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PATENT INFORMATION AND TRANSPARENCY:

A Methodology for Patent Searches on Essential Medicines in Developing Countries

July 2012

Patent Information and Transparency: A Methodology for Patent Searches on Essential Medicines in Developing Countries

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Table of Contents

Acronyms and Abbreviations	1
Background and Acknowledgements	3
Executive Summary	5
1. Introduction	9
1.1 Patent Information and Transparency.....	10
1.2 Organization of the Methodology	11
2. Patents on Medicines	13
2.1 Patenting of Inventions in Pharmaceutical Products	14
2.2 Patent Information from Patent Offices.....	16
2.2.1 Patent Offices in Developing Countries	16
2.2.2 Developed Country Patent Offices.....	19
2.3 WIPO PCT Database	20
2.4 Patent Searches by Law Firms.....	21
3. Searching for Medicine Patents	23
3.1 Patent Searches Using Molecular and Structural Formulae	24
3.2 Chemical Name Searching	25
3.3 CAS Registry Numbers	26
3.4 International Non-Proprietary Names (INN)	26
3.5 International Patent Classification (IPC)	27
3.6 Limitations of Chemical and Pharmaceutical Subject Matter Searches	28

4.	Developing a Methodology for Patent Searches	29
4.1	Sources of Patent Information	30
4.2	US FDA Orange Book	32
4.3	Health Canada Patent Register	34
4.3.1	Concept of “Relevant” Patent in the Health Canada System	35
4.4	Searching for Patent Information from FDA Orange Book and Health Canada..	37
4.5	Limitations of Using the FDA Orange Book and Health Canada Patent Register	37
4.6	Advantages of Using Health Canada and/or the Orange Book Patent Register ..	38
5.	Determining the Patent Landscape	39
5.1	Priority Patent Applications.....	39
5.1.1	Identifying Priority Patent Data for Pharmaceutical Products	40
5.2	Patent Families	40
5.2.1	Patent Family Searching.....	42
5.3	Patent Search and Verification of Patent Status at Regional and National Patent Offices.....	43
5.4	Analysis of Patent Claims	44
5.5	Limitations of the Methodology.....	45
6.	A Tool for Patent Searches	47
6.1	Using the Methodology.....	47
6.2	Facilitating Transparency of Patent Information	49
	Appendices: The WHO Patent Project and Patent Search Results	51
	Appendix 1A: WHO Patent Project.....	51
	Appendix 1B: Priority patent application data and INPADOC patent families for 19 antiretroviral drugs and combinations, using data from the Health Canada Patent Register and the US FDA Orange Book.....	53
	Appendix 1C: Results of patent search at the State Intellectual Property Office of the People’s Republic of China (SIPO), as of August 2006.....	63
	Appendix 1D: Results of patent search at the Companies and Intellectual Property Registration Office of South Africa (CIPRO), as of November 2006	70
	Appendix 1E: Results of patent search by Lawyers Collectives at the Indian Patent Offices, as of October 2006.....	76

Appendix 2:	Priority patent application data and INPADOC patent families for 19 antiretroviral drugs and combinations reported in the Health Canada Patent Registry and in the US Food and Drug Administration Orange Book	84
Appendix 3A:	Patent search on antiretroviral drugs at the State Intellectual Property Office of the Popular Republic of China (SIPO) as of August 2006.....	93
Appendix 3B:	Patent search on antiretroviral drugs at the Companies and Intellectual Property Registration Office of South Africa (CIPRO) as of November 2006	100
Appendix 3C:	Patent search on antiretroviral drugs conducted by Lawyers Collectives at the Indian Patent Offices as of October 2006	106

List of Acronyms and Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ANVISA	Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency–Brazil)
ARIPO	African Regional Intellectual Property Organization
ARV	Antiretroviral (medicines)
CAS	Chemical Abstracts Service
CIPRO	South African Companies and Intellectual Property Registration Office
EAPC	Eurasian Patent Convention
EPO	European Patent Office
FDA	Food and Drug Administration (US)
GSPOA	Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
HIV	Human Immunodeficiency Virus
INN	International Non-Proprietary Names
INPADOC	International Patent Documentation Center
INPI	Industrial Property Office (Brazil)
IPC	International Patent Classification
IUPAC	International Union of Pure and Applied Chemistry
LDCs	Least Developed Countries
MDG	Millennium Development Goals
MSF	Médicins Sans Frontières (Doctors without Borders)
NDA	New Drug Application
NDS	New Drug Submission
OAPI	Organisation Africaine de la Propriété Intellectuelle (African Intellectual Property Organization)
PCT	Patent Cooperation Treaty
PM (NOC)	Patented Medicines (Notice of Compliance)
SIPO	Chinese State Intellectual Property Office
SNDS	Supplement to a New Drug Submission

TRIPS	Agreement on Trade-related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
USPTO	US Patent and Trademarks Office
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Office
WTO	World Trade Organization

Background and Acknowledgements

The past decade has seen an impressive scale-up in access to antiretroviral HIV treatment, thanks to several factors, including dramatic price reductions due to generic competition. Despite this success, the gap persists and 53 percent of the people in need still not have access to treatment. At the same time, prices of newer antiretroviral (ARV) medicines, which are increasingly needed, are a lot higher. Similar is the situation with medicines for treatment of certain HIV co-infections such as multidrug-resistant tuberculosis and hepatitis C.¹ Many of these medicines are patent-protected. Knowing their patent status in countries and regions is instrumental for countries to lawfully access these medicines at affordable prices, provide a sustainable response to HIV and AIDS, and meet the MDG 6 targets to combat HIV/AIDS, malaria, and other diseases.

This Methodology for Patent Searches (Patent Methodology) has had a long evolution. First initiated as a pilot project in 2005 at the World Health Organization (WHO), it was developed with the technical assistance of the European Patent Office (EPO) and financial support from the Joint United Nations Programme on HIV/AIDS (UNAIDS). The objective was to develop methods for patent searches on essential medicines in developing countries, based on an earlier effort by Médecins sans Frontières (MSF). A summary of the WHO Patent Project and the results of the patent searches conducted using the Patent Methodology are appended in Appendix 1, below. In 2008, the United Nations Development Programme (UNDP) together with WHO and EPO, organized an expert consultation comprising representatives from patent offices, drug regulatory authorities, research institutions/universities and civil society organizations to provide a technical assessment of the methodology. Based on this project, the WHO Regional Offices of the South-East Asian and Western Pacific Regions, in 2010, published a brief guide on conducting patent searches.

With the release of this document, UNDP aims to develop a guide for conducting patent searches on essential medicines in developing countries. The main aim of the present document is two-fold; first, to set out the technical aspects of the rationale for the Methodology; and second, to describe how it should be developed as a tool for stakeholders, including health authorities and procurement agencies (which may not necessarily have extensive legal and patent expertise) in

¹ WHO, UNAIDS, UNICEF (2011), Global HIV/AIDS Response: Epidemic update and health sector progress towards Universal Access: Progress Report, at 2. See also: UNDP (2010), Good Practice Guide: Improving Access to ARV Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement, at 3–8.

developing countries to quickly search for patents on medicines, from publicly available (and free) sources of information.

The present document represents an updated compilation of earlier versions of the Patent Methodology and related works, including the following: (i) the Project Report of the WHO Patent Project, submitted to UNAIDS in December 2006; (ii) the unpublished paper entitled, “Determining the Patent Landscape of Essential Medicines in Developing Countries: Sources and Methodology” (December 2006) by Warren A. Kaplan, which analyzed the workings of the US FDA Orange Book patent list and the Health Canada Patent Register; (iii) the Discussion Paper, “The Patent Landscape of Essential Medicines in Developing Countries: Defining A Methodology” (October 2008) prepared by Cecilia Oh and Barbara Milani and presented at the UNDP-WHO-EPO consultation; and (iv) the article by Barbara Milani & Cecilia Oh (2011), “Searching for Patents on Essential Medicines in Developing Countries: A Methodology” published in the *International Journal of Intellectual Property Management*, Vol. 4, No.3, 2011.

This Methodology is coauthored by Barbara Milani and Cecilia Oh. The inputs and contributions of many individuals to the conceptualization and development of the Patent Methodology, over the period of its evolution, are gratefully acknowledged here.

In the implementation of the WHO Patent Project, contributions of the following are acknowledged: German Velasquez and Eloan Pinheiro, both formerly with WHO, provided advice and technical support in their supervisory roles while at WHO; Konstantinos Karachalios played an instrumental role in facilitating the collaboration of EPO; and Oliver Langer and Camilla Bonzano, also of EPO, provided technical support on the mechanics of patent searches.

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Finally, the inputs and assistance of Tenu Avafia and Savita Mullapudi Narasimhan in the conceptualization and finalization of this document are also gratefully acknowledged.

Executive Summary

Where patents pose a barrier, the Doha Declaration on the TRIPS Agreement and Public Health signed by WTO Members in 2001 had confirmed that governments may use a range of measures known as TRIPS public health flexibilities (such as compulsory licensing and parallel imports) to ensure access to affordable medicines. In order to make informed and effective use of these TRIPS flexibilities to procure or produce medicines, information about the patent status of the medicines is required.

In many developing countries, this information can sometimes be difficult to obtain. In this context, drug procurement agencies, can be hesitant in choosing the option to procure the more affordable generic versions, for fear of patent infringement. There is thus, a need for a cost-effective and pragmatic approach to speedily obtain data on the patent status of essential medicines, so that governments and procurement agencies can make informed decisions on available options for production and procurement of generic medicines. The WHO's 2008 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) has acknowledged the need for such accurate and up-to-date patent information, in order to effectively use such flexibilities. Accordingly, the GSPOA called for initiatives to facilitate the development of, and access to, global databases of health-related patents on governments. The Medicines Patent Pool, established in 2010, seeks to facilitate access to relevant patents on ARVs so as to enable generic production of new and adapted formulations of ARVs. As part of its work, the Medicines Patent Pool has established and maintains a patent database that provides information on the patent status of selected antiretrovirals in a number of low- and middle-income countries, but stresses that the list of medicines, patents and countries is not complete. This has further highlighted the need for accurate patent information on medicines.

Two characteristics of the current patent system are important factors contributing to the difficulties in obtaining relevant patent information on medicines; namely, the technical complexities related to patenting of pharmaceutical products and the lack of institutional capacity for the management of the patent system in developing countries. The Patent Methodology proposed in this paper is thus, premised on the fact that many developing countries do not have sufficient technical and financial resources to effectively respond to requests for patent information on

essential medicines. It also takes into consideration that the inaccessibility of relevant patent information on medicines is due to the use of technical language in patent applications, which does not readily link to the end-product medicine or pharmaceutical product. While medicines are often referred to by their International Non-Proprietary Names (INN), patent applications seldom use INNs in their description of the new invention.

A simple and practical method is described in this paper, which enables searches for relevant patent data from publicly available (and free) sources of information. Using a combination of data from patent offices and medicine regulatory authorities that are available on the Internet, this methodology provides an inexpensive and pragmatic option to perform a quick search and access patent information on essential medicines. The Patent Methodology spells out the four steps, by which the patent status of essential medicines can be ascertained.

The Patent Methodology: Step-by-step

In Step 1, the Methodology begins with the search for relevant patents related to a given medicine from the online information published by the US Food and Drug Administration (FDA) and Health Canada. Both US FDA and Health Canada publish information on pharmaceutical products that have been approved for marketing; the drug regulatory agencies in the US and Canada are required to maintain publicly available lists of approved pharmaceutical products (including their International Non Proprietary Names (INN)) and the patents claimed as relevant to them. Thus, in Step 1, the INN of a medicine is used to search for patents granted in the US and Canada over the said medicine. This patent information is sourced from the U.S. FDA Orange Book and Health Canada Patent Registry.

In Step 2, the US and Canadian patent information for the medicine obtained from the Orange Book and Health Canada is used to search for the priority patent applications related to the said medicine. Priority application numbers and dates are provided to patent applicants by patent offices when the first patent application claiming an invention is filed. These numbers are then cited during subsequent filings for the same or related subject matter before a patent office. Priority patent data can be searched for in Esp@ceNet, a public database created and maintained by the European Patent Office. Esp@ceNet compiles, in a standardized format the application numbers, dates and applicants from over 70 million patent documents worldwide, and provides free access to such patent information. The priority patent application data obtained from Esp@Net is cross-checked against the data from the US FDA Orange Book and Health Canada Patent Registry to ensure accuracy.

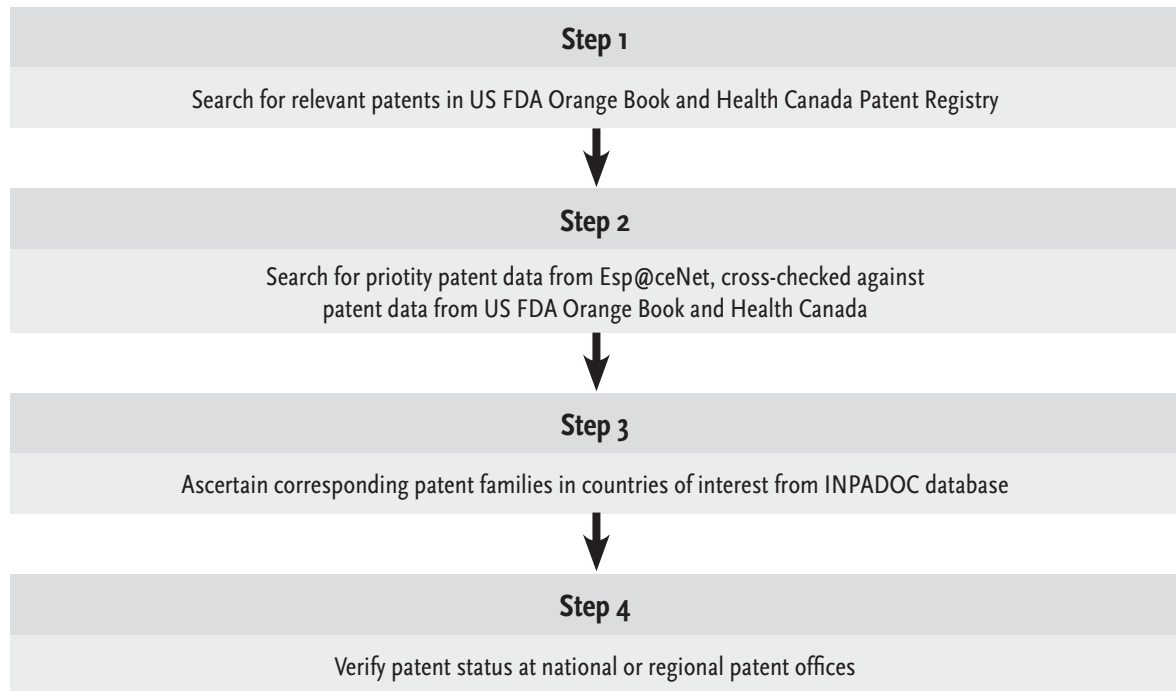
In Step 3 of the Methodology, the priority patent data obtained from Esp@ceNet is next used to search for the corresponding patent families for each of the US and Canadian patents, so as to

track where else in the world similar patent applications have been filed and granted. A “patent family” is a list of similar patent documents throughout the world that derive their origin from the priority patent; i.e., the first patent application to be filed. The first filing will from then on always be linked to the day on which the filing was made; i.e., the priority date. Hence, priority patent data opens the door to the patent family; so that the related patents on an invention filed around the world can be tracked. Thus, Step 3 is the search for patent applications and granted patents in the patent families corresponding to the US and Canadian patents related to a given medicine. The search can be made from the database of the International Patent Documentation Center Collection (INPADOC), which compiles the patent family information of some 95% of all published patents worldwide. The INPADOC database is accessible through Esp@ceNet.

Once the priority patent and patent family data are ascertained, Step 4 of the Methodology is to verify the information at the national patent office. Verification of the patent data obtained at the national patent offices is necessary to determine the status of patents and applications in individual countries, given that patents are territorial in nature. The priority patent and patent family data, obtained from the previous Steps, present a viable basis from which patent offices in developing countries can conduct targeted patent searches to verify and complete the patent landscape for a given medicine. The national patent office search in Step 4 should be able to confirm: (1) whether patent(s) has been in fact granted on the given medicine; and (2) whether or not it is still in force.

The Methodology described above is designed to be a pragmatic, yet systematic, approach to sourcing information on patent status of pharmaceutical products in developing countries. It can provide a useful preliminary assessment of the patent landscape for specified medicines to aid decision-making in medicines production and procurement, given that the existence or otherwise of patents on medicines will affect decisions relating to price negotiations, and where necessary, the use of TRIPS flexibilities. A diagrammatic presentation of the Methodology is provided below.

The Patent Methodology



1. Introduction

The economic rationale for patent protection assumes heavy costs for the development of a new product. Hence, a time-limited monopoly over the product is justified on the ground that it will provide the incentive for its development and commercialization, thereby reducing or eliminating the risk of a competitor copying and marketing the product without incurring the same costs, and preventing the inventor from recovering his costs. Patents therefore protect against such “free-riding” copiers. Patents are intended to promote innovation by requiring, as a condition of the grant of a patent, that patent applications disclose the invention.

The patent bargain described above requires the public disclosure of an invention in exchange for market exclusivity. The lack or absence of publicly available information about the patented invention will undermine this social bargain, and arguably, the rationale of the patent system. Transparency and accessibility of information should therefore, be a key principle of the patent system. Accordingly patent applications are public documents, published if and when the patent is issued. Patent applications are also typically published 18 months after their filing.

Although patent information is contained in public documents, it is not a simple matter to search for specific patents – for example, when search for patents to determine whether or not it is possible to procure or import generic versions of patented medicines. Despite long-standing concerns over the implications of patent protection on access to medicines, there is still considerable uncertainty regarding the existence of patents on particular medicines because there are often difficulties in obtaining such patent information, particularly in the developing countries. Furthermore, patent information on pharmaceutical products is often not easily accessible or available in an easily understood form.

In theory, it is possible to conduct patent searches for a medicine, using as a starting point the technical information on the compound, formulations, dosages or uses of a particular medicine. Such approaches, however, may be impractical particularly in a developing country context. As discussed below, these approaches require a high level of technical expertise and resources, including access to commercial (fee-based) databases, which may not be readily available in a number of developing countries. Moreover, most patent searches are inherently reliant on individual expertise, and do not

lend themselves to be reproduced and replicated as a methodology that can be applied by others. Patent searches can also be expensive and time-consuming – particularly in developing countries where the intellectual property management and administration systems are less advanced. An inexpensive and speedy method for conducting patent searches can therefore be a useful tool to facilitate access to relevant and accurate patent information.

1.1 Patent Information and Transparency

The global debate on patents and access to medicines led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health in 2001, which confirmed the right of WTO Members to limit exclusive patent rights through the use of TRIPS flexibilities when public health interests required it. Hence, where patents pose a barrier to the access to affordable medicines, countries may consider the use of a range of measures (including compulsory licensing and government use) to enable such access. While recognizing the right of developing countries to use the TRIPS flexibilities, WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) also acknowledged the need for accurate and up-to-date patent information, in order to effectively use such flexibilities. Accordingly, the GSPOA called for initiatives to facilitate the development of, and access to, global databases of health-related patents on governments. The GSPOA recognized the need to support efforts to determining the patent status of health products, in order to strengthen national capacities to analyze the information contained in those databases, and improve the quality of patents.

The question of whether or not a medicine is under patent protection is often a crucial factor in decisions on medicine procurement. Knowledge of the patent status of a medicine can inform decision-making on the options available for the procurement of medicines. A patent landscape allows for better-informed decision-making. It can help to make procurement decisions speedier and more efficient; it can help to procurement authorities quickly consider the most cost-effective options. A medicine procurement agency would essentially want to know whether there are patents that would prevent the importation of the generic equivalents of a medicine, including the formulation or dosage form, and its sale and distribution. A sparse patent landscape with few patents, for instance, may facilitate a quick decision to conduct a claims analysis since it would not incur great effort or resources, and potentially facilitate access to more affordable generic equivalents of needed medicines. A vital aspect of this decision-making process is the availability of accurate and up-to-date information about the patent status of essential medicines.

It may be argued that perhaps the most direct way to obtain patent information on medicines in a particular country may be to request such information from the patent holding pharmaceutical companies themselves. There are some problems with this approach – patent-holding companies may not wish to divulge information about their patent portfolio, particularly where

such information is of strategic and commercial value to them. Furthermore, where procurement agencies are looking into options for purchasing the more affordable generic versions of patented medicines, it is clearly not in the interest of the patent-holding pharmaceutical companies to provide full information about the patent status of their medicines.

This Methodology thus seeks to address the issue of how such patent information needs of developing countries can be met, and how such information can be made accessible to stakeholders in the interest of addressing public health problems. Two characteristics of the current patent system can however, make patent information on pharmaceutical products less accessible or available in an easily understood or transparent format. First, the technical complexity relating to the patenting of medicines, and secondly, the institutional capacity for the management of the patent system in developing countries.

The approach was to develop simple and practical methods to enable searches for relevant patent data from publicly available (and free) sources of information. The Methodology recognizes that there is often a lack of highly specialized patent expertise in many developing countries. It also takes into account the fact that there are differences in the use of language and terms between the public health field and the intellectual property arena. While public health practitioners often refer to medicines by their International Non-Proprietary Names (INN) (generic names) or trade names, patent documents seldom use INN or trade names in the description of the inventions for which patent protection is sought. Hence, the ability to use the generic or trade names of medicines to search for relevant patents is an important element in developing a useful methodology.

The aim of this Methodology can be summarized as follows: 1) to explain the technical rationale by detailing the strategy used for the collection and analysis of the patent data, including an assessment of limitations of other patent search options; and 2) to propose an approach for developing the Methodology as a tool for use by stakeholders in developing countries.

1.2 Organization of the Methodology

This Methodology is organized in the following manner:

Section 1 provides the context in which the need and justification for the Patent Methodology should be understood. Section 2 describes the key characteristics of the current patent system that contribute to the difficulties in obtaining relevant patent information on essential medicines; namely, the technical complexities related to patenting of pharmaceutical products and the lack of institutional capacity for the management of the patent system in developing countries. Section 3 assesses the available sources of patent information on essential medicines; i.e.,

subject matter patent searches, and employing commercial search firms and identifies some of the major limitations in using these sources to search for patents on medicines in developing countries. This explains the need and for accurate and up-to-date patent information on essential medicines in developing countries and provides the justification for a tool that enables speedy and economical patent searches on medicines in developing countries.

Sections 4 and 5 provide the conceptual framework for the Patent Methodology, and describe its essential elements. Section 4 explains rationale for the choice of sources of patent information; namely, the patent listings under the drug regulatory systems in the United States and Canada. Section 5 details how this patent data is analyzed to provide the priority patent data and corresponding patent families, which are then used as the basis for patent searches in national and regional patent offices, to determine the patent landscape of a selected medicine. Finally, Part 6 makes some proposals for the use of the Patent Methodology as a tool to assist in medicine procurement decision-making in developing countries.

2. Patents on Medicines

Patent rights are territorial. Patents are granted by national patent offices; their grant and validity being governed by the patent legislation in force in the country. In some cases, a regional patent office grants patents, which are collectively recognized by the countries that are members of a regional patent agreement.

Regional patent offices may administer a centralized system to examine and grant patents, which are then individually enforced in member countries. For example, the European Patent Office (EPO), as the regional patent office for its 38 Member States, may grant an EPO patent, which may be recognized by all or some of the Member States. In this case, such a patent is regarded as “bundle of nationally-enforceable” rights; that is, the rights accruing to the patent will have to be individually enforced in each member country². The African Regional Intellectual Property Organization (ARIPO) also administers a similar system; whereby ARIPO manages a centralized patent application procedure for its member states, but with national patent offices maintaining ultimate responsibility for granting patents³.

Regional patent offices may also establish a system for the grant of a single patent which is automatically recognized by the members of the regional patent office. The African Intellectual Property Organization, better known as OAPI (from the acronym of its name in French: Organisation Africaine de la Propriété Intellectuelle), is a regional patent organization for French-speaking Africa, and acts as the common patent authority for the 16 member states of the Bangui Agreement. Under the Bangui Agreement, a patent granted by OAPI is automatically recognized by all member states⁴. The Eurasian Patent Office similarly administers a uniform

² Further information on the EPO available at: <http://www.epo.org/>

³ ARIPO now has 18 member states, with the accession of the Republic of Rwanda in June 2011. Further information is available at: <http://www.aripo.org/>

⁴ Further information on OAPI is available at: <http://www.oapi.int/>

patent application procedure on the basis of a single Eurasian patent that is automatically recognized by the 9 member states party to the Eurasian Patent Convention (EAPC)⁵.

The fact that a patent has been granted by a patent office does not mean that this is the final say on the matter. Where on closer scrutiny, it is found that the patent does not meet one or more of the patentability criteria (as set out in the national patent law); its validity may be challenged. For example, if on closer scrutiny, it is found that the patent does not meet one or more of the patentability criteria (as set out in the national patent law); it may be possible to challenge its validity. Even where a patent has been properly granted, the patent holder must maintain the patent which, in virtually all cases, requires annual renewal by paying the required fees to the patent office. When the fees are not paid, the patent will lapse and is therefore no longer valid. Typically, all patent laws contain provisions for the revocation of patents, when a patent has been found to be invalid. National or regional patent legislation may also have provisions that exclude certain kinds of inventions: common examples being therapeutic or surgical methods. Patent legislation may also exclude the patenting of certain inventions, where the commercialization of such inventions would be contrary to *ordre public* or morality.

In order to determine the patent landscape for a medicine in a particular country, patent searches must therefore be undertaken at the national or regional level. Two characteristics of the patent system can make patent information on pharmaceutical products less accessible or available in an easily understood or transparent format. The first relates to the technical complexities in the patenting of pharmaceutical products, in which “inventions” rather than end products are protected; and second, the institutional capacity for the management of the patent system in developing countries. Each of these factors are explained in further detail below.

2.1 Patenting of Inventions in Pharmaceutical Products

A patent protects an “invention”. During the research and development process for a particular medicine, a number of “inventions” may result at different stages of this process. Pharmaceutical companies may apply for patent protection of these different inventions; hence the final pharmaceutical product may be covered by several patents protecting different inventions. The validity of these patents will depend on how the patentability criteria is applied in the country in which the patents are sought, but typically, these patents may relate to:

⁵ The 9 member states of EAPC are: Turkmenistan, Republic of Belarus, Republic of Tajikistan, Russian Federation, Republic of Kazakhstan, Republic of Azerbaijan, Kyrgyz Republic, Republic of Moldova, Republic of Armenia. Further information on EAPO and EPAC available at: <http://www.eapo.org/eng/ea/intro/>

- the chemical compound that provides the active ingredient in a medicine,
- the process or method for manufacture of the chemical compound or active ingredient;
- the process for the manufacture of the finished pharmaceutical product; or
- the use of a compound for the treatment of a condition or disease.

In addition, under certain patent systems, patents have also been granted for “inventions” that relate to modifications made to a known chemical compound or active ingredient, so as to polymorphs of the compound, as well as salts, esters, metabolites, pro-drugs and other derivatives. A new medical indication, that is, the discovery of a different effect of a known molecule on the human body, may also be patented as a new invention. Patents on formulations and compositions of a compound have been granted; for example, on the capsule, tablet, oral solution or controlled release formulation, as well as on the different dosage regimens of a medicine. Patents have also been granted on new combinations of known medicines; such as a fixed-dose combination combining two or more active ingredients into a single pill.

There is growing concern over the proliferation of patents that protect minor changes to, or derivatives of existing medicines or processes even while the number of patents on new chemical entities is small and declining⁶. In some instances, the changes for which the patents are applied are obvious, raising the question of whether the patents claimed over them do, in fact, meet the requirements of the patentability criteria. For example, patent protection may be claimed for new uses, forms, combinations and formulations of known medicines in a bid to extend the period of the patentee’s monopoly. This practice, referred to “ever-greening”, works to effectively delay the entry of competitive generic medicines into the market.

The TRIPS Agreements requires Member States to grant patents for inventions that are “new, involve an inventive step and are capable of industrial application”⁷, but leaves them to define these criteria according to their public interest priorities. Strict patentability criteria can be an important tool to ensure that only genuine inventions are granted patent protection⁸. While there are disputes on how strict or lax the patentability criteria should be, developing countries like India and the Philippines, for example, have amended their patent legislation to favor a

⁶ See for example, Correa C. 2007. Guidelines for the examination of pharmaceutical patents: Developing a public health perspective, ICTSD-UNCTAD-WHO-UNDP, at http://www.emro.who.int/EDB/media/pdf/patentability_guidelines.pdf

⁷ Article 27(1) TRIPS Agreement

⁸ Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, A/HRC/11/12, dated 31 March 2009; available at: http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf

public-health-friendly approach to this issue. Their patent laws exclude from patentability new forms of already known substances (unless they are significantly more efficacious) and new (or second) uses and combinations of known substances⁹.

Whilst this debate is still on-going, it remains the case that a single medicine can often be covered by a number of separate patents. Aside from the impact on generic entry, this also makes assessing which medicines are patent protected, by how many patents and in which countries, a complex task. Where the patent relates to the application or use of the promising compound, there is a need for technical expertise to be able to effectively search for the relevant patent data. These difficulties are compounded by the fact that medicines are often covered by multiple patents, as noted above, with differing expiration dates.

A robust patent search must therefore be able to identify the multiple patents on a product, and also reflect the fact that, even in countries where a chemical compound or the active ingredient in a pharmaceutical product is not patented, the pharmaceutical product containing the compound or active ingredient may still be covered by other patents, such as the formulation of the compound into the medicine, which may prevent the procurement of the generic version.

2.2 Patent Information from Patent Offices

Given that patents are territorial, the patent status of a medicine can differ from country to country. Being granted by national (and in some cases, regional) patent offices, patent information should ideally be obtained from the national or regional patent office granting the patents, to verify that the patents have in fact been granted and are currently valid in the country. Obtaining accurate and up-to-date patent data from patent offices can be fraught with difficulties, due in part, to the lack of institutional capacity in developing countries for managing the patent system and in part, to the way in which databases in patent offices are structured.

2.2.1 Patent Offices in Developing Countries

Substantive examination and management of patent applications is challenging and requires technical competence and access to sophisticated computer databases. Hence, the efficient administration of the intellectual property rights system demands adequate numbers of properly trained staff

⁹ Indian Patents Act, 1970, section 3 (d) and the Intellectual Property Code of the Philippines (amended by Section 5 of the Universally Accessible Cheaper and Quality Medicines Act of 2008), Section 22.1

and a reasonable degree of automated information systems. Many developing country patent offices do not yet have this capacity. For these reasons, developing countries often opt for a simple patent registration regime (relying on the granting of a patent by patent offices of developed countries like the US or EPO) or join a system of regional or international co-operation, such as OAPI and ARIPO in Africa, where substantive patent examinations are conducted through a centralized mechanism.

Few developing countries patent offices maintain patent databases that are publicly available and searchable. The lack of electronic databases storing such patent data means the need to rely on manual searches for patent information, which can be inaccurate, incomplete and time-consuming. In the recent WIPO study on the feasibility of establishing national patent register databases, it was noted that the “availability of legal status data of some 50 countries (most of them are developing countries and LDCs) is limited” because many of them do not have the legal status data in digital form and national on-line registers¹⁰. Although countries are increasingly modernizing their patent offices and develop means to electronically create, store, and retrieve digital information, at present acquiring patent data from developing countries is conditioned by the presence or absence of computerized systems and skilled professionals in the chemical and pharmaceutical area. The lack of electronic patent databases necessitates manual searches, which are time-consuming and more importantly, which require relevant information, such as priority patent data, to initiate. The larger patent offices, such as the Chinese State Intellectual Property Office (SIPO)¹¹ and the Brazilian Industrial Property Office (INPI)¹², are the notable exceptions, and have public databases that provide some degree of information.

In least-developed countries and smaller low-income developing countries, the availability of technical (scientific and engineering) and legal expertise also tends to be in short supply. There is a typically a shortage of technically trained experts, and those scientists and engineers who reside in the country are frequently reluctant to work for government agencies. Similarly, those lawyers available are likely to be drawn to the private sector. Moreover, where legal expertise does exist, it is generally not well versed in matters relating to intellectual property.

An earlier review of patent offices in developing countries had shown significant variations in terms of staff numbers and capacity¹³. It highlighted that the smaller patent offices in devel-

¹⁰ WIPO. Feasibility Study on the Establishment of National Patent Register Databases and Linkage to Patent Scope, CDIP/4/3 REV./STUDY/INF/3, Geneva 2011. Available at: http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_3_rev_study_inf_3.pdf

¹¹ http://www.sipo.gov.cn/sipo_English/zljs/default.htm

¹² <http://www.inpi.gov.br/>

¹³ Commission on Intellectual Property Rights: Study Paper 9, “Institutional Issues for Developing Countries in Intellectual Property Policymaking, Administration & Enforcement”, M. Leesti and T. Pengelly, at http://www.iprcommission.org/graphic/documents/study_papers.htm, last accessed 1 November 2006

oping countries have very limited human resource capacity; for example, the Ministry of Trade and Industry in Eritrea then had only one staff member, while the Registry of Companies and Intellectual Property of St Lucia had 9 posts. Many small developing countries also face an additional challenge – those patent offices receiving smaller numbers of applications – even several thousand a year – may not be able to justify employing enough examiners to cover all the scientific fields in which applications may be submitted.

The larger patent offices require more staff to keep up the demands of managing the intellectual property system. The Intellectual Property Institute of Kenya has a total staff strength that has fluctuated between 70–90 staff members over the 2004–2007 period¹⁴ and the four Patent Offices in India currently employ approximately 300 staff. It is likely that the patent offices will have to deal with ever-increasing numbers of patent applications, particularly in middle-income developing countries where the research and industrial capacities create greater incentives for patenting. In India for example, the patent offices are dealing with a substantial backlog of patent applications, reportedly numbering up to 70,000 applications¹⁵. This, despite the comparatively larger numbers of examiners, numbering up to 150¹⁶. These staff numbers of patent offices in developing countries are still not comparable with those of the developed country patent offices. The EPO's 2009 Annual Report lists a total of 6818 employees, of which 4197 are carrying out search, examination and opposition functions¹⁷. At the US Patent and Trademarks Office (USPTO), the number of employees at the end of fiscal year 2008 numbered 9,518, of which 6,055 were patent examiners¹⁸.

The lack of relevant capacity and expertise in national patent offices to effectively administer the patent system may raise questions about the ability to adequately examine the patent applications, and hence, the quality of the patents that are eventually granted. The lack of resources can also prevent patent offices from implementing and managing effective search mechanisms.

¹⁴ See Annual Reports of Kenya Industrial Property Institute 2004–2007, available at <http://www.kipi.go.ke/images/docs/annual%20report%202004%202008.pdf>

¹⁵ Silicon India, “Employee scarcity: 70,000 patents pending”, 17 February 2010, at http://www.siliconindia.com/shownews/Employee_scarcity__70000_patent_applications_pending-nid-65548.html, last accessed 2 November 2010

¹⁶ For more information, see for e.g., http://ipindia.gov.in/cgpdtm/AnnualReport_English_2009_2010.pdf and <http://spicyipindia.blogspot.com/2011/06/some-numbers-from-annual-reports-of.html>

¹⁷ <http://www.epo.org/about-us/office/annual-reports/2009/staff-resources.html>

¹⁸ http://www.uspto.gov/web/offices/com/annual/2008/ld_mda_01d.html

2.2.2 Developed Country Patent Offices

Since patents are granted by national (and in some cases, regional) patent offices, conclusive information about the grant and validity of patents should in theory be obtained from the patent office themselves. Where such information may be difficult to obtain accurately or speedily from patent offices in developing countries – due to the lack of institutional and other capacities as discussed above – one option could be to search for patent information from the databases maintained by patent offices in developed countries or those maintained by international organizations such as WIPO. There are however, limitations to the reliance on such patent databases, given the inherent aim and structure of the databases. The discussion below highlights these limitations.

Patent offices in many developed countries maintain databases that are designed to enable patent examiners to carry out searches of vast amounts of prior art documentation. The EPO system for search and examination, for example, includes a vast collection of more than 50 databases corresponding to over 30 million documents¹⁹ These databases, however, are not designed for searches aimed at identifying relevant patents that will affect the use of essential medicines in developing countries. Those are designed for the purposes of patent examination; i.e., to search patent documents and available literature for publication of information that would be novelty-destroying²⁰. The sophisticated EPO databases and search tools are not designed to identify patents related to a particular essential medicine. A search of these databases to identify relevant patents would yield hundreds of documents. Screening these documents to identify relevant patents would require a huge investment of highly specialized human resources.

