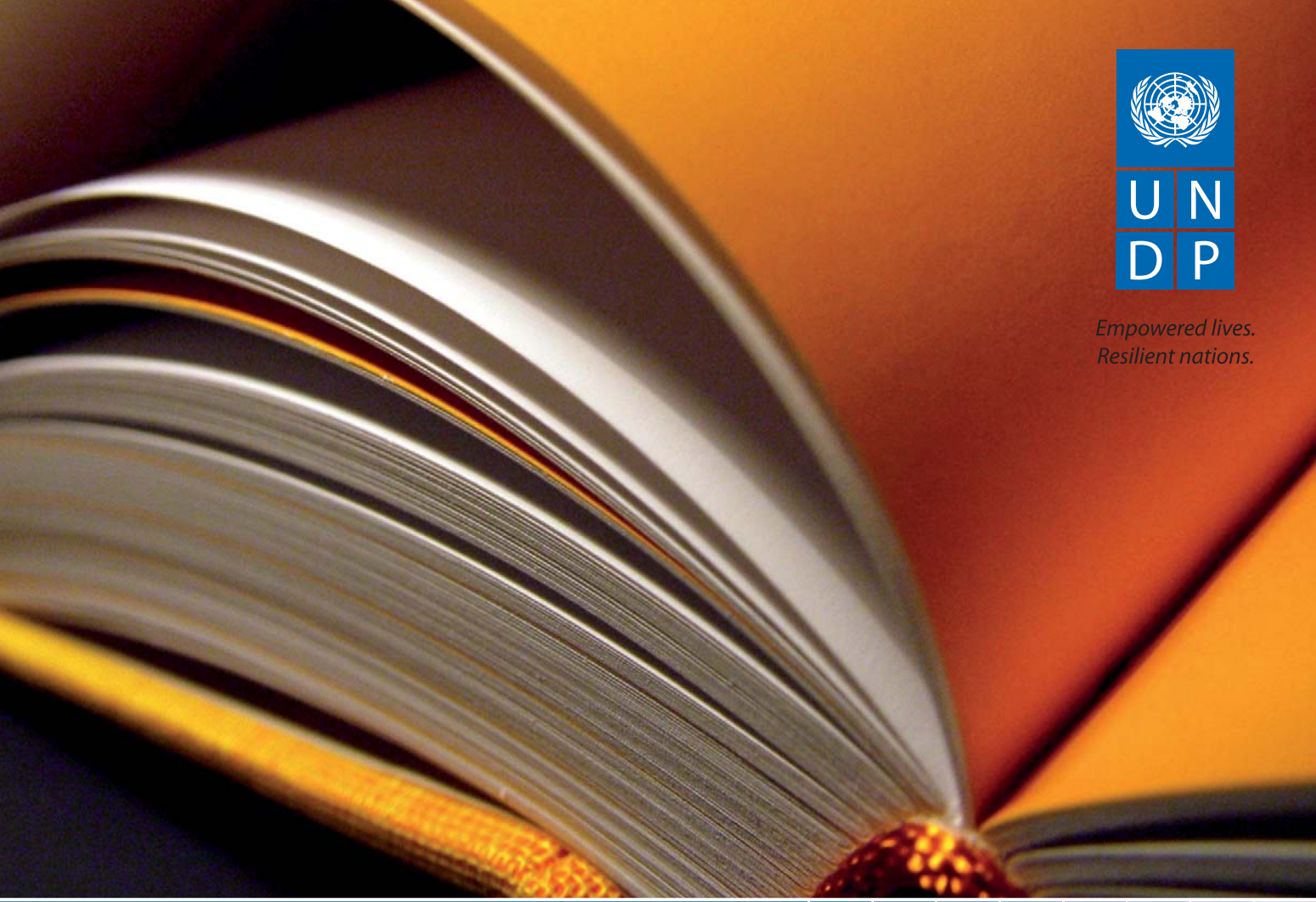

United Nations Development Programme

HIV/AIDS

PATENT INFORMATION AND TRANSPARENCY:

A Methodology for Patent Searches on Essential Medicines in Developing Countries

July 2012

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A Methodology for Patent Searches on Essential Medicines in Developing Countries

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Table of Contents

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 Médicins 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 un published 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.

The contribution of the expert participants at the UNDP-WHO-EPO consultation is also acknowledged: Frederick Abbott (Florida State University, USA), Tahir Amin (I-MAK), Tenu Avafia (UNDP), Anne Bowes (Office of Patented Medicines and Liaison, Health Canada, Canada), Pascale Boulet (DNDi), Carlos Correa (University of Buenos Aires, Argentina), Mandeep Dhaliwal (UNDP), Bertrand Gellie (European Patent Office), KM *Gopakumar (Third World Network),* Lisa Hamelmann (UNDP), Alexandra Heumber *(*Médicins Sans Frontières), Warren Kaplan (Boston University School of Public Health), John Kabare (ARIPO), Kostantinos Karachalios (European Patent Office), Boyan Konstantinov (UNDP), Oliver Langer (European Patent Office), Luciana Mermet (UNDP), Savita Mullapudi Narasimhan (UNDP), Jeffrey O'Malley (UNDP), Chan Park (Medicines Patent Pool), Daniel Ravicher (Public Patent Foundation), Renata Reis (Associação Interdisciplinar de AIDS, Brazil) Anthony So (Program on Global Health and Technology Access, Duke University), Ellen t'Hoen (Medicines Patent Pool), Gérman Velasquez (South Centre) and Robert Weissman (Essential Information).

