

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

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)	
SEATTLE CHILDREN’S HOSPITAL,)	
NOVARTIS VACCINES AND DIAGNOSTICS,)	
INC., and NOVARTIS PHARMACEUTICALS)	
CORPORATION,)	
)	Case No. 1:10-CV-05118
Plaintiffs,)	
)	Judge Robert M. Dow, Jr.
v.)	
)	Magistrate Judge Sidney I. Schenkier
AKORN, INC.,)	
)	
Defendant.)	
-----X)	

**MEMORANDUM IN SUPPORT OF PLAINTIFFS’ RENEWED MOTION
TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION**

Plaintiffs Seattle Children’s Hospital, Novartis Vaccines and Diagnostics, Inc., and Novartis Pharmaceuticals Corporation (collectively, “Plaintiffs”) submit this memorandum in support of their renewed motion to dismiss this action and to dismiss the counterclaim of defendant Akorn, Inc. (“Akorn”) for lack of subject matter jurisdiction.

I. INTRODUCTION

Since this Court issued its December 20, 2011 Memorandum Opinion and Order (D.I. 66) denying Plaintiffs’ Motion To Dismiss (D.I. 36) and granting Akorn’s Motion for Leave to Amend (D.I. 39), any possible remaining case or controversy has been mooted by the statutorily mandated forfeiture of any 180-day exclusivity of the first Abbreviated New Drug Application (“ANDA”) filer for a generic version of Novartis’ Tobramycin Inhalation Solution (“TOBI[®]”),

Teva Parenteral Medicines, Inc. (“Teva”), based on Teva’s failure to receive tentative FDA approval by December 29, 2011, 30 months after the June 29, 2009 submission of its ANDA.

Accordingly, Plaintiffs renew their motion to dismiss this action and also move to dismiss the counterclaim of non-infringement filed by Akorn on December 21, 2011 (D.I. 68) for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1) and 12(h)(3).

II. ARGUMENT

As explained in the prior briefing on Plaintiffs’ motion to dismiss and Akorn’s motion for leave to amend, Plaintiffs commenced this action on August 13, 2010 for infringement of U.S. Patent No. 5,508,269 (the “’269 Patent”) under 35 U.S.C. § 271(e)(2) based on Akorn’s filing of an ANDA to obtain FDA approval to market a generic version of the TOBI[®] drug product prior to the expiration of the ‘269 Patent. On June 27, 2011, Plaintiffs granted Akorn a covenant not to sue under the ‘269 Patent for its ANDA product, which as this Court recognized, resolved the issue of patent infringement. (Memo. in Support of Plaintiffs’ Motion to Dismiss, D.I. 37, Ex. 1; D.I. 66 at 8.)

Akorn’s sole reason for opposing dismissal and seeking to continue this action is to trigger, through a non-appealable court decision of patent non-infringement or invalidity, a forfeiture of any 180-day marketing exclusivity to which Teva may be entitled as the first ANDA filer for a generic version of TOBI[®]. (Akorn’s Opp. to Plaintiffs’ Motion to Dismiss, D.I. 45, at 3-4.)¹ Akorn maintained that notwithstanding the resolution of the infringement issue, Teva’s 180-day exclusivity remained a barrier to Akorn’s ability to market its ANDA product. (D.I. 66

¹ Under 21 U.S.C. § 355(j)(5)(D)(i)(I), a first ANDA filer’s 180-day exclusivity may be forfeited if the first ANDA filer fails to market its product within 75 days of a non-appealable court decision (other than a cert. petition to the Supreme Court) in an action involving a subsequent filer which has obtained tentative approval of its own ANDA. Thus, the court decision which could potentially trigger a forfeiture is an appellate decision.

at 9.) However, as Plaintiffs noted in their reply brief in support of their motion to dismiss, independent of the outcome of this action, under 21 U.S.C. § 355(j)(5)(D)(i)(IV) Teva would forfeit any entitlement to a 180-day marketing exclusivity if it did not obtain tentative FDA approval of its ANDA by December 29, 2011, 30 months after the June 29, 2009 filing date of its ANDA. (Plaintiffs' Reply Memo. in Support of Their Motion to Dismiss, D.I. 55, at 10 & n.13.)²

