conducting pediatric studies of pharmaceutical drugs. See S. Report No. 105-43, at 51 (1997); see also Assoc. of Am. Physicians and Surgeons, Inc. v. U.S.F.D.A., 226 F. Supp. 2d 204, 206 (D.D.C. 2002).

3. Impax's ANDA Did Not Automatically Convert from a Paragraph IV to a Paragraph II Certification

In support of its assertion that upon patent expiration, Astra no longer has a claim under § 271(e)(2), Impax contends

that upon patent expiry, its Paragraph IV certification was automatically converted to a Paragraph II certification thereby eliminating Astra's claim for infringement under § 271(e)(2). Impax cites Ranbaxy in support of this proposition; however, Ranbaxy does not mandate such a result.

In Ranabxy, the FDA determined that upon patent expiry, Ranbaxy was required to amend its certification pursuant to 21 C.F.R. § 314.94(a)(12)(viii)(C)(1), which requires an ANDA applicant to amend its certification "if, at any time before the effective date of approval of the application, the applicant learns that the submitted certification is no longer accurate." The FDA decided that upon expiration of the patents, the Paragraph IV certification converted to a Paragraph II certification -- even though Ranbaxy failed to amend its certification -- and "under a Paragraph II certification, the statute provides for a delayed ANDA approval for six months beyond the expiration of the patent." Ranbaxy, 374 F. Supp. 2d at 18. Thus, Ranbaxy was subject to the six-month period of pediatric exclusivity (even in the absence of a court order triggering § 355a(c)(2)(B)). The District Court for the District of Columbia affirmed this decision, finding that at the "magic moment" the patents expired "the Paragraph IV certification became invalid, and either converted as a matter of law to Paragraph II certifications or became inaccurate,

thereby creating an obligation on Ranbaxy's part to amend its ANDAs to reflect patent expiry and an inability on the part of the FDA to approve the ANDAs in their inaccurate form." Id. at 21.

Ranbaxy's ANDA is distinguishable from Impax's ANDA. In Ranbaxy, the generic applicant had only received "tentative" approval prior to the expiration of the patent. In the case at bar, Impax received final approval of its ANDA on November 8, 2002, prior to the trial on the merits and the expiration of the patents. Once an application is finally approved, the applicant is no longer under an obligation to amend its patent certification. See 21 C.F.R. § 314.94(A)(12)(viii)(C)(i) (requiring amendments before the effective date of approval). Thus, the rationale behind the automatic conversion of a Paragraph IV certification to a Paragraph II certification does not apply. Accordingly, the Court finds that Impax's Paragraph IV certification did not convert to a Paragraph II certification upon expiration of the patents, and Astra still has a viable claim for infringement under 271(e)(2).⁶

* * *


⁶ An order pursuant to § 271(e)(4)(A) would have the effect of converting Impax's final approval to an approval with a delayed effective date, which under the FDA's own regulations is a "tentative" approval. See Mylan v. Thompson, 389 F.3d 1272, 1281 (D.C. Cir. 2004) (citing 21 C.F.R. § 314.105(a)). Whether such a change in the "factual and legal landscape" would impose an obligation on Impax to amend its Paragraph IV certification and subsequently convert the certification to a Paragraph II certification, is not a question before us. See Mylan, 389 F.3d at 1284. The Court properly leaves that issue, if it arises, to be resolved by the FDA.

The Court concludes that this is not a case in which the court is powerless to "undo the effects of conduct that was not prevented by the time of decision." Wright & Miller, supra (citing Roche and other cases). Instead, an effective remedy is possible and within the Court's power -- either under 35 U.S.C. § 271(e)(4)(A) or the Court's general equitable powers. Accordingly, the case is not moot and the Court has jurisdiction over Astra's claim for infringement under 35 U.S.C. § 271(e)(2).

Conclusion

For the foregoing reasons, Impax's motion to dismiss for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1) is DENIED.

SO ORDERED:


Barbara S. Jones
UNITED STATES DISTRICT JUDGE

New York, New York
May 25, 2007