

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

IN RE:   ALFUZOSIN HYDROCHLORIDE   )  
          PATENT LITIGATION           )   MDL Docket No. 08-md-1941 (GMS)  
  )

**STIPULATION AND ORDER RE JUDGMENT**

1.       WHEREAS, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively, "sanofi-aventis") filed an action for patent infringement against Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") in this Court regarding Apotex's Abbreviated New Drug Application No. 79-013 ("ANDA 79-013") as filed on June 12, 2007 and the proposed generic product defined therein, *sanofi-aventis v. Apotex Inc., et al.*, Civil Action No. 07-792 (D. Del.) (the "Delaware Action").

2.       WHEREAS, on or about December 10, 2007 sanofi-aventis filed an action for patent infringement against Apotex in the United States District Court for the Southern District of Florida regarding Apotex's ANDA 79-013 and the proposed generic product defined therein, *sanofi-aventis v. Apotex Inc., et al.*, Civil Action No. 07-61800 (S.D. Fla.) (the "Florida Action").

3.       WHEREAS, on or about June 9, 2008, the Delaware Action and Florida Action were consolidated for pretrial proceedings with other related suits by the Judicial Panel of Multidistrict Litigation, *In re Alfuzosin Hydrochloride Patent Litigation*, MDL No. 08-md-1941 (D. Del.) (the "MDL Action").

4.       WHEREAS, on or about May 20, 2009, the parties filed a Stipulation of Dismissal with respect to Apotex's declaratory judgment counterclaims relating to the '940 patent.

5. WHEREAS, pursuant to a Stipulation and Order entered on October 27, 2009 (D.I. 142), the Delaware Action was stayed with respect to U.S. Patent No. 4,661,491 ("the '491 patent") and the parties agreed that if a judgment in favor of sanofi-aventis was entered against any Defendant in the MDL Action, that stay would be lifted and such a judgment would also be entered against Apotex.

6. WHEREAS, pursuant to a Stipulation and Order entered on October 27, 2009 (D.I. 142), any judgment entered in favor of sanofi-aventis as a result of a judgment in the MDL Action may be appealed by Apotex on the record in the MDL Action.

7. WHEREAS, pursuant to a Stipulation and Order entered on October 27, 2009 (D.I. 142), in the event that judgment in favor of sanofi-aventis is not appealed by Apotex, but is vacated, modified, affirmed or reversed on appeal in the MDL Action, then such judgment shall be applied in the same manner to any judgment entered in the Delaware Action.

8. WHEREAS, sanofi-aventis filed an action for patent infringement in this Court against Defendant Mylan Pharmaceuticals, Inc. ("Mylan") regarding Mylan's Abbreviated New Drug Application No. 79-014 ("ANDA 79-014") filed on June 12, 2007 and the proposed generic product defined therein, *sanofi-aventis v. Actavis South Atlantic LLC, et al.*, Civil Action No. 07-572 (D. Del.), which action was consolidated for pretrial proceedings with other related suits in the MDL Action.

9. WHEREAS, on August 3, 2010, the Court entered judgment that: (1) Mylan's proposed product described in ANDA 79-014 infringes the asserted claims of the '491 patent; (2) Mylan will induce infringement of the asserted claims of the '491 patent; (3) the asserted claims of the '491 patent are not invalid; (4) the effective approval date of Mylan's ANDA 79-014 shall not be earlier than the expiration date of the '491 patent, plus any

exclusivities afforded by 21 U.S.C. § 355a(c)(1)(B)(iii)[sic]; and (5) Mylan is enjoined from making, using, offering, or selling the product described in ANDA 79-014 within the United States or importing the described product into the United States until after the expiration date of the '491 patent, plus any exclusivities afforded by 21 U.S.C. § 355a(c)(1)(B)(iii)[sic].

IT IS HEREBY STIPULATED, subject to the approval of the Court:

1. that the stay of the Apotex Action is lifted and a judgment in the form attached shall be entered.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Jack B. Blumenfeld*

---

Jack B. Blumenfeld (# 1014)  
Maryellen Noreika (# 3208)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899-1347  
(302) 658-9200  
jblumenfeld@mnat.com  
mnoreika@mnat.com

*Attorneys for Plaintiffs  
sanofi-aventis and sanofi-aventis U.S. LLC*

*Of Counsel:*

William T. Vuk  
KIRKLAND & ELLIS, LLP  
601 Lexington Ave.  
New York, NY 10022  
(212) 446-4800

**SO ORDERED:**

This 14<sup>th</sup> day of Jan, 2010

POTTER ANDERSON & CORROON LLP

*/s/ David E. Moore*

---

Richard L. Horwitz (# 2246)  
David E. Moore (# 3983)  
Hercules Plaza, 6th Floor  
1313 N. Market Street  
P.O. Box 951  
Wilmington, DE 19801  
(302) 984-6000  
rhorwitz@pottersanderson.com  
dmoore@pottersanderson.com

*Attorney for Defendants  
Apotex Inc. and Apotex Corp.*

*Of Counsel:*

Steven E. Feldman  
Sherry L. Rollo  
HUSCH BLACKWELL SANDERS LLP  
WELSH KATZ  
120 S. Riverside Plaza, 22nd Floor  
Chicago, IL 60606  
(312) 655-1500



---

**HONORABLE GREGORY MASLETT  
UNITED STATES DISTRICT JUDGE**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

IN RE: ALFUZOSIN HYDROCHLORIDE )  
PATENT LITIGATION ) MDL Docket No. 08-md-1941 (GMS)  
)

**JUDGMENT**

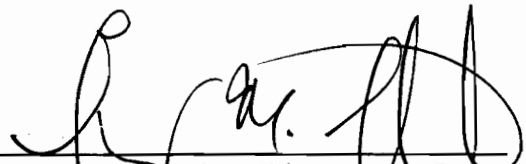
IT IS HEREBY ORDERED AND ADJUDGED:

1. that sanofi-aventis and sanofi-aventis U.S. LLC (collectively, "sanofi-aventis") asserted claims 1-5 (the "asserted claims") of U.S. Patent No. 4,661,491 ("the '491 patent") against Apotex Inc. and Apotex Corp. (collectively, "Apotex");
2. that the asserted claims of the '491 patent are not invalid;
3. that Apotex's proposed product described in Abbreviated New Drug Application No. 79-013 infringes the asserted claims of the '491 patent;
4. that Apotex will induce infringement of the asserted claims of the '491 patent;
5. that the effective date of any approval of Apotex's Abbreviated New Drug Application No. 79-013 under § 505(j) of the Federal Food, Drug & Cosmetic Act (21 U.S.C. § 355(j)) for the drug product described therein shall be a date not earlier than the expiration date of the '491 patent, plus any exclusivities afforded by 21 U.S.C. §§ 355a(c)(1)(B)(ii), 355a(c)(2); and
6. that Apotex, including its officers, agents, servants, employees, attorneys, and other persons who are in active concert or participation with Apotex who receive actual notice of this Judgment, are enjoined from making, using, offering, or selling the product described in Apotex's Abbreviated New Drug Application No. 79-013 within the United States

or importing the described product into the United States until after the expiration date of the '491 patent, plus any exclusivities afforded by 21 U.S.C. §§ 355a(c)(1)(B)(ii), 355a(c)(2).

**SO ORDERED:**

This 14<sup>th</sup> day of Jan, 2010



**HONORABLE GREGORY M. SLEET**  
**UNITED STATES DISTRICT JUDGE**