Furthermore, it should be noted that the databases and search tools at the EPO or other developed country patent offices are not able to provide comprehensive information regarding patents that have been granted (or applications that have been filed) in developing countries. The EPO's International Patent Documentation Centre (INPADOC) database maintains information on the legal status of patent documents, gathered from national patent offices, but the data is not complete because the databases may not provide up-to-date information about the validity of the patents granted. For example, they do not indicate if a patent has become invalid because patent fees have not been paid. This is because it relies on information provided by the national patent offices. (It should be noted that this particular limitation also applies to the Methodology proposed in this paper, since it relies on EPO and other international databases to identify priority patent

¹⁹ Of these 30 million, over 24 million are patents documentations, 2.5 million are articles selected out of 1500 periodicals and over 5.5 million are Japanese and Russian abstracts. <http://www.european-patent-office.org/epidos/docdb2.htm>

²⁰ The basic criteria to meet for patentability are novelty, inventive step and industrial applicability. Where a patent application cannot meet the novelty criterion, the application may be rejected.

and patent family data. This is why the Methodology includes a verification stage, wherein the patent status in each country will be verified by the relevant national or regional patent office).

2.3 WIPO PCT Database

The WIPO administers the Patent Cooperation Treaty (PCT) system of international patent applications for 144 member states. Under the PCT, inventors may file an international patent application with their national patent office or WIPO. The application is reviewed by an international searching authority, which issues a report on prior art and often an advisory opinion about whether an invention is patentable. Inventors then can use these materials in conjunction with patents filed in other countries or with regional patent offices.

Information on whether an international application has entered the national phase (i.e., patents that have been filed at national or regional patent offices) can now be accessed via the PCT “International Patent application” database at www.wipo.int/pctdb. This facility permits searches of all published international patent applications. The database also provides access to the International Preliminary Examination Report (a preliminary assessment of an invention’s patentability, issued by a major national patent office), where a patent office has requested the information be made available. But information on the status of an application once it has entered the national phase is available only for a select group of countries, and only a handful of developing countries. As of 2009, only 36 countries have provided data on the national phase although such information is expected to be increasingly available²¹. National phase data includes the national entry date, the national reference number that can be used to retrieve documents at the national patent offices, and whether a patent has been granted, withdrawn or refused²². However, the PCT does not require that applicants or national or regional patent offices inform WIPO whether they grant patents originating from the PCT application.

Like patent office databases, the WIPO PCT database is not structured to enable searches to directly identify relevant patents on a pharmaceutical product. One way to use the database to locate this information is to search for the chemical compound or INN in the search field of the PCT database (whether it appears on the front page of the application or in the full text). The same problems will, however, arise as in the context of national patent databases. First, this approach will exclude documents that identify the invention by other means; e.g., using the

²¹ See WIPO Standing Committee on Information Technologies: Standards and Documentation Working Group, SCIT/SDWG/11/8, October 7 2009 at http://www.wipo.int/edocs/mdocs/scit/en/scit_sdwg_11/scit_sdwg_11_8.pdf

²² <http://www.wipo.int/pctdb/en/content.html>

IUPAC nomenclature, structural diagram and chemical formula, or other methods. Second, the search will generate far too many documents; whose relevance for the pharmaceutical product of interest will need to be analyzed.

All patent applications are subject to revision, but the PCT system poses a special complication – a PCT application can result in different patents at the national level, due to the revision, restriction or deletion of the PCT application claims. PCT applications filed prior to 2004 designate the countries for which the applicant intends to enter into the national phase. These documents will be of interest especially for searches in countries for which data is not reported back into other databases such as INPADOC.

2.4 Patent Searches by Law Firms

Legal firms provide professional patent searches. These firms would have access to all or the most important commercial and public databases. Major IP law firms also typically use patent search companies to supplement their own internal searching. Law firms may also use overseas IP associates or local patent search firms who have access to more localized databases for individual countries or regions.

There are several limitations in relying on commercial law firms to determine the patent status of pharmaceutical products in the developing countries. These include the challenges inbuilt within the patent system as well in the patent offices of developing countries, as discussed above, but also the different degrees of expertise of foreign associates across countries, and the impossibility of standardizing search methods across commercial law firms and their associates. Another important factor is the cost of this approach – commercial legal services can be prohibitive. In paying for such services, procurement agencies would be diverting funds intended for the purchase of medicines.

3. Searching for Medicine Patents

National and international patent systems are designed to facilitate searches of previously disclosed inventions. As discussed in Part 2 above, patent databases are typically structured for the main purpose of allowing patent examiners to search for inventions that have been previously disclosed, in order to determine whether or not a patent application should be granted. Searches for patents on medicines, to determine whether or not generic versions of patent protected medicines may be procured, can thus be complicated and highly technical endeavors, and vastly more difficult where national patent data is not available electronically in robust form and on public or commercial databases.

The fact that a final pharmaceutical product, may comprise of a number of patented inventions further complicate matters. Patent information on medicines may be generally searchable by technical descriptions of the patented invention(s), but not through the use of the generic name or the brand name of the medicine, in which the invention(s) is eventually incorporated.

This Part assesses patent searching methods that may be used to identify patents on medicines; namely through searches for the chemical compounds that are typically the subject matter of the earliest patent application related to a pharmaceutical product.

A chemical compound with therapeutic activity can be described in several ways, and may also be disclosed in a patent document in some of these ways. These include the molecular formula, the structural diagram, the systematic names according to the International Union of Pure and Applied Chemistry (IUPAC) nomenclature, the Chemical Abstracts Service (CAS) Registry Numbers and the International Non-proprietary Name or the generic name (but this is rarely the case). The Chem Id Plus²³ database collects and displays information related to chemical compounds in a user-friendly way. A search on this database will provide one with an idea of the range of possibilities by which to describe a chemical compound within a patent document. This range of possibilities highlights the complexities involved in the search and analysis of patent documents in order to identify, analyze and define patents relevant to a medicine.

²³ <http://chem.sis.nlm.nih.gov/chemidplus/>

Identifying patents on medicines by searching for the chemical compounds within them can be performed using several methods:

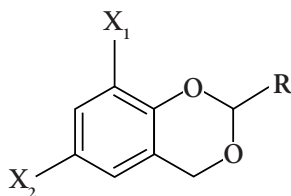
- molecular formula and structural diagram searching;
- name searching using the IUPAC nomenclature
- compound searching using the CAS Registry Numbers;
- generic name searching (INN); and
- search using the WIPO's International Patent Classification (IPC).

These methods of searching are examined and assessed below.

3.1 Patent Searches Using Molecular and Structural Formulae

Online searching using chemical structure information is unambiguous and a highly effective way to locate targeted information in a patent database. There are a number of commercial patent databases²⁴ that can be searched using some form of chemical structure information.

Specialized commercial databases are available for searching the so-called "Markush structures" that are described in patent documents²⁵. Chemical patents use a Markush structure to describe chemicals that are suitable for use in a chemical invention. A Markush structure is a chemical structure that contains functional equivalents (usually designated as X or Y) at one or more binding sites. The X or Y is said to represent one or more functional groups that could be contained in the structure. A single Markush structure may represent many chemicals that are functionally similar. An example of Markush structure in a patent claim is shown in the following diagram, where R = C2–C4 alkyl or C2–C4 alkenyl, and X1 and X2 each independently represent a chlorine or bromine.



²⁴ Beilstein Online, a commercial database, is an organic chemistry database containing bibliographic information in the form of an abstract that has information on chemical reaction, preparations, and derivatives. The database also includes patent numbers from the US, EPO, WIPO, and German patent offices. Beilstein Online can be searched using structures, CAS registry number (see below); the chemical name; and the molecular formula.

²⁵ The MARPAT database produced by Chemical Abstract Service can be searched using Markush structures. The database contains a bibliographic record of Markush structures found in the Chemical Abstracts file from 1988 to the present. This database allows for the retrieval bibliographic information relevant to a Markush structure in a patent. The database contains over 122,000 records from 29 national patent offices, including the European Patent Office and the World Intellectual Property Organization.

Key problems with undertaking patent searches based on molecular formulae and structural formulae include the following:

- this approach requires access to commercial databases that allow for such searches;
- undertaking a chemical structure search requires the considerable organic chemistry skills, in order to be able to understand the chemical structure of the patented medicine or to isolate the Markush groups for the medicine of interest;
- where the compound in question is widely used in chemical synthesis or analysis, as well as a compound in its own right, a simple search on a compound name or a structure can retrieve large quantities of irrelevant patent records; and
- this approach will not identify patents or applications that refer to the compound by means other than molecular and structural formulae, such as by using its IUPAC name or the International Non Proprietary Name.

3.2 Chemical Name Searching

It is also possible to do a patent search based on the chemical name. The IUPAC nomenclature of organic chemistry is a way of naming organic chemical compounds. This is based on the concept that every organic compound can be given a name from which an unambiguous structural formula can be drawn.

Medicine patent claims typically do not refer to the chemical IUPAC name (or names), however. Often, the priority document includes broad claims written in a “generic” format with various provisos and conditions describing a Markush group that could encompass many thousands of different specific chemical structures and compounds²⁶.

It will rarely be possible to use this information to determine a particular chemical name covered by a patent, making this method of patent searching generally unworkable.

²⁶ As an example, the HIV medicine, tenofovir, is described in the abstract of the US patent 5,922,695 as part of the following Markush formula: esters of antiviral phosphonmethoxy nucleotide analogs with carbonates and/or carbamates having the structure $-OC(R_2)2OC(O)X(R)a$, wherein R_2 independently is H, C1-C12 alkyl, aryl, alkenyl, alkynyl, alkyenylaryl, alkynylaryl, alkaryl, arylalkynyl, arylalkenyl or arylalkyl which is unsubstituted or is substituted with halo, azido, nitro or OR_3 in which R_3 is C1-C12 alkyl; X is N or O; *R is independently H, C1-C12 alkyl, aryl, alkenyl, alkynyl, alkyenylaryl, alkynylaryl, alkaryl, arylalkynyl, arylalkenyl or arylalkyl which is unsubstituted or is substituted with halo, azido, nitro, -O-, -N-, -NR₄-, -N(R₄)₂- or OR_3 , R_4 independently is -H or C1-C8 alkyl, provided that at least one R is not H; and a is 1 or 2, with the proviso that when a is 2 and X is N, (a) two R groups can be taken together to form a carbocycle or oxygen-containing heterocycle, or (b) one R additionally can be OR_3 ”.*

3.3 CAS Registry Numbers

Since 1907, the Chemical Abstracts Society has reviewed scientific journal and patent literature and allocates CAS numbers to those documents²⁷. The CAS confers unique identification numbers, which have no chemical or structural meaning in themselves, on chemical substances. The numbers identify compounds without the ambiguity of chemical nomenclatures²⁸. CAS has assigned over 25 million registry numbers for chemical substances. CAS registry numbers are used as “flags” in the patent system. The CAS database allows users to retrieve patent documents where a compound is described through the structural diagram, chemical formula, IUPAC name, fantasy name or by other means.

Using the CAS registry is probably the best means to overcome problems of compounds being described in patents in different ways; and so searching patents by using the CAS registry number is an effective method to ensure the results will include all patent documents referring to a specific compound. However, the number of documents that will be retrieved using a CAS registry number that is huge and hence, will take considerable time to sift through.

In addition, complex registration policies, and the addition of registered names from non-CAS sources, may cause ambiguity and confusion about proper assignment and structure definition. This is especially true for commercial compounds. Registry numbers are assigned by hand and misinterpretations of original documents do happen. Registry numbers cited in non-CAS resources, such as handbooks and even patent databases, may or may not be correctly assigned, and often are not checked for accuracy.

3.4 International Non-Proprietary Names (INN)

International non-proprietary names (INNs) facilitate the identification of medicines. Each INN is a unique name that is globally recognized and is public property. The INN system, as it exists today, was initiated in 1950 by a World Health Assembly resolution, requiring that each pharmaceutical substance or active pharmaceutical ingredient be given a unique name. These names, which must be distinctive in sound and spelling²⁹, are now globally recognized and public property.

²⁷ Coverage of the patents in CAS can be found at <http://www.cas.org/EO/patyyear.html>

²⁸ <http://www.cas.org/EO/regsys.html>

²⁹ An example is “Apixaban” for which the IUPAC name is 1-(4-methoxyphenyl)-7-oxo-6-[4-(2-oxopiperidin-1-yl)phenyl]-4,5,6,7-tetrahydro-1H-pyrazolo[3,4-c]pyridine-3-carboxamide.

The majority of pharmaceutical substances used today in medical practice are designated INNs. Non-proprietary names are intended for use in pharmacopoeias, labeling, product information, drug regulation and scientific literature, and advertising and other promotional materials. Occasionally, the INN is used as the product name of the generic medicine.

Medicine patents are filed early on in the pharmaceutical research and development (R&D) chain, however, and compounds of interest are unlikely to have an INN at the patenting stage, (fantasy names are more likely to be used). As a result, patent applications almost never use INNs; and the patent system is not designed to mandate amendments or addendums to include INNs. As a result, the INN does not present a viable basis for conducting patent searches.

3.5 International Patent Classification (IPC)

The International Patent Classification (IPC) system categorizes patents based on the scope and content of the patent, governed by the Strasbourg Agreement³⁰, a multilateral treaty administered by WIPO. The IPC, in its 8th edition³¹, divides technology into eight sections, with approximately 70 000 subdivisions. Each subdivision has a symbol consisting of Arabic numerals and letters of the Latin alphabet.

As present (November 2010), 61 states are party to the Strasbourg Agreement. However, the industrial property offices of more than 100 states party to the Patent Cooperation Treaty (PCT), four regional patent offices and the International Bureau of WIPO now use the IPC; hence its coverage is virtually universal.

Patents on pharmaceuticals are identified under the code A 61 K 30³² of the IPC. Although the IPC reduces the field of search for patent examiners, the IPC classification is not sufficiently calibrated to enable definitive patent searches on a therapeutic category of drugs; e.g., antiretroviral products, let alone a specific product.

Electronic databases may permit a search to overlay key words with IPC classifications, enabling a search, for example, for “HIV” or “antiretroviral” or “AIDS” for antiretroviral drugs within the IPC category of pharmaceutical patents. Yet such searches are likely to be over-inclusive,

³⁰ http://ipc-reform.european-patent-office.org/about_ipc/index.en.php

³¹ http://www.wipo.int/classifications/fulltext/new_ipc/ipcen.html

³² IPC category for “Preparation for medical, dental and toilet purposes”

retrieving far too many patents – which must then be screened against their relevance towards the drug or drugs of interests. Conversely, the combination search method may be under-inclusive, excluding other relevant patents that do not report the selected key word. Searching by IPC is therefore not an attractive option for patent searches on essential medicines.

3.6 Limitations of Chemical and Pharmaceutical Subject Matter Searches

A rigorous methodology to undertake pharmaceutical patent searches would require a combination of several different approaches described above, by skilled professionals with access to sophisticated commercial databases and tools.

There are still further problems with such an approach. Different search strategies and methods will be needed to locate patents claimed on drug compounds and its salts, esters, polymorphs, etc., drug formulations, and strength, use and dosage regimens.

Furthermore, process patents claiming as a function of their method of manufacture (so-called product-by-process patents (“a pharmaceutical composition, produced by the method A, B, C, etc.”) may not have a chemical name or identifying feature, and hence may not be searchable.

4. Developing a Methodology for Patent Searches

A methodology that can be applied and used systematically to obtain patent information speedily and with minimum cost would be a welcome tool in developing countries. Parts 4 and 5 of this document will describe the rationale and the workings of a simple and practical methodology to search for patent information on medicines in developing countries.

Two characteristics of the current patent system are important factors contributing to the difficulties in obtaining relevant patent information on medicines; namely, the technical complexities related to patenting of pharmaceutical products and the lack of institutional capacity for the management of the patent system in developing countries. The Methodology proposed in this paper is thus, premised on the fact that most developing countries do not have sufficient technical and financial resources to effectively respond to requests for patent information on essential medicines. It also takes into consideration that the inaccessibility of relevant patent information on medicines is due to the use of technical language in patent applications, which does not readily link to the end-product medicine or pharmaceutical product. While medicines are often referred to by their International Non-Proprietary Names (INN), patent applications seldom use INNs in their description of the new invention. As noted in Part 3 above, patent applications on new chemical entities or compounds are also usually filed well before the stage of product development – therefore, the applications seldom refer to the product itself. Similarly, searches on chemical and subject matter have been found to be difficult, expensive and time-consuming.

In light of these factors, the primary aim and rationale of the Methodology is to provide a preliminary means of obtaining patent information that:

- allows patents searches using the International Non Proprietary Name (INN) and even selecting the finished pharmaceutical product (a specific medicine formulation);
- enables patent searches without incurring cost; and
- does not require highly-specialized skills and significant time resources to identify.

4.1 Sources of Patent Information

The US Food and Drug Administration (FDA) and Health Canada publishes online information of pharmaceutical products (including their INNs) that have been approved for marketing in the two countries. This also includes a listing of patents related to the approved products. As such, the on-line patent registries of the U.S. FDA and Health Canada systems are key sources of patent data for building a systematic, cost and time-effective approach to identify priority patent applications for essential medicines. The Methodology thus makes use of the INN, as a first step, to retrieve relevant patent information on pharmaceutical products from the patent registries maintained by the US Food and Drug Administration (FDA) on its “Electronic Orange Book” and Health Canada.

In 2009, the US remained the world’s biggest single market, accounting for 37% of the global pharmaceutical sales³³. Together with Canada, it amounts to the most significant share of the global pharmaceutical market. There is therefore, every indication and reason to believe that virtually all important medicines for which there is a market in developing countries (i.e., non-neglected diseases) are registered in one or both of these countries.

Both the U.S. and Canada have linked patent and regulatory systems, which require the drug regulatory agencies to maintain publicly available lists of approved pharmaceutical products and the patents claimed as relevant to them. These linkage systems are part of complex regulatory regimes but the main effect of the patent listings is to prevent drug regulatory agencies from granting approval to generic versions of drugs for which an innovator company has a valid patent in place.

It should be noted that most countries do not have linked patent and drug regulatory systems. While a number of countries may have instituted mechanisms to enable the participation of the health sector in the grant of pharmaceutical patents; e.g., the drug regulatory agency of Brazil, Agência Nacional de Vigilância Sanitária (ANVISA), whose prior consent is required for the grant of pharmaceutical patent³⁴, these are not the same as the linked patent and regulatory systems in the US and Canada. Implementation of a linked patent-registration system is now increasingly included as an element of the “TRIPS-plus measures” in bilateral and other free trade agreements. Developing countries are cautioned against accepting provisions requiring this

³³ See for e.g., The Association of Research-Based Pharmaceutical Companies (vfa) <http://www.vfa.de/en/statistics/pharmaceuticalmarket> and Piribo - Online Business Intelligence for the Biopharma Industry, at http://www.piribo.com/publications/general_industry/pharmaceutical_market_trends_2008_2012.html (last accessed 2 November 2010)

³⁴ Brazil’s Industrial Property Law (IPL) 10196/2001, provides that pharmaceutical patents may only be granted with the prior consent of the Brazilian National Sanitary Supervision Agency (ANVISA).

linked system in their negotiations of free trade agreements, given the concerns that the linked patent and drug regulatory systems may be open to abuse, that can lead to unnecessary delays in the introduction of generic competition³⁵. This is particularly the case for developing countries – where capacity may not be present for the proper management and monitoring of the system³⁶.

Their existence in the developed countries, however, does make available important sources of information on patents on pharmaceutical products. As has been noted above, these patent registries are in the public domain, and hence, they represent a crucial source of free and publicly available patent information on pharmaceutical products.

In the US, the Drug Price Competition and Patent Term Restoration Act, also known as the “Hatch-Waxman Act” (Public Law 98-417), requires that all medicines approved for safety and effectiveness be listed in the FDA’s “Orange Book” (named after the color of its cover sheet). The listing of medicines approved by the FDA is available online and easily searchable using their INN or trade names. Alongside the approved medicines, manufacturers provide a list of relevant patents protecting the product³⁷. The FDA cannot grant marketing approval to generic suppliers to market in the US, a product that would infringe a patent listed in the Orange Book.

When filing drug marketing approval submissions with Health Canada, originator manufacturers may submit a list of patents “associated” with that drug. The Patented Medicines (Notice of Compliance) Regulations (Linkage Regulations) establish that the Canadian government cannot issue a market authorization to a generic manufacturer until patents listed with Health Canada expires.

Health Canada conducts a review of the patents listed by an applicant, to assess the patents’ relevance. The U.S. FDA does not conduct such a review and relies on a legal declaration by the applicant for submission.

³⁵ WHO 2006. “Data exclusivity and other TRIPS-plus measures”, Access to Medicines Briefing Note, WHO SEARO and WPRO, available at: http://www.searo.who.int/LinkFiles/Global_Trade_and_Health_GTH_No3.pdf (last accessed 2 November 2010)

³⁶ See for example, Correa, C. 2006. “Implications of bilateral free trade agreements on access to medicines”, WHO Bulletin 84(5), at <http://www.who.int/bulletin/volumes/84/5/en/index.html> and Medicins Sans Frontieres 2010. “Hearing Statement and Submission to the U.S. Trade Representative (USTR) regarding the 2010 Special 301 Review”, 18 February 2010, available at: <http://www.doctorswithoutborders.org/publications/reports/2010/MSF%20USTR%20Hearing%20Statement.pdf> (both last accessed on 2 November 2010)

³⁷ Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (21 U.S.C. 355, 360cc; 35 U.S.C. 156, 271, 282) (“Hatch-Waxman Amendments”)

4.2 US FDA Orange Book

An innovator company seeking marketing approval in the US must submit to the FDA a list of all patents relevant to its product and their corresponding expiry dates. This information is listed in the Orange Book. The FDA maintains an electronic version of the Orange Book, which is available on the Internet and gives detailed information on the patents covering drugs, the expiration dates of the patents, and also on data exclusivity³⁸. The Orange Book lists all drugs registered by US FDA, whether or not any patents or data exclusivity is claimed to be in effect. The electronic Orange Book is updated monthly, with new patent information updated daily.

U.S. rules require patent holders to submit a list of all patents relevant to their product and corresponding expiry dates³⁹ within 30 days after approval of a New Drug Application (NDA) or supplement to an NDA, or within 30 days after issuance of a patent⁴⁰. U.S. law requires patent holders to list patents that fall within the two categories:

- patents that claim the drug or a method of using the drug that is the subject of the NDA or amendment or supplement to it; or
- patents with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use or sale of the drug product⁴¹.

Patents that must be listed in the Orange Book can consist of patents that relate to the drug substance (active ingredient), drug product (formulation and composition, and method of use. Other patents for which information must be submitted include patents on product-by-process⁴² and polymorph patents⁴³.

³⁸ US FDA “Orange Book” website at . <http://www.fda.gov/cder/ob/>.

³⁹ See Code of Federal Regulations, Title 21, Food and Drugs, Part 314 (hereafter called 21 C.F.R. Section 314). See 21 C.F.R. Section 314.53 - Submission of patent information, at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=314.53> (last accessed on 2 November 2010)

⁴⁰ 21 C.F.R. Section 314.53 (c)(2)(ii)

⁴¹ 21 C.F.R. Section 314.53 (b)

⁴² Although not common, there may be patents on medicines with “product by process” type-claims, whereby the patents protect products defined by their method of manufacture. See also, 21 C.F.R. 314.53(c) (2)(i) (L); 21 C.F.R. 314.53(c) (2)(ii) (M)

⁴³ Polymorph patents claim the different forms of a drug substance or compound, although the forms would be considered the “same” active ingredient for ANDA approval purposes. See also, 21 C.F.R. 314.53(c) (2)(i) (M); 21 C.F.R. 314.53(c) (2)(ii) (M)

To list a patent, information must be provided on the active ingredients, dosage form, uses of the medicine as claimed in the patent and strength per unit⁴⁴. The route(s) of administration is not needed. Instead, it is required to stipulate whether or not the patent claim is to an active ingredient described in the NDA or supplement; whether the patent claim is to a polymorph that performs the same as the active ingredient described in the NDA; whether the patent claim is to a metabolite of the approved active ingredient or drug product; whether the patent is a process-by-product patent, and other similar information. The patent number, U.S. patent grant and expiration date are also required to be submitted.

For patents claim a drug substance or drug product, the applicant must submit information only on those patents that claim a drug product that is the subject to a pending or approved application, or that claim a drug substance (i.e., an active ingredient) that is a component of such a product⁴⁵. For patents that claim a method of use/treatment, the applicant must submit information only on those patents that claim indications or other conditions of use of a pending or approved application⁴⁶. “Off label” method of use patents that might apply to other medical conditions treatable by the marketed compound important in developing countries are not listed. However, many countries do not allow method of use/treatment patents.

The FDA has not directly addressed whether patents directed to drug delivery systems that do not recite the approved active ingredient or formulation should be listed in the Orange Book. Process patents (i.e., “method of making”) and patents claiming packaging, metabolites and intermediates, are not required to be listed in the Orange Book⁴⁷. The Orange Book listing requirements do not prevent biologics – virus, serum, vaccines and cell-derived active ingredients (i.e., recombinantly-derived proteins or other materials) – from being listed in the Orange Book⁴⁸, but generally they are not. This may mean that a number of new drugs are not listed in the Orange Book. The listing of patents not held by the NDA holder is possible; where an NDA holder is aware of patents held by others that meet the statutory standard outlined above, these patents should also be listed⁴⁹.

⁴⁴ For further details, see the reporting requirements under 21 C.F.R. Section 314.53 (c)(2)(i)(A-Q) and (c)(2)(ii)(A-P)

⁴⁵ 21 C.F.R. Section 314.53 (c)(2)(i)(M-N); Section 314.53(c)(2)(ii)(N)(1)

⁴⁶ 21 C.F.R. Section 314.53 (c)(2)(i)(O)(1-2); Section 314.53(c)(2)(ii)(P)(1-3)

⁴⁷ 21 C.F.R. Section 314.53 (b) - “Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered by this section, and information on these patents must not be submitted to FDA.”

⁴⁸ Patent listings in the Orange Book can be based on so-called “Section 505(b)(1) or (b)(2)” drug applications, the latter of which can include an application for a drug product containing an active ingredient(s) derived from animal or botanical sources or recombinant technology. See FDA Guidance for Industry, Applications Covered by Section 505(b)(2), at <http://www.fda.gov/CDER/GUIDANCE/2853dft.htm>, accessed 23 November 2006.

⁴⁹ 21 C.F.R. Section 314.53 (c)(2)(i)(Q) and 21 C.F.R. Section 314.53 (c)(2)(ii)(R)

Although there are contrary interpretations of FDA's authority, the FDA views its listing of patents as purely a ministerial requirement of the regulations. It is unwilling to undertake any kind of review of the submissions by NDA holders, to assess the relevance or underlying validity of listed patents⁵⁰. The agency simply relies on the patent owner's signed declaration stating that the patent covers an approved drug product's formulation, composition or use⁵¹.

4.3 Health Canada Patent Register

To obtain marketing approval in Canada, an originator manufacturer is required to file a new drug application to obtain a Notice of Compliance from the Minister of Health. With this application, the originator submits a form listing patents relevant for the drug formulation. In contrast to the FDA Orange Book procedures, the Minister of Health reviews the patent and decides if it is "relevant" and should be added to the Register.

Patents listed with the Ministry of Health in connection with new drug applications are added to the Health Canada Patent Register, a database of pharmaceutical patents that can be searched by INN and trade name. The Register displays the list of Canadian patents, patent expiry dates and other related information for registered drug formulations⁵². The database includes all drugs for which at least one patent has been listed. Other drugs, registered by Health Canada, but for which no patent has been listed, will not be reported in the Health Canada Patent Register.

The Patented Medicines (Notice of Compliance) Regulations (PM (NOC) Regulations)⁵³ govern the process of submitting patents for inclusion on the Health Canada Patent Register, in connection with the filing of a New Drug Submission (NDS) or a Supplement to a New Drug Submission (SNDS). The effect of the patent listing is that generic manufacturers must wait until the relevant listed patents expire or serve the manufacturer of the innovative product with a "notice of allegation", in order to obtain marketing approval for their products. The notice must specify why the listed patent should not prevent the generic drug from coming to market. The PM (NOC) Regulations permit the originator to commence legal proceedings in response

⁵⁰ *Alphapharm PTY v. Tommy G. Thompson* (Secretary of HHS) (D.D.C. 2004) (CA 03-2269) (listing of Orange Book patents merely "a ministerial act" and that the rules do not require the FDA "to police the listing process by analyzing whether the patents listed by NDA (New Drug Application) applicants actually claim the subject drugs or applicable methods of using those drugs." Case online at <http://www.dcd.uscourts.gov/03-2269.pdf>.

⁵¹ 21 C.F.R. Section 314.53(c)(2)(i)(Q);Section 314.53(c)(2)(ii)(R)

⁵² See http://www.hc-sc.gc.ca/dhp-mpps/prodpharma/patregbrev/index_e.html

⁵³ The Patented Medicines (Notice of Compliance) Regulations can be found at <http://laws.justice.gc.ca/eng/SOR-93-133/page-1.html> (last accessed 2 November 2010)

to the notice of allegation. The proceedings trigger an automatic stay of marketing approval for the generic product for up to 24 months.

The PM (NOC) regulations state that originator manufacturers who has filed for a Notice of Compliance may submit to Health Canada a list of all patents relevant to their product⁵⁴. This submission of the patent list is optional and a patent holder will not be later prevented from filing patent infringement lawsuits based on unlisted patents. The patent list must be submitted at the time an application for the notice of compliance is submitted but further patents may be added to the patent list after filing of the application for marketing approval, if it is done within 30 days of issuance of the patent⁵⁵. The patent lists are published in the official Patent Register. There is no limit to the number of patents that can be submitted for a drug.

The patent listing forms ask for the brand name, ingredients, dosage form, route(s) of administration, uses of the medicine and strength per unit, as well as the patent number, the filing date in Canada, the patent grant date and the expiration date. Third party patents can be placed on this list if the applicant for marketing approval has an exclusive license to the third party patent or has obtained the consent of the patent owner⁵⁶.

4.3.1 Concept of “Relevant” Patent in the Health Canada System

A patent can only be listed on the Health Canada Patent Register if it contains a claim for the medicine itself or a claim for the use of the medicine. To meet these criteria, a patent must contain at least one of the following claims⁵⁷:

- a claim for the approved medicinal “ingredient”⁵⁸;
- a claim for the approved “formulation”⁵⁹ or “dosage form” containing the medicinal ingredient; or

a claim for the approved use of the medicinal ingredient.

⁵⁴ PM (NOC) Regulations, Section 4(1)

⁵⁵ See PM (NOC) Regulations, Section 4(5) and (6)

⁵⁶ PM (NOC) Regulations, Section 4(4)(b)–(d)

⁵⁷ PM (NOC) Regulations, Section 4(2) (a)–(d)

⁵⁸ Product-by-process patents (generally quite rare for pharmaceutical products) also qualify for protection under the Regulations. Section 2 of the Regulations provides that a “claim for the medicinal ingredient includes a claim in the patent for the medicinal ingredient, whether chemical or biological in nature, when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent ...”

⁵⁹ A claim for the “formulation” is defined as a claim for a substance that is a mixture of medicinal and non-medicinal ingredients in a drug and that is administered to a patient in a particular dosage form; a claim for the dosage form is defined as a claim for a delivery system for administering a medicinal ingredient in a drug

Certain types of patents are not eligible to appear on the Health Canada list. A claim for different polymorphs constitutes a list-able “claim to a medicinal ingredient”, but no such recognition is given for claims to other forms of a medicinal ingredient (e.g., salts, esters, enantiomers or solvates). The Patented Medicines (Notice of Compliance) Regulations Guidance Document, which provides guidance on how to comply with the regulations notes that the following types of patent that would not be considered eligible for listing on the Patent Register⁶⁰:

- a purely process patent;
- a patent for a medical device;
- a patent for an intermediate used in the manufacture of the medicinal ingredient;
- a patent for a metabolite of the medicinal ingredient;
- a patent for an impurity present in the final drug product; or
- a patent for a different chemical form of the medicinal ingredient or uses thereof, including salts, esters and other derivatives of the medicinal ingredient.

In the case of a supplement to a new drug submission, a new patent may be submitted for listing if it contains a claim for the change that is being sought in the supplement to a new drug submission; i.e., if the supplement to a new drug submission is for a new formulation, dosage form or use, the patent must contain a claim for the new formulation, dosage form or use to be eligible for listing. In addition, the Regulations do not permit the listing of patents containing claims solely for the medicinal ingredient (including polymorphic forms)⁶¹.

or a formulation of a drug that includes within its scope that medicinal ingredient or formulation. The term “formulation” thus refers to the physical mixture of medicinal and non-medicinal ingredients administered to the patient by means of the approved drug. A “dosage form” patent would need to contain a claim to the specific dosage form described in the NDS. It would also need to include, among the medicinal substances the dosage form is intended or capable of delivering, express reference to the medicinal ingredient described in the NDS. Dosage forms include controlled-release tablets and capsules, implants and transdermal patches.

⁶⁰ Patented Medicines (Notice of Compliance) Regulations Guidance Document for Industry, at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/patmedbrev/pmreg3_mbreg3-eng.php (last accessed on 2 November 2010)

⁶¹ PM (NOC) Regulations, Section 4(3)

4.4 Searching for Patent Information from FDA Orange Book and Health Canada

As noted in description of the patent listings under the FDA Orange Book and Health Canada, there are some key differences under each system. The US FDA does not undertake a systematic review of the patent submissions to assess the relevance or underlying validity of listed patents. Health Canada however, conducts a review of the submissions to determine their relevance and rejects patents considered irrelevant. It can therefore be assumed that the Orange Book will yield a broader list of patents whilst the Health Canada's patent register will provide a narrower listing of relevant patents.

A search for patents on antiretroviral products marketed in the two territories indicates that the US FDA Orange book lists far more patents than the Health Canada Patent Register. A combination of patent information from these two sources should therefore provide a comprehensive listing of patents related or associated with the marketed pharmaceutical product. A comparison of the two sets of patent information from the Orange Book and Health Canada's patent register on antiretroviral drugs during the piloting phase of this Methodology, further showed that Canadian listed patents had full correspondence of priority with US listed patents, or their priority were part of the priority listed in the US listed patents.

4.5 Limitations of Using the FDA Orange Book and Health Canada Patent Register

The main limitation of relying on the Orange Book and Health Canada is that some categories of medicines, and hence some patents on medicines, will not be included in the patent lists. Of note is the fact that the Orange Book and Health Canada patent listings will not include medicines that are not marketed in the US and/or Canada. These include, for example certain fixed-dose combinations of ARVs, which however are marketed as single components and certain anti-malarial drugs and medicines for the treatment of the so-called "neglected diseases", for which there is basically no market in the US and Canadian territory. Since patent information sourced from the US FDA Orange Book and Health Canada's Patent Register is limited to pharmaceutical products submitted for approval or approved for marketing in the US and Canada, medicines or products that are not intended for marketing in the US or Canada will not be listed. This is the major limitation in relying on these sources to identify priority patents.

As discussed above, the Orange Book and the Health Canada Patent Register do not include certain categories of patents related to medicines. For the Orange Book, the FDA has made clear that certain previous listing practices would no longer be allowed, including the listing of patents for off-label uses, drug packaging and metabolites. Other categories of concern for which listing is not required include:

- patents on intermediates produced during the processing of an active pharmaceutical ingredient but not present in the final drug product. This is a potentially important limitation, because manufacture of a drug product in-country may be blocked by a third party-patent to a chemical intermediate needed in the process;
- diagnostic devices that do not contain the medicine; and
- process or manufacturing patents.

It is also noted that the patent lists are subject to change, with the addition and deletion of patents, thus it may be necessary to update patent information obtained from these lists.

A methodology that uses the patents listed in the US FDA Orange Book and Health Canada as a starting point to retrieve patent documents in third countries also has the limitation of excluding information on third-party enabling patents that assist in the manufacture or administration of an essential medicine and that are required for the manufacture or use of a particular medicine. These patent documents may not claim the medicine of interest per se as an active ingredient and thus will not be found using this approach. To the extent such third-party intellectual property is needed for a country to make, use, and sell a product within its borders, separate legal inquiries will be needed which are beyond the scope of this method.

4.6 Advantages of Using Health Canada and/or the Orange Book Patent Register

Despite the limitations noted above, using the Orange Book and Health Canada Patent Register to identify relevant patents on pharmaceutical products has distinct advantages, in that it eliminates the laborious, time-consuming and technically demanding patent searching on chemical structures and names and analysis of documents, as discussed in Part 3 above. The combination of the two patent lists offers a relatively straightforward way of identifying corresponding patents in developing countries.

5. Determining the Patent Landscape

Patent information sourced from the U.S. FDA Orange Book and Health Canada listings provide an initial list of the potentially relevant patents from which further analysis and searches are made to identify the priority patent applications and the patent families. Parts 5.1 to 5.3 below describe the remaining steps of: identification of relevant priority applications; search for corresponding patent families; and patent search and verification of patent status at regional and national patent offices.