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 faciltiate 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

Step 1

Search for relevant patents in US FDA Orange Book and Health Canada Patent Registry

↓

Step 2

Search for priotity patent data from Esp@ceNet, cross-checked against patent data from US FDA Orange Book and Health Canada

↓

Step 3

Ascertain corresponding patent families in countries of interest from INPADOC database

↓

Step 4

Verify patent status at national or regional patent offices

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 country[2]. 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 patents[3].

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 states[4]. The Eurasian Patent Office similarly administers a uniform

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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 declining[6]. 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 protection[8]. 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

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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 substances[9].

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 registers[10]. 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 capacity[13]. It highlighted that the smaller patent offices in devel-

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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 period[14] 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 applications[15]. This, despite the comparatively larger numbers of examiners, numbering up to 150[16]. 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 functions[17]. 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 examiners[18].

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.

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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 documents[19] 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-destroying[20]. 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 available[21]. 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 refused[22]. 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

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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 Plus[23] 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:

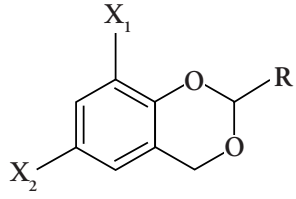
- molecular formula and structural diagram searching;
- name searching using the IUPAC nomenclature
- compound searching using the CAS Registry Numbers;
- generic name searching (INN); and
- search using the WIPO's International Patent Classification (IPC).

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 databases[24] 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 documents[25]. 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 compounds[26].

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.

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[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 phosphonomethoxy nucleotide analogs with carbonates and/or carbamates having the structure -OC(R2)2OC(O)X(R)a, wherein R2 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 OR3 in which R3 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 OR3*, R4 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 OR3".

3.3 CAS Registry Numbers

Since 1907, the Chemical Abstracts Society has reviewed scientific journal and patent literature and allocates CAS numbers to those documents[27]. 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 nomenclatures[28]. 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 spelling[29], are now globally recognized and public property.

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27 Coverage of the patents in CAS can be found at http://www.cas.org/EO/patyear.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 Agreement[30], a multilateral treaty administered by WIPO. The IPC, in its 8th edition[31], 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 30[32] 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 sales[33]. 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 patent[34], 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

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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 competition[35]. This is particularly the case for developing countries – where capacity may not be present for the proper management and monitoring of the system[36].

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 product[37]. 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.

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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 exclusivity[38]. 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 dates[39] within 30 days after approval of a New Drug Application (NDA) or supplement to an NDA, or within 30 days after issuance of a patent[40]. 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 product[41].

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-process[42] and polymorph patents[43].

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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/cfcfr/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 unit[44]. 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 product[45]. 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 application[46]. "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 Book[47]. 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 Book[48], 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 listed[49].

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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 patents[50]. The agency simply relies on the patent owner's signed declaration stating that the patent covers an approved drug product's formulation, composition or use[51].

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 formulations[52]. 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

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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-mps/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 product[54]. 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 patent[55]. 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 owner[56].

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 claims[57]:

- 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.

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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 Register[60]:

- 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].

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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 member[64]. The first filing will from then on always be linked to the day on which the filing was made; i.e., the priority date.

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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 country[66]. A broader definition involves those cases where the applications have at least one priority in common[67]. 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 patents[68]. 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.

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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 offices[69].

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 families[70]. 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 updated[71].

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

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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 database[72]. 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 WIPO[74]. 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.

