Goodmans LLP

Barristers & Solicitors
250 Yonge Street, Suite 2400
Toronto, Ontario Canada M5B 2M6
Telephone: 416.979.2211
Facsimile: 416.979.1234
goodmans.ca

Direct Line: 416.597.4142
hradomski@goodmans.ca

September 4, 2007

Our File No.: 051852

Delivered

Murray Wilson
Canadian Intellectual Property Office
Place du Portage I
50 Victoria St., Room C-114
Gatineau, Quebec K1A 0C9

Dear Mr. Wilson:

Re: Application Pursuant to Section 21.04 of the *Patent Act* and Canadian Letters Patent Nos. 2,311,988, 2,070,230, 2,068,790, 2,286,126, 2,059,263, 2,009,637, 2,216,634, 2,105,487, 2,030,056

We are counsel for Apotex Inc.

Please accept the attached application for filing with the Commissioner of Patents.

Yours very truly,

GOODMANS LLP

Per:

H.B. Radomski
GOODMANS\\5486679.1

SOLEMN OR STATUTORY DECLARATION UNDER PARAGRAPH 21.04(3)(*c*) OF THE PATENT ACT

In the matter of an application 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 tablet of lamivudine (150 mg) + nevirapine (200 mg) + zidovudine (300 mg), as provided in Schedule 1 to the *Patent Act*

(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 Apotex Inc. *(name of applicant)* hereby declares, in accordance with paragraph 21.04(3)(*c*) of the Act, that on July 13, 2007 *(date)*, being at least 30 days before the date of filing of the application for an authorization under section 21.04 of the Act, the undersigned

(*a*) sought from the patentee or, if there is more than one, from each of the patentees, namely,

	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

COPIE AU FAC-SIMILÉ CONFORME À L'ORIGINAL ATTESTATION ANNEXÉE.

HUISSIER DE JUSTICE

	Name of Patentee	Name and Address of Patentee's Representative or Address of Patentee	Patent Number
(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 Beschrankter Haftung	**SMART & BIGGAR/ FETHERSTONHAUGH** 438 University Avenue Suite 1500, Box 111 Toronto, Ontario M5G 2K8	2,030,056

(name(s) of the patentee(s)), by certified or registered mail addressed to

	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 Beschrankter Haftung	**SMART & BIGGAR/ FETHERSTONHAUGH** 438 University Avenue Suite 1500, Box 111 Toronto, Ontario M5G 2K8	2,030,056

(name(s) and postal address(es) of the patentee(s) or the representative(s) of the patentee(s), if any), a licence to manufacture and sell the pharmaceutical product for export to the country or WTO Member named in the application on reasonable terms and conditions and that such efforts have not been successful; and

(*b*) provided the patentee, or each of the patentees, as the case may be, by certified or registered mail, in the written request for a licence, with the information that is in all material respects identical to the information required under paragraphs 21.04(2)(*a*) to (*g*) of the Act.

2. The name, postal address and telephone number of the undersigned are as follows:

Apotex Inc., c/o Bruce D. Clark Ph.D., Vice-President, Regulatory and Medical Affairs

150 Signet Drive

Toronto, ON M9L 1T9

Tel: (416) 749-9300, Fax: (416) 401-3835

Dated at Toronto, the 28th day of August, 2007,

(John Hems for B. Clark)

Signature of applicant Goodmans LLP H Radomski Sept 4/07

GOODMANS\\5481762.1

No.: 10130 Client No.: 01005698 Re No.: 0062

OGILVY RENAULT
LLP / S.E.N.C.R.L., s.r.l.

Facsimile

Number of pages including this cover sheet: 5

Date: August 8, 2007
From: **Patrick E. Kierans**
Telephone: (416) 216-3904
Direct Fax: (416) 216-3930
E-Mail: pkierans@ogilvyrenault.com

To	Company - City	Phone	Fax
H.B. Radomski	Goodmans LLP	(416) 979-2211	(416) 979-1234

Message

OGILVY RENAULT

LLP / S.E.N.C.R.L., s.r.l.