5.1 Priority Patent Applications

Priority application numbers and dates are provided to applicants by patent offices when the first patent application claiming an invention is filed. These numbers are then cited during subsequent filings for the same or related subject matter before a patent office. The Paris Convention concerning subsequent applications on the same subject/invention states that “any person wishing to take advantage of the priority of a previous filing shall be required to make a declaration indicating the date of such filing and the country in which it was made”⁶². The priority application number can be used to connect related patent document “families” across national or regional patent offices, through databases and computerized search systems. Hence, the priority application number functions as an identifying code in the world intellectual property system.

WIPO recommends that patent offices should always provide priority application numbers in a format that complies with certain standards, as “the accurate recording of the priority application number by applicants [is] a critical concern of all industrial property offices”. WIPO considers

⁶² Paris Convention, Article 4 D (1) http://www.wipo.int/treaties/en/ip/paris/pdf/trtdocs_wo020.pdf

the correct presentation of priority application numbers to be extremely important and has requested that “the standard be implemented by industrial property offices as soon as possible”⁶³.

A priority patent application on an innovation when filed in a third country can be subject to changes. As a result, the patent claims of the priority patent application and of the granted patents in the different countries will likely differ. As a result, patents granted in different countries originating from the same priority application may substantially claim different innovative steps and therefore aspects of the medicine.

5.1.1 Identifying Priority Patent Data for Pharmaceutical Products

The patent information on the selected pharmaceutical products, obtained from the Orange Book and Health Canada listings, provide an initial list of potentially relevant patents from which further analysis and cross-checking was done to identify the priority patent application numbers for each of the pharmaceutical products. To ensure accuracy, this list is then checked against the patent data from the US Patent and Trademark Office (USPTO) and the Canadian Intellectual Property Office, both of which have publicly accessible on-line databases.

Priority data is not easy to extrapolate from the USPTO Internet database. On the other hand, Canadian Intellectual Property Office website provides priority patent data, including PCT application data, in a more accessible manner. The publicly-available EPO database, Esp@ceNet also provides priority patent data in a codified fashion for any recorded patent within its database. Hence, the proposed Methodology relied on all three on-line databases to retrieve and cross-check the priority application data (numbers, date and applicants) for the Canadian and US patents listed in the Orange Book and the Health Canada Patent Register.

5.2 Patent Families

A “patent family” is a list of roughly similar patent documents (linked by priority application numbers) from throughout the world that derive their origin from the priority patent; i.e., the first patent application to be filed. In short, this is a group of patent documents where every member has at least one common priority with at least one other member⁶⁴. The first filing will from then on always be linked to the day on which the filing was made; i.e., the priority date.

⁶³ WIPO, Geneva 2009. “Handbook on Industrial Property Information and Documentation”, Std. ST/10C, at <http://www.wipo.int/scit/en/standards/pdf/03-10-c.pdf>, (last accessed 29 August 2010)

⁶⁴ See <http://gb.espacenet.com/espacenet/gb/en/help/161.htm>, last accessed 26 January 2007

Hence, priority patent data opens the door to the patent family; so that the related patents on an invention filed around the world can be tracked. Looking up any of the family members can trigger the display of the entire family with the publication date of the various national or regional applications and the technical classification codes of the document(s)⁶⁵. This may sometimes generate patent families, containing hundreds of members and also of members who show no visible relationship to each other. Nevertheless, the ability to look up the patent family helps ensure that all members of interest in a patent family are found.

The term “patent family” can be defined in a number of ways, depending on the relationship between a patent document and its priority or of priorities, as follows:

- all documents having exactly the same priority or combination of priorities belong to one patent family;
- all the documents having at least one common priority belonging to the same patent family; and
- all the documents directly or indirectly linked via a priority document belong to one patent family.

The first is the narrowest definition of the patent family, which includes only those documents where the priorities cited and patent claims match exactly. Even under this definition there is no guarantee that the two documents will be the same. In the case of European patents that have entered into the national phase, the completeness and accuracy of data can vary significantly from country to country⁶⁶. A broader definition involves those cases where the applications have at least one priority in common⁶⁷. The third is the definition used by the International Patent Documentation Center Collection (INPADOC), which is more comprehensive than the way that patent families are compiled in other search engines and presents an advantage in casting the net wide to catch all relevant patents⁶⁸. The INPADOC database takes the patent application number as the connecting element, including documents having the same scope but lacking a common priority (e.g. if the country concerned has not ratified the Paris Convention, or if the application was filed too late to claim the priority). The INPADOC database covers some 95% of all patents published worldwide since 1973. In INPADOC, additional family links are established by analyzing inventor and applicant names.

⁶⁵ Lambert, N. 2006. “Announcing FamPat, a New International Patent Database from Questel Orbit”, at <http://www.infotoday.com/newsbreaks/nb050214-2.shtml>, last accessed 27 January 2007

⁶⁶ See generally, EPIDOS News Issue 4/2000, “Patent Family Systems”, at http://www.european-patent-office.org/news/epidosnews/source/epd_4_00/4_4_00_e.htm, last accessed 1 December 2006.

⁶⁷ http://www.european-patent-office.org/news/epidosnews/epd_4_00/index_e.htm

⁶⁸ INPADOC Patent Family Searching, at http://www.european-patent-office.org/inpadoc/pfs_index.htm, last accessed 2 December 2006.

5.2.1 Patent Family Searching

Once the priority patent application data is identified, the next step in the patent landscape Methodology is to search for the relevant patent families for each of the Canadian and US patents, so as to track where else in the world similar patent applications have been filed and granted. Extrapolated from the US and Canadian listed patents, the priority application numbers can, in theory, be used on their own to request applications and granted patents from national or regional patent offices. The patent family searching step, however, adds another layer of information that can guide the patent searches at the national and regional patent offices⁶⁹.

Although the EPO's internal database was used to search for patent families during the piloting of the Methodology, it is suggested that the INPADOC database could also be used in the same way to retrieve patent families⁷⁰. For developing countries, where relatively fewer patent applications are filed, use of either the narrower or broader patent family definition may still yield the same results. In using INPADOC, the search for patent families would be even more comprehensive. In addition, the INPADOC database can be accessed via the Internet, through EPO's Esp@ceNet. In this respect, Esp@ceNet represents a publicly-available and user-friendly interface to permit the search for patent families in the INPADOC database. INPADOC data reported in Esp@ceNet is automatically updated⁷¹.

The use of INPADOC, with its broader patent family definition, may have the advantage of identifying possible product-by-process patents and other patents which did not meet the eligibility criteria for "listable" patents of the FDA Orange Book or Health Canada. In this manner, it is casting a wider net to search for patent applications and patents that may be related to the medicine of interest.

No patent database will yield perfect and complete families in all cases. Database producers do what they can to ensure completeness, but it is not possible to guarantee it. Hence, patent family databases will inevitably have gaps in their stored information, depending to the frequency, accuracy and timeline of information sent by patent offices and uploaded onto the database

⁶⁹ For the information provided in the appendices, the EPO provided technical assistance for the patent family search, and the EPO's internal database, FAMI, was used to retrieve the patent families of the patents listed in the Orange Book and Health Canada Patent Register for the 19 selected pharmaceutical products. The FAMI database uses the so-called "simple family concept," i.e., the narrow definition of patent families requiring all documents claiming exactly the same priority(ies).

⁷⁰ The EPO's internal database, referred to as FAMI, employs a narrower definition of patent family.

⁷¹ The updates are reported in the statistics tables (updates once a week) on the Internet under the section "contents and coverage". See http://www.european-patent-office.org/inpadoc/statistics_dwld.htm

system. Furthermore, patent applications or granted patents that are not published will rarely appear in these databases. The use of priority patent data however, should be able to retrieve corresponding patent applications and granted patents.

5.3 Patent Search and Verification of Patent Status at Regional and National Patent Offices

From the patent families identified, further analysis has to be made on: (1) whether the patent has been in fact granted; and (2) whether or not it is still in force. These are questions that require verification by the national or regional patent offices. At present, it is not possible to confirm such information via other means.

WIPO's PCT applications can provide indicative information on where patents may be applied for, but this is not conclusive data relevant to the eventual grant of a patent. Although the PCT does not specifically require that applicants or national or regional patent offices inform WIPO about the status of specific international applications in the national phase, information on whether an international application has entered the national phase, as well as other information relating to the national phase can, where available, can now be accessed via the PatentScope database⁷². Where available, status information such as patent grant, withdrawal or refusal is also published.

WIPO began dissemination of PCT national phase information via the PatentScope® service in 2006. Since that time, more offices have joined the program and there is now information available from 46 offices, amounting to more than 3.5 million PCT national phase notifications in total (according to 2009 data)⁷³. It is expected that such information will become increasingly available, as an increasing number of national patent offices cooperate with WIPO⁷⁴. One limitation is that information on the national phase is only available where WIPO has received the relevant information, either directly from national patent offices or via the INPADOC database.

⁷² See www.wipo.int/pctdb, last accessed 3 December 2006

⁷³ The 46 patent offices are: ARIPO, Australia, Austria, Belarus, Belize, Bulgaria, Canada, China, Croatia, Cuba, Czech Republic, Egypt, EAPO, EPO, Finland, Georgia, Germany, Hungary, Israel, Japan, Kenya, Latvia, Lithuania, Malaysia, Mexico, New Zealand, Philippines, Poland, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey, Ukraine, United Arab Emirates, United Kingdom, United States of America, Uzbekistan, Vietnam, see <http://www.wipo.int/pctdb/en/nationalphase.jsp>,

⁷⁴ See World Intellectual Property Organization, "Statistics on Patents", at <http://www.wipo.int/ipstats/en/statistics/patents/>, last accessed 24 January 2007

In most cases, such information is only available after 30 months from the priority date, which is about 12 months after international publication. The timeliness of the available information varies according to the patent office supplying the data.

For the verification process by the national or regional patent offices, the Methodology provides 3 key sets of information to patent offices for verification, as follows:

- the country patent or application number and date;
- the priority application data (numbers and dates, e.g. US19950000654P 19950629); and
- PCT application numbers and dates identified through the patent family search.

Where the country patent or application data is not available, patent offices are asked to provide any available information against the priority data provided. The PCT application data presented may assist in retrieving corresponding patents granted at national level, if those applications originated from the PCT application. In sum, the patent offices are requested to verify the country patent or application number and dates, to provide the country application number and date, the expiry date of the patent, and the legal status of the document (in force, lapsed, withdrawn, etc.).

5.4 Analysis of Patent Claims

When verification of the patent status at the national or regional level is obtained, this information defines the patent landscape of the selected pharmaceutical products in the relevant country. The next level of inquiry is whether the granted patent claims an invention that will affect the proposed use of the medicine within the country.

A patent claim analysis of a specific patent document can properly determine the relevance for the importation, use or production of a specific generic version of the innovator product within a specific country. The claims within a priority patent may be subject to changes, as it is amended to meet the specific requirements of individual patent offices and the governing legislation. Despite originating from the same priority patent application, patents granted at the national or regional level may claim different inventions, such as when a number of priority applications are combined. As such, a patent claims analysis of US and Canadian patents or of the priority patents may only provide an indication of the protected invention(s). A claims analysis of the specific patent would therefore be required to determine the exact scope of the applicable patent protection. It should be noted that a claims analysis for the purposes of embarking on the manufacture and production of a pharmaceutical product requires a different and more detailed level of investigation than for the purposes of importing and using the generic equivalent of a medicine or finished pharmaceutical product.

5.5 Limitations of the Methodology

It must be emphasized here that the Methodology provides a tool to obtain preliminary patent information; as noted in Part 5.4 above, it does not replace the need for patent claim analysis. The Methodology, however, is a viable, practical and systematic approach that builds on existing concepts of the patent system; such as the priority application data identifying an invention and the patent family concept using publicly accessible and free databases.

As noted earlier, the Methodology also has an in-built limitation that medicines or products not intended for marketing in the US or Canada are not listed in the Orange Book or Health Canada patent lists. Due to the fact that the Orange Book and Health Canada does not require patent listings for vaccines and biological medicines, the Methodology may have limited applicability to search for patents on these products.

For medicines or products not found on the Orange Book or Health Canada patent lists, a different approach is needed. Such an approach would require a set of information; e.g., on the chemical compound, formulation, composition and manufacture, the mechanism of action, the medical use and the recommended dosages and regimes of the medicine in question. Patent searches would have to be done using this information. The large number of documents (applications and patents) would have to be screened for relevance, after which priority data and patent families may be identified. As has been pointed out however, the number of medicines or pharmaceutical products requiring this approach is likely to be small.

Although a degree of uncertainty is intrinsic in the present Methodology, it should be noted that any other search method is not exempted from uncertainty, as has been made clear in the discussion in Part 3 above.

6. A Tool for Patent Searches

There is no simple or fail-proof way to determine the patent landscape of medicines in developing countries. As a result, any methodology chosen will not be perfect but as discussed above, the present Methodology represents one of the least problematic of the methods for quickly searching and determining the patent landscape of medicines in developing countries. The Methodology can be replicated, used and adapted to search for patent information from public sources, without the need for highly-specialized experts or significant resources.

It provides a “snapshot” of patent information that can be verified at the national and regional patent offices. This snapshot will then provide the basis upon which informed decisions can be made; whether further, more detailed investigation is required as appropriate to the use for which the patent information is sought.

6.1 Using the Methodology

It is proposed that a broader effort to use the Methodology should be initiated, so patent searches at the national level should be extended to other patent offices in developing countries. This will provide the opportunity to further test the Methodology and at the same time, compile relevant useful patent information.

A three-stage process of testing and using the Methodology at the national level can be envisaged, as follows:

- **Stage 1: Training and bringing together stakeholders**

Training workshops should be organized, during which participants can learn and be trained on the use of the methodology, as well as the complexities of patenting of medicines in context specific countries and regions. This should include, among others, training on patentability criteria and analysis of country (and/or regional) patent systems administration and legal framework for use of TRIPS flexibilities.

These patent landscaping workshops would bring together relevant government agencies, such as the agencies with mandates for health, procurement and intellectual property, and to determine the list of medicines for which patent information is needed for a specific country or region. The workshops can also facilitate strategic planning sessions, in which the stakeholders should jointly decide on issues relating to the conduct of the patent searches, including:

- the list of medicines for which patent information is required;
- who will undertake the patent searches and analysis;
- how and by whom the patent information would be used.

Workshops can be important opportunities to bring together all stakeholders in the public health and intellectual property arenas at country, regional and global level, in order to engender effective means of collaboration to ensure that the patent system is able to respond to public needs.

- **Stage 2: Compiling patent resource database**

Patent information from patent landscaping efforts should be compiled and made freely available, so as to facilitate developing countries' medicines procurement decision-making, as well as to ensure transparency and accessibility of the administration of patent systems in developing countries. Both human and financial resources will clearly be required to maintain and update such a database, but these need not be significant. One option is the housing of such databases within the national patent or industrial property offices, which already have the task to compile and collate patent data.

As a repository of relevant information related patents on medicines, national patent resource database should be developed and established to compile and collate data on the following:

- data on the selected medicines and rationale for their selection;
- patent information related to the selected medicines; such as patent documents, priority patent data, and the status of the relevant patents;
- analysis of the approximate patent expiry dates and the estimated timeframe for possibility of generic introduction in relevant countries; and
- technical and legal information on mechanisms to address patent barriers to essential medicines.

- **Stage 3: Patent claims analysis**

There should also be efforts to begin the analysis of patent claims to determine their relevance for the procurement and production of generic medicines. As noted in Part 5.4 above, a patent claims analysis of granted patents in the country will properly determine the rele-

vance for the importation, use or production of a specific generic version of the innovator product within that country.

While a patent claims analysis may require specialized expertise that is not be easily accessible in-country, there is the option of requesting such technical assistance from international organizations and civil society groups with such expertise. For instance, patent claims analysis could also be undertaken virtually, via email, thereby reducing the cost and time involved. The fact that the patent landscape and the relevant patent documents - which are often difficult to obtain - can be made available to such experts will be important factors to facilitate this process.

6.2 Facilitating Transparency of Patent Information

During the debate that eventually led to the Doha Declaration on the TRIPS Agreement and Public Health in 2001, there had been discussion about ensuring the appropriate balance between the imperatives of intellectual property protection and of the public health interest in facilitating access to affordable medicines and treatments. The WHO and its Member States, in developing and adopting the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) in 2008, acknowledges the significance of the relationship between intellectual property rights protection and the achievement of positive public health outcomes.

Resolution WHA61.21 of the World Health Assembly notes that a key element of the GSPOA is the application and management of intellectual property to contribute to innovation and promote public health, and in particular the strategy called for, inter alia, the development of “user-friendly global databases which contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents”⁷⁵.

While the “global databases” are yet to be established, efforts to use the Methodology to collect and compile relevant patent data in national databases will contribute towards greater transparency in patent information and therefore promote better decision-making and strengthening capacities in developing countries for addressing the relationship between public health and intellectual property, and ultimately, the objectives of the GSPOA itself.

⁷⁵ See Element 5, Para 5.1(c) and (d) of WHA61.21, Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, May 2008, http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf

As noted in Part 1 above, the Methodology seeks to meet the patent information needs of developing countries, and to determine how such information can be made accessible to stakeholders in the interest of addressing public health problems. It does not however, shift the burden of facilitating and ensuring transparency of patent information from the patent system itself to those who seek or require such information. The responsibility of ensuring transparency ultimately lies with those who manage and administer the patent system, both at the national and global levels. It is also in their interest to demonstrate that the patent system can adequately respond to the public interest of enabling access to medicines and protecting public health.

Appendices

The WHO Patent Project and Patent Search Results

Appendix 1A:

WHO Patent Project

The pilot patent project at the WHO, was developed with support from UNAIDS over the period of 2005–2006. The WHO Patent Project had, as its overarching objective, the development of a systematic methodology to investigate and analyze the extent to which specified essential medicines are protected by patents in developing countries. The methodology would be able to help determine the patent “landscape” for essential medicines in developing countries, so as to be able to: (a) respond to requests for patent data from Member States, UN agencies and medicines procurement agencies to facilitate efficient and cost-effective medicines procurement; (b) provide relevant patent information to Member States to facilitate informed policy decisions regarding use of TRIPS (the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property) flexibilities; and (c) facilitate greater transparency of and access to patent information related to essential medicines.

The WHO Patent Project builds upon the method of search that was used by Médecins sans Frontières (MSF) in their compilation of patent data for their publication *Drug Patents under the Spotlight*⁷⁶. The European Patent Office (EPO) was a key partner in the pilot phase, providing training and technical support, including developing the search strategy to identify relevant patents on medicines in the context of the current capacity and limitations of the international patent system to retrieve information on pharmaceuticals. The Office of Patented Medicines and Liaison, Therapeutic Products Directorate, of Health Canada also provided assistance and information related to the patent registry in Canada. Consultations with the World Intellectual Property Office (WIPO) Secretariat also helped in the project design.

The methodology underwent a testing process in 2006, wherein patent searches were conducted, using the methodology, to determine the patent landscapes for 19 antiretroviral medicines and combinations, listed under the WHO HIV/AIDS Treatment Guidelines in 2005. As per the steps described above, the patent data for the 19 medicines and combinations were retrieved

⁷⁶ Drug patents under the spotlight: Sharing practical knowledge about pharmaceutical patents, *Medicins sans Frontieres*, 2004, Geneva, see http://www.accessmed-msf.org/fileadmin/user_upload/medinnov_access-patents/Patent%20report%20.pdf

from the Orange Book and Health Canada patent listings, after which the relevant priority data were identified. The priority patent application data and INPADOC patent families for the 19 antiretroviral medicines and combinations, retrieved from the Orange Book and the Health Canada Patent Register are listed in Appendix 1B below.

Three national patent offices were identified for the last step of the methodology; i.e., verification at the national level. This was undertaken at the State Intellectual Property Office of China (SIPO) and South African Companies and Intellectual Property Registration Office (CIPRO). Patent searches were also conducted by the Lawyers' Collective at the Indian Patent Offices.

The results from the patent searches in 2006 indicate that both patent offices China and South Africa were able to trace the patents granted at the national level through the priority patent and patent family data provided, through the use of the methodology. The patent searches at the patent offices were completed within few weeks for the 19 antiretroviral medicines and combinations. It should be noted that both patent offices relied on electronic databases for storing their country patent information and could easily verify and/or complete the set of data provided (country patent data, priority patent data, PCT application numbers). The patent search results from SIPO and CIPRO are listed in Appendixes 1C and 1D, respectively. In India, patent searches at the four Indian Patent Offices were also successful in locating patent applications or granted patents, but the searches required more time as well as some knowledge of the functioning of the patent offices of India. The reasons for this is that in 2006, the patent offices in India were still recently-established, and did not as yet have centralized electronic system record patent information. Appendix 1E below sets out the results of the patent searches conducted by the Lawyers' Collective at the Indian Patent Offices.

Appendix 1B:

Priority patent application data and INPADOC patent families for 19 antiretroviral drugs and combinations, using data from the Health Canada Patent Register and the US FDA Orange Book

Drug or combination	Patents listed in the Health Canada Patent Register and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Register and US FDA Orange Book	WIPO (WO)	Aripo (IP)	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Ritonavir (RTV)	C4271196	Abbott Laboratories US	US1966074390 19961121; WO1997/US207941 19971112	WO9822106 A Y 1998-05-28		BR9714310 A N 2000-05-02	CN1488914 A N 2000-05-29					ZA9710071 A N 1998-05-25
	US5914332	Abbott Laboratories US	US1996075320 19961121; US19950572226 19951213; WO1996/US20440 19961206	WO9721683 A Y 1997-06-19		BR1100397 A N 2000-04-11	CN1207288C 2005-06-22 CN1208405 A N 1999-02-17					ZA9610475 A N 1997-07-31
	C4228398	Abbott Laboratories US	US1996075320 19961121; US19950572226 19951213	WO9721683 A Y 1997-06-19		BR1100397 A N 2000-04-11	CN1207288C 2005-06-22 CN1208405 A N 1999-02-17					ZA9610475 A N 1997-07-31
	US624767	Abbott Laboratories US	US1998020973 19981208; US1996073101 19961121; US19950572226 19951213	WO9721683 A Y 1997-06-19		BR1100397 A N 2000-04-11	CN1207288C 2005-06-22 CN1208405 A N 1999-02-17					ZA9610475 A N 1997-07-31
	US5521651	Abbott Laboratories US	US19960393872 19960910; US19960347077 19960702; US19970966495 19971107; US19970966495 19971107; US19960031463P 19961121	WO9721683 A Y 1997-06-19	no family found							
Ritonavir (RTV) / Lopinavir (LPV)	US646388	Abbott Laboratories US	US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121	WO9721683 A Y 1997-06-19	no family found							
	US611214	Abbott Laboratories US	US20010946085 20010904; US20000230095P 20000905	WO9721683 A Y 1997-06-19	no family found							
	C42051670	Abbott Laboratories US	US19960616170 19961120; US19970416200 19970815; US19970776208 19971003	WO9721683 A Y 1997-06-19	no family found							
	C4213980	Abbott Laboratories US	US19920998114 19921229; US1992013887 19931202	WO9414486 A Y 1994-07-07								
	C4224738	Abbott Laboratories US	US1995000654P 19950629; US1995000349P 19950915; WO1996/US11015 19960628	WO9701549 A Y 1997-01-16								
US9446987	Abbott Laboratories US	US199208261609 19920330; US19950417879 19950406; US1992013887 19931202; US19920998114 19921229	WO9414486 A Y 1994-07-07			BR1100661 A N 2000-04-11						

Drug or combination	Patents Listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Aripo (AP)	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Ritonavir (RTV) / Lopinavir (LPV) (continued)	US567,682	Abbott Laboratories US	US1995041336 19950329; US1992098714 19921229; US1993015887 19931202; US1991077656 19911023; US19910746020 19910815; US19900616170 19901120; US19900518720 19900509; US19890461624 19891222; US19890405604 19890908; US19890355945 19890523	WO9414466 A Y 1994-07-07								
	US541206	Abbott Laboratories US	US1995042387 19950245; US1993015887 19931202; US1992098714 19921229; US1991077656 19911023; US19910746020 19910815; US19900616170 19901120; US19900518720 19900509; US19890461624 19891222; US19890405604 19890908; US19890355945 19890523	WO9414466 A Y 1994-07-07								
	US563553	Abbott Laboratories US	US19950417879 19950406; US1993015887 19931202; US1992098714 19921229; US1991077656 19911023; US19910746020 19910815; US19900616170 19901120; US19900518720 19900509; US19890461624 19891222; US19890405604 19890908; US19890355945 19890523	WO9414466 A Y 1994-07-07								
	US5648497	Abbott Laboratories US	US19950410623 19950324; US19940270220 19940823; US1993021673 19930914; US1991077656 19911023; US19910746020 19910815; US19900616170 19901120; US19900518720 19900509; US19890461624 19891222; US19890405604 19890908; US19890355945 19890523									

Drug or combination	Patents listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Aripo (AP)	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Ritonavir (RTV) / Lopinavir (LPV) (continued)	US5703403	Abbott Laboratories US	US2001035711 20010920; US1999038726 19990831; US1996068774 19960626; US1995000654P 19950629; US19950003849P 19950915	WO9701349 A Y 1997-01-16								
	US6232333	Abbott Laboratories US	US19970966495 19971107; US19960031463P 19961121									
	US5484801	Abbott Laboratories US	US19950440277 19950512; US1994028239 19940739; US19940189021 1994012	WO9520384 A Y 1995-08-03								
	US688096	Abbott Laboratories US	US19970822071 19970320; US1995043136 19950319; US1995013887 19951202; US1995098114 19951229	WO9701349 A Y 1997-01-16								
	US6037157	Abbott Laboratories US	US19950003849P 19950915; US1996068774 19960626; US1995000654P 19950629	WO9701349 A Y 1997-01-16								
Nevirapine (NVP)	CA2090056		US1989048393 19891177; US19900579001 19900906; US19900600390 19901019		AP79 A N 1992-04-30				OA952 A - 1994-08-15	RU204057 C N 1995-07-25		ZA9009246 A N 1992-07-29
	US516692	Boehringer Ingelheim Pharmaceuticals, Inc.	US1993091418 19930731; US1989039970 19890420; US1989039374 19890420; US1989039293 19890420; US1990050200 19900406; US1990050200 19900406; US19910740838 19910805		AP80 A N 1993-05-04, AP79 A N 1992-04-30				OA982 A - 1994-08-15 CN199511-30	RU202463 C N 1994-12-15 RU204057 C N 1995-07-25		ZA900901 A N 1995-03-31 ZA9009246 A N 1992-07-29
Atazanavir (ATV)	US64991	Novartis Finance Corporation	CH1996000018 19960422; CH1997000023 19970131	WO9740029 A Y 1997-10-30		BR9701877 A N 1998-09-29	CN1082508C C 2002-04-10 CN195010C C 200503-16 CN2016539 A N 1999-05-12 CN319587 A N 2001-10-31 CN1616453 A N 2005-05-18					ZA970387 A N 1997-10-22
	CA317736	Bristol-Myers Squibb Company US	US1998007968P 19980201; WO1998U52782 19981222	WO9936404 A Y 1999-07-22		BR984736 A N 2000-10-24	CN183188 A 2001-02-07 CN1116282C C N 2003-07-30					ZA990096 A N 2000-07-05
	US608738	Bristol-Myers Squibb Company	US1998027538 19981221; US1998007968P 19980201	WO9936404 A Y 1999-07-22		BR984736 A N 2000-10-24	CN183188 A 2001-02-07 CN116282C N 2003-07-30					ZA990096 A N 2000-07-05
Didanosine (DDI)	CA269044	US HEALTH (US)	US1989076916 19890816	WO8701384 A Y 1987-03-12								
	CA207573	US HEALTH (US)	US19900460490 19901003	WO9109605 A Y 1991-07-11								

Drug or combination	Patents Listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Aripo (AP)	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Didanosine (DDI) (continued)	CA2074215	SQUIBB BRISTOL MYERS CO (US)	US19910733547 19910722; US19920882204 19920513				CN1042299C 1999-03-03 CN1068739 A N 1993-02-10			RU2089193 C N 1997-09-10		ZA9205484 A N 1993-09-13
	US6861759	The United States of America as represented by the Department of Health	US19870084055 19870811; US1989769016 19850826	WO8701284 A Y 1987-03-12								
	US524639	U.S. Government, Dept. of Health and Human Services, C/o National	US19910663288 19910228; US19870084055 19870811; US19890420664 19890828; US1989769016 19850826; US19866937951 19861204	WO8701284 A Y 1987-03-12								
	US616566	The United States of America as represented by the Department of Health	US19930060643 19930480; US19910663288 19910228; US19890420664 19890828; US19870084055 19870811; US19866937951 19861204; US1989769016 19850826	WO8701284 A Y 1987-03-12								
Stavudine (d4T)	CA203447 US8978655	Yale University	US19866937951 19861204; US19910733547 19910722				CN1042299C 1999-03-03 CN1068739 A N 1993-02-10			RU2089193 C N 1997-09-10		ZA9205484 A N 1993-09-13
	CA2075189	Emory University (US)	US19970942660 19971002; US19920882204 19920513; US19910733547 19910722	WO911186 A Y 1991-08-08								ZA8970771 A N 1988-03-24
	CA2009637	Biochem Pharma INC (Canada)	US19910663288 19910222; US19900473318 19900201; US19910733547 19910722	WO911186 A Y 1991-08-08 WO9214729 A Y 1992-09-03 WO9214743 A Y 1992-09-03	AP136 A N 1991-08-05		CN1031640C 1996-12-25 CN1044817 A N 1990-08-22		OK9193 A N 1992-06-30	RU2092485 C N 1997-10-10		ZA9000943 A N 1990-10-31
	US9210085	Emory University	US19910663288 19910222; US19900473318 19900201	WO911186 A Y 1991-08-08 WO9214729 A Y 1992-09-03 WO9214743 A Y 1992-09-03		BR0205661 A N 1994-05-24	CN1031640C 1996-12-25 CN1044817 A N 1990-08-22 CN1037682C 1998-03-11 CN1065605 A N 1992-10-07 CN10847245C 2002-02-15 CN1109108C 2003-05-21 CN1127301 A N 1996-07-24 CN1203323 A N 1998-12-30 CN1418666 A N 2003-05-21		RU212558 C N 1999-01-27 RU2092485 C N 1997-10-10 RU212558 C N 1999-01-27		ZA9201351 A N 1993-08-20	

Drug or combination	Patents listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Aripo (A/P)	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Emtricitabine (FCT) (continued)	US5844639	Emory University	US1995007820 19950216; US19910659760 19910222; US19960473318 19960201	WO911186 A Y 1991-08-08 WO9214729 A Y 1992-09-03 WO9214743 A Y 1992-09-03		BR9205661 A N 1994-05-24	CN1037682C C 1998-09-11 CN1056965 A N 1992-10-07 CN1084745C C 2002-05-15 CN1109108C C 2003-05-21 CN1127201 A N 1996-07-24 CN1203332 A N 1998-12-30 CN1418966 A N 2003-05-21			RU1212558 C N 1999-01-27		ZAp201351 A N 1993-08-20
	US914331	Emory University	US19950488097 19950607; US19950831953 19950212; US19910659760 19910222; US19960473318 19960201; US19910736089 19910716	WO911186 A Y 1991-08-08 WO9214729 A Y 1992-09-03 WO9214743 A Y 1992-09-03		BR9205661 A N 1994-05-24	CN1037682C C 1998-09-11 CN1056965 A N 1992-10-07 CN1084745C C 2002-05-15 CN1109108C C 2003-05-21 CN1127201 A N 1996-07-24 CN1203332 A N 1998-12-30 CN1418966 A N 2003-05-21		RU1212558 C N 1999-01-27 RU1223774 C N 2004-09-10		ZAp201351 A N 1993-08-20	
	US6642245	Emory University	US19950473319 19950607; US19920831953 19920212; US19910736089 19910716; US19910659760 19910222; US19960473318 19960201	WO911186 A Y 1991-08-08 WO9214729 A Y 1992-09-03 WO9214743 A Y 1992-09-03		BR9205661 A N 1994-05-24	CN1037682C C 1998-09-11 CN1056965 A N 1992-10-07 CN1084745C C 2002-05-15 CN1109108C C 2003-05-21 CN1127201 A N 1996-07-24 CN1203332 A N 1998-12-30 CN1418966 A N 2003-05-21			RU1212558 C N 1999-01-27 RU1223774 C N 2004-09-10		ZAp201351 A N 1993-08-20
Tenofvir Disoproxil fumarate (TDF)	US9226595 (CA261619)	Gilead Sciences, Inc	US19970900746 19970725; US199600227088 19960716	WO9804659 A Y 1998-02-05		BR981045 A N 2000-08-22						
	US9393946	Gilead Sciences, Inc	US19970900752 19970725	WO9905150 A Y 1999-02-04		BR981045 A N 2000-08-22		IN190780 A N 2003-08-23				

PATENT INFORMATION AND TRANSPARENCY: A Methodology for Patent Searches on Essential Medicines in Developing Countries

Drug or combination	Patents Listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Aripo (AP)	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Tenofovir Disoproxil fumarate (TDF) /Lamivudine (continued)	US5977089	Gilead Sciences, Inc.	US19980187763 1998106; US1997090746 1997075; US1996002768P 1996076	WO9804569 A Y 1998-02-05	AP700 A N 1994-01-20				OA10058 A N 1996-10-14	RU2139059 C N 1999-10-10		ZA9203544 A N 1993-03-31
	US6043230	Gilead Sciences, Inc.	US19959374666 19950519; US19970900740 1997075; US1996002768P 1996076	WO9804569 A Y 1998-02-05								
Zidovudine (AZT) /Lamivudine (3TC)	CA2068790	Glaxo Group Limited	CA1991001624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344 A Y 1992-11-26	AP700 A N 1994-01-20		CN1045961C 1995-10-27 CN1068570 A N 1998-02-03		OA10058 A N 1996-10-14	RU2139059 C N 1999-10-10		ZA9203544 A N 1993-03-31
	CA311988	Glaxo Group Limited	CA19922070230 19920602; GB1991001902 19910603	WO9221676 A Y 1992-12-10	AP700 A N 1994-01-20				OA9913 A N 1994-09-15	RU2102933 C N 1998-01-20		ZA9204007 A N 1993-04-28
US5959582	Glaxo Group Limited	GB1991001902 19910603	WO9221676 A Y 1992-12-10	AP700 A N 1994-01-20					OA9913 A N 1994-09-15	RU2102933 C N 1998-01-20		ZA9204007 A N 1993-04-28
	CA2116654	The Wellcome Foundation Limited (U.K.)	WO1996E Poi 382 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9610093 A Y 1996-10-03	AP652 A N 1998-06-19	BR9607951 A N 1998-07-21	CN1103593C 2003-03-26 CN1185110 A N 1998-06-17		OA100616 A N 2001-03-15			ZAg602477 A N 1997-10-28
US5839021	Glaxo Group Limited	US19966666610 19960222; GB1991001624 19910516; GB19910021381 19911008; GB19910023581 19911106; US19940201976 19940328; US19922883169 19920515	WO9220344 A Y 1992-11-26	AP700 A N 1994-01-20			CN1045961C 1995-10-27 CN1068570 A N 1998-02-03		OA10058 A N 1996-10-14	RU2139059 C N 1999-10-10		ZA9203544 A N 1993-03-31
US6119320	Glaxo Group Limited	US19970955635 19971023; GB19960022688 19961031; US19960029540P 1996031	WO9804877 A Y 1998-05-07	AP067 A N 2002-05-01	BR971614 A N 1999-10-26				OA10038 A N 2002-02-06		UA64775 C N 1995-12-29	ZAg109726 A N 1995-04-29
Abacavir (ABC)	CA2033044	The Wellcome Foundation Limited (U.K.)	US1989045501 19891222	WO9804877 A Y 1998-05-07	AP196 A N 1992-06-30		CN1054481 A N 1991-10-02 CN1028106C C N 1995-04-05			RU2068849 C N 1996-11-10 RU2091386 C N 1997-09-27		ZAg10185 A N 1992-08-26
	CA134959 US5959500 US5954894	Bristol-Myers Squibb Co.	GB1988001585 19880627	WO9804877 A Y 1998-05-07	AP101 A N 1990-10-23							ZAg804837 A N 1991-03-27
US6294540	Glaxo Wellcome Inc.	WO1998E Poi 385 19980414; GB1997009945 19970517	WO9804877 A Y 1998-05-07	AP196 A N 1992-06-30	BR9809124 A N 2000-08-01 BR9809125 A N 2000-08-01 BR9809127 A N 2000-08-01	CN110194C C 2004-05-19 CN146323 A N 2000-08-16 CN151572 A N 2004-07-28		OA11004 A N 2003-10-22			ZAg80483 A N 1991-10-15 ZA9804085 A N 1999-11-15	
Abacavir (ABC) /Zidovudine (AZT) /Lamivudine (3TC)	CA2068790	Glaxo Group Ltd. (Gb)	CA1991001624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344 A Y 1992-11-26	AP700 A N 1994-01-20		CN1045961C 1995-10-27 CN1068570 A N 1998-02-03		OA10058 A N 1996-10-14	RU2139059 C N 1999-10-10		ZA9203544 A N 1993-03-31
	CA311988	Glaxo Group Ltd (Gb)	CA19922070230 19920602; GB1991001902 19910603	WO9221676 A Y 1992-12-10	AP700 A N 1994-01-20				OA9913 A N 1994-09-15	RU2102933 C N 1998-01-20		ZA9204007 A N 1993-04-28
US5959582	Glaxo Group Limited	GB1991001902 19910603	WO9221676 A Y 1992-12-10	AP700 A N 1994-01-20					OA9913 A N 1994-09-15	RU2102933 C N 1998-01-20		ZAg204007 A N 1993-04-28