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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 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 bringing 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 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 Médicins 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 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)	CA2271196	Abbott Laboratories US	US19960754390 19961121; WO1997US20794 19971112	WO9822106 A Y 1998-05-28		BR9714310 A N 2000-05-02	CN1248914 A N 2000-03-29					ZA9710071 A N 1998-05-25
	US5914332 CA2238978	Abbott Laboratories US	US19960753201 19961121; US19950572226 19951213; WO1996US20440 19961206	WO9721683 A Y 1997-06-19 WO9721685 A Y 1997-06-19		BR1100397 A N 2000-04-11	CN1207288C C 2005-06-22 CN1208405 A N 1999-02-17					ZA9610475 A N 1997-07-31
	US6284767	Abbott Laboratories US	US19980207873 19981208; US19960753201 19961121; US19950572226 19951213	WO9721683 A Y 1997-06-19 WO9721685 A Y 1997-06-19		BR1100397 A N 2000-04-11	CN1207288C C 2005-06-22 CN1208405 A N 1999-02-17					ZA9610475 A N 1997-07-31
	US6521651	Abbott Laboratories US	US19990393872 19990910; US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121		no family found							
	US6458818	Abbott Laboratories US	US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121		no family found							
	US6911214	Abbott Laboratories US	US20010946085 20010904; US20000230095P 20000905		no family found							
Ritonavir (RTV) / Lopinavir (LPV)	CA2055670	Abbott Laboratories US	US19900616170 19901120; US19910746020 19910815; US19910777626 19911023									
	CA2135890	Abbott Laboratories US	US19920998114 19921229; US19930158587 19931202	WO9414436 A Y 1994-07-07								
	CA2224738	Abbott Laboratories US	US19950000654P 19950629; US19950003849P 19950915; WO1996US11015 19960628	WO9701349 A Y 1997-01-16								
	US5846987	Abbott Laboratories US	US19970821609 19970320; US19950417879 19950406; US19930158587 19931202; US19920998114 19921229	WO9414436 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)	OAPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Ritonavir (RTV) / Lopinavir (LPV) (continued)	US5674882	Abbott Laboratories US	US19950413136 19950329; US19920998114 19921229; US19930158687 19931202; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19894056124 19891222; US19894056043 19890908; US19890355945 19890523	WO9414436 A Y 1994-07-07								
	US5541206	Abbott Laboratories US	US19950423387 19950425; US19930158687 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19894056124 19891222; US19894056043 19890908; US19890355945 19890523	WO9414436 A Y 1994-07-07								
	US5635523	Abbott Laboratories US	US19950417879 19950406; US19930158687 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19894056124 19891222; US19894056043 19890908; US19890355945 19890523	WO9414436 A Y 1994-07-07								
	US5648497	Abbott Laboratories US	US19950410623 19950324; US19940270210 19940823; US19930121673 19930914; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19894056124 19891222; US19894056043 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)	OAPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Ritonavir (RTV) / Lopinavir (LPV) (continued)	US6703403	Abbott Laboratories US	US20010957171 20010920; US19990387261 19990831; US19960687774 19960626; US19950000654P 19950629; US19950003849P 19950915	WO9701349 A Y 1997-01-16								
	US6232333	Abbott Laboratories US	US19970966495 19971107; US19960031463P 19961121									
	US5484801	Abbott Laboratories US	US19950440277 19950512; US19940283239 19940729; US19940189021 1994012	WO9520384 A Y 1995-08-03								
	US5886036	Abbott Laboratories US	US19970822071 19970320; US19950413136 19950329; US19930158587 19931202; US19920998114 19921229	WO9701349 A Y 1997-01-16								
	US6037157	Abbott Laboratories US	US19950003849P 19950915; US19960687774 19960626; US19950000654P 19950629	WO9701349 A Y 1997-01-16								
Nevirapine (NVP)	CA2030056		US19890438923 19891117; US19900579001 19900906; US19900600390 19901019		AP179 A N 1992-04-30				OA9852 A - 1994-08-15	RU2040527 C N 1995-07-25		ZA9009246 A N 1992-07-29
	US5366972	Boehringer Ingelheim Pharmaceuticals, Inc.	US19930091418 19930713; US19890340970 19890420; US19890372974 19890628; US19890438923 19891117; US19900579001 19900906; US19900600390 19901019; US19910740828 19910805		AP189 A N 1992-05-04 AP179 A N 1992-04-30				OA9852 A - 1994-08-15 OA9741 A N 1993-11-30	RU2024522 C N 1994-12-15 RU2040527 C N 1995-07-25		ZA9004991 A N 1992-03-25 ZA9009246 A N 1992-07-29
Atazanavir (ATV)	US5849911	Novartis Finance Corporation	CH19960001018 19960422; CH19970000223 19970131	WO9740029 A Y 1997-10-30		BR9701877 A N 1998-09-29	CN1082508C C 2002-04-10 CN1193010C C 2005-03-16 CN1216539 A N 1999-05-12 CN1319587 A N 2001-10-31 CN1616453 A N 2005-05-18					ZA9703387 A N 1997-10-22
	CA2317736	Bristol-Myers Squibb Company US	US19980071968P 19980120; WO1998US27382 19981222	WO9936404 A Y 1999-07-22		BR9814736 A N 2000-10-24	CN1283188 A 2001-02-07 CN1116282C C N 2003-07-30			RU2186070 C N 2002-07-27		ZA9900056 A N 2000-07-05
	US6087383	Bristol-Myers Squibb Company	US19980217538 19981221; US19980071968P 19980120	WO9936404 A Y 1999-07-22		BR9814736 A N 2000-10-24	CN1283188 A 2001-02-07 CN1116282C C N 2003-07-30			RU2186070 C N 2002-07-27		ZA9900056 A N 2000-07-05
Didanosine (DDI)	CA1269044	US HEALTH (US)	US19850769016 19850826	WO8701284 A Y 1987-03-12								
	CA2072573	US HEALTH (US)	US19900460490 19900103	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)	OAPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Didanosine (DDI) (continued)	CA2074215	SQUIBB BRISTOL MYERS CO (US)	US19910733547 19910722; US19920882204 19920513				CN1042299C C 1999-03-03 CN1068739 A N 1993-02-10			RU2089193 C N 1997-09-10		ZA9205484 A N 1993-09-13
	US4861759	The United States of America as represented by the Department of Health	US19870084055 19870811; US19850769016 19850826	WO8701284 A Y 1987-03-12								
	US5254539	U.S. Government, Dept. of Health and Human Services, c/o National	US19910663288 19910228; US19870084055 19870811; US19890420664 19890828; US19850769016 19850826; US19860937925 19861204	WO8701284 A Y 1987-03-12								
	US5616566	The United States of America as represented by the Department of Health	US19930056043 19930430; US19910663288 19910228; US19890420664 19890828; US19870084055 19870811; US19860937925 19861204; US19850769016 19850826	WO8701284 A Y 1987-03-12								
	US5880106	Bristol-Myers Squibb Company	US19970942660 19971002; US19920882204 19920513; US19910733547 19910722				CN1042299C C 1999-03-03 CN1068739 A N 1993-02-10			RU2089193 C N 1997-09-10		ZA9205484 A N 1993-09-13
Stavudine (D4T)	CA1293447 US4978655	Yale University	US19860942666 19861217									ZA8707171 A N 1988-03-24
Emtricitabine (FCT)	CA2075189	Emory University (US)	US19900473318 19900201, WO1991US00685 19910131	WO9111186 A Y 1991-08-08						RU2125558 C N 1999-01-27		
	CA2009637	Biochem Pharma INC (Canada)	CA19922152269 19921221; US19890308101 19890208		AP136 A N 1991-08-05		CN1033640C C 1996-12-25 CN1044817 A N 1990-08-22		OA9193 A N 1992-06-30	RU2092485 C N 1997-10-10		ZA9000943 A N 1990-10-31
	US5210085	Emory University	US19910659760 19910222; US19900473318 19900201	WO9111186 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 CN1065065 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 CN1418966 A N 2003-05-21			RU2125558 C N 1999-01-27		ZA9201251 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(AP)	Brazil (BR)	China (CN)	India (IN)	OAPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Emtricitabine (FCT) (continued)	US5814639	Emory University	US19930017820 19930216; US19910659760 19910222; US19900473318 19900201	WO9111186 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 CN1065065 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 CN1418966 A N 2003-05-21			RU2125558 C N 1999-01-27		ZA9201251 A N 1993-08-20
	US5914331	Emory University	US19950488097 19950607; US19920831153 19920212; US19910659760 19910222; US19900473318 19900201; US19910736089 19910726	WO9111186 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 CN1065065 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 CN1418966 A N 2003-05-21			RU2125558 C N 1999-01-27 RU2235724 C N 2004-09-10		ZA9201251 A N 1993-08-20
	US6642245	Emory University	US19950475339 19950607; US19920831153 19920212; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201	WO9111186 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 CN1065065 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 CN1418966 A N 2003-05-21			RU2125558 C N 1999-01-27 RU2235724 C N 2004-09-10		ZA9201251 A N 1993-08-20
	US6703396	Emory University	US19950402730 19950313; GB19910004741 19910306; GB19910009505 19910502; US19930092248 19930715; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201	WO9111186 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 CN1065065 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 CN1418966 A N 2003-05-21			RU2116789 C N 1998-08-10 RU2125558 C N 1999-01-27		ZA9201251 A N 1993-08-20 ZA9201658 A N 1993-09-06
Tenofovir Disoproxil fumarate (TDF)	US5922695 (CA2261619)	Gilead Sciences, Inc	US19970900746 19970725; US19960022708P 19960726	WO9804569 A Y 1998-02-05								
	US5935946	Gilead Sciences, Inc	US19970900752 19970725	WO9905150 A Y 1999-02-04		BR9811045 A N 2000-08-22	CN1554350 A N 2004-12-15 CN1264387 A N 2000-08-23 CN1745755	IN190780 A N 2003-08-23				