Toronto, August 8, 2007

BY FACSIMILE

H.B. Radomski
Goodmans LLP
Barristers & Solicitors
250 Yonge Street, Suite 2400
Toronto, Ontario M5B 2M6

Dear Mr. Radomski,

RE: Apotex Proposal for Humanitarian Export to Rwanda of HIV Drugs

We refer to your letter of July 13, 2007 advising of Apotex's proposal pursuant to section 21.04 of the *Patent Act* to provide an HIV fixed dose combination to Rwanda. You refer to patents owned by our clients, Glaxo Group Limited and The Wellcome Foundation Limited ("Glaxo").

Minister of Health Approval of the Apotex FDC

We assume that the Minister of Health has taken responsibility to determine whether the Apotex FDC is safe and efficacious. Glaxo does not market a fixed dose combination of zidovudine, lamivudine and nevirapine. Accordingly, Glaxo has no information regarding the safety and efficacy of the Apotex FDC and can make no representation in respect thereof. In the circumstances, Glaxo cannot accept any liability arising from the manufacture, sale and use of the Apotex FDC.

Glaxo Consent to Authorization

Glaxo recognizes Apotex's proposal as a humanitarian initiative under Canada's Access to Medicines Regime and consents to the Commissioner of Patents granting to Apotex an authorization under Glaxo's patents to manufacture and export to the Treatment Research AIDS Centre in Kigali, Rwanda, 15,600,000 tablets of a fixed dose combination of zidovudine, lamivudine and nevirapine (the "Apotex FDC") at a price of US$ 0.405 per tablet.

Glaxo is content with the controls created by Canada's Access to Medicines Regime which are designed to ensure that these essential medicines reach the patients for whom they are intended. The authorisation to be granted will naturally be subject to those controls.

OGILVY RENAULT
LLP/S.E.N.C.R.L., s.r.l.

We will be forwarding a copy of this letter to the Commissioner of Patents in order to communicate Glaxo's position in respect of this initiative.

We understand that Apotex proposes to supply this medicine on a no profit basis. In agreeing to a royalty rate of 0%, Glaxo relies on the representation that Apotex is deriving no profit from its sale of the Apotex FDC at the proposed price of USD $0.405 per tablet.

Anti-diversion Measures

Glaxo wishes to ensure that the Apotex FDC reaches and remains with the patients for whom it is intended. Glaxo would be pleased to receive information regarding the steps Apotex and its proposed purchaser will take to avoid diversion of the Apotex FDC to any markets other than Rwanda. In particular, we would appreciate receiving samples of the packaging Apotex proposes to use and details of the proposed shape and color of the tablet.

Glaxo assumes that Apotex will cooperate with Glaxo to detect and prevent any such diversion of the Apotex FDC should it occur.

Concerns Relating to Patient Safety Arising from the Proposed Use of APO-TRIAVIR as a Product Name

The Apotex FDC was placed on the WHO Prequalification Programme list for HIV/AIDS drugs on August 10, 2006 without reference to the name TRIAVIR. Rather, it refers only to the International Nonproprietary Name (INN) "zidovudine/lamivudine/nevirapine".

Both Health Canada and the WHO insist that drug names be distinctive in sound and appearance and should not be liable to confusion. This is important for the clear and unambiguous identification, safe prescribing and dispensing of medicines to patients.

Apotex proposes to sell its FDC under the name APO-TRIAVIR. As Apotex is aware, Glaxo markets a fixed dose combination anti-viral drug containing lamivudine, zidovudine and abacavir sulfate under the trade-mark TRIZIVIR® (the "Glaxo FDC"). The Glaxo FDC is marketed globally and the mark is registered in as many as 158 countries around the world. The Glaxo FDC is significantly different from the Apotex FDC, in that the Apotex FDC contains a different combination of products, and should not be confused with it by health authorities, health care providers or patients.

