

# APOTEX

ADVANCING GENERICS

September 10, 2009

VIA COURIER

Commissioner of Patents  
Canadian Intellectual Property Office  
165 Hôtel de Ville  
Gatineau, Quebec  
K1A 0C9



**Attention: Agnès Lajoie**

Dear Commissioner:

**Re: Apo-Triavir**

Attached please find a copy of the Form 10 – Application for Renewal of Authorization Under Section 21.12 of the Patent Act.

There is a possibility that we will not be able to ship the remaining quantity before the current authorization expires, therefore we are requesting the renewal.

Should you have any further questions, please feel free to contact me by telephone at (416) 401-7293 by fax number (416) 401-3809 or by email at [jhems@apotex.com](mailto:jhems@apotex.com).

Yours truly  
APOTEX INC.

John Hems  
Director, Regulatory Affairs



**APPLICATION FOR RENEWAL OF AUTHORIZATION UNDER SECTION 21.12 OF THE PATENT ACT**

In the matter of an application for renewal of authorization by Apotex Inc. (*name of applicant*) for export to Rwanda (*name of country or WTO Member*) of the following pharmaceutical product:

- (a) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*: A fixed dose combination of lamivudine (150 mg) + nevirapine (200 mg) + zidovudine (300 mg) (*name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product*); or
- (b) if the pharmaceutical product is a medical device: (*name of the pharmaceutical product as set out in Schedule 1 to the Act, its class, and its identifier within the meaning of section 1 of the Medical Devices Regulations*);

1. The undersigned, whose postal address and telephone number are  
Apotex Inc.,  
c/o Bruce D. Clark Ph.D., Vice-President, Regulatory and Medical Affairs,  
150 Signet Drive,  
Weston, Ontario, M9L 1T9,  
Tel: (416) 401-7875, Fax: (416) 401-3809

hereby applies for a renewal of authorization number CAMR-1 that was granted on September 19<sup>th</sup>, 2007 (*date*) authorizing the making, construction and use of the patented invention(s) identified in the patent numbers below, solely for purposes directly related to the manufacture of 8,720,640 Tablets (*unexported quantity*) of the above-mentioned pharmaceutical product and its sale for export to the above-mentioned country or WTO member.


2. For each patented invention to which the application for renewal relates, the name(s) of the patentee(s) of the invention, the name(s) and postal address(es) of the representative(s) of the patentee(s) or, if no representative has been appointed, the postal address(es) of the patentee(s), and the patent number(s) issued in respect of the invention are as follows:

Name of Patentee	Name and Address of Patentee's Representative or Address of Patentee	Patent Number
(a) Glaxo Group Limited	RICHES, McKENZIE & HERBERT LLP 2 Bloor Street East, Suite 1800 Toronto, Ontario, M4W 3J5	2,311,988 2,070,230 2,068,790
(b) Glaxo Group Limited	OGILVY RENAULT LLP Royal Bank Plaza, South Tower 200 Bay Street, Suite 3800, P.O. Box 84 Toronto, Ontario, M5J 2Z4	2,286,126
(c) Wellcome Foundation Limited	OGILVY RENAULT LLP Royal Bank Plaza, South Tower 200 Bay Street, Suite 3800, P.O. Box 84 Toronto, Ontario, M5J 2Z4	2,216,634 2,105,487
(d) Shire Biochem Inc.	SMART & BIGGAR/FETHERSTONHAUGH 438 University Avenue Suite 1500, Box 111 Toronto, Ontario, M5G 2K8	2,059,263 2,009,637
(e) Boehringer Ingelheim Pharmaceuticals Inc., Dr. Karl Thomae Gesellschaft Mit Beschränkter Haftung	SMART & BIGGAR/FETHERSTONHAUGH 438 University Avenue Suite 1500, Box 111 Toronto, Ontario, M5G 2K8	2,030,056

3. The undersigned hereby certifies that


- (a) the quantities of the pharmaceutical product that were authorized under authorization number CAMR-1 to be manufactured and sold for export under section 21.04 of the Act were not or will not be exported before the authorization ceases to be valid; and
- (b) the undersigned has complied with the terms of the authorization and the requirements of sections 21.06 to 21.08 of the Act.

Dated at Toronto, the 9<sup>th</sup> day of September, 2009,



Signature of Applicant

Sworn before me this 9th day of September, 2009,



Signature of Commissioner for Oaths

JOANNE MAURO, a Commissioner, etc.,  
City of Toronto, for Apotex Inc. and its subsidiaries,  
associates and affiliates.  
Expires June 25, 2010.

Canada