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)
Tenofovir Disoproxil fumarate (TDF) (continued)	US5977089	Gilead Sciences, Inc.	US19980187763 19981106; US19970900746 19970725; US19960022708P 19960726	WO9804569 A Y 1998-02-05								
	US6043230	Gilead Sciences, Inc.	US19990314606 19990519; US19970900746 19970725; US19960022708P 19960726	WO9804569 A Y 1998-02-05								
Zidovudine (AZT) / Lamivudine (3TC)	CA2068790	Glaxo Group Limited	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344 A Y 1992-11-26			CN1045961C C 1999-10-27 CN1068570 A N 1993-02-03		OA10058 A N 1996-10-14	RU2139059 C N 1999-10-10		ZA9203544 A N 1993-03-31
	CA2311988	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	RU2102393 C N 1998-01-20		ZA9204007 A N 1993-04-28
	US5905082	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
	CA2216634	The Wellcome Foundation Limited (U.K.)	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025 A Y 1996-10-03	AP652 A N 1998-06-19	BR9607851 A N 1998-07-21	CN1103593C C 2003-03-26 CN1185110 A N 1998-06-17		OA10616 A N 2001-03-15			ZA9602477 A N 1997-10-28
	US5859021	Glaxo Group Limited	US19960605610 19960222; GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106; US19940219176 19940328; US19920883169 19920515	WO9220344 A Y 1992-11-26			CN1045961C C 1999-10-27 CN1068570 A N 1993-02-03		OA10058 A N 1996-10-14	RU2139059 C N 1999-10-10		ZA9203544 A N 1993-03-31
	US6113920	Glaxo Group Limited	US19970955635 19971023; GB19960022681 19961031; US19960029240P 19961031	WO9818477 A Y 1998-05-07	AP1067 A N 2002-05-01	BR9712614 A N 1999-10-26			OA11038 A N 2002-02-06		UA64725 C N 1999-12-29	ZA9709726 A N 1999-04-29
Abacavir (ABC)	CA2033044	The Wellcome Foundation Limited (U.K.)	US19890455201 19891222		AP196 A N 1992-06-30		CN1054981 A N 1991-10-02 CN1028106C C 1995-04-05			RU2068849 C N 1996-11-10 RU2091386 C N 1997-09-27		ZA9010365 A N 1992-08-26
	CA1340589 US5089500 US5034394	Burroughs Wellcome Co.	GB19880015265 19880627		AP101 A N 1990-10-23							ZA8904837 A N 1991-03-27
	US6294540	Glaxo Wellcome Inc.	WO1998EP02835 19980514; GB19970009945 19970517	WO9852570 A Y 1998-11-26 WO9852571 A Y 1998-11-26 WO9852949 A Y 1998-11-26		BR9809124 A N 2000-08-01 BR9809126 A N 2000-08-01 BR9809127 A N 2000-08-01	CN1150194C C 2004-05-19 CN1263529 A N 2000-08-16 CN1515572 A N 2004-07-28		OA11304 A N 2003-10-22			ZA9804083 A N 1999-11-15 ZA9804085 A N 1999-11-15
Abacavir (ABC)/ Zidovudine (AZT) / Lamivudine (3TC)	CA2068790	Glaxo Group Ltd. (Gb)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344 A Y 1992-11-26			CN1045961C C 1999-10-27 CN1068570 A N 1993-02-03		OA10058 A N 1996-10-14	RU2139059 C N 1999-10-10		ZA9203544 A N 1993-03-31
	CA2311988	Glaxo Group Ltd (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		ZA9204007 A N 1993-04-28
	US5905082	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