Given the obvious similarities between TRIZIVIR and TRIAVIR in sound and appearance, Apotex's proposed use of the name APO-TRIAVIR for its FDC, suggests the product is Apotex's version of TRIZIVIR. This would create confusion and imperil patient safety wherever the Apotex FDC would be distributed. This is a concern of which you are already aware.

OGILVY RENAULT
LLP/SENCRL

Given WHO's clear prefercnce for the use of INN names only, Glaxo assumes that, in order to avoid any possibility of confusion and to protect patient safety, Apotex will abandon its proposal to use the name APO-TRIAVIR in relation to the Apotex FDC and will refer only to the WHO approved INN "zidovudine/lamivudine/nevirapine" on its packaging, labelling and related documents.

We wish to make it clear that Glaxo grants no rights under any of its trade-marks and expresaly reserves its position in relation to its trade-marks.

Please let us know whether Glaxo can be of further assistance with respect to Apotex's application to the Commissioner of Patents for an authorization under the cited patents to manufacture and export the Apotex FDC.

Yours very truly,

Patrick B. Kierans

PEK/JG/dg

OGILVY RENAULT
LLP/S.E.N.C.R.L., s.r.l.

cc:	Minister of Health Submission & Information Policy Division Bureau of Policy and Coordination Therapeutic Products Programme 1st Floor, Room A-110 (A.L. 0201A1) Finance Building, Tunney's Pasture Ottawa, Ontario K1A 1B9	Via Mail and Facsimile: (613) 946-5610
	Attention: David K. Lee, Patent Officer - Legal	(with copy of letter of July 13, 2007)
cc:	Commissioner of Patents Place du Portage I 50 Victoria St., Room C-114 Gatineau, Quebec K1A 0C9	*Via Mail* (with copy of letter of July 13, 2007)
cc:	Boehringer Ingelheim Pharmaceuticals, Inc. c/o Smart & Biggar P.O. Box 2999, Station D 55 Metcalfe Street, Suite 900 Ottawa, Ontario K1P 5Y6	*Via Mail and Facsimile: (416) 591-1690* (with copy of letter of July 13, 2007)
cc:	Shire Biochem Inc. c/o Smart & Biggar P.O. Box 2999, Station D 55 Metcalfe Street, Suite 900 Ottawa, Ontario K1P 5Y6	*Via Mail and Facsimile: (416) 591-1690* (with copy of letter of July 13, 2007)

Shire BioChem Inc.
2250, boul. Alfred-Nobel, Bureau 500, Ville Saint-Laurent, Qc. Canada, H4S 2C9
2250 Alfred-Nobel blvd., suite 500, St-Laurent, Quebec Canada, H4S 2C9
☎ : (514) 787-2321 Fax / Télécopieur : (514) 787-2423

Fax/Télécopie

Shire

To/Destinataire:	**Mr. H. B. Radomski**	**Fax Nº / Nº de télécopieur : 416-979-1234**
Company / Société :	**Goodmans LLP**	
From / Expéditeur :	Antonio Aveledo	**Fax Nº / Nº de télécopieur :** (514) 787-2423
		Direct Line / Ligne Directe: (514) 787-2321
		E-Mail / Courriel : aaveledo@shire.com
Date :	August 13, 2007	**Nº of Pages / Nbre de pages:** 3

Subject / Objet : **Response to your letter of July 13, 2007**

Dear Mr. Radomski:

Please find enclosed our response to your letter of July 13, 2007.

Would you be kind enough to acknowledge receipt of this facsimile.