While the Court noted in its December 20, 2011 opinion, “[t]o date, Teva’s exclusivity period has not begun and has not been forfeited,”³ that is no longer the case -- under the Hatch-Waxman Act, Teva’s right to a 180-day exclusivity was forfeited when it did not receive a tentative approval of its ANDA by December 29, 2011. 21 U.S.C. § 355(j)(5)(D)(i)(IV);⁴ *Medeva Pharma Suisse A.G. v. Par Pharmaceuticals, Inc.*, 774 F. Supp. 2d 691, 697 (D.N.J. 2011) (granting motion to dismiss where the first filer “forfeited its market exclusivity on

² Akorn is in agreement with the June 29, 2009 filing date of Teva’s ANDA, which is the date reported on the FDA’s website for the first filed Paragraph IV certification on TOBI[®]. (Akorn’s Counterclaim for Declaratory Judgment, D.I. 68, ¶ 20; Memo. in Opp. to Akorn’s Motion for Leave to Amend, D.I. 48., at 13 n.10.) The FDA’s website also reports the grant of final and tentative approvals and shows that Teva did not receive a tentative approval of its ANDA by December 29, 2011. A copy of the page of the FDA website (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=TOBRAMYCIN>) listing all approvals granted for tobramycin to date, including tobramycin inhalation solution (TOBI[®]), is attached hereto as Exhibit A, showing that, Teva has not received such tentative approval as of the filing of this motion.

³ D.I. 66 at 5.

⁴ The only exception to forfeiture by the first filer is if the failure to obtain tentative approval within 30 months “is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.” 21 U.S.C. § 355(j)(5)(D)(i)(IV). That exception is inapplicable here as there is no evidence that there was any change in the requirements for ANDA approval that resulted in Teva’s failure to obtain tentative approval by December 29, 2011.

account of its failure to obtain tentative approval of its ANDA within 30 months of filing its application for approval”).⁵

Thus, Akorn’s contention at the time that “[t]he only way for Akorn to remove Teva’s exclusivity period, whether through expiration or forfeiture, as a barrier to the approval of Akorn’s ANDA is to obtain a final judgment that the 269 Patent is invalid or not infringed,” did not take into consideration that Teva’s 180-day exclusivity period would be forfeited if Teva did not receive tentative FDA approval by December 29, 2011. (D.I. 45 at 4.) Since Teva’s first-filer 180-day exclusivity has now been forfeited, there is no barrier to the approval of Akorn’s ANDA and its entry into the market upon an FDA determination that Akorn has met the statutory safety and efficacy requirements for ANDA approval. Therefore, there is no case or controversy remaining which can support subject matter jurisdiction in this action.⁶

III. CONCLUSION

Based on the absence of a justiciable case or controversy, Plaintiffs respectfully request that this action and Akorn’s counterclaim be dismissed without prejudice.

⁵ Plaintiffs make this renewed motion based on Teva’s failure to obtain a tentative approval within 30 months without waiver of the alternative argument raised in their initial motion that Akorn cannot show an immediate, redressable injury without having obtained a tentative approval of Akorn’s ANDA, a necessary requisite for a court decision to trigger the forfeiture of Teva’s 180-day exclusivity.

⁶ Plaintiffs wish to bring to the Court’s attention a motion to dismiss that was filed on December 22, 2011 and is now pending in a case before Judge Leinenweber in *Shire Canada Inc. v. Alkem Laboratories, Ltd.*, No. 11 C 206 (N.D. Ill.) (a copy of the motion and memorandum in support is attached hereto as Exhibit B). In that Hatch-Waxman action, the plaintiffs granted the defendant a covenant not to sue and moved to dismiss for lack of case or controversy for two independent reasons: (1) the first filing ANDA applicants had failed to obtain tentative approvals within 30 months, which forfeited the first filers’ 180-day exclusivity, and (2) the defendant had not obtained a tentative approval of its own ANDA, a requisite for a court decision to trigger a forfeiture of the first filers’ 180-day exclusivity. Plaintiffs submit that given the forfeiture of Teva’s 180-day exclusivity as of December 29, 2011, the grounds for dismissal here for lack of subject matter jurisdiction are the same as presented by Shire’s motion.

Dated: January 6, 2012

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CERTIFICATE OF SERVICE

I hereby certify that on January 6, 2012, I served the foregoing Memorandum in Support of Plaintiffs' Renewed Motion to Dismiss for Lack of Subject Matter Jurisdiction via the Court's ECF system on counsel of record for Akorn, Inc.

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