Drug or combination	Patents listed in the Health Canada, Patents Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada, Patents Registry and US FDA Orange Book	WIPO (WO)	Aripo (AP)	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Abacavir (ABC)/ Zidovudine (AZT) / Lamivudine (3TC) (continued)	US56417191	GlaxoSmithKline	WO1995E0732; 19950328; GB19950006489; 19950330; GB19950006490; 19950330	WO95030025; 1995-10-03	AP52; A N; 1998-06-19	BR9607851; A N; 1998-07-21	CN1035931 C; 2003-09-26; CN1185110 A N; 1998-06-17		Oh0616; A N; 2001-03-15			ZA9602477; A N; 1997-10-28
Abacavir (ABC)/ Lamivudine (3TC)	CA311988	Glaxo Group Ltd. (GB)	CA1992070290; 19920602; GB1991001902; 19910603	WO9221676; A Y; 1992-12-10	AP300; A N; 1994-01-20				Oh0933; A N; 1994-09-15	RU0203933; C N; 1998-01-20		ZA9204607; A N; 1993-04-28
	US56417191	GlaxoSmithKline	WO1995E0732; 19950328; GB19950006489; 19950330; GB19950006490; 19950330	WO95030025; 1995-10-03	AP52; A N; 1998-06-19	BR9607851; A N; 1998-07-21	CN1035931 C; 2003-09-26; CN1185110 A N; 1998-06-17		Oh0616; A N; 2001-03-15			ZA9602477; A N; 1997-10-28
	US5959582	Glaxo Group Limited	GB1991001902; 19910603	WO9221676; A Y; 1992-12-10	AP300; A N; 1994-01-20				Oh0933; A N; 1994-09-15	RU0203933; C N; 1998-01-20		ZA9204607; A N; 1993-04-28
Lamivudine (3TC)	CA2009280; US5959582	1af Biochem International Inc. (Canada)	GB1992000861; 19920922; WO1991GB007061; 19910392	WO9117159; A Y; 1991-11-14	AP182; A N; 1992-06-30		CN1056146 C; 2000-09-06; CN1028142 A N; 1992-01-29; CN1088545 A N; 1995-09-20; CN1144900 C; 2004-06-23; CN1265743 A N; 2001-12-19; CN1091696 C; 1997-10-22		Oh0539; A N; 1993-01-31	RU0209338; C N; 1997-12-20		ZA9003933; A N; 1992-02-28
	CA2009280; US5959582	Glaxo Group Limited	GB1991001902; 19910603	WO9221676; A Y; 1992-12-10	AP300; A N; 1994-01-20				Oh0933; A N; 1994-09-15	RU1039333; C N; 1998-07-20		ZA9204607; A N; 1993-04-28
	CA2286126	Glaxo Group Limited	GB19970006295; 19970924; US1997004235; 19970924; WO1998E01626; 19980920	WO9842321; A Y; 1998-10-01	AP141; A N; 2003-01-29	BR9808660; A N; 2000-03-08	CN1191061 C; 2003-03-02; CN1255849; A N; 2000-06-07					ZA9802367; A N; 1999-09-20
	CA2100269 (Rep B); US5332246	1af Biochem Int. (CA)	GB19910000939; 19910109; GB19910009913; 19910507; WO1992CA00001; 19920103	WO9211832; A Y; 1992-07-23	AP141; A N; 2003-01-29	BR9808660; A N; 2000-03-08	CN1191061 C; 2003-03-02; CN1255849; A N; 2000-06-07					ZA9802367; A N; 1999-09-20
	US6004668	Glaxo Wellcome Inc.	US1997004235; 19970924; GB1991001902; 19910603	WO9842321; A Y; 1998-10-01	AP141; A N; 2003-01-29	BR9808660; A N; 2000-03-08						ZA9802367; A N; 1999-09-20
Indinavir (IDV)	CA2081970	Merck & Co., Inc.	US19910789508; 19911108; US19920888385; 19920515	WO9309096; A Y; 1993-05-13						RU117154; C N; 2001-07-27; RU2191416; C N; 1999-06-10		ZA9208365; A N; 1993-05-05
	US5413999	Merck & Co., Inc.	US19930009038; 19930507; US19930040720; 19930331; US19920888385; 19920515; US19910789508; 19911108	WO9309096; A Y; 1993-05-13; WO9422480; A Y; 1994-10-13; WO9426717; A Y; 1994-11-24		BR9606576; A N; 1996-01-30; BR960593; A N; 1996-01-02	CN1176550; A N; 1998-09-18; CN1126469; A N; 1996-07-10; CN1120916; A N; 1996-04-10; CN100919C; 2002-09-04					ZA9208365; A N; 1993-05-05; ZA9606576; A N; 1996-01-30; ZA960593; A N; 1996-01-02; ZA9603104; A N; 1996-01-02; ZA960410; CN100919C; 2002-09-04
	US6649661	Merck & Co., Inc.	US19980004688; 19980904; US19990001587; 19990707		no family found							

PATENT INFORMATION AND TRANSPARENCY: A Methodology for Patent Searches on Essential Medicines in Developing Countries

Drug or combination	Patents Listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Aripo (AP)	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Indinavir (IDV) (continued)	US5689761	Merck & Co., Inc.	US1995038213 19950201 US1995054805 19950427; US1995092607 19950807	WO9403399 A Y 1996-08-08		BR9607714 A N 1998-01-13	CN117922 A N 1998-04-22 CN1160081C 2004-08-04 CN1350552 A N 2000-04-19 CN221608 A N 1999-07-07 CN107295C C 2003-05-07 CN1090277 A N 1994-08-03 CN051769C C 2000-04-26			RU8186775 C N 2002-08-10		ZA9500722 A N 1995-08-26 ZA9505724 A N 1994-03-03
Efavirenz (EFV)	C2e101572	Merck & Co., Inc.	US1995046026 19950602; US19940188005 19940188; US1993004805 19930427; US19920926607 19920807	WO9403440 A Y 1994-02-17			CN1350552 A N 2000-04-19 CN221608 A N 1999-07-07 CN107295C C 2003-05-07 CN1090277 A N 1994-08-03 CN051769C C 2000-04-26			RU8186775 C N 2002-08-10		ZA9305724 A N 1994-03-03
	US5519021	Merck & Co., Inc.	US1995046026 19950602; US19940188005 19940188; US1993004805 19930427; US19920926607 19920807	WO9403440 A Y 1994-02-17 WO9320989 A Y 1995-08-03			CN1350552 A N 2000-04-19 CN221608 A N 1999-07-07 CN107295C C 2003-05-07 CN1090277 A N 1994-08-03 CN051769C C 2000-04-26			RU8186775 C N 2002-08-10		ZA9305724 A N 1994-03-03
	US565169	Merck & Co., Inc.	US1995048528 19950602; US19940188005 19940188; US1993004805 19930427; US19920926607 19920807	WO9403440 A Y 1994-02-17 WO9320989 A Y 1995-08-03			CN1350552 A N 2000-04-19 CN221608 A N 1999-07-07 CN107295C C 2003-05-07 CN1090277 A N 1994-08-03 CN051769C C 2000-04-26			RU8186775 C N 2002-08-10		ZA9305724 A N 1994-03-03
	US5811423	Merck & Co., Inc.	US19920815780 19920312; US1995048528 19950602; US19940188005 19940188; US1993004805 19930427; US19920926607 19920807	WO9403440 A Y 1994-02-17 WO9320989 A Y 1995-08-03			CN1350552 A N 2000-04-19 CN221608 A N 1999-07-07 CN107295C C 2003-05-07 CN1090277 A N 1994-08-03 CN051769C C 2000-04-26			RU8186775 C N 2002-08-10		ZA9305724 A N 1994-03-03
	US6693907	Merck & Co., Inc.	US1995038213 19950201; US1995048528 19950602; US19940188005 19940188; US1993004805 19930427; US19920926607 19920807; US20010000337 20010109	WO9833782 A Y 1998-08-06			CN1350552 A N 2000-04-19 CN221608 A N 1999-07-07 CN107295C C 2003-05-07 CN1090277 A N 1994-08-03 CN051769C C 2000-04-26					ZA9305724 A N 1994-03-03
	US6999864	Bristol-Myers Squibb Company	US2004089749 20040624; US20030447690 20030929; US20010000337 20010109; US1992082744 19920312; US19980008824 19980102; US19970097385P 19970205; US19970042867P 19970408	WO9833782 A Y 1998-08-06			CN1350552 A N 2000-04-19 CN221608 A N 1999-07-07 CN107295C C 2003-05-07 CN1090277 A N 1994-08-03 CN051769C C 2000-04-26					ZA9305724 A N 1994-03-03

Drug combination	Patents listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Aripo (AP)	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Efavirenz (EFV) (continued)	US5623855 US555133	Du Pont Pharmaceuticals Company Bristol Myers Squibb Company	US 599028502 19990406; US 5986008925P 19980407 US 600108467 20010402; US 599028502 19990406; US 5986008925P 19980407	WO951239 A Y 1995-10-14 WO951239 A Y 1995-10-14		BR908810 A N 2000-12-19 BR958810 A N 2000-12-19	CN196412 A N 2001-05-23 CN1146419C C 2004-04-21 CN196412 A N 2001-05-23 CN1146419C C 2004-04-21		UA7207 C N 2001-02-15 UA7207 C N 2001-02-15			ZA200004313 A N 2001-11-07 ZA200004313 A N 2001-11-07
Nefinavir (NFV)	US5444926 CA2173328 US5925243	Agouron Pharmaceuticals, Inc. (US)	US 592013343 19931007; US 592013356 19931007; US 5940190764 19940202; WO1994US11307 19941007 US 595048183 19950607; US 5940190764 19940202; US 592013343 19931007; US 592013356 19931007; US 592013254 19931018; US 592095502 19921222	WO9509843 A Y 1995-04-13 WO9509843 A Y 1995-04-13	AP600 A N 1997-07-23 AP600 A N 1997-07-23	BR940782 A N 1997-09-18 BR940782 A N 1997-09-18 BR9505161 A N 1994-11-01	CN1046569C 1999-11-10 CN1952110 1999-11-10 CN1931942 A N 1996-09-25 CN195237C C 2005-04-06 CN186272 A N 2000-08-09 CN186272 A N 2000-08-09 CN195237C C 2000-08-09 CN195237C C 2005-04-06 CN1931942 A N 1996-09-25 CN195237C C 2005-04-06 CN1952410 A N 1994-11-01 CN1046569C C 1999-11-10	OA10718 A N 2001-11-02 OA10718 A N 2001-11-02	RU2139286 C N 1999-10-10 RU2139286 C N 1999-10-10		ZA9407815 A N 1996-07-08 ZA9407815 A N 1996-07-08	
Saquinavir (SQV)	CA1340588 CA209433 US5196438	F. Hoffmann-La Roche & Co. Aktiengesellschaft (Switzerland) Hoffmann-La Roche Inc.	CB 988001940 19860613; CB 989000893 19890410 US 595048183 19950607; US 5940190764 19940202; US 592013343 19931007; US 592013356 19931007	WO9509843 A Y 1995-04-13 WO9509843 A Y 1995-04-13	AP600 A N 1997-07-23 AP600 A N 1997-07-23	BR940782 A N 1997-09-18 BR9006264 A N 1991-09-24	CN1046569C 1999-11-10 CN1952110 1999-11-10 CN1931942 A N 1996-09-25 CN195237C C 2005-04-06 CN186272 A N 2000-08-09	IN172553 A N 1995-09-25 IN172553 A N 1995-09-25	OA9334 A N 1992-09-15 OA9334 A N 1992-09-15		ZA8904285 A N 1990-02-28 ZA9009743 A N 1991-08-28	
	CA209433 US5196438	Hoffmann-La Roche Inc.	CB 9890027913 19891211 US 595048183 19950607; US 5940190764 19940202; WO1996EP0491 19960604	WO9509843 A Y 1995-04-13	Zimbabwe ZW17490 A N 1992-06-17	BR9006264 A N 1991-09-24 BR9006264 A N 1991-09-24	CN1046569C 1999-11-10 CN1952110 1999-11-10 CN1931942 A N 1996-09-25 CN195237C C 2005-04-06 CN186272 A N 2000-08-09	IN172553 A N 1995-09-25 IN172553 A N 1995-09-25	OA9334 A N 1992-09-15 OA9334 A N 1992-09-15		ZA8904285 A N 1990-02-28 ZA9009743 A N 1991-08-28	
	US5608228 CA221435	Hoffmann-La Roche Inc.	US 595048183 19950607; US 5940190764 19940202; WO1996EP0491 19960604	WO9509843 A Y 1995-04-13		BR9006264 A N 1991-09-24 BR9006264 A N 1991-09-24	CN1046569C 1999-11-10 CN1952110 1999-11-10 CN1931942 A N 1996-09-25 CN195237C C 2005-04-06 CN186272 A N 2000-08-09	IN172553 A N 1995-09-25 IN172553 A N 1995-09-25	OA9334 A N 1992-09-15 OA9334 A N 1992-09-15		ZA8904285 A N 1990-02-28 ZA9009743 A N 1991-08-28	
	US519277	Hoffmann-La Roche Inc.	EP 998019183 19981117	WO0208942 A Y 2000-05-25		BR951444 A N 2001-08-07	CN126535 A N 2001-12-12 CN172649C C 2004-10-27	RU219911 C N 2003-12-27				ZA200003891 A N 2002-08-14

Drug or combination	Patents Listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Arjo (AP)	Brazil (BR)	China (CN)	India (IN)	OAPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)	
Enfuvirtide (Z0)	US5464933	Duke University	US19930073028 19930607	WO9448920 A Y 1994-12-22									
	US613448	Duke University	US19950554616 19951106; US19930073028 19930607	WO9448920 A Y 1994-12-22									
	US675491	Timeris, Inc	US1988097082 19880508; US19950481957 19950607; WO19960150493 19960606	WO9640101 A Y 1996-12-19		BR060912 A N 1999-05-04	CN1026588 A N 1998-09-09						
Amprenavir (APV)	CA214328	Vertex Pharmaceuticals, Incorporated (USA)	US19920941982 19920908; WO19930588458 19930907	WO9409599 A Y 1994-09-17	AP900 A N 1995-08-02	BR1100824 A N 1999-08-31	CN1061396 C 2001-01-31; CN1087747 A N 1994-06-01			RU2135496 C N 1999-08-27			
	US585397	Vertex Pharmaceuticals, Incorporated (USA)	US19930142327 19931124; US19920941982 19920908; WO19930588458 19930907	WO9409599 A Y 1994-09-17	AP900 A N 1995-08-02	BR1100824 A N 1999-08-31	CN1087747 A N 1994-06-01; CN1061396 C 2001-01-31			RU2135496 C N 1999-08-27			
	CA2249396	GLAXO GROUP LIMITED (U.K.)	GB1996006572 19960206; US1996003869P 19960222; US1992082828 19920202; WO1997090458 19970321	WO9735587 A Y 1997-10-02	AP150 A N 2003-03-14	BR0708238 A N 1999-08-03	CN1225587 A N 1999-08-31		OA0880 A N 2001-10-11		UA6773 C N 2004-07-15	ZA9702387 A N 1997-12-10	
US5646180	Vertex Pharmaceuticals Incorporated	US19950567199 19951205	WO9720554 A Y 1997-06-12	AP864 A N 2000-08-11	BR0619861 A N 1999-05-18		CN102350 A N 1998-12-30		OA0691 A N 2001-05-04	RU2202658 C N 2003-05-10	UA61902 C N 2003-12-15	ZA9610199 A N 1997-06-17	
	US572490	Vertex Pharmaceuticals Incorporated	US19950424819 19950419; US19950393460 19950223; US19930142327 19931124; US19920941982 19920908	WO9409599 A Y 1994-09-17; WO9633184 A Y 1996-10-24	AP950 A N 2001-09-28; AP900 A N 1995-08-02	BR6608032 A N 1999-01-12; BR1100824 A N 1999-08-31	CN1187735 A N 1998-05-13; CN1087747 A N 1994-06-01; CN1061396 C 2001-01-31						
		US675079	Smithkline Beecham Corporation	US1997082828 19970520; US1996003869P 19960322	WO9735587 1997-10-02	AP150 A N 2003-03-14	BR0708238 A N 1999-08-03	CN1225587 A N 1999-08-31		OA0880 A N 2001-10-11			ZA9702387 A N 1997-12-10

Data compiled by B. Milani and COH in April-August 2006.

Appendix 1C:

Results of patent search at the State Intellectual Property Office of the People's Republic of China (SIPO), as of August 2006

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Assignee	Information from EPO databases on China (CN) (Published application and publication date)	Information from EPO databases on China (CN) (patent numbers and issued date)	SIPO patent numbers found for the listed priorities	For patents: SIPO application date	For patents: SIPO issued date	For patents: SIPO expiry date	For patents: Patent status (whether the patent is valid or has lapsed).
Ritonavir (RTV)	US1996075490; 19961211; WO1997US20794; 19971112	CA2271196	Abbott Laboratories US	CN148914 A N 2000-03-29	CN1250219C 04-12	97199780.2	1997.11.12	2006.04.12	2017.11.12	valid
	US1996075201; 19961211; US1995072216; 19951213; WO1996US20440; 19961216	US5791432; CA2233978	Abbott Laboratories US	CN1208405 A N 1999-02-17	CN1207288C 06-22	96199904.7	1996.12.16	2005.6.22	2016.12.16	valid
	US1998020783; 19981208; US1996075201; 19961211; US1995072216; 19951213	US628,476	Abbott Laboratories US	CN1208405 A N 1999-02-17	CN1207288C 06-22					
	US1999039382; 19990910; US1999034707; 19990704; US1997096649; 19971107; US19960031463P; 19961121	US6321651	Abbott Laboratories US							
	US1999034707; 19990704; US1997096649; 19971107; US19960031463P; 19961121	US64438.8	Abbott Laboratories US							
	US2001094668; 20010904; US2000023099P; 20000905	US611714	Abbott Laboratories US							
	US199006170; 1990120; US1991074620; 19910815; US1991077766; 19911023	CA255970	Abbott Laboratories US							
	US1992095814; 19921229; US1993019887; 19931202	CA235890	Abbott Laboratories US							
	US199000654P; 19900609; US199000384P; 19900915; WO1996US17015; 19960628	CA2224738	Abbott Laboratories US							
	US1997082160; 19970320; US1995041787; 19950406; US1993019887; 19931202; US1992095814; 19921229	US574682	Abbott Laboratories US							
	US1995041316; 19950928; US1993029814; 19931229; US1992019887; 19921202									
	US1991077766; 19911023; US1991074620; 19910815; US199006170; 1990120; US1990058770; 19900509; US19880456124; 19891222; US19880405604; 19890908; US19890355945; 19890923									
	US1995042387; 19950925; US1993019887; 19931202; US1992095814; 19921229; US1991077766; 19911023; US1991074620; 19910815; US199006170; 1990120; US1990058770; 19900509; US19890456124; 19891222; US19890355945; 19890923	US5141206	Abbott Laboratories US							

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Assignee	Information from EPO databases on China (CN) (Published application and publication date)	Information from EPO databases on China (CN) (Patent numbers and issued date)	SIPO patent numbers found for the listed priorities	For patents: SIPO application date	For patents: SIPO issued date	For patents: SIPO expiry date	For patents: (whether the patent is valid or has lapsed)	
Itinavir / Lopinavir (RTV LPV) (continued)	US 5950478B2; 5950406; 59501583; 5951202; 5950295B1; 5951229; 5951077766; 59511003; 5951074620; 5950815; 5950066170; 5950120; 5950056730; 59500559; 5950450724; 5951222; 5950405604; 59509308; 5950935945; 59509523		US 5955523	Abbott Laboratories US								
	US 5950410823; 5950324; 5950407210; 5954823; 59503012167; 5950914; 5950917766; 59511003; 595091074620; 5950815; 5950066170; 5950120; 5950056730; 59500559; 5950450724; 5951222; 5950405604; 59509308; 5950935945; 59509523		US 5648497	Abbott Laboratories US								
	US 59010971; 20010909; 5950528201; 5950931; 5950068774; 5950066; 5950000654P; 5950065; 5950503849; 59509515		US 6034903	Abbott Laboratories US								
	US 595040277; 5950532; 59504028239; 5940729; 59504018201; 594012		US 6232333	Abbott Laboratories US								
	US 595040277; 5950532; 59504028239; 5940729; 59504018201; 594012		US 5484801	Abbott Laboratories US								
	US 595041336; 5950532; 595050413887; 5951202; 5950295B1; 5951229		US 5886036	Abbott Laboratories US								
	US 595003849P; 5950915; 5950068774; 5950066; 5950000654P; 5950065		US 6037157	Abbott Laboratories US								
	US 989043893; 9891117; 9900579001; 9900906; 990060390; 9901019		CA 209096	BOEHRINGER INGELHEIM PHARMA (DE); THOMAE CMBH DR K (DE)	CN1216539 A; 19990512; 2002-04-10	CN1082588C; 2005-03-16	97194025,8	1997.4.14	2002.4.10	2017.4.14	Valid	
	US 993009148; 9933073; 995040970; 99504420; 995037374; 9950628; 995043893; 9951117; 9900579001; 9900906; 990060390; 9901019; 9910740828; 9910805		US 5166972	Boehringer Ingelheim Pharmaceuticals, Inc.	CN1216539 A; 19990512; 2002-04-10	CN1082588C; 2005-03-16	11034847	1997.4.14	2005.3.16	2017.4.14	Valid	
	CH196000108; 1960422; CH197000223; 1970131		US 5449911	Novartis Finance Corporation	CN1216539 A; 19990512; 2002-04-10	CN1082588C; 2005-03-16	2004100791875;	missing data	No patent	No patent	No patent	
			WO9936404	Bristol-Myers Squibb Company US	CN1216539 A; 19990512; 2002-04-10	CN1082588C; 2005-03-16	98817415	1997.4.14	2003.7.30	2017.4.14	Valid	

Drug or combination	Priority number(s) of Patent number(s) listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Assignee	Information from EPO database on China (CN) (published application and publication date)	Information from EPO database on China (CN) (patent numbers and issued date)	SIPO patent numbers found for the listed priorities	For patents: SIPO application date	For patents: SIPO issued date	For patents: SIPO expiry date	For patents: Patents status (whether the patent is valid or has lapsed).
Atazanavir (ATV) (continued)	US198007338 19801231; US198007198P 1980120		US668738	Bristol-Myers Squibb Company	CN1183188 A 20010207 CN1168282 C N 20030730						
Didanosine (DDI)	US19850769016 19850826	WO9701284	CA1269044	US HEALTH (US)							
	US19900460490 19900103	WO9109605	CA2072573	US HEALTH (US)							
	US19910733347 19910722; US19920882204 19920513		CA2074215	SQUIBB BRISTOL MYERS CO (US)	CN1068739 A N 19930210	CN1042299C 19990903	9210867,1	1992.7.21	1999.3.3	2007.7.21	Valid
	US1987008405 19870811; US19850769016 19850826		US4861739	The United States of America as represented by the Department of Health							
	US19910663288 19910228; US1987008405 19870811; US1980420664 19800828; US19850769016 19850826; US19860937925 19861204		US5254539	U.S. Government, Dept. of Health and Human Services, c/o National							
	US19930565048 19930490; US1991063288 19910228; US19920882204 19920513; US1982084055 19820811; US19860937925 19861204; US19850769016 19850826		US5616966	The United States of America as represented by the Department of Health							
	US19970944660 19971002; US19920882204 19920513; US19910733347 19910722		US5480106	Bristol-Myers Squibb Company	CN1042299C 19990903 CN1068739 A N 19930210						
Stavudine (D4T)	US19860942666 19861217		CA1233447 US4978655	Yale University							
Emtricitabine (FTC)	US1990047318 19900201; WO1991US06685 19910331	WO911186	CA207589	EMORY UNIVERSITY (US)							
	CA100213260 1992121; US1989058101 19890208		CA2096517	BIOCHEM PHARMA INC. (Canada)	CN1064817 A N 19900822	CN1031640C 19961225	91010612,2	1990.2.8	1996.12.25	2005.2.8	Valid
	US19910659760 19910222; US1990047318 19900201		US5210085	Emory University	CN1065065 A 19921007	CN1097682C 19980311	92109815	1992.2.22	11/05/1998	2007.2.22	Valid
	US199007820 19900116; US19910659760 19910222; US1990047318 19900201		US5414639	Emory University	CN1103332 A 19981230	CN1082745C 20020515	98108905,4	1998.05.15	15/05/2002	2018.05.15	valid
	US19950488097 19950607; US1992083103 19920212; US19910659760 19910222; US1990047318 19900201; US19910736089 19910726		US5914931	Emory University	CN1127201 A 19960724	CN1109108C 20030521	9109814,4	1995.08.18	21/05/2003	2015.08.18	valid
					CN1418966 A N 20030521	Non-issued	2144035,6	2002.09.30	No patent		No patent

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Assignee	Information from EPO databases on China (CN) (published application and publication date)	Information from EPO databases on China (CN) (patent numbers and issued date)	SIPO patent numbers found for the listed priorities	For patents: SIPO application date	For patents: SIPO issued date	For patents: SIPO expiry date	For patents: Patent status (whether the patent is valid or has lapsed)
Emtricitabine (rCT) (continued)	US 1995047339 19950607; US 1992083103 19920012; US 1991073068 19910726; US 1991065700 19910224; US 1990047318 19900201		US 564246	Emory University	CN1037682C 1998-03-11 CN105065 A N 1992-10-07 CN1084745C 2002-05-15 CN109108C 2002-05-21 CN1127301 A N 1986-07-24 CN120332 A N 1988-05-21 CN148366 A N 2003-05-21						
					US 5670396	Emory University	CN1037682C 1998-03-11 CN105065 A N 1992-10-07 CN1084745C 2002-05-15 CN109108C 2003-05-21 CN1127301 A N 1986-07-24 CN120332 A N 1988-05-21 CN148366 A N 2003-05-21				
Tenofovir disoproxil fumarate (TDF)	US 19970900746 19970725; US 1996022708P 19960726		US 5923895	Gilead Sciences, Inc							
					US 5935946	Gilead Sciences, Inc	CN154330 A N 2004-12-15 CN154839 A N 2000-08-23	CN1251679C 2006 04 19 2004-12-15 Non-issued	200410046290.x 98807435.4	1998.7.23 1998.7.23	2006.4.19
Tenofovir disoproxil fumarate (TDF) (continued)	US 19980187763 19981061; US 19970900746 19970725; US 1996022708P 19960726		US 5977089	Gilead Sciences, Inc.							
					US 604230	Gilead Sciences, Inc					
Zidovudine/Lamivudine (AZT)/3TC	GB 19910010624 19910516; GB 1991002381 19910088; GB 1991002381 19911106	WO 9220344	CA 2068790	Glaxo Group Limited	CN1068570 A N 1993-02-03	CN1045961C 1999-10-27	9210453	1992.5.15	1999.10.27	2005.5.15	Valid
					CA 211988	Glaxo Group Limited					
Zidovudine/Lamivudine (AZT)/3TC	GB 1991001902 19910603	WO 9221676	US 5900282	Glaxo Group Limited							
					CA 216654	THE WELLCOME FOUNDATION LIMITED (U.K.)	CN118910 A N 1996-06-17	CN103591C 2003-03-26	96194050.6	1996.3.28	2003-03-26
Zidovudine/Lamivudine (AZT)/3TC	WO 1996E 00352 19960328; GB 19950000489 19950331; GB 19950000489 19950330	WO 9510025	US 5959021	Glaxo Group Limited	CN1045961C A N 1993-02-03						

Drug or combination	Priority number(s) of Patent number listed in Health Canada, Patent Registry and US FDA Orange Book	PCT applications	Patent numbers listed in Health Canada, Patent Registry and US FDA Orange Book	Assignee	Information from FPO database on China (CN) (if applicable application and publication date)	Information from FPO database on China (CN) (patent numbers and issued date)	SIPO patent numbers found for the listed priorities	For patents: SIPO application date	For patents: SIPO issued date	For patents: SIPO expiry date	For patents: Patents status (whether the patent is valid or has lapsed)
Zidovudine/ Lamivudine (AZT/3TC) (continued)	US 19709555; 19970031; CA 99002268; 1991051; US 199002324P; 1991051		US 511320	Glaxo Group Limited	CN1054981 A N 1991-10-02	CN10281066 C 1995-04-05	9 1100671	1990.12.21	05/04/1995	2005.12.21	Valid
Abacavir (ABC)	US 1989045201; 19891222 GB 1988010525; 19880627	WO855949	CA 2033044 CA 140589 US 5389500 US 5149394 US 5694540	THE WELLCOME FOUNDATION LIMITED (U.K.) Burroughs Wellcome Co. Glaxo Wellcome Inc.	CN126329 A 2000.08.16 CN195372 A N 2004.07.28	CN119194 C 2004.05.19 Non-issued	98807073.1 3102321.3	1998.5.14	19/05/2004	2018.5.14	Valid
Abacavir/ Zidovudine/ Lamivudine (ABC/AZT/3TC)	GB 19910010624; 19910516; GB 19910021381; 19911008; GB 19910023381; 19911106	WO9220344	CA 2068790	GLAXO GROUP LTD (GB)	CN1045961 C 1999-10-27 CN1068570 A N 1993-02-03						
(ABC/3TC)	CA 1992070230; 19920602; GB 19910011902; 19910603	WO9221676	CA 211988 US 5990282	GLAXO GROUP LTD (GB) Glaxo Group Limited	CN105110 A N 1998-06-17	CN105991 C 2003-03-26	9 694050.6	1996.3.28	26/05/2003	2016.3.28	valid
	WO 1996EP0352; 19960328; GB 1995000449; 19950330; GB 1995000649; 19950330	WO965005	US 5647191	GlaxoSmithKline							
	CA 1992070230; 19920602; GB 19910011902; 19910603	WO965005	CA 211988 US 5647191	GLAXO GROUP LTD (GB) GlaxoSmithKline	CN105993 C C 2003-03-26 CN105110 A N 1998-06-17						
	GB 19910011902; 19910603	WO9221676	US 5990282	Glaxo Group Limited							
Lamivudine (3TC)	GB 1990000861; 19900902; WO 1991 GB07006 19910502	WO917199	CA 2059265	IFB BIOCHEM INTERNATIONAL INC. (Canada)	CN110855 A 1995.09.20 2000-09-06	CN1056145 C 2000-09-06	9 4109429.4	1994.8.15	06/09/2000	2014.8.15	Valid
	CA 1992132659; 19921211; US 1989028101; 19890208	WO921676	CA 2009677 US 5047407	BioChem Pharma, Inc.	CN126743 A 2001.12.19	CN1154900 C 2004-05-23	9 9126580.7	1994.8.15	23/06/2004	2014.8.15	Valid
	GB 19910011902; 19910603	WO9221676	CA 2070230 US 5905082	Glaxo Group Limited	CN1058214 A 1992.01.29	CN1056166 C 1997-10-22	9 1102778.5	1991.14.30	22/10/1997	2006.4.30	Valid
	GB 19970006395; 19970326; US 1997004233P; 19970324; WO 1998EP01626 19980320	WO9842321	CA 2386126	Glaxo Group Limited	CN1044817 A N 1990-08-22	CN1031640 C 1996-12-25	9 0100612.2	1990.2.8	25/12/1996	2005-2.8	Valid
	GB 19910000359; 19910105; GB 1991000911; 19910507; WO 1992-Ch0001 19920103	WO921182	CA 200269 (Ilep B) US 532446	IFB BIOCHEM INT (CA)							
	US 1997004233P; 19970324 GB 19910011902; 19910603	WO9842321	US 6004968	Glaxo Wellcome Inc.	CN119106 C C 2005-09-02 CN125849 A N 2000-06-07	CN119061 C 2005-03-02	9880712.2	1998.3.20	2005-03-02	2018.3.20	Valid
Indinavir (IDV)	US 1991079508; 19911008; US 1991088835; 19920505	WO930906	CA 2081970	Merck & Co., Inc.							

Drug or combination	Priority number(s) of Patent number listed in Health Canada, Patent Registry and US FDA Orange Book	PCT applications	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Assignee	Information from EPO database on China (CN) (if published application and publication date)	Information from EPO database on China (CN) (patent numbers and issued date)	SIPO patent numbers found for the listed priorities	For patents: SIPO application date	For patents: SIPO issued date	For patents: SIPO expiry date	For patents: Patents (whether the patent is valid or has lapsed)
Mefenivir (NFV) (continued)	US 1995048183; 199506077; US 19940190764; 19940202; US 1993013383; 199310077; US 19930133656; 199310077; US 19930137254; 199310087; US 19920995621; 19921222		US 593243	Agouron Pharmaceuticals, Inc. (US)	CN1195737C 2005-04-06	CN1195737C 2005-04-06	991051645	1994.10.7	06/04/2005	2014.10.7	valid
	US 19990283152; 19990401; US 1995048183; 199506077; US 19940190764; 19940202; US 1993013383; 199310077; US 19930133656; 199310077		US 6162812	Agouron Pharmaceuticals, Inc. (US)	CN1131942 A N 1996-09-23; CN11862272 A N 2000-08-09	CN1046269C 1999-11-10; CN1195737C 2005-04-06	991051645	1994.10.7	06/04/2005	2014.10.7	valid
	GB 98801940; 19880613; GB 98900837; 19890410		CN134058	F. Hoffmann-La Roche & Co. Aktiengesellschaft (Switzerland)		CN1046269C 1999-11-10	949353545	1994.10.7	1999-11-10	2014.10.7	valid
	GB 9890027913; 19890211		CA2030433; US 5196438	Hoffmann-La Roche Inc. (Switzerland)	CN10324282 A 1991-06-26	CN1034805C 1997-05-07	901099317	1990.12.10	07/05/1997	2015.12.10	valid
	US 19950484931; 19950606; US 19960616331; 19960707; WO 1996E/P0429; 19960604	WO 9619142	US 6008228; CA 2242125	Hoffmann-La Roche Inc.	CN1138983 A 1997-01-01; CN1186234 A N 1998-07-01	CN1065399C 2001-05-30; CN1092960C 2002-10-23	961074663; 96194327	1990.12.10	2001-05-30; 23/10/2002	2015.12.10; 2016.6.4	valid
EP 9880121831; 19981117	WO 0028942	US 6332717	Hoffmann-La Roche Inc.	CN1126533 A N 2001-12-12	CN1172649C 2004-10-27	98813957	1999.11.11	27/10/2004	2019.11.11	valid	
Enfuvirtide (F20)	US 9930073208; 19990607	WO 0428020	US 6464933	Duke University							
	US 9950546; 1995106; US 9930073208; 19990607		US 633418	Duke University							
	US 99807892; 19980299; US 9950481857; 19950607; WO 1996US 09499; 19960606		US 6475491	Trimeris, Inc.	CN1192688 A N 1998-09-09	rejected (2006-04-05)	96196091	1996.6.6	no patent		rejected (2006-04-05)
	US 9930294; 19920908; WO 1993US 0458; 19930907	WO 9406159	CA 243208	Verte Pharmaceuticals, Incorporated (USA)	CN1087247 A N 1994-06-01	CN1063399C 2001-01-31	93173701	1993.8.8	31/01/2001	2013.8.8	valid
	US 9930142827; 19931124; US 992041682; 19920908; WO 1993US 0458; 19930907	WO 9405619	US 538397	Verte Pharmaceuticals, Incorporated (USA)	CN1255387 A N 1999-08-11	Non-issued	97932268	1997.3.21	no patent		
Amprenavir (APV)	GB 996006372; 19960246; US 996003893P; 19960322; US 9970820848; 19970246; WO 1997EP 01438; 19970251	WO 9728587	CA 249316	Glaxo Group Limited (U.K.)	CN1087247 A N 1994-06-01	CN1063399C 2001-01-31	93173701	1993.8.8	31/01/2001	2013.8.8	valid
	US 9959567199; 19951205	WO 9720554	US 646180	Verte Pharmaceuticals Incorporated	CN1205330 A N 1998-12-30	seem as withdrawn (2003-8-13)	961988159	1996.12.5	No patent		seen as withdrawn (2003-8-13)
	US 995042483; 19950419; US 9950393460; 19950223; US 9930142827; 19931124; US 992041682; 19920908		US 723490; Verte Pharmaceuticals Incorporated		CN1087247 A N 1994-06-01	CN1063399C 2001-01-31	93173701	1993.8.8	31/01/2001	2013.8.8	valid
	US 9970820848; 19970246; US 996003893P; 19960322		US 6730679	SmithKline Beecham Corporation	CN1181755 A N 1998-05-13	seem as withdrawn (2001-07-25)	961993164	1996.04.18	no patent		seen as withdrawn (2001-07-25)
	US 9970820848; 19970246; US 996003893P; 19960322				CN1255387 A N 1999-08-11						

Data collected from SIPO in August/October 2006 by B. Mflani.