Best regards,

Antonio Aveledo
Intellectual Property Advisor
514-787-2319
aaveledo@shire.com

COPIE CONFORME AU FAC-SIMILÉ
REÇU PAR TÉLÉCOPIEUR ET TEL
QUE PRÉCISÉ À L'ARTICLE
ANT
HUISSIER DE JUSTICE

Shire BioChem Inc.
2250 Alfred-Nobel Blvd., Suite 500
Ville Saint-Laurent, Quebec H4S 2C9 Canada
Tel. 514 787-2300 Fax 514 787-2427
www.shire.com

Shire

CONFIDENTIAL

Mr. H. B. Radomski
Goodmans LLP
Barristers & Solicitors
250 Yonge Street, Suite 2400
Toronto, ON, M5B 2M6

Montréal, August 13, 2007

By Fax and Courier

Dear Mr. Radomski:

Re: Licensing Request re: Patent. No. 2,059,263 and 2,009,637

We have received your July 13, 2007 letter, addressed to our patent agents of record, Smart & Biggar, relaying a request from Apotex Inc. ("Apotex") for a licence in respect of patent numbers 2059263 and 2009637, of which Shire BioChem Inc. ('Shire') is the owner.

Shire supports the humanitarian aims of Canada's Access to Medicines Regime ("CAMR"). We understand that Rwanda has notified the World Trade Organization of its intention to invoke Paragraph 6 of the Doha Declaration by notifying that it expects, over the next two years, to import 260,000 packs of so-called "triple therapy" consisting of zidovudine, lamivudine and nevirapine. In the context of its licence request, Apotex has clearly identified to Shire that Rwanda is the country of intended export for the 15,600,000 tablets of a fixed dose combination (FDC) tablet of lamivudine (150 mg) + nevirapine (200 mg) + zidovudine (300 mg), a combination of medicinal ingredients that appears in Schedule 1 to the *Patent Act*. **The patents for which a licence is requested from Shire relate to the said combination product.**

Shire does not object to the issuance of a compulsory licence of the '263 and '637 patents under the provisions of the *Patent Act* for the purpose of Apotex manufacturing the FDC in Canada for export to Rwanda. In addition, we note Apotex's request for a royalty-free licence. Shire agrees, on the representations of Apotex that the product supplied will be on a cost basis, to work with Apotex to attempt to arrange a mechanism whereby such royalty is effectively waived.

The manner in which the product will be manufactured and distributed is unclear. We assume that the 260,000 packs of the FDC requested by Rwanda will each contain 60 tablets (which would amount to 15,600,000 tablets) and seek your confirmation that the FDC product will be sold in packs of 60 tablets.

Of course, we assume the product will be marked in accordance with all applicable regulations and that the product's appearance will be posted on a website as required under the *Patent Act*. We also understand that the requirements under the *Food and Drug Regulations*, more precisely in section C.07, provide that, in the event that a compulsory licence issues, any product exported must be labelled and marked in a particular manner. Moreover, section C.07 provides that the applicant (Apotex) must establish and maintain records with respect to the product authorized to be sold for auditing purposes. Shire believes these provisions will aid in tracking product after it leaves Canada, and will assist against improper or illicit diversion of product which would be contrary to the humanitarian objectives of the CAMR.

We trust that Apotex shares Shire 's concern to avoid diversion of product, and will make every effort to ensure that the residents of Rwanda will, in fact, receive the product as intended.

We look forward to receiving a copy of the contract between Apotex and the government of Rwanda in accordance with the CAMR, in advance of the first export of any lot of the product to Rwanda.

Yours truly,

Claude Perron
VP & General Manager

SOLEMN OR STATUTORY DECLARATION UNDER CLAUSE 21.04(3)(*d*)(i)(B) OF THE PATENT ACT

In the matter of an application 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 tablet of lamivudine (150 mg) + nevirapine (200 mg) + zidovudine (300 mg), as provided in Schedule 1 to the *Patent Act*

(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 Apotex Inc. *(name of applicant)* hereby declares, in accordance with clause 21.04(3)(*d*)(i)(B) of the Act, that the pharmaceutical product to which the application relates is the pharmaceutical product that is specified in the notice in writing that the WTO Member has provided to the TRIPS Council.