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)
Abacavir (ABC)/ Zidovudine (AZT) / Lamivudine (3TC) (continued)	US6417191	GlaxoSmithKline	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025 A Y 1996-10-03	AP652 A N 1998-06-19	BR9607851 A N 1998-07-21	CN1103593C C 2003-03-26 CN1185110 A N 1998-06-17		OA10616 A N 2001-03-15			ZA9602477 A N 1997-10-28
Abacavir (ABC)/ Lamivudine (3TC)	CA2311988	Glaxo Group Ltd. (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		ZA9204007 A N 1993-04-28
	US6417191	GlaxoSmithKline	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025 A Y 1996-10-03	AP652 A N 1998-06-19	BR9607851 A N 1998-07-21	CN1103593C C 2003-03-26 CN1185110 A N 1998-06-17		OA10616 A N 2001-03-15			ZA9602477 A N 1997-10-28
	US5905082	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
Lamivudine (3TC)	CA2059263	Iaf Biochem International Inc. (Canada)	GB19900009861 19900502; WO1991GB00706 19910502	WO9117159 A Y 1991-11-14	AP182 A N 1992-06-30		CN1056145C C 2000-09-06 CN1058214 A N 1992-01-29 CN1108655 A N 1995-09-20 CN1154500C C 2004-06-23 CN1326743 A N 2001-12-19 CN1036196C C 1997-10-22		OA9559 A N 1993-01-31	RU2099338 C N 1997-12-20		ZA9103293 A N 1992-02-26
	CA2009637 US5047407	BioChem Pharma, Inc.	CA19922152269 19921221; US19890308101 19890208		AP136 A N 1991-08-05		CN1044817 A N 1990-08-22 CN1033640C C 1996-12-25		OA9193 A N 1992-06-30	RU2092485 C N 1997-10-10		ZA9000943 A N 1990-10-31
	CA2070230 US5905082	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
	CA2286126	Glaxo Group Limited	GB19970006295 19970326; US19970042353P 19970324; WO1998EP01626 19980320	WO9842321 A Y 1998-10-01	AP1141 A N 2003-01-29	BR9808060 A N 2000-03-08	CN1191061C C 2005-03-02 CN1255849 A N 2000-06-07					ZA9802367 A N 1999-09-20
	CA2100269 (hep B) US5532246	Iaf Biochem Int. (Ca)	GB19910000039 19910103; GB19910009913 19910507; WO1992CA00001 19920103	WO9211852 A Y 1992-07-23								
	US6004968	Glaxo Wellcome Inc.	US19970042353P 19970324 GB19910011902 19910603	WO9842321 A Y 1998-10-01	AP1141 A N 2003-01-29	BR9808060 A N 2000-03-08	CN1191061C C 2005-03-02 CN1255849 A N 2000-06-07					ZA9802367 A N 1999-09-20
Indinavir (IDV)	CA2081970	Merck & Co., Inc.	US19910789508 19911108; US19920883825 19920515	WO9309096 A Y 1993-05-13						RU2171254 C N 2001-07-27 RU2131416 C N 1999-06-10		ZA9208563 A N 1993-05-05
	US5413999	Merck & Co., Inc.	US19930059038 19930507; US19930040729 19930331; US19920883825 19920515; US19910789508 19911108	WO9309096 A Y 1993-05-13 WO9422480 A Y 1994-10-13 WO9426717 A Y 1994-11-24		BR9406576 A N 1996-01-30 BR9406503 A N 1996-01-02	CN1176250 A N 1998-03-18 CN1126469 A N 1996-07-10 CN1120316 A N 1996-04-10 CN1090187C C 2002-09-04			RU2171254 C N 2001-07-27 RU2139052 C N 1999-10-10 RU2131416 C N 1999-06-10		ZA9208563 A N 1993-05-05 ZA9402255 A N 1994-11-01 ZA9403104 A N 1995-11-06
	US6645961	Merck & Co., Inc.	US19980045885 19980304; US19970040158P 19970307		no family found							