Appendix 1D:

Results of patent search at the Companies and Intellectual Property Registration Office of South Africa (CIPRO), as of November 2006

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	FTC applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information from EPO databases on CIPRO (ZA) (Published application/ patent and publication date)	CIPRO application numbers found for the listed priorities	CIPRO patent numbers found for the listed priorities	Application date	For patents: issued date	For patents: expiry date	For patents: (whether patent is valid or has lapsed)	
Ritonavir (RTV)	US1996075499019961121; WO1997105207941997112	WO822106	Abbott Laboratories US	CA217196	Z4971007; A N 1996-0525	1997/10071	1997/10071	07/11/1997	29/07/1998	07/11/2017	in force	
	US1996075320119961121; US199507221619951213; WO1996015204019961206	WO9721685	Abbott Laboratories US	US5914332 CA238978	Z49610475; A N 1997-0731	1996/10475	1996/10475	12/12/1996	20/10/1997	12/12/2016	in force	
	US199802087319981008; US1996075320119961121; US199507221619951213		Abbott Laboratories US	US5824767	Z49610475; A N 1997-0731	1996/10475	1996/10475	12/12/1996	29/10/1997	12/12/2016	in force	
	US199903987219990910; US199903470719990702; US1997096649519971107; US19960031463P19961121		Abbott Laboratories US	US6521651								
	US199903470719990702; US1997096649519971107; US19960031463P19961121		Abbott Laboratories US	US5448818								
	US200104668320010904; US20000239099P20000905		Abbott Laboratories US	US691214								
	US199906167019990120; US199107462019910815; US199107776619911023		Abbott Laboratories US	CA205670								
	US1999029811419991229; US199901388719991202	WO9414436	Abbott Laboratories US	CA213890								
	US1995000654P19950639; US1995003849P19950915; WO1996015101519960628	WO9701349	Abbott Laboratories US	CA224278								
	US199708160919970320; US199501017919950406; US199501388719951202; US199509811419951229		Abbott Laboratories US	US5846987								
	US199504131619950929; US199209811419921229; US199301388719931202; US199107776619911023; US199107462019910815; US19900616701990120; US199001873019900509; US1989045812419891222; US1989040560419890908; US1989035594519890923		Abbott Laboratories US	US5167482								
	US199504338719950405; US199504183719951202; US199509811419951202; US199107462019910815; US19900616701990120; US199001873019900509; US1989045812419891222; US1989040560419890908; US1989035594519890923		Abbott Laboratories US	US541206								

Drug or combination	Priority number(s) of Patent number listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent number listed in Health Canada Patent Registry and US FDA Orange Book	Information from EPO database on CIPO (ZA) (Published application/ patent and publication date)	CIPO application numbers assigned for the listed priorities	Application date	For patents: issued date	For patents: expiry date	For patents: Patent status (whether patent is valid or has lapsed)	
Ritonavir (RTV) / Lopinavir (LPV) (continued)	US 1995/041787.9 1995/0406; US 1993/019887 1993/1202; US 1992/09811.4 1992/1239; US 1991/077766 1991/1031; US 1991/074620 1991/0815; US 1990/061670 1990/1201; US 1990/058730 1990/0509; US 1989/045612.4 1989/1222; US 1989/040960.4 1989/0908; US 1989/035945 1989/0933		Abbott Laboratories US	US 5695323							
	US 1995/041063.1 1995/0324; US 1994/027210 1994/0625; US 1993/012179 1993/0914; US 1991/077766 1991/1031; US 1991/066670 1991/0815; US 1990/058730 1990/0509; US 1989/045612.4 1989/1222; US 1989/040960.4 1989/0908; US 1989/035945 1989/0933		Abbott Laboratories US	US 5648497							
	US 2001/097171 2001/0920; US 1999/0387261 1999/0831; US 1996/068774 1996/0626; US 1995/000654P 1995/0639; US 1995/003849P 1995/0915		Abbott Laboratories US	US 6703403							
	US 1997/096495 1997/1097; US 1996/051453P 1996/1121		Abbott Laboratories US	US 5633333							
	US 1995/040477 1995/0112; US 1994/028239 1994/0729; US 1994/018921 1994/012		Abbott Laboratories US	US 5484801							
	US 1997/082071 1997/0320; US 1995/041339 1995/0929; US 1993/019887 1993/1202; US 1992/09811.4 1992/1239		Abbott Laboratories US	US 586656							
	US 1995/003849P 1995/0915; US 1996/068774 1996/0626; US 1995/000654P 1995/0639		Abbott Laboratories US	US 6037157							
	US 1996/043893 1996/1117; US 1996/007900 1996/0906; US 1996/006039 1996/0109			CA 609056	Z 4900246 A N 1992-0729	1990/09246	19/11/1990	29/07/1992	19/11/2010	in force	
	US 1993/009148 1993/0713; US 1989/040970 1989/0420; US 1989/037974 1989/0628; US 1989/043893 1989/1117; US 1990/057900 1990/0906; US 1990/060039 1990/1019; US 1991/074028.8 1991/0805		Behringer Ingelheim Pharmaceuticals, Inc.	US 5366972	Z 4900499 A N 1992-0325	1990/04991	27/06/1990	25/03/1992	27/06/2010	in force	
	CA 1996/001018 1996/0422; CA 1997/000229 1997/0131			CA 609056	Z 4900246 A N 1992-0729	1990/09246	19/11/1990	29/07/1992	19/11/2010	in force	
	US 1998/007968P 1998/0100; WO 1998/015273.2 1998/1222	WO 9935404	Novartis Finance Corporation	US 5449911	Z 4970387 A N 1997-10-22	1997/03387	21/04/1997	31/12/1997	21/04/1997	in force	
	US 1998/007968P 1998/0100; US 1998/007968P 1998/0100	WO 9710124	Bristol-Myers Squibb Company US	CA 217726	Z 4900096 A N 2000-07-05	1999/00096	05/01/1999	27/09/2000	05/01/2019	in force	
	US 1985/076916 1985/0826	WO 8710124	Bristol-Myers Squibb Company	US 6287383	Z 4900096 A N 2000-07-05	1999/00096	05/01/1999	27/09/2000	05/01/2019	in force	
	US 1990/046490 1990/0103	WO 9109605	US HEALTH (US)	CA 469044							
			US HEALTH (US)	CA 6072573							

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information from EPO databases on CIPO (LA) (Published application/parent and publication date)	CIPO application numbers found for the listed priorities	CIPO patent numbers found for the listed priorities	Application date	For patents: issued date	For patents: expiry date	For patents: Patent status (whether patent is valid or has lapsed)	
Didanosine (DDI) (continued)	US 5199 073347 1997022; US 5192 082204 1992013 US 5195 076910 1995026		Squibb Bristol Myers Co. (US) The United States of America as represented by the Department of Health	CA 074205 US 5281799	ZA9205484 A N 1993-09-13	1992/05484	1992/05484	21/07/1992	24/11/1993	21/07/2012	in force	
	US 5199 0663288 1997028; US 5198 004605 1987081; US 5198 042664 1989088; US 5198 076916 1985086; US 5198 0037925 1986104		U.S. Government, Dept. of Health and Human Services, c/o National	US 5254539								
	US 5193 006042 1995049; US 5190 0663288 1997028; US 5198 042664 1989088; US 5197 004605 1987081; US 5195 076910 1995026		The United States of America as represented by the Department of Health	US 5161666								
	US 5197 0942660 1997002; US 5192 082204 1992013; US 5191 073347 1997022		Bristol-Myers Squibb Company	US 5188016	ZA9205484 A N 1993-09-13	1992/05484	1992/05484	21/07/1992	24/11/1993	21/07/2012	in force	
	US 5198 0694266 1986127		Yale University	CA 93447 US 5497865	ZA870717 A N 1988-03-24	1987/07171	1987/07171	23/09/1987	25/05/1988	23/09/2007	in force	
	US 5190 047318 19900201; WO 1991/050685 19910131	WO 91/1186	Emory University (US)	CA 075189								
	CA 922132 1992121; US 5195 091810 1995008		Biochem Pharma Inc. (Canada)	CA 009467	ZA9000943 A N 1990-10-31	1990/00943	1990/00943	08/02/1990	31/10/1990	08/02/2010	in force	
	US 5199 0659760 1991022; US 5199 047318 19900201		Emory University	US 5210085	ZA901251 A N 1993-08-20	1992/01251	1992/01251	20/02/1992	27/10/1993	20/02/2012	in force	
	US 5193 007820 1993016; US 5199 0659760 1991022; US 5190 047318 19900201		Emory University	US 5184639	ZA920751 A N 1993-08-20	1992/0751	1992/0751	20/02/1992	27/10/1993	20/02/2012	in force	
	US 5195 048807 1995067; US 5192 081163 1992012; US 5199 0659760 1991022; US 5190 047318 19900201; US 5191 073689 19910726		Emory University	US 51914331	ZA901251 A N 1993-08-20	1992/01251	1992/01251	20/02/1992	27/10/1993	20/02/2012	in force	
	US 5195 047339 1995067; US 5192 081163 1992012; US 5199 073689 19910726; US 5199 0659760 1991022; US 5190 047318 19900201		Emory University	US 5664245	ZA920751 A N 1993-08-20	1992/0751	1992/0751	20/02/1992	27/10/1993	20/02/2012	in force	
	US 5195 040370 1995033; GB 91000474 1991026; GB 91000471 1991026; US 5192 002244 1992012; US 5191 073689 19910726; US 5199 0659760 1991022; US 5190 047318 19900201		Emory University	US 5670396	ZA901251 A N 1993-08-20	1992/01251	1992/01251	20/02/1992	27/10/1993	20/02/2012	in force	
US 5197 000746 1997075; US 5190 02708P 1990020		Gilead Sciences, Inc	US 522595	ZA920758 A N 1993-09-06	1992/0758	1992/0758	05/05/1992	24/11/1993	05/05/2012	in force		
US 5197 000752 1997075		Gilead Sciences, Inc	US 5193546									
US 5198 018761 1988106; US 5197 000746 1997075; US 5195 040370 1995033		Gilead Sciences, Inc	US 517789									

Drug or combination	Priority number(s) of Patent number(s) listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent number listed in Health Canada Patent Registry and US FDA Orange Book	Information from EPO database or CIPO (ZA) (if published application/ patent and publication date)	CIPO application numbers found for the listed issue priorities	CIPO patent numbers found for the listed priorities	Application date	For patents: issued date	For patents: expiry date	For patents: Patent status (whether patent is valid or has lapsed)
Tenofovir Disoproxil fumarate (TDF) (continued)	US 19990314606, 19990519; US 19970900746, 19970725; US 19960022708P, 19960726		Gilead Sciences, Inc.	US6043230							
	GB 990000624, 19990516; GB 990002381, 19991106; GB 990002381, 19991106	WO9220344	Gilead Group Limited	Ck068790	ZA9903344 A N 19990331	1999/03344	1999/03344	15/05/1992	31/05/1993	15/05/2012	in force
	CA 99207030, 19920602; GB 990001902, 19910603		Gilead Group Limited	Ck231088	ZA9904007 A N 19990428	1999/04007	1999/04007	02/06/1992	28/04/1993	02/06/2012	in force
Zidovudine (AZT) / Lamivudine (3TC)	GB 990001902, 19910603	WO9221676	Gilead Group Limited	US595082	ZA9904007 A N 19990428	1999/04007	1999/04007	02/06/1992	28/04/1993	02/06/2012	in force
	WO 1996EPO352, 19960328; GB 995000489, 19950330; GB 9950006490, 19950330	WO9651025	The Wellcome Foundation Limited (U.K.)	Ck2216834	ZA9602477 A N 19971028	1996/02477	1996/02477	28/05/1996	31/12/1997	28/05/2016	in force
	US 1996060560, 19960222; GB 990000624, 19990516; GB 990002381, 19991106; GB 990002381, 19991106; US 994021976, 19940328; US 9920883169, 19920515		Gilead Group Limited	US5859201	ZA9903344 A N 19990331	1999/03344	1999/03344	15/05/1992	31/05/1993	15/05/2012	in force
Abacavir (ABC)	US 1997095963, 19971033; GB 996002268, 19961031; US 19960029246P, 19961031		Gilead Group Limited	US6119220	ZA990726 A N 19990429	1997/09726	1997/09726	20/10/1997	28/07/1999	20/10/2017	in force
	US 9890455201, 19891222		The Wellcome Foundation Limited (U.K.)	Ck030344	ZA990365 A N 19990326	1999/10365	1999/10365	21/12/1990	26/08/1992	21/12/2000	in force
	GB 9880019565, 19880627		Burroughs Wellcome Co.	CA 1340589 US 6889000 US 694394	ZA8904837 A N 19910927	1989/04837	1989/04837	26/06/1989	27/03/1991	26/06/2009	in force
Abacavir (ABC) / Zidovudine (AZT) / Lamivudine (3TC)	WO 1998EPO2835, 19980514; GB 9970009946, 19970517	WO9859949	Gilead Wellcome Inc.	US6994640	ZA9804083 A N 19991115	1998/04083	1998/04083	14/05/1998	26/01/2000	14/05/2018	in force
	GB 990000624, 19990516; GB 990002381, 19991106; GB 990002381, 19991106	WO9220344	Gilead Group Ltd. (GB)	Ck068790	ZA9903344 A N 19990331	1999/03344	1999/03344	15/05/1992	31/05/1993	15/05/2012	in force
	CA 99207030, 19920602; GB 990001902, 19910603	WO9221676	Gilead Group Limited (GB)	Ck231088	ZA9904007 A N 19990428	1999/04007	1999/04007	02/06/1992	28/04/1993	02/06/2012	in force
Abacavir (ABC) / Lamivudine (3TC)	WO 1996EPO352, 19960328; GB 995000489, 19950330; GB 9950006490, 19950330	WO9651025	GileadSmithKline	US641791	ZA9602477 A N 19971028	1996/02477	1996/02477	28/05/1996	31/12/1997	28/05/2016	in force
	WO 1996EPO352, 19960328; GB 995000489, 19950330; GB 9950006490, 19950330	WO9651025	GileadSmithKline	US641791	ZA9602477 A N 19971028	1996/02477	1996/02477	28/05/1996	31/12/1997	28/05/2016	in force
	CA 99207030, 19920602; GB 990001902, 19910603	WO9221676	Gilead Group Limited	US595082	ZA9904007 A N 19990428	1999/04007	1999/04007	02/06/1992	28/04/1993	02/06/2012	in force
Lamivudine (3TC)	GB 990000624, 19990516; WO 1991 GB0706, 19910592; US 989008101, 19890208	WO911719	IAF BioChem International Inc. (Canada)	Ck059665	ZA910393 A N 19990428	1991/0393	1991/0393	30/04/1991	26/02/1992	30/04/2001	in force
	CA 99207030, 19920602; GB 990001902, 19910603	WO9221676	Gilead Group Limited	US595082	ZA9904007 A N 19990428	1999/04007	1999/04007	02/06/1992	28/04/1993	02/06/2012	in force

PATENT INFORMATION AND TRANSPARENCY: A Methodology for Patent Searches on Essential Medicines in Developing Countries

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information from EPO databases on CIPO (ZA) Published application/ Patent and publication date)	CIPO application numbers found for the listed priorities	CIPO patent numbers found for the listed priorities	Application date	For patents: issued date	For patents: expiry date	For patents: Patent status (whether patent is valid or has lapsed)
Lamivudine (3TC) (continued)	GB 19910011902; 19910603	WO9221676	Glaxo Group Limited	CA2070230; US5905082	ZA9224007 A N 1993-04-28	1992/04007	1992/04007	02/05/1992	28/04/1993	02/05/2012	in force
	GB 19970006295; 199702616; US 1997004233P; 19970254; WO 1998EP01626; 19980920	WO9842321	Glaxo Group Limited	CA2286126	ZA980267 A N 1999-09-20	1998/02367	1998/02367	19/09/1998	24/11/1999	19/09/2018	in force
	GB 19910000099; 199101091; GB 19910009913; 199105077; WO 1992CA00011; 199201093	WO9211852	IAF BioChem Int. (CA)	CA1002619 (Inep B) US532246	ZA920267 A N 1999-09-20	1998/02367	1998/02367	19/09/1998	24/11/1999	19/09/2018	in force
	US 1997004233P; 19970254 GB 19910011902; 19910603	WO9842321	Glaxo Wellcome Inc.	US5004968	ZA920267 A N 1999-09-20	1998/02367	1998/02367	19/09/1998	24/11/1999	19/09/2018	in force
	US 19910078508; 199101108; US 1992088385; 19920915	WO9309096	Merck & Co., Inc.	CA2081970	ZA9208663 A N 1993-05-05	1992/08663	1992/08663	06/11/1992	30/07/1993	06/11/2012	in force
	US 19930059258; 19930507; US 1993040729; 19930311; US 1992088385; 19920915; US 1991078308; 19911108	WO9309096	Merck & Co., Inc.	US5413999	ZA9208663 A N 1993-05-05	1992/08663	1992/08663	06/11/1992	30/07/1993	06/11/2012	in force
	US 1998004688; 19980004; US 1997004015P; 19970907	WO9403440	Merck & Co., Inc.	US6645961	ZA9403104 A N 1995-11-06	1994/03104	1994/03104	30/09/1994	28/12/1994	30/09/2014	lapsed
	US 1995058213; 19950201	WO9623309	Merck & Co., Inc.	US6682761	ZA9600722 A N 1996-08-26	1996/00722	1996/00722	31/01/1996	30/10/1996	31/01/2016	lapsed
	US 1993005480; 19930407; US 1992092667; 19920807	WO9403440	Merck & Co., Inc.	CA2101732	ZA9305724 A N 1994-03-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force
	US 1995046028; 19950602; US 19940188001; 19940218; US 1993005480; 19930427; US 1992092667; 19920807	WO9403440	Merck & Co., Inc.	US5919021	ZA9305724 A N 1994-03-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force
US 1995046028; 19950602; US 19940188001; 19940218; US 1993005480; 19930427; US 1992092667; 19920807	WO9403440	Merck & Co., Inc.	US565169	ZA9305724 A N 1994-03-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force	
US 1999028274; 19990331; US 1998008824; 19980210; US 199700738P; 19970205; US 1997004280P; 19970408; US 2001000037; 2001019	WO9823309	Merck & Co., Inc.	US5811423	ZA9905724 A N 1994-03-03	1999/05724	1999/05724	06/08/1999	28/04/1994	06/08/2013	in force	
US 20040891749; 20040624; US 20030447690; 200302919; US 2001000037; 2001019; US 1999028274; 19990331; US 1998008824; 19980210; US 199700738P; 19970205; US 1997004280P; 19970408	WO9823309	Bristol-Myers Squibb Company	US6939864	ZA0004313 A N 2001-11-07	2000/04313	2000/04313	21/08/2000	30/10/2002	21/08/2020	in force	
US 1999028274; 19990331; US 1998008824; 19980210; US 199700738P; 19970205; US 1997004280P; 19970408	WO9823309	Bristol-Myers Squibb Company	US653895	ZA0004313 A N 2001-11-07	2000/04313	2000/04313	21/08/2000	30/10/2002	21/08/2020	in force	
US 20001082407; 200010402; US 1999028274; 19990406; US 1998008824; 19980210	WO9823309	Bristol-Myers Squibb Company	US653333	ZA0004313 A N 2001-11-07	2000/04313	2000/04313	21/08/2000	30/10/2002	21/08/2020	in force	

Drug or combination	Priority number(s) of Patent number listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent number listed in Health Canada Patent Registry and US FDA Orange Book	Information from EPO database on CIPO (ZA) (Published application/ patent and publication date)	CIPO application number found for the listed IPRa priorities	Application date	For patents: issued date	For patents: expiry date	For patents: Patent status (whether patent is valid or has lapsed)
Nefirivir (NFV)	US1993013343 19931007; US1993013166 19931007; US19940190764 19940202; WO1994A1511307 19941007	WO9502843	Agouron Pharmaceuticals, Inc. (US)	US5484926CA273328	ZA9407815 A N 1996-07-28	1994/07815	06/10/1995	28/08/1996	06/10/2015	in force
	US1995028181 19950607; US19940190764 19940202; US1993013343 19931007; US1993013166 19931007; US1992095821 19921222		Agouron Pharmaceuticals, Inc. (US)	US5592343	Z49407815 A N 1996-07-28	1994/07815	06/10/1995	28/08/1996	06/10/2015	in force
	US19990283152 19990401; US1995048181 19950607; US19940190764 19940202; US1993013343 19931007; US1993013166 19931007		Agouron Pharmaceuticals, Inc. (US)	US6162812	ZA9407815 A N 1996-07-28	1994/07815	06/10/1995	28/08/1996	06/10/2015	in force
	GB1988019460 19880613; GB1990008039 19900410		F. Hoffmann-La Roche & Co. Altengieselschaft (Switzerland)	CA1340588	Z48904285 A N 1990-02-28	1989/04285	06/05/1989	28/02/1990	06/06/2009	in force
	GB1989027913 19891211		Hoffmann-La Roche Inc.	CA0910433 US5916438	ZA9009743 A N 1991-08-28	1990/09743	04/12/1990	28/08/1991	04/12/2010	in force
	US1995048181 19950606; US1996016231 19960507; WO1996E02421 19960604	WO9691142	Hoffmann-La Roche Inc.	US6008228 CA2224175	ZA9604448 A N 1996-12-06	1996/04448	30/05/1996	26/02/1997	30/05/2016	in force
	EP19820121831 19821117	WO0028942	Hoffmann-La Roche Inc.	US6332717	ZA000193891 A N 2002-08-14	2001/03891	14/05/2001	30/10/2002	14/05/2021	in force
	US19930073028 19930607	WO9448920	Duke University	US5464933						
	US1995054616 19951106; US19930073028 19930607		Duke University	US6133418						
	US19980973952 19980293; US1995048181 19950607; WO19950509499 19960606		Trimeris, Inc.	US6475491						
Amprenavir (APV)	US19920241982 19920908; WO1993US08428 19930907	WO9405619	Vetex Pharmaceuticals, Incorporated (USA)	CA1432708						
	US1993014237 19931124; US19920241982 19920908; WO1993US08428 19930907	WO9405619	Vetex Pharmaceuticals, Incorporated (USA)	US585397						
	GB1986006372 19860316; US196001893P 19600322; US19970280248 19970220; WO1997EP01438 19970221	(WO9735587)	Glaxo Group Limited (UK)	CA2409316	ZA9702877 A N 1997-12-10	1997/02877	19/03/1997	25/02/1998	19/03/2017	in force
	US1995067199 19951205	WO9720554	Vetex Pharmaceuticals Incorporated	US5646180	ZA9610139 A N 1997-08-17	1996/10139	03/12/1996	27/08/1997	03/12/2016	lapsed
	US19950424819 19950419; US19950934660 19950223; US1993014237 19931124; US19920241982 19920908		Vetex Pharmaceuticals Incorporated	US5734900						
	US19970280248 19970220; US1996001893P 19960322		SmithKline Beecham Corporation	US6720679	ZA9702877 A N 1997-12-10	1997/02877	19/03/1997	25/02/1998	19/03/2017	in force

Data collected from CIPO in November 2006 by B.Milani.

Appendix 1E:

Results of patent search by Lawyers Collectives at the Indian Patent Offices, as of October 2006

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry an US FDA Orange Book	FCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information sourced by EPO internal databases for India (IN)	Application numbers found for the listed priorities by Lawyers Collective	Patent numbers found for the listed priorities by Lawyers Collective	Application date	For patents: issued date	For patents: expiry date	For patents: Patent status (whether patent is valid or has lapsed)
Rionvir (RTV) / Lopinavir (LPV)	US 5960754990 19961121; WO 1997 0526734 19971112	WO 9822106	Abbott Laboratories US	CA2717196							
	US 5960753201 19961121; US 5950722216 19951213; WO 1996 0520440 19961206	WO 9721685	Abbott Laboratories US	US 5914332 CA2288778							
	US 5980207873 19981208; US 5960753201 19961121; US 5950722216 19951213	o	Abbott Laboratories US	US 5824767							
	US 5990039872 19990910; US 5990034207 19990702; US 59700866495 19971107; US 5960031463P 19961121	o	Abbott Laboratories US	US 5621651							
	US 5990034207 19990702; US 59700866495 19971107; US 5960031463P 19961121	o	Abbott Laboratories US	US 544888							
	US 5990034207 19990702; US 59700866495 19971107; US 5960031463P 19961121	o	Abbott Laboratories US	US 5691274							
	US 5990032909P 20000905	o	Abbott Laboratories US	CA 051670							
	US 5990061670 19901120; US 5991074620 19910815; US 5991077766 19911023	o	Abbott Laboratories US	CA 153890							
	US 599008114 19921229; US 5990013887 19931202	WO 9414436	Abbott Laboratories US	CA 224738							
	US 5995000654P 19950639; US 5995003849P 19950915; WO 1996 051015 19960628	WO 9701349	Abbott Laboratories US	US 5846987							
	US 5970081609 19970320; US 5995001879 19950406; US 5990013887 19931202; US 5990098114 19921229	o	Abbott Laboratories US	US 5674882							
	US 5995041316 19950929; US 5992098114 19921229; US 5990013887 19931202; US 5991077766 19911023; US 5991074620 19910815; US 5990061670 19901120; US 5990018730 19900509; US 59890458124 19891222; US 59890405604 19890908; US 5989035945 19890923	o	Abbott Laboratories US	US 541206							
	US 5995041387 19950945; US 5990013887 19931202; US 5990098114 19921229; US 5991077766 19911023; US 5990061670 19901120; US 5990018730 19900509; US 59890458124 19891222; US 59890405604 19890908; US 5989035945 19890923	o	Abbott Laboratories US								

Drug or combination	Priority number(s) of Patent number listed in Health Canada Patent Registry an US FDA Orange Book	PCT applications	Assignee	Patent number listed in Health Canada Patent Registry and US FDA Orange Book	Information sourced by EPO internal databases for India (IN)	Application number found for the listed priorities by Lawyers Collective	Patent numbers found for the listed priorities by Lawyers Collective	Application date	For patents: issued date	For patents: expiry date	For patents: Patent status (whether patent is valid or has lapsed)	
Ritonavir (RTV) / Lopinavir (LPV) (continued)	US 1995041787 19950406; US 1993013887 19931202; US 1992098814 19921229; US 1991077766 19911031; US 1991074620 19910815; US 1990061670 19901120; US 1990058730 19900509; US 19890456124 19891222; US 19890405604 19890908; US 19890355945 19890923	0	Abbott Laboratories US	US 595523								
	US 19950410631 19950324; US 1994070210 19940625; US 1993012103 19930914; US 1991077766 19911031; US 1991074620 19910815; US 1990058730 19900509; US 19890456124 19891222; US 19890405604 19890908; US 19890355945 19890923	0	Abbott Laboratories US	US 5648497								
	US 20010957171 20010920; US 19990387261 19990831; US 19980687774 19980626; US 1995000654P 19950629; US 19950003849P 19950915	0	Abbott Laboratories US	US 6703403								
	US 19970366495 19971107; US 1996051483P 19961121	0	Abbott Laboratories US	US 633333								
	US 19950440277 19950912; US 1994028239 19940729; US 19940189021 1994012	0	Abbott Laboratories US	US 5484801								
	US 1997082071 19970320; US 1995043130 19950929; US 1993013887 19931202; US 1992098814 19921229	0	Abbott Laboratories US	US 586596								
	US 19950003849P 19950915; US 199608774 19960626; US 1995000654P 19950629	0	Abbott Laboratories US	US 6037157			2485/DEL/1998		24/08/1998			Under examination, pre grant opposition filed
	US 1996043893 19961117; US 1996079001 19960906; US 1996060790 19961019	0		CA 0309056								
	US 19930091418 19930713; US 1989040970 19890420; US 1989037974 19890628; US 1989043893 19891117; US 19900579001 19900906; US 19900600390 19901019; US 19910740828 19910805	0		Beuhner Ingelheim Pharmaceuticals, Inc.	US 5466972							
	CH 19960001016 19960422; CH 1997000222 19970331	0		Novartis Finance Corporation	US 5449911				21.04.1997			Under examination, pre grant Opposition filed
	US 198007968P 1980201; WO 1998US27382 19981222	WO9936404		Bristol-Myers Squibb Company US	CA 2317736							
	US 19980217338 19981221; US 1998007968P 19980120	0		Bristol-Myers Squibb Company	US 6087983							
	US 1995076916 19950826	WO9701284		US HEALTH (US)	CA 269044							
	US 19900460490 19900103	WO9109605		US HEALTH (US)	CA 072973							
	US 1991073347 19910722; US 1992082204 19920513	0		SQUIBB BRISTOL MYERS CO (US)	CA 074915							

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry an US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information sourced by EPO internal databases for India (IN)	Application numbers found for the listed priorities by Lawyers Collective	Patent numbers found for the listed priorities by Lawyers Collective	Application date	For patents: issued date	For patents: expiry date	For patents: Patent status (whether patent is valid or has lapsed)	
Didanosine (DDI) (continued)	US 5987004;055 19870811; US 5987076;016 19850826	0	The United States of America as represented by the Department of Health	US54861799								
	US 5991065;288 19910228; US 5992004;035 19970811; US 5990424;664 19890828; US 5990769;016 19950826; US 5986099;925 19861204	0	U.S. Government, Dept. of Health and Human Services, c/o National	US554439								
	US 5993056;043 19930430; US 5991066;328 19910228; US 5989042;664 19890828; US 5987004;055 19870811; US 5986099;925 19861204; US 5987076;016 19850826	0	The United States of America as represented by the Department of Health	US5616566								
	US 5997094;266 19971002; US 5992088;204 19920533; US 5991073;147 19910722	0	Bristol-Myers Squibb Company	US588106								
	US 5986094;266 19861217	0	Yale University	CA1293447 US4978655								
	US 5990473;18 19900201; WO 991135;068;5 19910731	WO 9911186	EMORY UNIVERSITY (US)	CA073789								
	CA 992312;659 19921221; US 5989018;011 19890208	0	BIOCHEM PHARMA INC. (Canada)	CA0009167								
	US 5991065;960 19910222; US 5990473;18 19900201	0	Emory University	US5110085								
	US 5993078;20 19930716; US 5991065;960 19910222; US 5990473;18 19900201	0	Emory University	US5494639								
	US 5995048;897 19950607; US 5992083;103 19920212; US 5991065;960 19910222; US 5990473;18 19900201; US 5991073;689 19910726	0	Emory University	US5914331								
US 5995047;339 19950607; US 5992083;103 19920212; US 5991073;689 19910726; US 5991065;960 19910222; US 5990473;18 19900201	0	Emory University	US5664245									
US 5995042;730 19950333; GB 9910004;741 19910306; GB 9910009;903 19910502; US 5993092;244 19930735; US 5991073;689 19910726; US 5991065;960 19910222; US 5990473;18 19900201	0	Emory University	US670396									
US 5997090;746 19970725; US 5996022;708P 19960726	0	Gilead Sciences, Inc	US5922695									
US 5997090;752 19970725	0	Gilead Sciences, Inc	US5935346		IN 19780 A N 2003-0823	896/DEL/2002 A		09/04/2002			Under Examination-pre grant Opposition filed	
US 5981087;651 19811016; US 5997090;746 19970725; US 5996022;708P 19960726	0	Gilead Sciences, Inc.	US5977889									
US 5999031;4606 19990519; US 5997090;746 19970725; US 5996022;708P 19960726	0	Gilead Sciences, Inc	US604330									
GB 9910106;24 19910616; GB 9910038;1 19911008; GB 9910038;8 19911106	WO 9320344	Gilead Sciences, Inc	CA068790									

Drug or combination	Priority number(s) of Patent number(s) listed in Health Canada Patent Registry an US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information sourced by EPO internal databases for India (IN)	Application numbers found for the listed priorities by Lawyers Collective	Patent numbers found for the listed priorities by Lawyers Collective	Application date	For patents: issued date	For patents: expiry date	For patents: Patent status (whether patent is valid or has lapsed)
Zidovudine (AZT) / Lamivudine (3TC) (continued)	CA 992207030 1992602; GB 991001902 19910603	o	Gilaxo Group Limited	CA2310888							
	GB 991001902 19910603	WO221676	Gilaxo Group Limited	US595082							
	WO 1996EP0352 19960328; GB 9950006489 1995039; GB 9950006490 19950390	WO9650205	The Wellcome Foundation Limited (U.K.)	CA2216634							
	US 996069610 19960222; GB 990000624 1990016; GB 990003381 19911008; GB 990003381 19911008; US 994020176 19940228; US 992088316 19920515	o	Gilaxo Group Limited	US5859021							
Abacavir (ABC)	US 997095535 19971023; GB 99602268 19961031; US 9960029240P 19961031	o	Gilaxo Group Limited	US6113920		2044/CAL/1997		28/10/1997			Withdrawn, Application Rejected
	US 999044520 19991222	o	The Wellcome Foundation Limited (U.K.)	CA2031944							
	GB 9880015265 19880627	o	Burroughs Wellcome Co.	CA 340589 US 5089200 US 594394							
	WO 1998EP0285 19980514; GB 997000946 19970517	WO985949	Gilaxo Wellcome Inc.	US609460		872/CAL/1998		14/05/1997			Under examination, pre grant Opposition filed
Abacavir (ABC)/ Zidovudine (AZT) / Lamivudine (3TC)	GB 991001902 19910603; GB 991001902 19910603	WO221676	Gilaxo Group Limited	CA2310888							
	WO 1996EP0352 19960328; GB 9950006489 1995039; GB 9950006490 19950390	WO9650205	GilaxoSmithKline	US647191							
	CA 992207030 1992602; GB 991001902 19910603	WO221676	Gilaxo Group Ltd. (GB)	CA2310888							
	WO 1996EP0352 19960328; GB 9950006489 1995039; GB 9950006490 19950390	WO9650205	GilaxoSmithKline	US647191							
Abacavir (ABC)/ Lamivudine (3TC)	CA 992207030 1992602; GB 991001902 19910603	o	Gilaxo Group Ltd. (GB)	CA2310888							
	WO 1996EP0352 19960328; GB 9950006489 1995039; GB 9950006490 19950390	WO9650205	GilaxoSmithKline	US647191							
	GB 991001902 19910603	WO221676	Gilaxo Group Limited	US595082							
	GB 990000986 19900922; WO 1991GB20706 19910524	WO911719	GilaxoSmithKline	US647191							
Lamivudine (3TC)	US 9970042333P 19970324; WO 1998EP01626 19980320	o	BioChem Pharma, Inc.	CA2009677 US 5947407							
	GB 991001902 19910603	WO221676	Gilaxo Group Limited	US595082							
	GB 997006295 19970326; US 9970042333P 19970324	WO9842321	Gilaxo Group Limited	CA2286126							
	WO 1998EP01626 19980320	WO221676	Gilaxo Group Limited	US595082							
Lamivudine (3TC)	GB 991000059 19910105; GB 991000911 19910507; WO 1992CA0001 19920109	WO211852	IAF BioChem Int. (CA)	CA200269 (Ilep B) US 532246							No opposition have been filed yet, no request for examination filed.
	US 9970042333P 19970324; GB 991001902 19910603	WO9842321	Gilaxo Wellcome Inc.	US6009688		479/CAL/1998		23/05/1998 A			

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information sourced by EPO internal databases for India (IN)	Application numbers found for the listed priorities by Lawyers Collective	Patent numbers found for the listed priorities by Lawyers Collective	Application date	For patents: issued date	For patents: expiry date	For patents: Patent status (whether patent is valid or has lapsed)	
Indinavir (IDV)	US1991078508 19911108; US1992088385 19920715	WO9309096	Merck & Co., Inc.	CA081970								
	US1993059195 19930507; US1993040729 19930311; US1992083825 19920515; US1991079508 19911108	o	Merck & Co., Inc.	US5413999								
	US1998004685 19980304; US1997020401 5P 19970307	o	Merck & Co., Inc.	US6643961								
	US1995038213 19950201	WO965399	Merck & Co., Inc.	US689761								
	US1993054805 19930427; US199209246607 19920807	WO9403440	Merck & Co., Inc.	CA101572								
	US1995046026 19950602; US1994018003 19940218; US1993054805 19930427; US199209246607 19920807	o	Merck & Co., Inc.	US519021								
	US1995043828 19950502; US19940188005 19940128; US1993054805 19930427; US199209246607 19920807	o	Merck & Co., Inc.	US5663169								
	US19970815780 19970312; US1995043829 19950602; US19940188005 19940218; US1993054805 19930427; US199209246607 19920807	o	Merck & Co., Inc.	US581123								
	US19990282744 19990331; US1998008824 19980120; US1997037785P 19970205; US19970204287P 19970408; US20010000537 2001019	o	Merck & Co., Inc.	US6639071								
	US20040837749 20040654; US2003047690 20030529; US20010000537 2001019; US19990282744 19990331; US1998008824 19980120; US1997037785P 19970205; US19970204287P 19970408	o	Bristol-Myers Squibb Company	US6939964								
US19990286902 19990406; US1998008829 2P 19980407	o	DuPont Pharmaceuticals Company	US6388695									
US2001082407 20010402; US19990286902 19990406; US1998008829 2P 19980407	o	Bristol-Myers Squibb Company	US655133									
Nelfinavir (NFV)	US1993013343 19931007; US19930131656 19931007; US19940190764 19940202; WO19940151307 19941007	WO9509843	Agouron Pharmaceuticals, Inc. (US)	US5464966 CA17338								
	US1995048183 19950607; US19940190764 19940202; US1993013343 19931007; US19930131656 19931007; US19930137254 19931008; US19920995621 19921222	o	Agouron Pharmaceuticals, Inc. (US)	US592443								
	US19990283152 19990401; US1995048183 19950607; US19940190764 19940202; US1993013343 19931007; US19930131656 19931007	o	Agouron Pharmaceuticals, Inc. (US)	US6162812								

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry an US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information sourced by EPO internal databases for India (IN)	Application numbers found for the listed priorities by Lawyers Collective	Patent numbers found for the listed priorities by Lawyers Collective	Application date	For patents: issued date	For patents: expiry date	For patents: Patent status (whether patent is valid or has lapsed)
Siquimavir (SQV)	GB 9880013940 19880613; GB 9890008075 19890410	0	F. HOFFMANN-LA ROCHE & CO. AKTIEN GESELLSCHAFT (Switzerland)	CA 240588							
	GB 989002919 19891211	0	Hoffmann-La Roche Inc.	CA 209433 US 5196438	IN 2553 A N 19952955						
	US 9950468493 19950606; US 9960616333 19960507; WO 1996EP02431 19960604	WO 9659142	Hoffmann-La Roche Inc.	US 600828 CA 224195	IN 92899 A N 2004-05-29						
	EP 998012183 19981117	WO 0028942	Hoffmann-La Roche Inc.	US 6392717							
Enfuvirtide (T20)	US 9930073028 19930607	WO 9428920	Duke University	US 5464933							
	US 995054616 19951106; US 9930073028 19930607	0	Duke University	US 633418							
	US 9980973952 19980529; US 9930481957 19950607; WO 1996US09499 19960606	0	Trimeris, Inc.	US 6475491							
Amprenavir (APV)	US 9920941082 19920908; WO 1993US08458 19930907	WO 9405659	Vertex Pharmaceuticals, Incorporated (USA)	CA 2443208							
	US 993044237 19931124; US 9920941082 19920908; WO 1993US08458 19930907	WO 9405659	Vertex Pharmaceuticals, Incorporated (USA)	US 583397							
	GB 996006671 19960316; US 996003827 19960322; US 9920941082 19920908; WO 1993EP01439 19930331	(WO 9373587)	GLAXO GROUP LIMITED (UK)	CA 2449316	727/Del/1997				21/09/1997		Under Examination, Pre grant Opposition filed
	US 9950567199 19951205	WO 9770554	Vertex Pharmaceuticals Incorporated	US 646180							
	US 9950424819 19950419; US 9950354600 19950223; US 993044237 19931124; US 9920941082 19920908	0	Vertex Pharmaceuticals Incorporated	US 723490							
	US 997082848 19970220; US 996003833P 19960322	0	SmithKline Beecham Corporation	US 6730679					21/09/1997		Under Examination, Pre grant Opposition filed

Data collected from the Indian Patent Offices in October 2006 by Lawyers Collective.