2. The name, postal address and telephone number of the undersigned are as follows:

Apotex Inc., c/o Bruce D. Clark Ph.D., Vice-President, Regulatory and Medical Affairs

150 Signet Drive

Toronto, ON M9L 1T9

Tel: (416) 749-9300, Fax: (416) 401-3835

Dated at Toronto, the 28th day of August, 2007,

(John Hems for B. Clark)

Signature of applicant

Goodmans LLP/H Radomski Sept 4/07

GOODMANS\\5481769.1

COPIE CONFORME AU FAC-SIMILÉ REÇU PAR TÉLÉCOPIEUR ET TEL QUE PRÉCISÉ À L'ATTESTATION ANNEXÉE.

HUISSIER DE JUSTICE

REPUBLIC OF RWANDA

MINISTRY OF HEALTH
MINISTER OF STATE IN-CHARGE
OF HIV/AIDS AND OTHER
EPIDEMICS

To Whom It May Concern,

I, Dr. Innocent Nyaruhirira, certify that I am the Minister of State in charge of HIV/AIDS and other epidemics at the Rwanda Ministry of Health. I certify that the Treatment and Research AIDS Center (TRAC) is an agency of the Rwanda Ministry of Health and that Dr. Anita Asiimwe is the Director of TRAC, that this is a true copy of a letter sent by her on 11th May, 2007.

Sincerely,

Dr. Innocent Nyaruhirira
Minister of State in Charge of HIV/AIDS and Other Epidemics

COPIE CONFORME AU FAC-SIMILÉ
REÇU PAR TÉLÉCOPIEUR ET TEL
QUE PRÉCISÉ À L'ATTESTATION
ANNEXÉE.

HUISSIER DE JUSTICE

TRAC
TREATMENT & RESEARCH AIDS CENTER
Centre de Traitement et de Recherche sur le SIDA

11th May, 2007

Council on TRIPS
World Trade Organization
Centre William Rappard,
Rue de Lausanne 154,
CH-1211 Geneva 21,
Switzerland

Notification to Council for TRIPS pursuant to General Council Decision of August 30, 2003 on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health:

Based on Rwanda's present evaluation of its public health needs, we expect to import during the next two years 260,000 packs of TriAvir, a fixed-dose combination product of Zidovudine, Lamivudine and Nevirapine (hereinafter referred to as the "Product") manufactured in Canada by Apotex, Inc. However, because it is not possible to predict with certainty the extent of the country's public health needs, we reserve the right to modify the foregoing estimate as necessary or appropriate.

Pursuant to Paragraph 7 of the Doha Declaration and implementation thereof by the TRIPS Council (Decision of the Council for TRIPS of 27 June 2002), we have decided that we will not enforce rights provided under Part II Section 5 of the TRIPS Agreement that may have been granted within Rwanda's territory with respect to the Product.

Sincerely,
Dr Anita Asiimwe
Director
TRAC

Boulevard de la Révolution, B.P 2717 Kigali
Tél. : (250)578472 ; Fax : (250)578473
E-mail : tracinfo@tracrwanda.org

WORLD TRADE ORGANIZATION

IP/N/9/RWA/1
19 July 2007

(07-3075)

Council for Trade-Related Aspects of Intellectual Property Rights

Original: English

NOTIFICATION UNDER PARAGRAPH 2(A) OF THE DECISION OF 30 AUGUST 2003 ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

RWANDA

The following notification from Rwanda's Government Centre for the Treatment & Research on AIDS (TRAC) has been received from the Delegation of Rwanda on 17 July 2007 for circulation to the Council for TRIPS.

Based on Rwanda's present evaluation of its public health needs, we expect to import during the next two years 260,000 packs of TriAvir, a fixed-dose combination product of Zidovudine, Lamivudine and Nevirapine (hereinafter referred to as the "Product") manufactured in Canada by Apotex, Inc. However, because it is not possible to predict with certainty the extent of the country's public health needs, we reserve the right to modify the foregoing estimate as necessary or appropriate.

Pursuant to Paragraph 7 of the Doha Declaration and implementation thereof by the TRIPS Council (Decision of the Council for TRIPS of 27 June 2002), we have decided that we will not enforce rights provided under Part II Section 5 of the TRIPS Agreement that may have been granted within Rwanda's territory with respect to the Product.