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)
Indinavir (IDV) (continued)	US6689761	Merck & Co., Inc.	US19950982113 19950201	WO9623309 A Y 1996-08-08		BR9607714 A N 1998-01-13	CN1179722 A N 1998-04-22 CN1160081C C 2004-08-04					ZA9600722 A N 1996-08-26
Efavirenz (EFV)	CA2101572	Merck & Co., Inc.	US19930094805 19930427; US19920926607 19920807	WO9403440 A Y 1994-02-17			CN1250652 A N 2000-04-19 CN1221608 A N 1999-07-07 CN1107595C C 2003-05-07 CN1090277 A N 1994-08-03 CN1051765C C 2000-04-26			RU2186775 C N 2002-08-10		ZA9305724 A N 1994-03-03
	US5519021	Merck & Co., Inc.	US19950460026 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807	WO9403440 A Y 1994-02-17 WO9320389 A Y 1995-08-03			CN1250652 A N 2000-04-19 CN1221608 A N 1999-07-07 CN1107595C C 2003-05-07 CN1090277 A N 1994-08-03 CN1051765C C 2000-04-26			RU2186775 C N 2002-08-10		ZA9305724 A N 1994-03-03
	US5663169	Merck & Co., Inc.	US19950458728 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807	WO9403440 A Y 1994-02-17 WO9320389 A Y 1995-08-03			CN1250652 A N 2000-04-19 CN1221608 A N 1999-07-07 CN1107595C C 2003-05-07 CN1090277 A N 1994-08-03 CN1051765C C 2000-04-26			RU2186775 C N 2002-08-10		ZA9305724 A N 1994-03-03
	US5811423	Merck & Co., Inc.	US19970815780 19970312; US19950458529 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807	WO9403440 A Y 1994-02-17 WO9320389 A Y 1995-08-03			CN1250652 A N 2000-04-19 CN1221608 A N 1999-07-07 CN1107595C C 2003-05-07 CN1090277 A N 1994-08-03 CN1051765C C 2000-04-26			RU2186775 C N 2002-08-10		ZA9305724 A N 1994-03-03
	US6639071	Merck & Co., Inc	US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408; US20010000037 20001019	WO9833782 A Y 1998-08-06			CN1185425 A N 2002-12-18 CN1246113 A N 2000-03-01 CN1191422C C 2005-03-02 CN1073991C C 2001-10-31					
	US6939964	Bristol-Myers Squibb Company	US20040891749 20040624; US20030447690 20030529; US20010000037 20010119; US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408	WO9833782 A Y 1998-08-06			CN1185425 A N 2002-12-18 CN1246113 A N 2000-03-01 CN1191422C C 2005-03-02 CN1073991C C 2001-10-31					