Additional patent data on antiretroviral drugs collected by Lawyers Collective India in October 2006

Drug or combination	Patent Title	Priority number(s) provided by Lawyers collective	Priority numbers from espacenet for the PCT applications	Assignee	Patent numbers Health Canada Orange Book	WIPO (WO)	Information sourced by EPO internal databases for India (IN)	Application numbers found for the listed priorities by Lawyers Collective	Patent numbers found for the listed priorities by Lawyers Collective	Application date	For patents: issued date	For patents: expiry date	For patents: enforcement status indicating if according to Indian Patent office requirements, the patent is enforced or lapsed. For applications: as applicable.
Ritonavir (RTV) / Lopinavir (LPV)	Kalitra	US 9990232826 19990604		Abbott Laboratories US		WO0074677		IN/PCT/2001/0312/ MUM		27/10/2001			Has been abandoned
Efavirenz	A Process for Preparing Form 1 of Crystalline Efavirenz	65 (088,681) 19980611, WO/99/051319 19990610	US 998008838P 19980611	Bristol Myers Squibb Pharma Company Ltd.		WO9964405		IN/PCT/2000/00533/ MUM		27/10/2000			Awaiting information from Mumbai patent office
	A Process for Preparing Form 2 of Crystalline Efavirenz	65 (088,681) 19980611, WO/99/051319 19990610	US 998008838P 19980611	Bristol Myers Squibb Pharma Company Ltd.		WO9964405		718/MUMNP/2003 (Divisional application of IN/PCT/2000/00533/ MUM)		21/07/2003			Request for examination has been filed on 28/12/2005
	A Process for Preparing Form 4 of Crystalline Efavirenz	US 998008838P 19980611 US 999029421 19990610 US 999029421 US 667372	US 998008838P 19980611	Bristol Myers Squibb Pharma Company Ltd.		WO9964405		737/MUMNP/2003 (Divisional application of IN/PCT/2000/00533/ MUM)		25/07/03			No request has been made for examination
Combination of efavirenz and saquinavir	Condensed Naphthyridines as HIV Reverse Transcriptase Inhibitors (Tricyclic Compounds Useful in Reverse Transcriptase Inhibitors)	US 999060299 19991019 US 2000022677 20000817 US 20001019 US 2004002498	US 9990160329P 19991019 US 2000022677P 20000817	Bristol Myers Squibb Pharma Company Ltd.		WO0028037		IN/PCT/2002/00970/ MUM (PCT/ ChO) (00890)		05/06/2002			No request for examination has been made
Nevirapine (Improvement)	Non Nucleoside Reverse Transcriptase Inhibitors	US 2000021329 20000616 US 20000296538 US 20001218 US 2002028807	US 2000021329P 20000616, US 20000296538P 20001218	Boehringer Ingelheim Ltd.		WO0095358		IN/PCT/2002/01632/ MUM (PCT/ ChO) (00890)		22/10/2002			Awaiting information from Mumbai patent office
Ritonavir (RTV) (Polymorph)	Ritonavir (RTV)	US 998109345 19980720, US 9990246093 19990604	US 9980109345 19980720, US 9990246093 19990604	Abbott Laboratories US		WO0004016		PCT/2001/00018/ MUM		09/04/2005			FER issued on 01.10.2006, 2 oppositions have been filed
Lopinavir (Crystalline form)	Lopinavir (Product Patent)	US 2000038257 20000330, US 2001079356 20010227	US 2000038257 20000330, US 2001079356 20010227	Abbott Laboratories US		WO0174787		IN/PCT/02/01243/ MUM		09/11/2002			FER issued on 16.10.2006, 2 oppositions have been filed
Lopinavir	Lopinavir (Process Patent)	US 20000651919 20000831	US 20000651919 20000831	Abbott Laboratories US		WO0218349		295/MUMNP/2003 A		24/02/2003			Request for examination has been filed on 29/12/2005

Drug or combination	Patent Title	Priority number(s) provided by Lawyers collective	Priority numbers from equivalent for the PCT applications	Assignee	Patent numbers Health Canada Orange Book	WIPO (NO)	Information sourced by EPO Journal database for India (IN)	Application numbers provided for the listed priorities by Lawyers Collective	Patent numbers found for the listed priorities by Lawyers Collective	Application date	For patents: issued date	For patents: expiry date	For patents: status according to Indian Patent office requirements, the patent is enforced or lapsed. For applications: as applicable.
Fosamprenavir	Lenixa (Calcium (3S) Tetrahydro-3-funaryl (1S,2R)-3-[(4-Aminophenyl) Sulphonyl] (isobutyl) Amino)-Benzyl-2 (Phosphonoxy) Propylcarbamate)	9815567.4 (WO) 9958P04991 19990715; GB 9980015567 19980718	GB 9980015567 19980718	Glaxo Group Limited		WO0004033		IN/PCT/2001/000939		01/10/2001			Under Examination, no oppositions filed yet
Combination of amprenavir zidovudine and abacavir	Antiviral Combinations	60/0221	—	Glaxo Group Limited				1206/CAL/1997 A		03/11/2005			Request for examination has not been filed

Data collected from the Indian Patent Offices in October 2006 by Lawyers Collective.

Appendix 2:

Priority patent application data and INPADOC patent families for 19 antiretroviral drugs and combinations reported in the Health Canada Patent Registry and in the US Food and Drug Administration Orange Book

Drug or combination	Patents listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Aripo(AP)	Brazil (BR)	China (CN)	India (IN)	OAPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Ritonavir (RTV)	Ckz271936	Abbott Laboratories US	US 19960574390 1996121; WO19970520794 1997112	WO9821206 1998-05-28	A Y	BR9714310 2000-05-02	CN1248914 2000-03-29					Z49710071 1998-05-23
	US5944332 Ckz38578	Abbott Laboratories US	US 19960574201 1996121; US 19960572226 1996213; WO1996US20440 19961206	WO9721683 1997-06-19 WO9721685 1997-06-19	A Y A Y	BR1100937 2000-04-11	CN1207288C 2005-06-22 CN1208405 1999-02-17					Z49610475 1997-07-31
	US624767	Abbott Laboratories US	US 19980207873 1998208; US 19960573201 1996121; US 19960572226 1995213	WO9721683 1997-06-19 WO9721685 1997-06-19	A Y A Y	BR1100937 2000-04-11	CN1207288C 2005-06-22 CN1208405 1999-02-17					Z49610475 1997-07-31
	US621651	Abbott Laboratories US	US 1999093872 19990910; US 19990947077 19990702; US 19970666495 1997107; US 19960037463P 1996121		no family found							
	US646881	Abbott Laboratories US	US 19990947077 19990702; US 19970666495 1997107; US 19960037463P 1996121		no family found							
	US691214	Abbott Laboratories US	US20010946608; 20000904; US2000023005P 2000095		no family found							
	Ckz05670	Abbott Laboratories US	US 1990061670 1990120; US 19910746020 19910815; US 19910777656 19911023									
	Ckz135890	Abbott Laboratories US	US 1992098814 19921229; US 1993095857 19931202	WO9414436 1994-07-07	A Y							
	Ckz24738	Abbott Laboratories US	US 19950000654P 19950639; US 1995003844P 19950915; WO 1996US11015 19960628	WO9701349 1997-01-16	A Y							
	US846987	Abbott Laboratories US	US 19978281600 19970320; US 19950413720 19950406; US 1995095887 19951226; US 1996093814 19961229	WO9414436 1994-07-07	A Y	BR1100661 2000-04-11						
Ritonavir (RTV) / Lopinavir (LPV)	US674882	Abbott Laboratories US	US 19950413136 19950328; US 1992098814 19921229; US 1993095857 19931202; US 19910777656 19911023; US 19910746020 19910815; US 1990061670 1990120; US 1990051870 19900509; US 19890456124 19891222; US 1989045604 19890908; US 1989035946 19890923	WO9414436 1994-07-07	A Y							
	US511206	Abbott Laboratories US	US 1995042387 19950425; US 1992098814 19921229; US 1993095857 19931202; US 19910777656 19911023; US 19910746020 19910815; US 1990061670 1990120; US 1990051870 19900509; US 19890456124 19891222; US 1989045604 19890908; US 1989035946 19890923	WO9414436 1994-07-07	A Y							

Drug or combination	Patents listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Atip/AP	Brazil (BR)	China (CN)	India (IN)	OAPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Ritonavir (RTV) / Lopinavir (LPV) (continued)	US5635523	Abbott Laboratories US	US1992417879 19924066; US199205887 19921202; US1992058814 19921229; US1991077626 19911023; US1991074620 19910815; US1990061670 19901120; US1990051870 19900909; US19892456124 19891222; US1989245604 19890908; US1989235945 19890923	WO9414436 A Y 1994-07-07								
	US5648497	Abbott Laboratories US	US1992410653 19920324; US1992026210 19920625; US1992026217 19920914; US1991077626 19911023; US1991066170 19910815; US1990051870 19900909; US19892456124 19891222; US1989245604 19890908; US1989235945 19890923									
	US6703403	Abbott Laboratories US	US2001095771 20010920; US1999038726 19990831; US1996687774 19960626; US1995000654P 19950629; US1995003849P 19950915	WO9701349 A Y 1997-01-16								
	US623333	Abbott Laboratories US	US19970956485 19971107; US19960031463P 19961121									
	US5444801	Abbott Laboratories US	US1992440277 19920512; US19944028329 19940729; US19944083021 19940102	WO9520384 A Y 1995-08-03								
	US5886036	Abbott Laboratories US	US1997082207 19970320; US199241336 19920229; US199205887 19921202; US1992059814 19921229	WO9701349 A Y 1997-01-16								
	US6037157	Abbott Laboratories US	US1995003849P 19950915; US1996687774 19960626; US1995000654P 19950629	WO9701349 A Y 1997-01-16	AP79 A N 1992-04-30				OA852 A - 1994-08-15	RU2000527 C N 1995-07-25		ZA900246 A N 1995-07-29
	US6300056		US1990438923 19911177; US1990579001 19900906; US1990660390 19901019		AP189 A N 1992-05-04 AP179 A N 1992-04-30				OA852 A - 1994-08-15 OA974 A N 199311-30	RU2004522 C N 1994-12-15 RU200227 C N 1995-07-25		ZA900691 A N 1992-03-23 ZA9009246 A N 1992-07-29
	US5366972	Boehringer Ingelheim Pharmaceuticals, Inc.	US19930091418 19930713; US19890340970 19890420; US19890372974 19890628; US19890438923 19891177; US1990579001 19900906; US1990660390 19901019; US1991074628 19910805									
	US649911	Novartis Finance Corporation	CH1996000108 19960422; CH1997000223 19970131	WO9740029 A Y 1997-10-30	BR9701877 A N 1998-09-29		CH182508C C 2002-04-10 CN1195010C C 2005-03-16 CN121059 A N 1999-05-12 CN1319587 A N 2001-10-31 CN161653 A N 2005-05-18					ZA970387 A N 1997-10-22
CA317736	Bristol-Myers Squibb Company US	US19980071968P 19981020; WO19981527382 19981222	WO9956404 A Y 1999-07-22	BR984736 A N 2000-10-24		CH1283188 A 2001-02-07 CN1116282C C N 2009-07-30			RU2186070 C N 2002-07-27		ZA9900056 A N 2000-07-05	

Drug or combination	Patents listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Aripiprazole (AP16)	Brazil (BR)	China (CN)	India (IN)	OMPI (P)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Atazanavir (ATV) (continued)	US6087383	Bristol-Myers Squibb Company	US1998027338 19981221; US19980071968P 19981020	WO9936404 1999-07-22	A Y	BR984736 2000-10-24	CN1281188 A 2001-02-07 CN1116282C C N 2003-07-30			RU2186070 C N 2002-07-27		ZA9900056 A N 2000-07-05
Didanosine (DDI)	CA269044	US Health	US19850769016 19850826	WO8701284 1987-03-12	A Y							
	CA207573	US Health (US)	US19900460490 19900103	WO9109605 1991-07-11	A Y							
	CA2074215	Squibb Bristol Myers Co. (US)	US19910733547 19910722; US19920822204 19920513				CN1042259C 1999-03-03 CN1068739 A N 1993-02-10			RU2089193 C N 1997-09-10		ZA9205484 A N 1993-09-13
	US6861759	The United States of America as represented by the Department of Health	US19870840551 19870811; US19870769016 19870826	WO8701284 1987-03-12	A Y							
	US5246359	U.S. Government, Dept. of Health and Human Services, c/o National	US19910663288 19910228; US19870084055 19870811; US19890420664 19890828; US19850769016 19850826; US19860937925 19861204	WO8701284 1987-03-12	A Y							
	US6161666	The United States of America as represented by the Department of Health	US19910056048 19910230; US19910663288 19910228; US19890420664 19890828; US19870084055 19870811; US19860937925 19861204; US19870769016 19870826	WO8701284 1987-03-12	A Y							
	US6880106	Bristol-Myers Squibb Company	US19970942660 19970202; US19920822204 19920513; US19910733547 19910722				CN1042259C 1999-03-03 CN1068739 A N 1993-02-10			RU2089193 C N 1997-09-10		ZA9205484 A N 1993-09-13
Stavudine (d4t)	CA203447 US6978655	Yale University	US19860942666 19861217									ZA870771 A N 1988-03-24
Emtricitabine (FTC)	CA207189	Emory University (US)	US19900473318 19900201; WO1991US0085 19910101	WO911186 1991-08-08	A Y					RU212558 1999-01-27		
	CA2009637	BioChem Pharma Inc. (Canada)	CA1922152569 19921221; US19890308101 19890208		AP16 A N 1991-08-05		CN1037640C 1996-12-25 CN1044817 A N 1990-08-22		O49193 A N 1992-06-30	RU2002485 C N 1997-10-10		ZA9000943 A N 1990-10-31
	US610085	Emory University	US19910699760 19910222; US19900473318 19900201	WO911186 1991-08-08 WO9214729 1992-09-03 WO9214743 1992-09-03	A Y A Y A Y	BR9205661 1994-05-24	CN1037640C 1998-03-11 CN1065065 A N 1992-10-07 CN108745C 2002-05-15 CN1109108C 2003-05-21 CN117301 A N 1996-07-24 CN1203232 A N 1998-12-30 CN148566 A N 2003-05-21			RU212558 C N 1999-01-27		ZA920751 A N 1993-08-20

Drug or combination	Patents listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Pricing number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Atip(M/P)	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Emtricitabine (FTC) (continued)	US5844639	Emory University	US1995007820 19950216; US19910659760 19910222; US19900473318 19900201	WO911186 A Y 1991-08-08 WO9214729 A Y 1992-09-03 WO9214743 A Y 1992-09-03		BR9205661 A N 1994-05-24	CN1037682C C 1998-03-11 CN1050565 A N 1992-10-07 CN1084745C C 2002-05-15 CN1109108C C 2003-05-21 CN1127301 A N 1996-07-24 CN1203232 A N 1998-12-30 CN1418866 A N 2003-05-21			RU2125558 C N 1999-01-27		ZA9201251 A N 1993-08-20
	US5914331	Emory University	US19950488097 19950607; US1992081151 19920212; US19910659760 19910222; US19900473318 19900201; US19910736809 19910726	WO111186 A Y 1991-08-08 WO9214729 A Y 1992-09-03 WO9214743 A Y 1992-09-03		BR9205661 A N 1994-05-24	CN1037682C C 1998-03-11 CN1050565 A N 1992-10-07 CN1084745C C 2002-05-15 CN1109108C C 2003-05-21 CN1127301 A N 1996-07-24 CN1203232 A N 1998-12-30 CN1418866 A N 2003-05-21			RU2125558 C N 1999-01-27 RU235724 C N 2004-09-10		ZA9201251 A N 1993-08-20
Tenofovir Disoproxil fumarate (TDF)	US6442445	Emory University	US19950473339 19950607; US1992081151 19920212; US19910736809 19910726; US19900473318 19900201	WO911186 A Y 1991-08-08 WO9214729 A Y 1992-09-03 WO9214743 A Y 1992-09-03		BR9205661 A N 1994-05-24	CN1037682C C 1998-03-11 CN1050565 A N 1992-10-07 CN1084745C C 2002-05-15 CN1109108C C 2003-05-21 CN1127301 A N 1996-07-24 CN1203232 A N 1998-12-30 CN1418866 A N 2003-05-21			RU2125558 C N 1999-01-27 RU235724 C N 2004-09-10		ZA9201251 A N 1993-08-20
	US6703396	Emory University	US19950473320 19950313; CB19910004721 19910306; US19910009551 19910302; US19930092228 19930715; US19907316080 19907246; US19910659760 19910222; US19900473318 19900201	WO911186 A Y 1991-08-08 WO9214729 A Y 1992-09-03 WO9214743 A Y 1992-09-03 WO9215308 A Y 1992-09-17		BR9205661 A N 1994-05-24	CN1037682C C 1998-03-11 CN1050565 A N 1992-10-07 CN1084745C C 2002-05-15 CN1109108C C 2003-05-21 CN1127301 A N 1996-07-24 CN1203232 A N 1998-12-30 CN1418866 A N 2003-05-21			RU2125558 C N 1999-01-27 RU235724 C N 2004-09-10		ZA9201251 A N 1993-08-20 ZA9201658 A N 1993-09-06
Tenofovir Disoproxil fumarate (TDF)	US922635 (CA2261619)	Gilead Sciences, Inc	US19970900746 19970725; US19960027768P 19960726	WO9804969 A Y 1998-02-05								
	US935946	Gilead Sciences, Inc	US19970900752 19970725	WO9905190 A Y 1999-02-04		BR81045 A N 2000-08-22	CN1584390 A N 2004-12-15 CN1264887 A N 2000-08-23 CN1745755	IN100780 A N 2003-08-23				
	US977089	Gilead Sciences, Inc.	US19980187769 19981106; US19970900746 19970725; US19960027768P 19960726	WO9804969 A Y 1998-02-05								

PATENT INFORMATION AND TRANSPARENCY: A Methodology for Patent Searches on Essential Medicines in Developing Countries

Drug or combination	Patents listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Aripiprazole (AP)	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Tenofovir Disoproxil fumarate (TDF) (continued)	US6043230	Glaxo Sciences, Inc	US19990314606 19990519; US1997090746 19970725; US19960022788P 19960726	WO9804569 A Y 1998-02-05								
	CA2087990	Glaxo Group Limited	GB19910010624 19910516; GB1991002338 19911008; GB1991002338 19911106	WO9920244 A Y 1999-11-26			CN1045961C 1999-10-27 CN108870 A N 1999-02-03		OA10058 A N 1996-10-14	RU2199053 C N 1999-10-10		ZA9903544 A N 1999-03-31
	CA311988	Glaxo Group Limited	CA19922070230 19920602; GB19910011902 19910603	WO9221676 A Y 1992-12-10	AP300 A N 1994-01-20			OA9913 A N 1994-09-15	OA9913 A N 1994-09-15	RU2102393 C N 1998-01-20		ZA9904007 A N 1999-04-28
	US590502	Glaxo Group Limited	GB19910011902 19910603	WO9221676 A Y 1992-12-10	AP300 A N 1994-01-20			OA9913 A N 1994-09-15	OA9913 A N 1994-09-15	RU2102393 C N 1998-01-20		ZA9904007 A N 1999-04-28
	CA2116634	THE WELLCOME FOUNDATION LIMITED (U.K.)	WO9960923 19990308; GB19950006489 19950330; GB19950006490 19950330	WO9660025 A Y 1996-10-03	AP652 A N 1998-06-19	BR6607851 A N 1998-07-21	CN103393C 2003-03-26 CN18510 A N 1998-06-17		OA10616 A N 2001-03-15			ZA9604277 A N 1997-10-28
US6199021	Glaxo Group Limited	US19960605610 19960222; GB19910010624 19910516; GB1991002338 19911008; GB1991002338 19911106; US19940219716 19940328; US19950083169 19950515	WO9220244 A Y 1992-11-26	AP1067 A N 2002-05-01	BR772614 A N 1999-10-26	CN1045961C 1999-10-27 CN108870 A N 1999-02-03		OA10058 A N 1996-10-14	RU2199053 C N 1999-10-10		ZA9903544 A N 1999-03-31	
US6119920	Glaxo Group Limited	US1997095635 19971023; GB19950022681 19950331; US199600239240P 19960331	WO9804877 A Y 1998-05-07	AP1067 A N 2002-05-01					OA10616 A N 2001-03-15		UA62723 C N 1999-12-29	ZA9709726 A N 1999-04-29
Abacavir (ABC) / Zidovudine (AZT) / Lamivudine (3TC)	CA203044	The Wellcome Foundation Limited (U.K.)	US1989045201 19891222	WO98570 A Y 1998-11-26	AP196 A N 1992-06-30	CN105488 A N 1991-10-02 CN1028106C C 1995-04-05				RU2088249 C N 1996-11-10 RU2091386 C N 1997-09-27		ZA990365 A N 1999-08-26
	CA1340980 US9089500 US924334	Burroughs Wellcome Co.	GB1988001565 19880627	WO98570 A Y 1998-11-26	AP101 A N 1990-10-23							ZA8904837 A N 1991-03-27
	US6294540	Glaxo Wellcome Inc.	WO1998E0283 19980514; GB19970009945 19970517	WO98570 A Y 1998-11-26	BR9809174 A N 2000-08-01 BR9809176 A N 2000-08-01 BR9809177 A N 2000-08-01	CN1150194C 2004-05-19 CN1265329 A N 2000-08-16 CN1515372 A N 2004-07-28		OA11304 A N 2003-10-22				ZA9804083 A N 1999-11-15 ZA9804085 A N 1999-11-15
	CA2087990	Glaxo Group Limited (GB)	GB19910010624 19910516; GB1991002338 19911008; GB1991002338 19911106	WO9220244 A Y 1992-11-26	AP1067 A N 2002-05-01	CN1045961C 1999-10-27 CN108870 A N 1999-02-03			OA10058 A N 1996-10-14	RU2199053 C N 1999-10-10		ZA9903544 A N 1999-03-31
	CA311988	Glaxo Group Limited (GB)	CA19922070230 19920602; GB19910011902 19910603	WO9221676 A Y 1992-12-10	AP300 A N 1994-01-20				OA9913 A N 1994-09-15	RU2102393 C N 1998-01-20		ZA9904007 A N 1999-04-28
	US590502	Glaxo Group Limited	GB19910011902 19910603	WO9221676 A Y 1992-12-10	AP300 A N 1994-01-20				OA9913 A N 1994-09-15	RU2102393 C N 1998-01-20		ZA9904007 A N 1999-04-28
	US641791	GlaxoSmithKline	WO1996E01332 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025 A Y 1996-10-03	AP652 A N 1998-06-19	BR6607851 A N 1998-07-21	CN103393C 2003-03-26 CN18510 A N 1998-06-17		OA10616 A N 2001-03-15			ZA9602477 A N 1997-10-28
Abacavir (ABC) / Lamivudine (3TC)	CA311988	Glaxo Group Limited (GB)	CA19922070230 19920602; GB19910011902 19910603	WO9221676 A Y 1992-12-10	AP300 A N 1994-01-20				OA9913 A N 1994-09-15	RU2102393 C N 1998-01-20		ZA9904007 A N 1999-04-28
	US641791	GlaxoSmithKline	WO1996E01332 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025 A Y 1996-10-03	AP652 A N 1998-06-19	BR6607851 A N 1998-07-21	CN103393C 2003-03-26 CN18510 A N 1998-06-17		OA10616 A N 2001-03-15			ZA9602477 A N 1997-10-28
	US590502	Glaxo Group Limited	GB19910011902 19910603	WO9221676 A Y 1992-12-10	AP300 A N 1994-01-20				OA9913 A N 1994-09-15	RU2102393 C N 1998-01-20		ZA9904007 A N 1999-04-28

Drug or combination	Patents listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Atip/AP	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Lamivudine (3TC)	C4205263	Inf Biochem International Inc. (Canada)	GB1990009861 19900502; WO1990009861 19900502	WO9117159 A Y 1991-11-14	AP82 A N 1992-06-20		CN1056145C 2000-09-06 CN1058214 A N 1992-08-24 CN1108555 A N 1992-01-29 CN1108655 A N 1995-09-20 CN1154900C 2004-06-23 CN1267643 A N 2001-12-19 CN1091966C 1997-10-22		OA939 A N 1993-01-31	RU2099338 C N 1997-12-20		ZA910393 A N 1992-02-26
	C4209637	BioChem Pharma, Inc.	CA1932135269 19921221; US199204353P 19920208		AP16 A N 1991-08-05		CN104487 A N 1990-08-22 CN1031640C 1996-12-23		OA913 A N 1992-06-30	RU2092485 C N 1997-10-10		ZA900943 A N 1990-10-31
	C4207230	Glaxo Group Limited	GB19910011902 19910603	WO9221676 A Y 1992-12-10	AP300 A N 1994-01-20				OA9913 A N 1994-09-15	RU2102393 C N 1998-01-20		ZA9204007 A N 1993-04-28
	C4228626	Glaxo Group Limited	GB19970006255 19970926; US1997004335P 19970924; WO1998EP01026 19980320	WO9442321 A Y 1994-10-01	AP141 A N 2003-01-29	BR9808060 A N 20000328	CN1191066C 2005-03-02 CN1253849 A N 2000-06-07					ZA9802367 A N 1999-09-20
	C4210226 (Item B)	Inf Biochem Int (CA)	GB19910000039 19910103; GB199100009913 19910507; WO1992CA00001 19920103	WO9211852 A Y 1992-07-23								
Indinavir (IDV)	US6004968	Glaxo Wellcome Inc.	US1992004235P 19920924; GB19910011902 19910603	WO9442321 A Y 1994-10-01	AP141 A N 2003-01-29	BR9808060 A N 20000328	CN1191066C 2005-03-02 CN1253849 A N 2000-06-07					ZA9802367 A N 1999-09-20
	C42081970	Merck & Co., Inc.	US19910789508 19911081; US199200883825 19920515	WO9390916 A Y 1993-05-13						RU2171354 C N 2001-07-27; RU2131416 C N 1999-06-10		ZA920865 A N 1993-05-05
	US413939	Merck & Co., Inc.	US19930059038 19930507; US19930040729 19930331; US19920083825 19920515; US19910789508 19911081	WO9390916 A Y 1993-05-13; WO9422480 A Y 1994-10-13; WO9426717 A Y 1994-11-24		BR9406576 A N 1996-01-30; BR9401593 A N 1996-01-02	CN1176550 A N 1998-03-18; CN1126469 A N 1996-07-10 CN120316 A N 1996-04-10 CN109187C 2002-09-04			RU2171354 C N 2001-07-27 RU213902 C N 1999-10-10; RU2131416 C N 1999-06-10		ZA920865 A N 1993-05-05; ZA940235 A N 1994-11-01; ZA9403104 A N 1995-11-06
	US664961	Merck & Co., Inc.	US19980046885 19980304; US19970040158P 19970307		no family found							
	US6689761	Merck & Co., Inc.	US19950382113 19950201	WO9603509 A Y 1996-08-08		BR9607714 A N 1998-01-13	CN1179722 A N 1998-04-22 CN1160081C 2004-08-04					ZA9600722 A N 1996-08-26
Efavirenz (EFV)	C42101572	Merck & Co., Inc.	US19930054805 19930427; US19920026607 19920807	WO9403440 A Y 1994-02-17						RU2186775 C N 2002-08-10		ZA9510724 A N 1994-03-03

Drug or combination	Patents listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Aripiprazole (AP)	Brazil (BR)	China (CN)	India (IN)	OMPI (P)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Efavirenz (EFV) (continued)	US5519021	Merck & Co., Inc.	US19924602; 19920602; US1994088005; 19940128; US19930054805; 19930427; US1992026607; 19920807	WO9403440 A Y 1994-02-17; WO9320389 A Y 1995-08-03			CN1250652 A N 2000-04-19 CN1216608 A N 1999-07-07 CN1075959 C 2003-05-07 CN1090277 A N 1994-08-03 CN1057765 C 2000-04-26			RU12186775 C N 2002-08-10		ZA9305724 A N 1994-03-03
	US5651169	Merck & Co., Inc.	US199549528; 19950602; US1994088005; 19940128; US19930054805; 19930427; US1992026607; 19920807	WO9403440 A Y 1994-02-17; WO9320389 A Y 1995-08-03			CN1250652 A N 2000-04-19 CN1216608 A N 1999-07-07 CN1075959 C 2003-05-07 CN1090277 A N 1994-08-03 CN1057765 C 2000-04-26			RU12186775 C N 2002-08-10		ZA9305724 A N 1994-03-03
Efavirenz (EFV) (continued)	US5811423	Merck & Co., Inc.	US1997081780; 19970312; US1995049539; 19950602; US1994088005; 19940128; US19930054805; 19930427; US1992026607; 19920807	WO9403440 A Y 1994-02-17; WO9320389 A Y 1995-08-03			CN1250652 A N 2000-04-19 CN1216608 A N 1999-07-07 CN1075959 C 2003-05-07 CN1090277 A N 1994-08-03 CN1057765 C 2000-04-26			RU12186775 C N 2002-08-10		ZA9305724 A N 1994-03-03
	US6639071	Merck & Co., Inc.	US1992082744; 19920331; US1996000882; 19960120; US19970037389; 199702058; US1997004807; 199704068; US20010000537; 200101019	WO9833782 A Y 1998-08-06			CN1354545 A N 2001-12-18 CN1246113 A N 2000-09-30 CN1073464 C 2002-09-26 CN1073991 C 2001-10-31					
Efavirenz (EFV) (continued)	US6939964	Bristol-Myers Squibb Company	US20040891749; 20040624; US20030447690; 200305939; US20010000537; 200101019; US19990288744; 19990331; US19980008824; 19980120; US19970037389; 199702058; US1997004807; 199704068	WO9833782 A Y 1998-08-06			CN1354545 A N 2001-12-18 CN1246113 A N 2000-09-30 CN1073464 C 2002-09-26 CN1073991 C 2001-10-31					
	US6238695	DuPont Pharmaceuticals Company	US19920386902; 199204066; US19960008925; 19960407	WO9951239 A Y 1999-10-14		BR9908810 A N 2000-12-19	CN1354545 A N 2001-12-18 CN1246113 A N 2000-09-30 CN1073464 C 2002-09-26 CN1073991 C 2001-10-31			UA72207 C N 2001-02-15		ZA200004313 A N 2001-11-07
Nelfinavir (NFV)	US6205333	Bristol-Myers Squibb Company	US20010824071; 20010402; US19990288902; 199904066; US19980008925; 19980407	WO9951239 A Y 1999-10-14		BR9908810 A N 2000-12-19	CN1354545 A N 2001-12-18 CN1246113 A N 2000-09-30 CN1073464 C 2002-09-26 CN1073991 C 2001-10-31			UA72207 C N 2001-02-15		ZA200004313 A N 2001-11-07
	US5484926 C017328	Agencium Pharmaceuticals, Inc. (US)	US1993033543; 19931007; US1993033690; 19931007; US19940907094; 19940202; WO1994031397; 19941007	WO9509849 A Y 1995-04-13	AP600 A N 1997-07-23	BR9407782 A N 1997-03-18	CN1046869 C 1999-11-10 CN103942 A N 1996-09-25 CN1057375 C 2002-04-06 CN1246113 A N 2001-10-31	OK10718 A N 2001-11-02		RU2139280 C N 1999-10-10		ZA9407815 A N 1995-07-28

Drug or combination	Patents listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Antip/AP	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Nefinavir (NFV) (continued)	US5923343	Agouron Pharmaceuticals, Inc. (US)	US199248181 19924607; US1994090764 19940202; US1993033543 19931007; US1993033696 19931007; US1993037254 19931018; US1992095651 19921222	WO9509843 A Y 1995-04-13	AP600 A N 1997-07-23	BR9407782 A N 1997-03-18 BR9505161 A N 1994-11-01	CN1262272 A N 1999-11-10 CN1195777C C 2005-04-06 CN1131942 A N 1996-09-25 CN1092410 A N 1994-09-21 CN1046269C C 1999-11-10		OA10718 A N 2001-11-02	RU2139280 C N 1999-10-10		ZA9407815 A N 1996-07-08
	US6162812	Agouron Pharmaceuticals, Inc. (US)	US1992082152 19920401; US1992461813 19920607; US1994090764 19940202; US1993033543 19931007; US1993033696 19931007	WO9509843 A Y 1995-04-13	AP600 A N 1997-07-23	BR9407782 A N 1997-03-18	CN1046269C C 1999-11-10 CN1052482 A N 1996-09-25 CN1066539C C 2005-04-06 CN1131942 A N 1996-09-25 CN1628772 A N 2000-08-29		OA10718 A N 2001-11-02	RU2139280 C N 1999-10-10		ZA9407815 A N 1996-07-08
Saqumvir (SQV)	CA1340588	F. Hoffmann-La Roche & Co. Aktiengesellschaft (Switzerland)	GB19880013940 19880613; GB19880008035 19890410		Zimbabwe ZW17490 A N 1992-06-17	BR9506564 A N 1991-09-24	CN1046269C C 1999-11-10 CN1052482 A N 1996-09-25 CN1066539C C 2005-04-06 CN1131942 A N 1996-09-25 CN1628772 A N 2000-08-29		OA9334 A N 1992-09-15	RU2071470 C N 1997-01-10		ZA9500943 A N 1991-08-28
	CA2030433 US1919648	Hoffmann-La Roche Inc.	GB19880027913 19881211	WO9691942 A Y 1996-12-12		BR9506564 A N 1991-09-24						
Enfuvirtide (T20)	US6525777	Hoffmann-La Roche Inc.	EP19880212181 19881117	WO0008942 A Y 2000-05-25		BR9515444 A N 2001-08-07	CN1321535 A N 2001-12-12 CN1172049C C 2004-10-27			RU2129991 C N 2003-12-27		ZA00103891 A N 2002-08-14
	US5464933	Duke University	US19930073028 19930607	WO9442820 A Y 1994-12-22								
	US6131418	Duke University	US1992054616 19921061; US19930073028 19930607	WO9442820 A Y 1994-12-22								
	US6475491	Trimeris, Inc.	US1998077952 19980219; US19992481957 19990607; WO1996US09499 19960606	WO9640191 A Y 1996-12-19		BR9609132 A N 1999-05-04	CN1192688 A N 1998-09-09					
Amiprenavir (APV)	CA2143208	Vertex Pharmaceuticals, Incorporated (USA)	US1992041982 19920908; WO1993US08463 19930907	WO9405939 A Y 1994-09-17	AP390 A N 1995-08-02	BR1100824 A N 1999-08-31	CN1061393C C 2001-01-31 CN1087347 A N 1994-06-01			RU2135496 C N 1999-08-27		ZA9902387 A N 1997-12-10
	US583397	Vertex Pharmaceuticals, Incorporated (USA)	US1993044327 19931124; US1992041982 19920908; WO1993US08463 19930907	WO9405939 A Y 1994-09-17	AP390 A N 1995-08-02	BR1100824 A N 1999-08-31	CN1087347 A N 1994-06-01 CN1061393C C 2001-01-31			RU2135496 C N 1999-08-27		
CA2249336	Glaxo Group Limited (U.K.)	GB19960006372 19960326; US19960013899 19960322; US19970082088 19970320; WO1997EP01438 19970321	WO9735587 A Y 1997-10-02	AP150 A N 2003-03-14	BR9708238 A N 1999-08-03	CN1225587 A N 1999-08-11			OA10880 A N 2001-10-11	UA6773 C N 2004-07-15		ZA9902387 A N 1997-12-10

Drug or combination	Patents listed in the Health Canada Patent Registry and US FDA Orange Book	Patent Assignee	Priority number(s) of Patents listed in the Health Canada Patent Registry and US FDA Orange Book	WIPO (WO)	Arjep (AP)	Brazil (BR)	China (CN)	India (IN)	OMPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
AmplenaVir (APV) (continued)	US5646180	Vertex Pharmaceuticals Incorporated	US1992057199 1992205	WO9720554 A Y 1997-06-12	AP864 A N 2000-08-11	BR9611861 A N 1999-05-18	CN120330 A N 19981230		OA10691 A N 2001-05-04	RU2203658 C N 2003-05-10	UA61902 C N 20091215	ZA9610139 A N 1997-06-17
	US775490	Vertex Pharmaceuticals Incorporated	US1992424819 1992419; US1992393460 1992026; US1992042327 1992124; US1992941952 19920968	WO9440599 A Y 1994-09-17; WO9633184 A 1 1996-10-24	AP950 A N 2001-03-28; AP990 A N 1995-08-02	BR9608032 A N 1999-01-12; BR100824 A N 1999-08-31	CN118755 A N 1998-05-23 CN1007347 A N 1994-06-01 CN100399C C 2001-01-31			RU215496 C N 1999-08-27		
US6790679	SmithKline Beecham Corporation	SmithKline Beecham Corporation	US19970820248 19970320; US1996001389P 19960322	WO973587 A Y 1997-10-02	AP150 A N 2003-03-14	BR9708238 A N 1999-08-03	CN122587 A N 1999-08-11		OA10880 A N 2001-10-11			ZA9702387 A N 1997-12-10

Data compiled by B. Milani and C. Oh in April/August 2006.

