FOLEY
FOLEY & LARDNER LLP

FOLEY & LARDNER LLP
ATTORNEYS AT LAW
WASHINGTON HARBOUR
3000 K STREET, N.W., SUITE 500
WASHINGTON, D.C. 20007-5143
202.672.5300 TEL
202.672.5399 FAX
www.foley.com

WRITER'S DIRECT LINE
202.672.5430
drosen@foley.com EMAIL

December 7, 2007

**VIA FACSIMILE & FEDERAL EXPRESS**

Mr. Gary Buehler
Director, Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room – MPN II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Dockets Management Branch
Food and Drug Administration
Room 1061, Mail Stop HFA-305
5630 Fishers Lane
Rockville, MD 20852.

**Re: FDA Docket # 2007N-0382**
**Ramipril Capsules and 180-Day Generic Drug Exclusivity**

Dear Mr. Buehler:

On behalf of Cobalt Pharmaceuticals, Inc. ("Cobalt") we are providing a copy of the Federal Circuit's Order of December 3, 2007, denying Aventis' and King Pharmaceuticals' petition for panel rehearing and rehearing *en banc*. *See Aventis Pharma Deutschland Gmbh v. Lupin, Ltd.*, Civil Action No. 06-1530 (RDG) (Fed. Cir. December 3, 2007). As noted in the Court's Order, the mandate of the Court will issue on December 10, 2007. Once the Court's

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mandate is issued, Cobalt's 180 day exclusivity for its Ramipril Capsules (ANDA # 76-549) will be triggered.

Given the imminent triggering of Cobalt's exclusivity in just a few days, the concerns previously raised by other applicants that FDA must act to prevent the "blockage" or "parking" of Cobalt's exclusivity are now moot. Under the circumstances, the other tentatively approved ANDAs may be granted final approval only upon the expiration of Cobalt's 180-day exclusivity.

Sincerely yours,

David L. Rosen, B.S. Pharm, J.D.
Nathan A. Beaver

Cc: Elizabeth Dickinson, Esq.

# UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2006-1530, -1555

AVENTIS PHARMA DEUTSCHLAND GMBH,

Plaintiff-Cross Appellant,

and

KING PHARMACEUTICALS, INC.,

Plaintiff-Cross Appellant,

v.

LUPIN, LTD.
and LUPIN PHARMACEUTICALS, INC.,

Defendants-Appellants.

ORDER

NOTE: This order is nonprecedential.

# UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

## ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Cross-Appellants,* and a response thereto having been invited by the court and filed by the Appellants, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on December 10, 2007.

FOR THE COURT,

Jan Horbaly

Jan Horbaly
Clerk

Dated: 12/03/2007

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

DEC - 3 2007

JAN HORBALY
CLERK

cc: William A. Rakoczy
F. Dominic Cerrito, Joel Katcoff
Jeffrey B. Elikan

AVENTIS PHARMA V LUPIN LTD, 2006-1530 ,-1555
(DCT - 2:05-CV-421)

*A brief of amicus curiae filed on behalf of Pharmaceutical Research and Manufacturers of America.