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)
Efavirenz (EFV) (continued)	US6238695	DuPont Pharmaceuticals Company	US19990286902 19990406; US19980080925P 19980407	WO9951239 A Y 1999-10-14		BR9908810 A N 2000-12-19	CN1296412 A N 2001-05-23 CN1146419C C 2004-04-21				UA72207 C N 2001-02-15	ZA200004313 A N 2001-11-07
	US6555133	Bristol-Myers Squibb Company	US20010824071 20010402; US19990286902 19990406; US19980080925P 19980407	WO9951239 A Y 1999-10-14		BR9908810 A N 2000-12-19	CN1296412 A N 2001-05-23 CN1146419C C 2004-04-21				UA72207 C N 2001-02-15	ZA200004313 A N 2001-11-07
Nelfinavir (NFV)	US5484926 CA2173328	Agouron Pharmaceuticals, Inc. (US)	US19930133543 19931007; US19930133696 19931007; US19940190764 19940202; WO1994US11307 19941007	WO9509843 A Y 1995-04-13	AP600 A N 1997-07-23	BR9407782 A N 1997-03-18	CN1046269C C 1999-11-10 CN1131942 A N 1996-09-25 CN1195737C C 2005-04-06 CN1262272 A N 2000-08-09		OA10718 A N 2001-11-02	RU2139280 C N 1999-10-10		ZA9407815 A N 1996-07-08
	US5952343	Agouron Pharmaceuticals, Inc. (US)	US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007; US19930137254 19931018; US19920995621 19921222	WO9509843 A Y 1995-04-13	AP600 A N 1997-07-23	BR9407782 A N 1997-03-18 BR9305161 A N 1994-11-01	CN1262272 A N 2000-08-09 CN1195737C 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)	US19990283152 19990401; US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007	WO9509843 A Y 1995-04-13	AP600 A N 1997-07-23	BR9407782 A N 1997-03-18	CN1046269C C 1999-11-10 CN1131942 A N 1996-09-25 CN1195737C C 2005-04-06 CN1262272 A N 2000-08-09		OA10718 A N 2001-11-02	RU2139280 C N 1999-10-10		ZA9407815 A N 1996-07-08
Saquinavir (SQV)	CA1340588	F. Hoffmann-La Roche & Co. Aktien-gesellschaft (Switzerland)	GB19880013940 19880613; GB19890008035 19890410									ZA8904285 A N 1990-02-28
	CA2030433 US5196438	Hoffmann-La Roche Inc.	GB19890027913 19891211		Zimbawe ZW17490 A N 1992-06-17	BR9006264 A N 1991-09-24	CN1034805C C 1997-05-07 CN1052482 A N 1991-06-26 CN1066329C C 2001-05-30 CN1138983 A N 1997-01-01	IN172553 A N 1993-09-25	OA9334 A N 1992-09-15	RU2071470 C N 1997-01-10		ZA9009743 A N 1991-08-28
	US6008228 CA2224125	Hoffmann-La Roche Inc.	US19950468493 19950606; US19960616233 19960507; WO1996EP02431 19960604	WO9639142 A Y 1996-12-12		BR9610842 A N 1999-07-13	CN1186434 A N 1998-07-01 CN1092960C C 2002-10-23	IN192899 A N 2004-05-29	OA10546 A N 2002-05-29			ZA9604448 A N 1996-12-06
	US6352717	Hoffman-La Roche Inc.	EP19980121831 19981117	WO0028942 A Y 2000-05-25		BR9915444 A N 2001-08-07	CN1326335 A N 2001-12-12 CN1172649C C 2004-10-27			RU2219911 C N 2003-12-27		ZA200103891 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)	Aripo(AP)	Brazil (BR)	China (CN)	India (IN)	OAPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Enfuvirtide (T20)	US5464933	Duke University	US19930073028 19930607	WO9428920 A Y 1994-12-22								
	US6133418	Duke University	US19950554616 19951106; US19930073028 19930607	WO9428920 A Y 1994-12-22								
	US6475491	Trimeris, Inc.	US19980973952 19980529; US19950481957 19950607; WO1996US09499 19960606	WO9640191 A Y 1996-12-19		BR9609152 A N 1999-05-04	CN1192688 A N 1998-09-09					
Amprenavir (APV)	CA2143208	Vertex Pharmaceuticals, Incorporated (USA)	US19920941982 19920908; WO1993US08458 19930907	WO9405639 A Y 1994-03-17	AP390 A N 1995-08-02	BR1100824 A N 1999-08-31	CN1061339C C 2001-01-31 CN1087347 A N 1994-06-01			RU2135496 C N 1999-08-27		
	US5585397	Vertex Pharmaceuticals, Incorporated (USA)	US19930142327 19931124; US19920941982 19920908; WO1993US08458 19930907	WO9405639 A Y 1994-03-17	AP390 A N 1995-08-02	BR1100824 A N 1999-08-31	CN1087347 A N 1994-06-01 CN1061339C C 2001-01-31			RU2135496 C N 1999-08-27		
	CA2249336	GLAXO GROUP LIMITED (U.K.)	GB19960006372 19960326; US19960013893P 19960322; US19970820848 19970320; WO1997EP01438 19970321	WO9735587 A Y 1997-10-02	AP1150 A N 2003-03-14	BR9708238 A N 1999-08-03	CN1225587 A N 1999-08-11		OA10880 A N 2001-10-11		UA67723 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	BR9611861 A N 1999-05-18	CN1203530 A N 1998-12-30		OA10691 A N 2001-05-04	RU2203658 C N 2003-05-10	UA61902 C N 2003-12-15	ZA9610139 A N 1997-06-17
	US5723490	Vertex Pharmaceuticals Incorporated	US19950424819 19950419; US19950393460 19950223; US19930142327 19931124; US19920941982 19920908	WO9405639 A Y 1994-03-17 WO9633184 A Y 1996-10-24	AP950 A N 2001-03-28 AP390 A N 1995-08-02	BR9608032 A N 1999-01-12 BR1100824 A N 1999-08-31	CN1181755 A N 1998-05-13 CN1087347 A N 1994-06-01 CN1061339C C 2001-01-31			RU2135496 C N 1999-08-27		
	US6730679	SmithKline Beecham Corporation	US19970820848 19970320; US19960013893P 19960322	WO9735587 A Y 1997-10-02	AP1150 A N 2003-03-14	BR9708238 A N 1999-08-03	CN1225587 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 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	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).
Ritonavir (RTV)	US19960754390 19961121; WO1997US20794 19971112	WO9822106	CA2271196	Abbott Laboratories US	CN1248914 A N 2000-03-29	CN1250219C 2006-04-12	97199780,2	1997.11.12	2006.04.12	2017.11.12	valid
	US19960753201 19961121; US19950572226 19951213; WO1996US20440 19961206	WO9721685	US5914332 CA2238978	Abbott Laboratories US	CN1208405 A N 1999-02-17	CN1207288C C 2005-06-22	96199904,7	1996.12.6	2005.6.22	2016.12.6	valid
	US19980207873 19981208; US19960753201 19961121; US19950572226 19951213		US6284767	Abbott Laboratories US	CN1208405 A N 1999-02-17	CN1207288C C 2005-06-22					
	US19990393872 19990910; US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121		US6521651	Abbott Laboratories US							
	US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121		US6458818	Abbott Laboratories US							
	US20010946085 20010904; US20000230095P 20000905		US6911214	Abbott Laboratories US							
Ritonavir/ Lopinavir (RTV/ LPV)	US19900616170 19901120; US19910746020 19910815; US19910777626 19911023		CA2055670	Abbott Laboratories US							
	US19920998114 19921229; US19930158587 19931202	WO9414436	CA2135890	Abbott Laboratories US							
	US19950000654P 19950629; US19950003849P 19950915; WO1996US11015 19960628	WO9701349	CA2224738	Abbott Laboratories US							
	US19970821609 19970320; US19950417879 19950406; US19930158587 19931202; US19920998114 19921229		US5846987	Abbott Laboratories US							
	US19950413136 19950329; US19920998114 19921229; US19930158587 19931202; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		US5674882	Abbott Laboratories US							
	US19950423387 19950425; US19930158587 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		US5541206	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: Patent status (whether the patent is valid or has lapsed).
ritonavir/ lopinavir (RTV/ LPV) (continued)	US19950478791 19950406; US19930138671 19931202; US19920998114 19921229; US19910777628 19911023; US19910746020 19910815; US19900616170 19901120; US19900618739 19900509; US19894046124 19891222; US19894045604 19890908; US19890355945 19890523		US5635523	Abbott Laboratories US							
	US19950410623 19950324; US19940270210 19940823; US19930121673 19930914; US19910777628 19911023; US19910746020 19910815; US19900616170 19901120; US19900618739 19900509; US19894046124 19891222; US19894045604 19890908; US19890355945 19890523		US5648497	Abbott Laboratories US							
	US20010957171 20010920; US19990387261 19990831; US19960687774 19960626; US19950000654P 19950629; US19950003849P 19950915		US6703403	Abbott Laboratories US							
	US19970966495 19971107; US19960031463P 19961121		US6232333	Abbott Laboratories US							
	US19950440277 19950512; US19940283239 19940729; US19940189021 19940112		US5484801	Abbott Laboratories US							
	US19970820171 19970320; US19950413136 19950329; US19930138587 19931202; US19920998114 19921229		US5886036	Abbott Laboratories US							
	US19950003849P 19950915; US19960687774 19960626; US19950000654P 19950629		US6037157	Abbott Laboratories US							
Nevirapine (NVP)	US19890438923 19891117; US19900573901 19900906; US19900600390 19901019		CA2030056	BOEHRINGER INGELHEIM PHARMA (DE); THOMAE GMBH DR K (DE)							
	US19930009418 19930713; US19890340970 19890420; US19890372974 19890628; US19890438923 19891117; US19900573901 19900906; US19900600390 19901019; US19910740828 19910805		US5366972	Boehringer Ingelheim Pharmaceuticals, Inc.							
Atazanavir (ATV)	CH19960001018 19960422; CH19970000233 19970131		US6849911	Novartis Finance Corporation	CN1216539A 1999-05-12	CN1082598C C 2002-04-10	97194025.8	1997.4.14	2002.4.10	2017.4.14	Valid
					CN1319587A 2001-10-31	CN1193010C C 2005-03-16	1103494.7	1997.4.14	2005.3.16	2017.4.14	Valid
					CN1611645 A N 2005-05-18	Non-issued	200410079187.5;	missing data	No patent		No patent
	US19980071968P 19980120; WO1998US27382 19981222	WO9936404	CA2317736	Bristol-Myers Squibb Company US	CN1285188 A 2001-02-07	CN1116282C C N 2003-07-30	98812741.5	1997.4.14	2003.7.30	2017.4.14	Valid