051852

Goodmans LLP

Barristers & Solicitors
250 Yonge Street, Suite 2400
Toronto, Ontario Canada M5B 2M6
Telephone: 416.979.2211
Facsimile: 416.979.1234
goodmans.ca

Direct Line: 416.597.4142
hradomski@goodmans.ca

July 13, 2007

Our File No.: 051852

By Registered Mail

Agent for Glaxo Group Limited re Canadian Letters Patent Nos. 2,311,988, 2,070,230, 2,068,790
RICHES, MCKENZIE & HERBERT LLP
2 Bloor Street East, Suite 1800
Toronto, Ontario M4W 3J5

Agent for Glaxo Group Limited re Canadian Letters Patent No. 2,286,126
OGILVY RENAULT LLP
Royal Bank Plaza, South Tower
200 Bay Street, Suite 3800, P.O. Box 84
Toronto, Ontario M5J 2Z4

Agent for Shire Biochem Inc. re Canadian Letters Patent Nos. 2,059,263, 2,009,637
SMART & BIGGAR/FETHERSTONHAUGH
438 University Avenue
Suite 1500, Box 111
Toronto, Ontario M5G 2K8

Agent for the Wellcome Foundation Limited re Canadian Letters Patent Nos. 2,216,634, 2,105,487
OGILVY RENAULT LLP
Royal Bank Plaza, South Tower
200 Bay Street, Suite 3800, P.O. Box 84
Toronto, Ontario M5J 2Z4

Agent for Boehringer Ingelheim Pharmaceuticals, Inc.; Dr. Karl Thomae Gesellschaft Mit Beschrankter Haftung re Canadian Letters Patent No. 2,030,056
SMART & BIGGAR/FETHERSTONHAUGH
438 University Avenue
Suite 1500, Box 111
Toronto, Ontario M5G 2K8

Dear Sirs/Mesdames:

Re: Licensing Request for Patents Associated with the Drug TriAvir: Canadian Letters Patent No. 2,311,988, 2,070,230, 2,068,790, 2,286,126, 2,059,263, 2,009,637, 2,216,634, 2,105,487, 2,030,056

We are the solicitors for Apotex Inc. ("Apotex").

We have identified you as the Canadian representatives for the patentees in respect of the above noted patents, nominated pursuant to section 29 of the *Patent Act*. We understand the above noted patents to be the patents associated with an anti-viral drug, containing lamivudine, nevirapine and zidovudine, sometimes known as "TRIAVIR".

COPIE CONFORME AU FAC-SIMILE
REÇU PAR TÉLÉCOPIEUR
QUE PRÉCISÉ À L'ATTE
ANNEXÉ
HUISSIER DE JUSTICE

Goodmans LLP

Please accept this letter and the attached documentation as a request for licence in respect of the above noted patents, as described in subsection 21.04(c) of the *Patent Act*.

Apotex wishes to manufacture, under licence, a generic version of this drug, to be marketed as APO-TRIAVIR, exclusively for export to the Treatment & Research Aids Center, Rwanda. As Apotex intends to sell the product at its own cost, it requests a royalty-free licence. The licence will be for two years in order to facilitate the sale described below.

Apotex proposes to sell APO-TRIAVIR on the following terms:

- A fixed dose combination tablet of lamivudine (150 mg) + nevirapine (200 mg) + zidovudine (300 mg), as provided in Schedule 1 to the *Patent Act*, will be manufactured and sold;
- 15,600,000 tablets will be manufactured and sold at a price of USD$0.405 per tablet;
- the sales will occur pursuant to licences from all known patentees of the relevant patents, whose agents are addressed in this letter;
- the drugs will be exported to a Rwanda (a country listed in Schedule 2 to the *Patent Act*); and
- Treatment and Research AIDS Center, an agency of the Rwanda Ministry of Health, will purchase and receive the drug product for sale in Rwanda.