Appendix 3A:

Patent search on antiretroviral drugs at the State Intellectual Property Office of the Popular Republic of China (SIPO) as of August 2006

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Patent numbers listed in Health Canada Patent Registry and USFDA Orange Book	Assignee	Information from EPO databases on China (CN) (Published application and publication date)	Information from EPO databases on China (CN) (patent numbers and issued date)	SIPO patent numbers found for the listed priorities	For patents: SIPO application date	For patents: SIPO issued date	For patents: SIPO expiry date	For patents: enforcement status indicating if, according to SIPO requirements, the patent is enforced or lapsed.	
Ritonavir (RTV)	US596075;69019961121; WO19970520794 19971112	WO9822106	Ck27196	Abbott Laboratories US	CN124894 A N 2000-09-29	CN1520219C 2006-04-12	97199780,2	1997.11.12	2006.04.12	2017.11.12	valid	
	US596075;320119961121; US595572;21619951213; WO199601520440 19961206	WO9721685	US5914332 Ck238978	Abbott Laboratories US	CN1208405 A N 1999-02-17	CN1207288C 2005-06-22	96199904,7	1996.12.6	2005.6.22	2016.12.6	valid	
	US9802078; 1981028; US98007320119961121; US995072;21619951213		US5884767	Abbott Laboratories US	CN1208405 A N 1999-02-17	CN1207288C 2005-06-22						
	US9900398; 7219990910; US99003470719990702; US997096649519971107; US9960031463P 19961121		US6521651	Abbott Laboratories US								
	US99003470719990702; US997096649519971107; US9960031463P 19961121		US549888	Abbott Laboratories US								
	US20010946685; 20010904; US20000230099P; 20000905		US6911214	Abbott Laboratories US								
	US99006167019901120; US991074602019910815; US991077766619911023		Ck205670	Abbott Laboratories US								
	US99209881; 41992129; US99301988719931202	WO9414436	Ck135890	Abbott Laboratories US								
	US99500065; 4P 19950659; US9950038&9P 19950915; WO1996015101015 19960628	WO9701349	Ck224738	Abbott Laboratories US								
	US997081600 19970720; US9980017870 19980406; US999019887 19991202; US99209881; 41992129		US5846987	Abbott Laboratories US								
	US995041316 19950929; US99209881; 41992129; US993019887 19931202; US9910777666 19911023; US9910746020 19910815; US990061670 19901120; US990038730 19900509; US9890456124 19891222; US9890405604 19890908; US9890355945 19890923		US5674882	Abbott Laboratories US								
	US99209881; 41992129; US9910777666 19911023; US990061670 19901120; US9890456124 19891222; US9890405604 19890908; US9890355945 19890923		US541206	Abbott Laboratories US								

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Assignee	Information from EPO databases on China (CN) (Published application and publication date)	Information from EPO databases on China (CN) (patent numbers and issued date)	SIPO patent numbers found for the listed priorities	For patents: SIPO application date	For patents: SIPO issued date	For patents: SIPO expiry date	For patents: enforcement status indicating if, according to SIPO requirements, the patent is enforced or lapsed.	
Ritonavir (RTV) Lopinavir (LPV) (continued)	US 59504178.9, 19950406; US 59301388.7, 19931202; US 59209811.4, 1992123; US 599107766.6, 1991103; US 5991074620, 19910815; US 590066170, 1990120; US 590008730, 19900909; US 5989045612.4, 19891222; US 598904560.4, 19890908; US 5989035945, 19890923		US565233	Abbott Laboratories US								
	US 5950410623, 19930324; US 594020210, 19940823; US 593012103, 19930914; US 599107766, 19911003; US 5991074620, 19910815; US 590008730, 1990120; US 590008730, 19900909; US 5989045612.4, 19891222; US 598904560.4, 19890908; US 5989035945, 19890923		US5648497	Abbott Laboratories US								
	US 5200195717, 20001020; US 5990387261, 19990831; US 596068774, 19960626; US 595000654P, 19950639; US 5950003849P, 19950915		US6703403	Abbott Laboratories US								
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	US 5950440277, 19950912; US 594028239, 19940729; US 5940189201, 1994012		US5484801	Abbott Laboratories US								
	US 5970822071, 19970320; US 595043136, 19950929; US 593013687, 19931202; US 592098814, 1992123		US5886056	Abbott Laboratories US								
	US 5950003849P, 19950915; US 596068774, 19960626; US 595000654P, 19950639		US6037157	Abbott Laboratories US								
	US 989043893, 19891117; US 990057900, 19900906; US 990060390, 19901019		Ck090056	Boehringer Ingelheim Pharma (DE); Thome GmbH DRK (DE)								
	US 9930091418, 19930713; US 988040970, 19880420; US 9880072974, 19880628; US 988043893, 19881117; US 990057900, 19900906; US 990060390, 19901019; US 9910740828, 19910805		US5366972	Boehringer Ingelheim Pharmaceuticals, Inc.								
	CH 98600018, 19960422; CH 99700023, 19970131		US5849911	Novartis Finance Corporation	CN121639A, 1999-05-12 CN131987A, 2001-10-31	CN108508C, 2002-04-10 CN19910C, 2005-03-16 Non-issued	9719405,8 1109494,7 200410079187,5	1997.4.4 1997.4.4 missing data	2002.4.10 2005.3.16 No patent	2017.4.14 2017.4.14	Valid Valid No patent	
	US 1998007168P, 19980120; WO 1998052782, 19981222		WO9936404	Bristol-Myers Squibb Company US	CN161643 A, N, 2005-05-18 CN183188 A, 2001-02-07	CN116282C, C, N, 2003-07-30	98812741,5	1997.4.4	2003.7.30	2017.4.14	Valid	

Drug or combination (DD)	Priority number(s) of Patent number listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Patent number listed in Health Canada Patent Registry and US FDA Orange Book	Assignee	Information from EPO database on China (CN) (Published application and publication date)	Information from EPO database on China (CN) (patent numbers and issued date)	SIPO patent numbers found for the listed priorities	For patents: SIPO application date	For patents: SIPO issued date	For patents: SIPO expiry date	For patents: enforcement status in Canada if according to SIPO requirements, the patent is enforced or lapsed.	
Arzanimir (ATV) (continued)	US198027338 1988121; US198007968P 1998020		US682783	Bristol-Myers Squibb Company	CN1283188 A 2001-02-07 CN116282C C N 2003-07-30	CN1042993C 1999-03-03	92108571	1998.7.21	1999.3.3	2007.7.21	Valid	
	US1980769016 19950826	WO9701284	CA2616044	US Health (US)								
	US19900460490 19900103	WO9109605	CA607353	US Health (US)								
	US199073167 19907022; US1990888204 19905513		CA6074215	Squibb/Bristol Myers Co. (US)	CN1068739 A N 1999-03-10	CN1042993C 1999-03-03		1998.7.21	1999.3.3	2007.7.21	Valid	
	US19870084095 19870811; US19850769016 19850826		US4861759	The United States of America as represented by the Department of Health								
	US1990865288 19910228; US1990084695 19900818; US1989420664 19890828; US19850769016 19850826; US19860937953 19861044		US5294939	U.S. Government, Dept. of Health and Human Services, c/o National								
	US1990056043 19900430; US1990665288 199010228; US19890420664 19890828; US19870084095 19870811; US19860937953 19861044; US19850769016 19850826		US5616566	The United States of America as represented by the Department of Health								
	US1990944660 19901002; US1990888204 19900515; US19910731547 19910722		US5880106	Bristol-Myers Squibb Company	CN1042993C 1999-03-03 CN1068739 A N 1999-03-10							
	US1986094666 19861217		CA193447 US4978655	Yale University								
	Stavudine (d4T)	US1990047218 19900201; WO1991US06685 1991031	WO9111186	CA6075189	Emory University (US)							
CA19922132859 19921221; US1989038101 19890208			CA6009657	BioChem Pharma Inc. (Canada)	CN1044817 A N 1990-08-22	CN1033640C 1996-12-25	90100612.2	1990.2.8	1996.12.25	2005.2.8	Valid	
US19910659760 19910222; US1990047318 19900201			US5210085	Emory University	CN1065065 A 1992.10.07	CN1037882C 1998-03-11	92101981.5	1992.2.22	11/03/1998	2007.2.22	Valid	
US199007820 19900216; US19910659760 19910222; US1990047318 19900201			US5814639	Emory University	CN1203332 A 1998.12.30	CN1084746C 2002-05-15	98108905.4	1998.05.15	15/05/2002	2018.05.15	valid	
US1990048897 19900607; US1992081103 19920212; US19910659760 19910222; US1990047318 19900201; US19910716089 19910726			US5914331	Emory University	CN112701 A 1995.07.24 2009-05-21	CN1109108C 2009-05-21	95109814.4	1995.08.18	21/05/2003	2015.08.18	valid	
				Emory University	CN148966 A N 2009-05-21	Non-issued	2144033.6	2002.09.30	No patent	No patent	No patent	No patent
				Emory University								
				Emory University								
				Emory University								
				Emory University								

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Assignee	Information from EPO databases on China (CN) (Published application and publication date)	Information from EPO databases on China (CN) (patent numbers and issued date)	SIPO patent numbers found for the listed priorities	For patents: SIPO application date	For patents: SIPO issued date	For patents: SIPO expiry date	For patents: enforcement status indicating if, according to SIPO requirements, the patent is enforced or lapsed.	
Emtricitabine (FTC) (continued)	US 595047339 19950607; US 5992083113 19920212; US 5991073689 19910726; US 5991065960 19910222; US 599047318 19900201		US6642245	Emory University	CN1037682C 1998-09-11 CN1065065 A N 1992-10-07 CN108746C C 2002-0515 CN1109108C C 2003-05-20 CN1127301 A N 1996-07-24 CN1209332 A N 1998-12-30 CN1418666 A N 2003-05-20							
	US 595040730 19950331; GB 930004741 19910304; US 599009354 19910304; US 599009354 19910304; US 599106586 19910728; US 599069396 19910222; US 599047318 19900201			US570396	Emory University	CN1037682C 1998-09-11 CN1065065 A N 1992-10-07 CN108746C C 2002-0515 CN1109108C C 2003-05-20 CN1127301 A N 1996-07-24 CN1209332 A N 1998-12-30 CN1418666 A N 2003-05-20						
Tenofovir disoproxil fumarate (TDF)	US 5970900746 19970725; US 5960022708P 19960726		US5922695	Gilead Sciences, Inc	CN155350 A N 2004-12-15	CN1251679C 2006-04-19	200410046290x	1998.7.23	2006.4.19	2018.7.23	Valid	
	US 5970900752 19970725		US5955946	Gilead Sciences, Inc	CN1264387 A N 2000-08-23	Non-issued	9880735.4	1998.7.23			No patent	
Zidovudine/ Lamivudine (AZT/3TC)	US 598018765 1981106; US 5970900746 19970725; US 5960022708P 19960726		US597089	Gilead Sciences, Inc.								
	US 5990314606 19900519; US 5970900746 19970725; US 5960022708P 19960726		US6043130	Gilead Sciences, Inc								
	GB 9910010624 19910516; GB 991001381 19911008; GB 991002381 19911108	WO9220344	Ck606790	Ciavo Group Limited	CN106870 A N 1995-02-03	CN104596C C 1999-10-27	9910483	1992.5.15	1999.10.27	2005.5.15	Valid	
	CA 92207030 19920602; GB 9910011902 19910603		Ck311988	Ciavo Group Limited								
	GB 9910011902 19910603	WO9221676	US5950282	Ciavo Group Limited								
	WO 1996140352 19960328; GB 9950006489 19950330; GB 9950006490 19950330	WO9630025	Ck216654	The Wellcome Foundation Limited (U.K.)	CN118510 A N 1998-06-17	CN110893C C 2003-03-26	961949506	1996.3.28	2003-03-26	2016.3.28	Valid	
	US 596065610 19960222; GB 9910010624 19910516; GB 991002381 19911008; GB 991002381 19911108; US 594001970 19940326; US 5992083113 19920515		US5950201	Ciavo Group Limited	CN104596C C 1999-10-27; CN106870 A N 1995-02-03							
	US 5997095565 19971093; GB 996002268 19961031; US 596002940P 19961031		US611920	Ciavo Group Limited								

Drug or combination	Priority number(s) of Patent number listed in Health Canada, Patent Registry and US FDA Orange Book	PCT applications	Patent number listed in Health Canada Patent Registry and US FDA Orange Book	Assignee	Information from EPO database on China (CN) (Published application and publication date)	Information from EPO database on China (CN) (patent numbers and issued date)	SIPO patent numbers found for the listed priorities	For patents: SIPO application date	For patents: SIPO issued date	For patents: SIPO expiry date	For patents: enforcement status in Canada if according to SIPO requirements, the patent is enforced or lapsed.
Abacavir (ABC)	US 5980455/20119891222		CA2033044	The Wellcome Foundation Limited (U.K.)	CN 105498 A N 1991-10-02	CN 1028104C C 1995-04-05	91100071	1990.12.21	05/04/1995	2005.12.21	Valid
	GB 9880105/205; 19880627		CA 140569 US 5089500 US 5094994	Burroughs Wellcome Co.							
Abacavir/ Zidovudine/ Lamivudine (ABC/AZT) (3TC)	WO 1988EP02835 19880514; GB 997009945; 19970517	WO885949	US 5694640	Claxo Wellcome Inc.	CN 1263328 A 2000.08.16	CN 1150194C C 2004-05-19	98807073.1	1988.5.14	19/05/2004	2018.5.14	Valid
	GB 9910010624 1910016; GB 9910021381 19911008; GB 9910023381 19911106	WO9220344	CA2068790	Claxo Group Ltd. (GB)	CN 151572 A N 2004-07-28	Non-issued		31029213	1988.5.14		No patent
(ABC) (3TC)	CA 992207030 19920602; GB 991001902 19910603	WO9221676	CA2311988 US 5905082	Claxo Group Ltd. (GB) Claxo Group Limited	CN 108110 A N 1998-06-17	CN 108959C C 2003-03-26	96194050.6	1986.3.28	26/05/2003	2016.3.28	valid
	WO 996EP0352 19960328; GB 995000449 19950330; GB 995000649 19950330	WO9610025	US 5471791	ClaxoSmithKline							
(ABC) (3TC)	CA 992207030 19920602; GB 991001902 19910603	WO9610025	CA2311988	Claxo Group Ltd. (GB)							
	WO 996EP0352 19960328; GB 995000449 19950330; GB 995000649 19950330	WO9610025	US 5471791	ClaxoSmithKline	CN 103953C C 2003-03-26 CN 1081510 A N 1998-06-17						
Lamivudine (3TC)	GB 990000865 19900902; WO 991 GB07006 19910502	WO9117159	CA2059263	IAF BioChem Int. (Canada)	CN 108855 A 1995.09.20	CN 1056145C C 2000-09-06	94109429.4	1994.8.15	06/09/2000	2014.8.15	Valid
	CA 9922132659 19921221; US 9890208101 19890208	WO9221676	CA2004657 US 047407	BioChem Pharma, Inc.	CN 1326743 A 2001.12.19	CN 1154509C C 2004-06-23	9912680.7	1994.8.15	23/06/2004	2014.8.15	Valid
Indinavir (IDV)	GB 991001902 19910603	WO9221676	CA2070230 US 5905082	Claxo Group Limited	CN 1058214 A 1992.01.29	CN 1036196C C 1997-10-22	91102778.5	1991.4.30	22/10/1997	2006.4.30	Valid
	GB 9970066395 19970326; US 9970042333P 19970324; WO 1988EP01626 19880320	WO8842321	CA2386126	Claxo Group Limited	CN 1044817 A N 1990-08-22	CN 1033640C C 1996-12-25	90100612.2	1990.2.8	25/12/1996	2005.2.8	Valid
Indinavir (IDV)	GB 9910000359 19910103; GB 9910009912 19910307; WO 1992-Ch00001 19920103	WO9211852	CA 100266 (Ilep B) US 532246	IAF BioChem Int. (CA)	CN 1191061C C 2005-03-02	CN 1191061C C 2005-03-02	98805122.2	1988.3.20	2005-03-02	2018.3.20	Valid
	US 991009508 19911008; US 992088385 19920515	WO9309066	CA2081970	Merck & Co., Inc.	CN 1955849 A N 2000-06-07						
Indinavir (IDV)	US 991009508 19911008; US 992088385 19920515	WO9309066	CA2081970	Merck & Co., Inc.	CN 1176350 A N 1998-09-18	seen as rejected (1999.08.11)	97100833	1997.2.1	no patent		seen as rejected (1999.08.11)
	US 9910040729 19930331; US 992088385 19920515; US 991078508 19911108	WO9309066	US 5413999	Merck & Co., Inc.	CN 126469 A N 1996-07-10	seen as rejected (1999.08.11)	94196591	1994.4.26	no patent		seen as rejected (1999.08.11)

PATENT INFORMATION AND TRANSPARENCY: A Methodology for Patent Searches on Essential Medicines in Developing Countries

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Patent numbers listed in Health Canada Patent Registry and USFDA Orange Book	Assignee	Information from EPO databases on China (CN) (Published application and publication date)	Information from EPO databases on China (CN) (Patent numbers and issued date)	SIPO patent numbers found for the listed priorities	For patents: SIPO application date	For patents: SIPO issued date	For patents: SIPO expiry date	For patents: enforcement status indicating requirements, the patent is enforced or lapsed.	
Indinavir (IDV) (continued)	US198004885; 19980304; US197004058P; 19970507		US5645361	Merck & Co., Inc.	CN120316 A N 1996-04-10	CN1090186C 2002-09-04	94191071	1994.3.24	2002.09.04	2014.03.24	valid	
	US199508213; 19950201	WO962399	US6689761	Merck & Co., Inc.	CN1179722 A N 1998-04-22	CN1160081C 2004-08-04	961929103	1996.1.29	04/08/2004	2016.1.29	valid	
Efavirenz (EFV)	US1993054805; 19930427; US1920926607; 19920807	WO9409440	C6101572	Merck & Co., Inc.	CN1350652 A N 2000-04-19	Non-issued	991181085	1999.8.20	no patent		No patent	
	US1995045828; 19950602; US1940188005; 19940128; US1992054805; 19920427; US19920926607; 19920807		US519021	Merck & Co., Inc.	CN1221608 A 1999.07.07	CN1070595C 2009-05-07	98121399.x	1998.10.10	07/05/2003	2018.10.10	valid	
	US1993028274; 19930311; US198008824; 19801205; US1997037385P; 19970205; US1997044280P; 19970408; US2001000037; 2001019		US563169	Merck & Co., Inc.	CN1090277 A 1994-08-03	CN1051767C 2000-04-26	93117660.3	1993.8.6	26/04/2000	2013.8.6	valid	
	US1990082744; 19900311; US198008824; 19801205; US1997037385P; 19970205; US1997044280P; 19970408; US2001000037; 2001019		US56519071	Merck & Co., Inc.	CN1350652 A N 2000-04-19	CN1070595C 2009-05-07						
	US20040891749; 20040624; US20030447690; 20030229; US2001000037; 2001019; US1999028274; 19990311; US198008824; 19801205; US1997037385P; 19970205; US1997044280P; 19970408		US5811423	Merck & Co., Inc.	CN1350652 A N 2000-04-19	CN1070595C 2009-05-07						
	US1990082744; 19900311; US198008824; 19801205; US1997037385P; 19970205; US1997044280P; 19970408; US2001000037; 2001019		US65318695	Merck & Co., Inc.	CN138425 A N 2002-12-18	CN191242C 2005-03-02	11227095	1998.2.2	2005-03-02	2018.2.2	2018.2.2	valid
	US20040891749; 20040624; US20030447690; 20030229; US2001000037; 2001019; US1999028274; 19990311; US198008824; 19801205; US1997037385P; 19970205; US1997044280P; 19970408		US6931964	Bristol-Myers Squibb Company	CN1246113 A 2000-03-01	CN1070595C 2009-05-07	98820371.4	1998.2.2	2001-10-31	2018.2.2	valid	
	US1990082744; 19900311; US198008824; 19801205; US1997037385P; 19970205; US1997044280P; 19970408		US65318695	DuPont Pharmaceuticals Company	CN106512 A N 2001-03-23	CN1146419C 2004-04-21	99804801.1	1999.4.1	2004-04-21	2019.4.1	2019.4.1	valid
Nelfinavir (NFV)	US1993013383; 19931007; US1993013596; 19931007; US1940188005; 19940128; WO19940511507; 19941007	WO9509843	US5461925; C6217328	Agenon Pharmaceuticals, Inc. (US)	CN131942 A 1996-09-25	CN1046269C 1999-11-10	9419354.5	1994.10.7	10/11/1999	2014.10.7	valid	
	US199508181; 19950607; US1940188005; 19940128; US1993013383; 19931007; US1993013596; 19931007; US1993013724; 19931008; US1992095621; 19921222		US595243	Agenon Pharmaceuticals, Inc. (US)	CN1263272 A 2000-08-09	CN195737C 2005-04-06	99105164.5	1994.10.7	06/04/2005	2014.10.7	2014.10.7	valid

Drug or combination	Priority number(s) of Patent number(s) listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Patent number listed in Health Canada Patent Registry and US FDA Orange Book	Assignee	Information from EPO database on China (CN) (Published application and publication date)	Information from EPO database on China (CN) (patent numbers and issued date)	SIPO patent numbers found for the listed priorities	For patents: SIPO application date	For patents: SIPO issued date	For patents: SIPO expiry date	For patents: enforcement status in force if according to SIPO requirements, the patent is enforced or lapses.
Nefinavir (NFV) (continued)	US 5990283; 5990401; US 5950483; 5950607; US 5940907; 5940202; US 5930338; 5931007; US 5930338; 5931007		US 5616282	Azurion Pharmaceuticals, Inc. (US)	CN131942 A N 1996-09-25; CN126272 A N 2000-08-09	CN1046269C C 1999-11-10	94193534.5	1994.10.7	1999-11-10	2014.10.7	valid
	GB 9880013940 1988063; GB 9890008035 19890410		CA 1340588	F. Hoffmann-La Roche & Co. Aktiengesellschaft (Switzerland)	CN1052482 A 1991.06.26	CN1034809C C 1997-05-07	90109391.7	1990.12.10	07/05/1997	2015.12.10	valid
	GB 9890073028 19930607		CA 0904431 US 5196438	Hoffmann-La Roche Inc.	CN1138885 A 1997.01.01	CN1066339C C 2001-05-30	961074663	1990.12.10	2001-05-30	2015.12.10	valid
	US 9950468493; 1995066; US 99606633; 19960507; WO 1996E P0421 19960604	WO 9659142	US 5600828; CA 224125	Hoffmann-La Roche Inc.	CN186434 A N 1998-09-01	CN1092966C C 2002-10-23	9619427	1996.6.4	23/10/2002	2016.6.4	valid
	EP 9880121831 19981117	WO 0028942	US 6392717	Hoffman-La Roche Inc.	CN132633 A N 2001-12-12	CN1172649C C 2004-10-27	99813395.7	1999.11.11	27/10/2004	2019.11.11	valid
Entinivir (T20)	US 9930073028 19930607	WO 9448920	US 5464933	Duke University							
	US 9950546 16 19951106; US 9930073028 19930607		US 6133418	Duke University							
	US 998097952 19980939; US 9950481957 19950607; WO 1996US 09499 19960606	WO 9405659	CA 0143208	Trimeris, Inc.	CN192688 A N 1998-09-09	rejecter (2006-04-05)	96196051	1996.6.6	no patent	2013.9.8	rejected (2006 04 05)
Amiprenavir (APV)	US 993014237 1993124; US 920941982 1992098; WO 1993US 0448 19930907	WO 9405659	US 5985997	Vertex Pharmaceuticals, Incorporated (USA)	CN108747 A N 1994-06-01	CN106139C C 2001-01-31	9317370.1	1993.9.8	31/01/2001	2013.9.8	valid
	GB 986006372 19860246; US 996001893P 19960322; US 997080848 19970220; WO 1997EP 01438 19970231	(WO 9735587)	CA 0248336	Vertex Pharmaceuticals, Incorporated (USA)	CN123587 A N 1999-08-11	Non-issued	9719229.8	1997.3.21	no patent	2013.9.8	valid
	US 995067199 19951205	WO 972054	US 5646180	Glaxo Group Ltd. (GB)	CN108747 A N 1994-06-01	CN106139C C 2001-01-31	9317370.1	1993.9.8	31/01/2001	2013.9.8	valid
	US 995042481 0 19950419; US 995093460 19960223; US 993014237 1993124; US 9920941382 19920908			Vertex Pharmaceuticals Incorporated	CN20330 A N 1998-12-30	seen as withdrawn (2003-8-13)	9619886.9	1996.12.5	No patent		seen as withdrawn (2003-8-13)
				Vertex Pharmaceuticals Incorporated	CN108747 A N 1994-06-01	CN106139C C 2001-01-31	9317370.1	1993.9.8	31/01/2001	2013.9.8	valid
				SmithKline Beecham Corporation	CN18755 A N 1998-05-13	seen as withdrawn (2001-07-23)	96193364	1996.04.18	no patent		seen as withdrawn (2001-07-23)

Data collected from SIPO in August-October 2006 by B. Mflani.

Appendix 3B:

Patent search on antiretroviral drugs at the Companies and Intellectual Property Registration Office of South Africa (CIPRO) as of November 2006

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and USFDA Orange Book	Information from EPO databases on CIPRO (ZA) (Published application/ patent and publication date)	CIPRO application numbers found for the listed priorities	CIPRO patent numbers found for the listed priorities	Application date	For patents: issued date	For patents: expiry date	For patents: enforcement status indicating if, according to CIPRO requirements, the patent is enforced or lapsed.	
Ritonavir (RTV) / Lopinavir (LPV)	US 5960753; 6901996; 1121; WO/97/05079; 941997/112	WO9822106	Abbott Laboratories US	CA27196	ZA97/0071 A N 1998-05-25	1997/10071	1997/10071	07/11/1997	29/07/1998	07/11/2007	in force	
	US 5960753; 2011996; 1121; US 5960753; 2161995; 1121; WO 1996/0520440 1996/1206	WO9721685	Abbott Laboratories US	US 5914332; CA2238978	ZA96/0475 A N 1997-07-31	1996/10475	1996/10475	12/12/1996	29/10/1997	12/12/2006	in force	
	US 598020787; 1998/1208; US 5960753; 2011996; 1121; US 5960753; 2161995; 1121		Abbott Laboratories US	US 5824767	ZA96/0475 A N 1997-07-31	1996/10475	1996/10475	12/12/1996	29/10/1997	12/12/2006	in force	
	US 5990347071 19990704; US 5970966495 19971107; US 596031463P 19961121		Abbott Laboratories US	US 5623165								
	US 5990347071 19990704; US 5970966495 19971107; US 596031463P 19961121		Abbott Laboratories US	US 5458818								
	US 5990347071 19990704; US 5970966495 19971107; US 596031463P 19961121		Abbott Laboratories US	US 5691214								
	US 5990347071 19990704; US 5970966495 19971107; US 596031463P 19961121		Abbott Laboratories US	CA2053670								
	US 5990347071 19990704; US 5970966495 19971107; US 596031463P 19961121		Abbott Laboratories US	CA2735890								
	US 5990347071 19990704; US 5970966495 19971107; US 596031463P 19961121		Abbott Laboratories US	CA2224738								
	US 5990347071 19990704; US 5970966495 19971107; US 596031463P 19961121		Abbott Laboratories US	US 5846987								
	US 5990347071 19990704; US 5970966495 19971107; US 596031463P 19961121		Abbott Laboratories US	US 5674882								
	US 5990347071 19990704; US 5970966495 19971107; US 596031463P 19961121		Abbott Laboratories US	US 541206								
	US 5990347071 19990704; US 5970966495 19971107; US 596031463P 19961121		Abbott Laboratories US									
	US 5990347071 19990704; US 5970966495 19971107; US 596031463P 19961121		Abbott Laboratories US									
	US 5990347071 19990704; US 5970966495 19971107; US 596031463P 19961121		Abbott Laboratories US									

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information from EPO databases on CIPRO (ZA) (Published Application/ Patent and publication date)	CIPRO application numbers found for the listed priorities	CIPRO patent numbers found for the listed priorities	Application date	For patents: issued date	For patents: expiry date	For patents: enforcement status in force, if according to CIPRO requirements, the patent is enforced or lapsed.	
Ritonavir (RTV) / Lopinavir (LPV) (continued)	US 595504178; 919550406; US 593019887; 19931202; US 592098814; 19921229; US 599107766; 19911033; US 599107460; 19910815; US 599066170; 1990120; US 599058730; 19900509; US 5989456124; 19891222; US 5989049604; 19890908; US 5989035945; 19890933		Abbott Laboratories US	US 5635933								
	US 5955041063; 19930324; US 594027820; 19940625; US 593021169; 19930914; US 599107766; 19911033; US 599066170; 1990120; US 599058730; 19900509; US 5989456124; 19891222; US 5989049604; 19890908; US 5989035945; 19890933		Abbott Laboratories US	US 5648497								
	US 2001095717; 20010920; US 599038726; 19990831; US 598608774; 19860626; US 5995000654P; 19950639; US 5995000389P; 19950915		Abbott Laboratories US	US 6703403								
	US 597096649; 19971097; US 596051463P; 19961121		Abbott Laboratories US	US 6332333								
	US 5955044077; 19950912; US 594028239; 19940729; US 5940189021; 1994012		Abbott Laboratories US	US 548480								
	US 597082071; 19970320; US 59504339; 19950929; US 59301989; 19931202; US 592098814; 19921229		Abbott Laboratories US	US 5886956								
	US 5955000389P; 19950915; US 598608774; 19860626; US 5995000654P; 19950639		Abbott Laboratories US	US 6637157								
	US 5989048993; 19891117; US 5990579001; 19900906; US 5990660390; 19901019			CA 990056	Z49009246 A N 1992-07-29	1990/09246	1990/09246	19/11/1990	29/07/1992	19/11/2010	in force	
	US 599309148; 19930713; US 5989040970; 19890420; US 5989037974; 19890628; US 5989048993; 19891117; US 5990579001; 19900906; US 5990660390; 19901019; US 59910740828; 19910805		Boehringer Ingelheim Pharmaceuticals, Inc.	US 5366972	Z49004991 A N 1992-09-25	1990/04991	1990/04991	27/06/1990	25/03/1992	27/06/2010	in force	
	CH 9560001018; 19960422; CH 9570000229; 19970131				Z49009246 A N 1992-07-29	1990/09246	1990/09246	19/11/1990	29/07/1992	19/11/2010	in force	
	US 598007968P; 19981001; WO 99/0152732; 19981222	WO 9956404	Novartis Finance Corporation	US 5849911	Z49703387 A N 1997-10-22	1997/03387	1997/03387	21/04/1997	31/12/1997	21/04/1997	in force	
	US 598007958; 19981221; US 598007968P; 19981001		Bristol-Myers Squibb Company US	CA 317796	Z49900056 A N 2000-07-05	1999/00056	1999/00056	05/01/1999	27/09/2000	05/01/2019	in force	
	US 5985076916; 19850826	WO 9701284	US HEALTH (US)	CA 1269044	Z49900056 A N 2000-07-05	1999/00056	1999/00056	05/01/1999	27/09/2000	05/01/2019	in force	
	US 5990046490; 19900103	WO 9109605	US HEALTH (US)	CA 307573								