We kindly request a response to this licensing request within 30 days of your receipt of this letter. If Apotex does not receive a reasonable response within that time period, Apotex will file with the Commissioner of Patents documentation substantially in the form attached, seeking a compulsory licence in accordance with section 21.04 of the *Patent Act*.

Yours very truly,

GOODMANS LLP

Per: H.B. Radomski/jm

H.B. Radomski
Att.
bcc: M. Hastie, B. Sherman, J. Hems, I. Hughes

GOODMANS\5469540.1

FORM 1

(Section 4)

APPLICATION FOR AUTHORIZATION UNDER SECTION 21.04 OF THE PATENT ACT

1. The undersigned hereby applies for an authorization under section 21.04 of the Act.

2. The pharmaceutical product that the undersigned intends to manufacture and sell for export under the authorization is

(*a*) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*

A fixed dose combination tablet of lamivudine (150 mg) + nevirapine (200 mg) + zidovudine (300 mg), as provided in Schedule 1 to the *Patent Act*

(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).

3. The maximum quantity of the pharmaceutical product that the undersigned intends to manufacture and sell for export under the authorization is

15,600,000 tablets

4. For each patented invention to which the application 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

	Name of Patentee	Name and Address of Patentee's Representative or Address of Patentee	Patent Number
(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 Beschrankter Haftung	**SMART & BIGGAR/ FETHERSTONHAUGH** 438 University Avenue Suite 1500, Box 111 Toronto, Ontario M5G 2K8	2,030,056

5. The name of the WTO Member or country that has notified, respectively, the TRIPS Council or the Government of Canada in writing of its requirement for the pharmaceutical product named in the application, and to which the pharmaceutical product is to be exported, is

Rwanda (*Patent Act*, Schedule 2 country)

6. The name, postal address and telephone number of the person or entity referred to in paragraph 21.04(2)(*f*) of the Act, to which the pharmaceutical product is to be sold, are as follows:

Treatment & Research AIDS Center, c/o Dr. Anita Asiimwe, Director

Boulevard de La Revolution, B.P. 2717

Kigali

tel.: +(250) 578472 fax: +(250) 578473

7. For the purpose of subsection 21.06(1) of the Act, the website address of the undersigned is

http:// www.apotex.ca

8. The name, postal address and telephone number of the undersigned are as follows:

Apotex Inc., c/o Bruce D. Clark Ph.D., Vice-President, Regulatory and Medical Affairs

150 Signet Drive

Toronto, ON M9L 1T9

Tel: (416) 749-9300, Fax: (416) 401-3835

Dated at _____ the _____ day of _____,

_____

Signature of applicant

_____ _____

GOODMANS\\5469542.1

REGISTERED MAIL RECEIPT

FILE # 051852

DATE July 13 2007

LAWYER/CLERK : Jessica Michael

TRACKING LABEL :

Registered / Recommandé
Domestic / Régime intérieur

To / Destinataire
Name / Nom: Riches, McKenzie + Herbert
Address / Adresse: 2 Bloor ste
City / Ville: Toronto
Province / Postal Code / Code postal:

FOR DELIVERY CONFIRMATION / POUR CONFIRMER LA LIVRAISON
1 888 550-6333
www.canadapost.ca
www.postescanada.ca

Declared Value / Valeur déclarée: $ 7.88

Item No. / N° de l'article: 79 171 077 941

CUSTOMER RECEIPT / REÇU DU CLIENT

EATON CENTRE POST OFFICE
370789
2007 -07- 13
TORONTO, ONTARIO
M5B 2H0

Registered / Recommandé
Domestic / Régime intérieur

To / Destinataire
Name / Nom: Ogilvy Renault
Address / Adresse:
City / Ville: Toronto
Province / Postal Code / Code postal:

FOR DELIVERY CONFIRMATION / POUR CONFIRMER LA LIVRAISON
1 888 550-6333
www.canadapost.ca
www.postescanada.ca

Declared Value / Valeur déclarée: $

Item No. / N° de l'article: 79 171 077 924

CUSTOMER RECEIPT / REÇU DU CLIENT

Registered / Recommandé
Domestic / Régime intérieur

To / Destinataire
Name / Nom: Ogilvy Renault
Address / Adresse:
City / Ville: Toronto
Province / Postal Code / Code postal:

FOR DELIVERY CONFIRMATION / POUR CONFIRMER LA LIVRAISON
1 888 550-6333
www.canadapost.ca
www.postescanada.ca

Declared Value / Valeur déclarée: $

Item No. / N° de l'article: 79 171 077 936

CUSTOMER RECEIPT / REÇU DU CLIENT

Registered / Recommandé
Domestic / Régime intérieur

To / Destinataire
Name / Nom: Smart + Biggar
Address / Adresse:
City / Ville: Toronto
Province / Postal Code / Code postal:

FOR DELIVERY CONFIRMATION / POUR CONFIRMER LA LIVRAISON
1 888 550-6333
www.canadapost.ca
www.postescanada.ca

Declared Value / Valeur déclarée: $

Item No. / N° de l'article: 79 171 077 805

CUSTOMER RECEIPT / REÇU DU CLIENT

Registered / Recommandé
Domestic / Régime intérieur

To / Destinataire
Name / Nom: Smart + Biggar
Address / Adresse:
City / Ville: Toronto
Province / Postal Code / Code postal:

FOR DELIVERY CONFIRMATION / POUR CONFIRMER LA LIVRAISON
1 888 550-6333
www.canadapost.ca
www.postescanada.ca

Declared Value / Valeur déclarée: $

Item No. / N° de l'article: 79 171 077 815

CUSTOMER RECEIPT / REÇU DU CLIENT

COPIE CONFORME AU FAC-SIMILÉ
REÇU PAR TÉLÉCOPIEUR ET TEL
PRÉCISÉ À L'ATTE
AU
HUISSIER DE JUSTICE

CANADA, PROVINCE DE QUÉBEC

APOTEX INC.
Partie Demanderesse

CANADIAN INTELLECTUAL PROPERTY OFFICE a/s MURRAY WILSON
Partie Défenderesse

ATTESTATION D'AUTHENTICITÉ

Je, soussigné, Frédéric Hurens Huissier de justice de la province de Québec, ayant un bureau d'affaires au 50-C BOULEVARD ST-RAYMOND #201, GATINEAU, QC, CANADA, J8Y 1R7, certifie sous mon serment d'office que le 4 septembre 2007 à 13:00, j'ai reçu par télécopieur LA PRÉSENTE « SOLEMN OR STATUTORY DECLARATION UNDER PARAGRAPH 21.04(3)(c) OF THE PATENT ACT AND PIECES» .

L'expéditeur de ce document est GOODMANS
et le numéro de télécopieur émetteur est 416-979-1234.

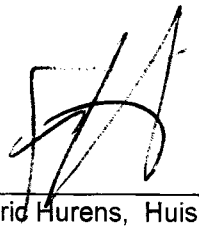
Conformément à l'article 82.1 du Code de procédure civile, j'ai préparé des copies conformes du fac-similé du document reçu par télécopieur.

Le total de mes honoraires et déboursés s'élève à 67.80.

Je dresse en conséquence la présente attestation d'authenticité pour servir et valoir ce que de droit.

Gatineau, 4 septembre 2007

ATTESTATION D'AUTHENTICITÉ	37,50 $
PHOTOCOPIES	12,00 $
FAX	10,00 $
SOUS-TOTAL	59,50 $
TPS	3,57 $
TVQ	4,73 $
TOTAL	67,80 $



Frédéric Hurens, Huissier de justice
Permis # 902

Goodmans (GOOD)
a/s : BYRON RAPHAEL
v/d : 051852

(Q) ADMIN 0 E0904 I0904-13:53 REF:4762-1-1-1

Waters et associés
50 Boulevard St-Raymond 201
Gatineau, QC, CA, J8Y 1R7
Tél. : (819) 595-5999 Fax : (819) 595-1444
T.P.S. : 143423010T T.V.Q. : 1023286561