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information from EPO databases on CIPRO (ZA) (Published application/ patent and publication date)	CIPRO application numbers found for the listed priorities	CIPRO patent numbers found for the listed priorities	Application date	For patents: issued date	For patents: expiry date	For patents: enforcement status indicating if, according to CIPRO requirements, the patent is enforced or lapses.	
Didanosine (DDI) (continued)	US 5191073347 1910722; US 51920882204 1920513		Squibb Bristol Myers Co. (US)	CA2074215	ZA9205484 A N 1993-09-13	1992/05484	1992/05484	21/07/1992	24/11/1993	21/07/2012	in force	
	US 51970084055 1970811; US 51950769010 19350826		The United States of America as represented by the Department of Health	US 5861759								
	US 519910663288 19910228; US 519870084055 19870811; US 519890426664 19890828; US 519850769016 19850826; US 519860097925 19861204		U.S. Government, Dept. of Health and Human Services, c/o National	US 5254039								
	US 51930056042 19300430; US 51910663288 1910228; US 51950426664 19890828; US 51970084055 1970811; US 51980097925 19801204; US 51950769016 19350826		The United States of America as represented by the Department of Health	US 5161666								
	US 519970942660 19970022; US 51920882204 1920513; US 5191073347 1910722		Bristol-Myers Squibb Company	US 5280106	ZA9205484 A N 1993-09-13	1992/05484	1992/05484	21/07/1992	24/11/1993	21/07/2012	in force	
	US 519860942666 19861217		Yale University	CA293447 US4978655	ZA8707171 A N 1988-09-24	1987/07171	1987/07171	23/09/1987	25/05/1988	23/09/2007	in force	
	US 51900047318 19000201; WO 1991 US 06685 19910131	WO 9111186	Emory University (US)	CA2075189								
	CA 922132 269 1921221; US 51950908101 1950908		BioChem Pharma Inc. (Canada)	CA2000657	ZA9000943 A N 1990-10-31	1990/00943	1990/00943	08/02/1990	31/10/1990	08/02/2010	in force	
	US 519010659760 19101022; US 51990047318 19000201		Emory University	US 5210085	ZA9201351 A N 1993-08-20	1992/01351	1992/01351	20/02/1992	27/10/1993	20/02/2012	in force	
	US 5193007820 19301016; US 519910659760 19101022; US 51990047318 19000201		Emory University	US 5384639	ZA9201351 A N 1993-08-20	1992/01351	1992/01351	20/02/1992	27/10/1993	20/02/2012	in force	
	US 51902048807 19850607; US 51920881163 19920212; US 519010659760 19101022; US 51900047318 19000201; US 5191073347 1910726		Emory University	US 51914331	ZA8201351 A N 1993-08-20	1992/01351	1992/01351	20/02/1992	27/10/1993	20/02/2012	in force	
	US 51995047339 19950607; US 51920881163 19920212; US 519910736089 19910726; US 519910659760 19101022; US 51990047318 19000201		Emory University	US 56642245	ZA9201351 A N 1993-08-20	1992/01351	1992/01351	20/02/1992	27/10/1993	20/02/2012	in force	
	US 51902047318 19000201; CA 910009101 19100906; US 5190202244 19820715; US 5191073347 1910726; US 519010659760 19101022; US 51990047318 19000201		Emory University	US 5703936	ZA8201351 A N 1993-08-20	1992/01351	1992/01351	20/02/1992	27/10/1993	20/02/2012	in force	
US 51970900746 19707975; US 5196002708P 19360726		Gilead Sciences, Inc	US 5392495	ZA9201688 A N 1993-09-06	1992/01688	1992/01688	05/03/1992	24/11/1993	05/03/2012	in force		
US 51970900752 19970723		Gilead Sciences, Inc	US 5393946									
US 51980187761 19811065; US 51970900746 19707975; US 5196002708P 19360726		Gilead Sciences, Inc.	US 5377089									

Drug or combination	Priority number(s) of Patent number(s) listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information from EPO databases on CIPO (ZA) (Published Application/ Patent and Publication date)	CIPO application numbers found for the listed priorities	CIPO patent numbers found for the listed priorities	Application date	For patents: issued date	For patents: expiry date	For patents: enforcement status in force, if according to CIPO requirements, the patent is enforced or lapses.
Tenofovir Disoproxil fumarate (TDF) (continued)	US 19990314606 19990519; US 19970900746 19970725; US 1996022708P 19960726		Gilead Sciences, Inc	US604339							
	GB 9910010624 19990516; GB 991002381 19991106; GB 991002381 19991106	WO9220344	Claeo Group Limited	CA2068790	Z4920344 A N 1993-03-31	1992/03544	1992/03544	15/05/1992	31/03/1993	15/05/2012	in force
Zidovudine (AZT) / Lamivudine (3TC)	CA 992207030 19920602; GB 9910011902 19910603		Claeo Group Limited	CA3311888	Z49204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	GB 9910011902 19910603	WO9221676	Claeo Group Limited	US590582	Z49204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
Abacavir (ABC) / Zidovudine (AZT) / Lamivudine (3TC)	WO 1996E P0352 19960328; GB 995000489 19950330; GB 9950006490 19950330	WO9650025	The Wellcome Foundation Limited (U.K.)	CA2216654	Z49602477 A N 1997-10-28	1996/02477	1996/02477	28/03/1996	31/12/1997	28/03/2016	in force
	US 1996060560 19960222; GB 9910010624 19990516; GB 991002381 19991106; GB 991002381 19991106; US 994021976 19940328; US 9920883169 19920515		Claeo Group Limited	US5859021	Z49203544 A N 1993-03-31	1992/03544	1992/03544	15/05/1992	31/03/1993	15/05/2012	in force
Abacavir (ABC) / Zidovudine (AZT) / Lamivudine (3TC)	US 9890455201 19891222; GB 9880019565 19880827		The Wellcome Foundation Limited (U.K.)	CA2033044	Z49100565 A N 1992-08-26	1990/0365	1990/0365	27/12/1990	26/08/1992	27/12/2010	in force
	WO 1998E P02835 19980514; GB 9970009946 19970517	WO9852949	Claeo Wellcome Inc.	US694640	Z49804083 A N 1999-11-15	1998/04083	1998/04083	14/05/1998	26/01/2000	14/05/2018	in force
Abacavir (ABC) / Zidovudine (AZT) / Lamivudine (3TC)	GB 9910010624 19990516; GB 991002381 19991106; GB 991002381 19991106	WO9220344	Claeo Group Limited (GB)	CA2068790	Z49203544 A N 1993-03-31	1992/03544	1992/03544	15/05/1992	31/03/1993	15/05/2012	in force
	CA 992207030 19920602; GB 9910011902 19910603	WO9221676	Claeo Group Limited (GB)	CA3311888	Z49204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
Abacavir (ABC) / Lamivudine (3TC)	WO 1996E P0352 19960328; CA 995000489 19950330; GB 9950006490 19950330	WO9650025	ClaeoSmithKline	US5417191	Z49602477 A N 1997-10-28	1996/02477	1996/02477	28/03/1996	31/12/1997	28/03/2016	in force
	WO 1996E P0352 19960328; GB 995000489 19950330; GB 9950006490 19950330	WO9650025	ClaeoSmithKline	US5417191	Z49602477 A N 1997-10-28	1996/02477	1996/02477	28/03/1996	31/12/1997	28/03/2016	in force
Lamivudine (3TC)	GB 9910011902 19910603; WO 1991 GB0706 19910502	WO9221676	Claeo Group Limited	US590582	Z49204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	CA 992212669 19921221; US 9890028101 19890208	WO9117159	JAF BioChem International Inc.(Canada)	CA200943	Z4900943 A N 1990-10-31	1991/0943	1991/0943	30/04/1991	26/02/1992	30/04/2001	in force

PATENT INFORMATION AND TRANSPARENCY: A Methodology for Patent Searches on Essential Medicines in Developing Countries

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information from EPO databases on CIPO (ZA) (Published application/ patent and publication date)	CIPO application numbers found for the listed priorities	CIPO patent numbers found for the listed priorities	Application date	For patents: issued date	For patents: expiry date	For patents: enforcement status indicating if, according to CIPO requirements, the patent is enforced or lapsed.	
Lamivudine (3TC) (continued)	GB 19910011902; 1991 0463	WO921676	Ciavo Group Limited	CA2070230; US5950582	Z4924007 A N 1993-04-28	1992/0407	1992/0407	02/06/1992	28/04/1993	02/06/2012	in force	
	GB 19970066235; 199702616; US 1997004233P; 199702616; WO 1998EP01626; 199802620	WO9842321	Ciavo Group Limited	CA288126	Z49802367 A N 1998-09-26	1998/02367	1998/02367	19/05/1998	24/11/1999	19/05/2018	in force	
	GB 19910000039; 199101031; GB 19910009913; 199105077; WO 1992CA00001; 199201093	WO9211822	IAF BioChem Int. (CA)	CA2100269 (hep B) US5322246								
	US 1997004233P; 199702616; GB 19910011902; 1991 0463	WO9842321	Ciavo Wellcome Inc.	US5004988	Z49802367 A N 1998-09-26	1998/02367	1998/02367	19/05/1998	24/11/1999	19/05/2018	in force	
	US 19910785608; 199111088; US 1992088385; 199202015	WO9309096	Merck & Co., Inc.	CA2081970	Z49208163 A N 1993-05-05	1992/08163	1992/08163	06/11/1992	30/07/1993	06/11/2012	in force	
	US 19930592518; 199305077; US 19930040725; 199303311; US 1992088385; 199202015; US 19910785608; 199111088		Merck & Co., Inc.	US5413999	Z49208163 A N 1993-05-05	1992/08163	1992/08163	06/11/1992	30/07/1993	06/11/2012	in force	
	US 1998004688; 199800044; US 1997004015P; 199709207		Merck & Co., Inc.	US6645961	Z49403104 A N 1995-11-06	1994/03104	1994/03104	30/03/1994	28/12/1994	30/03/2014	lapsed	
	US 19950582113; 199502021	WO9623909	Merck & Co., Inc.	US6689761	Z49600722 A N 1996-08-26	1996/00722	1996/00722	31/01/1996	30/10/1996	31/01/2016	lapsed	
	US 1993054805; 199304027; US 19920924667; 199208067	WO9405440	Merck & Co., Inc.	CA2101572	Z49305724 A N 1994-09-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force	
	US 1995054805; 199505602; US 1994088003; 19940218; US 1993054805; 19930427; US 19920924667; 199208067		Merck & Co., Inc.	US5519021	Z49305724 A N 1994-09-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force	
US 1995054805; 199505602; US 1994088003; 19940218; US 1993054805; 19930427; US 19920924667; 199208067		Merck & Co., Inc.	US565169	Z49305724 A N 1994-09-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force		
US 19990282744; 199903311; US 199800824; 19980120; US 199703735P; 19970205; US 1997004287P; 19970408; US 2001000537; 2001019		Merck & Co., Inc.	US6539071	Z49305724 A N 1994-09-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force		
US 20040891749; 20040624; US 20030447690; 20030259; US 2001000537; 2001019; US 19990282744; 199903311; US 199800824; 19980120; US 199703735P; 19970205; US 1997004287P; 19970408		Bristol-Myers Squibb Company	US6539964									
US 19990282744; 19990406; US 199800824P; 19980407		DuPont Pharmaceuticals Company	US623695	Z490004313 A N 2001-11-07	2000/04313	2000/04313	22/08/2000	30/01/2002	22/08/2020	in force		
US 20010824071; 20010402; US 19990282744; 19990406; US 199800824P; 19980407		Bristol-Myers Squibb Company	US6555133	Z490004313 A N 2001-11-07	2000/04313	2000/04313	22/08/2000	30/01/2002	22/08/2020	in force		

Drug or combination	Priority number(s) of Patent number listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information from EPO database on CIPO (ZA) (Published application/ patent and publication date)	CIPO application numbers found for the listed priorities	CIPO patent numbers found for the listed priorities	Application date	For patents: issued date	For patents: expiry date	For patents: enforcement status in force, if according to CIPO requirements, the patent is enforced or lapsed.	
Nelfinavir (NFV)	US1993013343 19931007; US1993013366 19931007; US19940190764 19940202; WO1994A151307 19941007	WO9503843	Agouron Pharmaceuticals, Inc. (US)	US2484926 CA2173328	Z4940785 A N 1996-07-08	1994/0785	1994/0785	06/10/1995	28/08/1996	06/10/2015	in force	
	US1995048181 19950607; US19940190764 19940202; US1993013383 19931007; US1993013724 19931008; US1992095821 19921222		Agouron Pharmaceuticals, Inc. (US)	US595243	Z4940785 A N 1996-07-08	1994/0785	1994/0785	06/10/1995	28/08/1996	06/10/2015	in force	
	US19990283152 19990401; US1995048181 19950607; US19940190764 19940202; US1993013383 19931007; US1993013366 19931007		Agouron Pharmaceuticals, Inc. (US)	US6162812	Z4940785 A N 1996-07-08	1994/0785	1994/0785	06/10/1995	28/08/1996	06/10/2015	in force	
	GB198801946 1988061; GB199000859 19900410		F. Hoffmann-La Roche & Co. Aktiengesellschaft (Switzerland)	CH340588	Z48904285 A N 1996-02-28	1989/04285	1989/04285	06/06/1989	28/02/1990	06/06/2009	in force	
	GB1989027913 19891211		Hoffmann-La Roche Inc.	CA2094438 US5196438	Z49009743 A N 1991-08-28	1990/09743	1990/09743	04/12/1990	28/08/1991	04/12/2010	in force	
	US1995048181 19950606; US1996018331 19960507; WO1996EPO421 19960604	WO9659142	Hoffmann-La Roche Inc.	US5608228 CA2224125	Z46604448 A N 1996-12-06	1996/04448	1996/04448	30/05/1996	26/02/1997	30/05/2016	in force	
	EP19820121831 19821117	WO0028942	Hoffmann-La Roche Inc.	US532717	Z4200103891 A N 2002-08-14	2001/03891	2001/03891	14/05/2001	30/10/2002	14/05/2021	in force	
	US19930073028 19930607	WO9428920	Duke University	US464933								
	US1995054616 19951106; US19930073028 19930607		Duke University	US6133418								
	US19980973952 19980299; US1995048181 19950607; WO19950509499 19960606		Trimeris, Inc.	US547491								
Amprnavir (APV)	US1992094182 19920908; WO1993US048 19930907	WO9405639	Vertex Pharmaceuticals, Incorporated (USA)	CA2143208								
	US1993044237 19931124; US1992094182 19920908; WO1993US048 19930907	WO9405639	Vertex Pharmaceuticals, Incorporated (USA)	US595397								
	GB198606372 19860316; US199601833P 19960322; US1997028048 19970210; WO1997EPO1438 19970231	(WO9755587)	Clao Group Limited (U.K.)	CA2249386	Z49702387 A N 1997-12-10	1997/02387	1997/02387	19/03/1997	25/02/1998	19/03/2017	in force	
	US1995067199 19951205	WO9720554	Vertex Pharmaceuticals Incorporated	US564680	Z4660139 A N 1997-06-17	1996/0139	1996/0139	03/12/1996	27/08/1997	03/12/2016	lapsed	
	US199504248 19950419; US1995093466 19950223; US19930142827 19931124; US1992094182 19920908		Vertex Pharmaceuticals Incorporated	US5723490								
US1997028048 19970210; US199601833P 19960322		SmithKline Beecham Corporation	US670679	Z49702387 A N 1997-12-10	1997/02387	1997/02387	19/03/1997	25/02/1998	19/03/2017	in force		

Data collected from CIPO in November 2006 by B. Milani.

Appendix 3C:

Patent search on antiretroviral drugs conducted by Lawyers Collectives at the Indian Patent Offices as of October 2006.

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information sourced by EPO internal databases for India (IN)	Application numbers found for the listed priorities by Lawyers Collective	Application date	For patents: issued date	For patents: expiry date	For patents: enforcement status indicating if, according to Indian patent office requirements, the patent is enforced or lapsed. For applications: as applicable.
Ritonavir (RTV)	US1996075499; 19961121; WO1997/052079; 19971112	WO9822106	Abbott Laboratories US	Ck27196						
	US1996075320; 19961121; US1995072426; 19951213; WO1996/052040; 19961206	WO9721685	Abbott Laboratories US	US9914332 Ck238978						
	US1998020787; 19981208; US1996075320; 19961121; US1995072426; 19951213	o	Abbott Laboratories US	US884767						
	US1990039872; 19900910; US1990034707; 19900702; US19970366495; 19971107; US19960031463P; 19961121	o	Abbott Laboratories US	US6321619						
	US1999034707; 19990702; US19970366495; 19971107; US19960031463P; 19961121	o	Abbott Laboratories US	US498818						
	US2000023909P; 20000905	o	Abbott Laboratories US	US691214						
	US1990061670; 19901120; US1991074620; 19910815; US1991077766; 19911023	o	Abbott Laboratories US	Ck2051670						
	US1992098114; 19921229; US1993013887; 19931202	WO9414436	Abbott Laboratories US	Ck2135890						
	US1995000654P; 19950639; US1995003849P; 19950915; WO1996/0511015; 19960628	WO9701349	Abbott Laboratories US	Ck2224738						
	US1997081609; 19970320; US199500417892; 19950406; US1993013887; 19931202; US1992098114; 19921229	o	Abbott Laboratories US	US846987						
	US1995041336; 19950323; US1992098114; 19921229; US1993013887; 19931202; US1991077766; 19911023; US1991074620; 19910815; US1990061670; 19901120; US1990018730; 19900509; US19890456124; 19891122; US19890405604; 19890908; US19890355945; 19890923	o	Abbott Laboratories US	US674882						
	US1995043387; 19950945; US1993013887; 19931202; US1992098114; 19921229; US1991077766; 19911023; US1990061670; 19901120; US1990018730; 19900509; US19890456124; 19891122; US19890405604; 19890908; US19890355945; 19890923	o	Abbott Laboratories US	US541206						

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent number listed in Health Canada Patent Registry and US FDA Orange Book	Information sourced by EPO in internal databases for India (IN)	Application numbers found for the listed priorities by Lawyers Collective	Patent numbers found for the listed priorities by Lawyers Collective	Application date	For patents: issued date	For patents: expiry date	For patents: enforcement status indicating if applicable, if the patent is enforced or lapsed. For applications: as applicable.	
Ritonavir (RTV) / Lopinavir (LPV) (continued)	US 1995041787, 199504066, US 1993015887, 199312002, US 1992098114, 199212239, US 1991077766, 199110033, US 1991074620, 199108155, US 1990066170, 199011200, US 1990058730, 199005059, US 19890458124, 198912222, US 19890405604, 198909088, US 19890355945, 198909133	0	Abbott Laboratories US	US 5635293								
	US 19950410631, 199503244, US 199403760, 199408254, US 1993017161, 199309144, US 1992017166, 199216466, US 1991071600, 199103187, US 1990066170, 199011200, US 1990058730, 199005059, US 19890458124, 198912222, US 19890405604, 198909088, US 19890355945, 198909133	0	Abbott Laboratories US	US 5648497								
	US 20010957171, 200101020; US 19990387261, 199908311; US 19980687774, 199806246; US 1995000654P, 199506395; US 1995003849P, 19950915	0	Abbott Laboratories US	US 6703403								
	US 1997096648, 199710071; US 1996051465P, 199610121	0	Abbott Laboratories US	US 6333333								
	US 19950440277, 199509124; US 1994028239, 199407295; US 19940189021, 1994012	0	Abbott Laboratories US	US 5484801								
	US 1997082071, 199703200; US 1995043130, 199509230; US 1993013830, 199312002, US 1992098114, 199212239	0	Abbott Laboratories US	US 886056								
	US 1995003849P, 19950915; US 199608774, 199606246; US 1995000654P, 199506395	0	Abbott Laboratories US	US 6637157								
	US 1996043893, 199611171; US 1996073001, 199609066; US 1996060390, 199610119	0	Abbott Laboratories US	Ch 090056								
	US 1993091418, 199307133; US 1989040970, 198904200; US 1989037374, 198906246; US 1989043893, 198911171; US 19900579001, 199009066; US 19900600390, 199010195; US 19910740828, 199108055	0	Boehringer Ingelheim Pharmaceuticals, Inc.	US 566972	2485/DEL/1998			24/08/1998				Under examination, pre grant opposition filed
	CH 199600010 B, 19960422; CH 199700022, 1997031	0	Novartis Finance Corporation	US 549911	807/MAS/1997			21.04.1997				Under examination, pre grant Opposition filed
	US 198807968P, 19880200; WO 1988US27382, 19881222	WO9336404	Bristol-Myers Squibb Company US	Ch 317736								
	US 1988021738, 19881221; US 198807968P, 19880200	0	Bristol-Myers Squibb Company	US 608735								
	US 19890769106, 19890826	WO9701284	Us Health (US)	Ch 269044								
	US 19900460490, 19900103	WO9109605	Us Health (US)	Ch 072573								

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information sourced by EPO Internal databases for India (IN)	Application numbers found for the listed priorities by Lawyers Collective	Patent numbers found for the listed priorities by Lawyers Collective	Application date	For patents: issued date	For patents: expiry date	For patents: enforcement status indicating if, according to Indian patent office requirements, the patent is enforced or lapsed. For applications: as applicable.	
Didanosine (DD) (continued)	US 5991073347 19910722; US 5992082204 19920513	0	Squibb Bristol Myers Co. (US)	CA074215								
	US 5997008405 19970811; US 5997059010 19950826	0	The United States of America as represented by the Department of Health	US 586759								
	US 5991066328 19910228; US 5987008405 19970811; US 5989042664 19890828; US 5989769016 19890826; US 59860097925 19861004	0	U.S. Government, Dept. of Health and Human Services, c/o National	US 5954039								
	US 5990056043 19900430; US 5991066328 19910228; US 5990420664 19890828; US 5997008405 19970811; US 59860097925 19861004; US 5989769016 19890826	0	The United States of America as represented by the Department of Health	US 5616566								
	US 59970942660 19970022; US 5992082204 19920513; US 5991073347 19910722	0	Bristol-Myers Squibb Company	US 5880106								
	US 59860942666 19861217	0	Yale University	CA 993447 US 497855								
	US 5990047318 19900201; WO 1991 US 00685 19910131	WO 911186	Emory University (US)	CA 073189								
	CA 192215269 1921221; US 599030810 1990208	0	Biochem Pharma Inc. (Canada)	CA 000957								
	US 5991069760 19910222; US 5990047318 1990201	0	Emory University	US 9210085								
	US 5993007820 19930216; US 5991069760 19910222; US 5990047318 1990201	0	Emory University	US 814659								
	US 5995048897 19950607; US 5992081103 19920212; US 5991069760 19910222; US 5990047318 1990201; US 59910716289 19910726	0	Emory University	US 9914331								
	US 5995047339 19950807; US 5992081103 19920212; US 59910716289 19910726; US 5991069760 19910222; US 5990047318 1990201	0	Emory University	US 642245								
	US 59950402701 19950313; GB 19910004741 19910906; GB 19910009304 19910902; US 59930022428 19930715; US 59910716289 19910726; US 5991069760 19910222; US 5990047318 1990201	0	Emory University	US 6709396								
	US 59970900746 19970725; US 5996002708P 19960726	0	Gilead Sciences, Inc	US 592695								
US 59970900752 19970725	0	Gilead Sciences, Inc	US 935946	IN 199780 A N 896/DEL/2002 A			09/04/2002				Under Examination, pre grant Opposition filed	
US 5998018765 1988106; US 59970900746 19970725; US 5996002708P 19960726	0	Gilead Sciences, Inc.	US 977089									

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Tenofovir Disoproxil fumarate (TDF) (continued)	US 19990314606, 199905191, US 19970900746, 199707251, US 19960022708P, 199607746	0	Gilead Sciences, Inc	US 624,330							
Zidovudine (AZT) / Lamivudine (3TC)	GB 9910010624, 199105161, GB 991002381, 199111061, GB 991002381, 199111061, CA 992207030, 199206021, GB 9910011902, 199106031, GB 9910011902, 199106031	WO 9220344	Claxo Group Limited	Claxo 68790							
	US 996065610, 199602221, GB 991002381, 199111061, GB 991002381, 199111061, GB 991002381, 199111061, US 994020175, 199402381, US 994020175, 199402381, US 994020175, 199402381, US 994020175, 199402381	0	Claxo Group Limited	Claxo 311888							
	US 997095535, 199710931, GB 996002268, 19961031, US 9960029240P, 19961031	WO 9221676	Claxo Group Limited	US 950582							
Abacavir (ABC)	US 998945320, 19891222	WO 9610025	The Wellcome Foundation Limited (U.K.)	Claxo 216654		2044/CAL/1997		28/10/1997			Withdrawn, Application Rejected
	GB 9880015265, 19880627	0	The Wellcome Foundation Limited (U.K.)	Claxo 03044							
	WO 1998EP02851, 199805141, GB 997000946, 19970517	WO 985249	Burnhoughs Wellcome Co.	CA 134089, US 9808900, US 9804894							
Abacavir (ABC)/ Zidovudine (AZT) / Lamivudine (3TC)	WO 1998EP02851, 199805141, GB 997000946, 19970517, GB 9910010624, 199105161, GB 991002381, 199110081, GB 991002381, 199111061	WO 9220344	Claxo Wellcome Inc	US 5954540		872/CAL/1998		14/05/1997			Under examination, pre grant Opposition filed
	CA 992207030, 199206021, GB 9910011902, 199106031, GB 9910011902, 199106031	0	Claxo Group Ltd (GB)	Claxo 68790							
	WO 1996EP0352, 19960328, GB 9950000449, 199503301, GB 9950000449, 199503301, GB 9950000449, 199503301	WO 9221676	Claxo Group Limited	Claxo 311888							
Abacavir (ABC)/ Lamivudine (3TC)	WO 1996EP0352, 19960328, GB 9950000449, 199503301, GB 9950000449, 199503301, GB 9950000449, 199503301	WO 9610025	ClaxoSmithKline	US 5417191							
	CA 992207030, 199206021, GB 9910011902, 199106031	0	Claxo Group Ltd (GB)	Claxo 311888							
	WO 1996EP0352, 19960328, GB 9950000449, 199503301, GB 9950000449, 199503301, GB 9950000449, 199503301	WO 9610025	ClaxoSmithKline	US 5417191							
Lamivudine (3TC)	GB 990009861, 199009021, WO 1991GB00700, 199105021, CA 992213246, 19921221, US 19890018101, 198900208	WO 9117159	1uf Biochem International Inc. (Canada)	Claxo 052453							
	US 19890018101, 198900208	0	BioChem Pharma, Inc.	Claxo 009637, US 9047407							

PATENT INFORMATION AND TRANSPARENCY: A Methodology for Patent Searches on Essential Medicines in Developing Countries

Drug or combination	Priority number(s) of Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	PCT applications	Assignee	Patent numbers listed in Health Canada Patent Registry and US FDA Orange Book	Information sourced by EPO Internal databases for India (IN)	Application numbers found for the listed priorities by Lawyers Collective	Application date	For patents: issued date	For patents: expiry date	For patents: enforcement status indicating if, according to Indian patent office requirements, the patent is enforced or lapsed. For applications: as applicable.
Lamivudine (3TC) (continued)	GB 991001902; 9910603	WO921676	Cisao Group Limited	CA2070390 US5905082						
	GB 997006295; 99702616; US 997004233P; 9970324; WO 9981EPO1626; 9980920	WO9842321	Cisao Group Limited	CA280126						
	GB 991000039; 99101091; GB 991000913; 9910507; WO 9921CA0001; 99210103	WO9211852	Inf Biochem Int (CA)	CA1002619 (hep B) US5322246						
	US 997004233P; 9970324 GB 991001902; 9910603	WO9842321	Cisao Wellcome Inc.	US5004968	479/CAL/1998	23/05/1998 A				No opposition have been filed yet, no request for examination filed.
	US 991078568; 9911108; US 992088385; 9920515	WO9309096	Merck & Co., Inc.	CA2081970						
	US 993005958; 9930507; US 993004075; 9930311; US 992088385; 9920515; US 991078568; 9911108	o	Merck & Co., Inc.	US413999						
	US 998004688; 9980304; US 997004015P; 9970907	o	Merck & Co., Inc.	US6646961						
	US 995038213; 9950201	WO962399	Merck & Co., Inc.	US6689761						
	US 993054805; 9930427; US 9920246607; 9920807	WO9409440	Merck & Co., Inc.	CA2101572						
	US 995046026; 9950602; US 9940188001; 9940282; US 9930054805; 9930427; US 9920246607; 9920807	o	Merck & Co., Inc.	US519021						
US 995043828; 9950502; US 9940188001; 9940282; US 9930054805; 9930427; US 9920246607; 9920807	o	Merck & Co., Inc.	US5665169							
US 997081780; 9970312; US 995043829; 9950602; US 9940188001; 9940282; US 9930054805; 9930427; US 9920246607; 9920807	o	Merck & Co., Inc.	US811433							
US 999028274; 9990931; US 998008824; 9980120; US 997003738P; 9970205; US 997004287P; 9970408; US 9910000537; 2001019	o	Merck & Co., Inc.	US6639071							
US 9904689749; 20040624; US 99039447690; 200392959; US 9901000337; 2001019; US 999028274; 9990331; US 998008824; 9980120; US 997003738P; 9970205; US 997004287P; 9970408	o	Bristol-Myers Squibb Company	US639964							
US 999028692; 9990406; US 9980088925P; 9980407	o	DuPont Pharmaceuticals Company	US638695							
US 99010824071; 20010402; US 999028692; 9990406; US 9980088925P; 9980407	o	Bristol-Myers Squibb Company	US6553133							

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Nefinavir (NFV)	US19930133843 199310077; US19930133656 199310077; US19940190764 19940202; WO1994A1511307 19941007	WO9505843	Agouron Pharmaceuticals, Inc. (US)	US484926 CA2173328								
	US19950481831 199506077; US19940190764 19940202; US19930133843 199310077; US19930133656 199310077; US19920958261 19921222	0	Agouron Pharmaceuticals, Inc. (US)	US5952348								
	US19900283152 19900401; US19950481831 199506077; US19940190764 19940202; US19930133843 199310077; US19930133656 199310077	0	Agouron Pharmaceuticals, Inc. (US)	US6162812								
	GB1988013946 19880613; GB199000829 19900410	0	F. Hoffmann-La Roche & Co. Aktiengesellschaft (Switzerland)	Ch340588								
	GB19890027913 19891211	0	Hoffmann-La Roche Inc.	CA09483 US5196438	IN17253 A N 1993-09-25							
	US19950481831 19950606; US1996008231 19960907; WO1996F0042# 19960604	WO9659142	Hoffmann-La Roche Inc.	US560828 Ch224125	IN92899 A N 2004-05-29							
	EP19980121831 19981117	WO0028942	Hoffmann-La Roche Inc.	US6592717								
	US19930073028 19930607	WO9478920	Duke University	US464933								
	US1995054616 19951106; US19930073028 19930607	0	Duke University	US6133418								
	US19880071851 19880298; US19920481897 19920607; WO1996US9499 19960606	0	Trimeris, Inc.	US6475491								
Amiprenavir (APV)	US1992094182 19920908; WO1991US04848 19930907	WO9405619	Vertex Pharmaceuticals, Incorporated (USA)	CA143208								
	US1993014237 19931146; US199041082 19900908; WO1993US04848 19930907	WO9405619	Vertex Pharmaceuticals, Incorporated (USA)	US558397								
	GB1996006372 19960316; US1996003893P 19960322; US1997082048 19970320; WO1997EP01438 19970321	(WO9735587)	Gilead Group Limited (U.K.)	CA249336	727/De/1/1997				21/05/1997			Under Examination, Pre grant Opposition filed
	US19950567199 19951205	WO9710554	Vertex Pharmaceuticals Incorporated	US646180								
	US19950424819 19950419; US1995093460 19950223; US1993014237 19931146; US1992094182 19920908	0	Vertex Pharmaceuticals Incorporated	US723490								
US1997082048 19970320; US1996003893P 19960322	0	SmithKline Beecham Corporation	US730679	727/De/1/1997				21/05/1997			Under Examination, Pre grant Opposition filed	

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Additional patent data on antiretroviral drugs collected by Lawyers Collective India in October 2006

Drug or combination	Patent Title	Priority number(s) provided by Lawyers collective	Priority numbers from expected for the PCT applications	Assignee	Patent numbers Health Canada Orange Book	WIPO (WO)	Information sourced by EPO internal databases for India (IN)	Application numbers found for the listed priorities by Lawyers Collective	Patent numbers found for the listed priorities by Lawyers Collective	Application date	For patents issued date	For patents expiry date	For patents enforcement status indicating if according to Indian Patent office requirements, the patent is enforced or lapsed. For applications as applicable, Has been abandoned
Ritonavir (RTV) / Lopinavir (LPV)	Kaletra	US19990325826 19990604	US1998008888P 19980611	Abbott Laboratories US		WO0074677	IN/PCT/2001/01312/MUM			22/10/2001			For patents enforcement status indicating if according to Indian Patent office requirements, the patent is enforced or lapsed. For applications as applicable, Has been abandoned
Efavirenz	A Process for Preparing Form 1 of Crystalline Efavirenz	60/0288081 19980611 WO1999/05199 19990610	US1998008888P 19980611	Bristol Myers Squibb Pharma Company Ltd.		WO9964405	IN/PCT/2000/00553/MUM			27/10/2000			Awaiting information from Mumbai patent office
	A Process for Preparing Form 2 of Crystalline Efavirenz	60/0288081 19980611 WO1999/05199 19990610	US1998008888P 19980611	Bristol Myers Squibb Pharma Company Ltd.		WO9964405	IN/PCT/2000/00553/MUM	718/MUMNP/2003 (Divisional application of IN/PCT/2000/00553/MUM)		21/07/2003			Request for examination has been filed on 28/12/2005
	A Process for Preparing Form 4 of Crystalline Efavirenz	US1998008888P 19980611 US19990529421 19990610 US19990529421 19990610	US1998008888P 19980611	Bristol Myers Squibb Pharma Company Ltd.		WO9964405	IN/PCT/2000/00553/MUM	737/MUMNP/2003 (Divisional application of IN/PCT/2000/00553/MUM)		25/07/03			No request has been made for examination
Combination of efavirenz and saquinavir	Condensed Naphthyridines as HIV Reverse Transcriptase Inhibitors (Tricyclic Compounds Useful in Reverse Transcriptase Inhibitors)	US19990603219 19990109 US20000226171 20000817 US200001019 US200002498	US199901603219P 19990109 US20000226171P 20000817	Bristol Myers Squibb Pharma Company Ltd.		WO0129037	IN/PCT/2002/00570/MUM (PCT/CA) 00890			05/06/2002			No request for examination has been made
Nevirapine (Improment)	Non Nucleoside Reverse Transcriptase Inhibitors	US20000123293 20000616 US20000256938 1999001218 US200202807	US20000123293P 20000616; US20000256938P 20001218	Boehringer Ingelheim Ltd.		WO0195358	IN/PCT/2002/01622/MUM (PCT/CA) 00890			22/10/2002			Awaiting information from Mumbai patent office
Ritonavir (RTV) (Polymorph)	Ritonavir (RTV)	US1998119345 19980720 US19990326093 19990604	US1998119345 19980720; US19990326093 19990604	Abbott Laboratories US		WO0004016	PCT/2001/00018/MUM			03/04/2005			FER issued on 10.10.2006, 2 oppositions have been filed
Lopinavir (Crystalline form)	Lopinavir (Product Patent)	US200038257 20000330, US20010793536 20010227	US2000038257 20000330; US20010793536 20010227	Abbott Laboratories US		WO0174787	IN/PCT/02/01243/MUM			09/11/2002			FER issued on 16.10.2006, 2 oppositions have been filed
Lopinavir	Lopinavir (Process Patent)	US20000651919 20000831	US20000651919 20000831	Abbott Laboratories US		WO0218349	559/MUMNP/2003 A			24/02/2003			Request for examination has been filed on 29/12/2005
Fosamprenavir	Lexiva (Calcium (5S) Tetrahydro-3-Funaryl (1S,2R)-3-[[4-(Aminophenyl) Sulphonyl] (Isobutyl) Amino]-1-Benzyl-2-(Phosphonoxy) Propylcarbamate)	9815674 (WO1999EP04991 19990705; GB1998005567 19980718)	GB1998005567 19980718	Glaxo Group Limited		WO0004033	IN/PCT/2001/00099			01/10/2001			Under Examination, no oppositions filed yet
Combination of amprenavir zidovudine and abacavir	Antiviral Combinations	60/0221		Glaxo Group Limited			1206(CA)/1997 A			03/11/2005			Request for examination has not been filed

Data collected from the Indian Patent Offices in October 2006 by Lawyers Collective.

Where patents pose a barrier, the Doha Declaration on the TRIPS Agreement and Public Health, signed by WTO Members in 2001 had confirmed that governments can and should use measures known as the TRIPS public health flexibilities, to ensure access to affordable medicines. However, patent information is sometimes difficult to obtain, especially in developing countries. With the release of this Methodology, UNDP aims to facilitate pharmaceutical patent searches for a broad array of stakeholders in developing countries, including health authorities and procurement agencies. The present Methodology allows quick searches from publicly available, free of charge sources of information. It thereby supports the sustainable procurement and supply of essential medicines, as well as the informed and effective use of the TRIPS Agreement public health flexibilities.



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