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).
Atazanarir (ATV) (continued)	US19980217538 19981221; US19980071968P 19980120		US6087383	Bristol-Myers Squibb Company	CN1283188 A 2001-02-07 CN1116282C C N 2003-07-30						
Didanosine (DDI)	US19850769016 19850826	WO8701284	CA1269044	US HEALTH (US)							
	US19900460490 19900103	WO9109605	CA2072573	US HEALTH (US)							
	US19910733547 19910722; US19920882204 19920513		CA2074215	SQUIBB BRISTOL MYERS CO (US)	CN1068739 A N 1993-02-10	CN1042299C C 1999-03-03	92108657,1	1992.7.21	1999.3.3	2007.7.21	Valid
	US19870084055 19870811; US19850769016 19850826		US4861759	The United States of America as represented by the Department of Health							
	US19910663288 19910228; US19870084055 19870811; US19890420664 19890828; US19850769016 19850826; US19860937925 19861204		US5254539	U.S. Government, Dept. of Health and Human Services, c/o National							
	US19930056043 19930430; US19910663288 19910228; US19890420664 19890828; US19870084055 19870811; US19860937925 19861204; US19850769016 19850826		US5616566	The United States of America as represented by the Department of Health							
	US19970942660 19971002; US19920882204 19920513; US19910733547 19910722		US5880106	Bristol-Myers Squibb Company	CN1042299C C 1999-03-03 CN1068739 A N 1993-02-10						
Stavudine (D4T)	US19860942666 19861217		CA1293447 US4978655	Yale University							
Emtricitabine (FCT)	US19900473318 19900201, WO1991US00685 19910131	WO9111186	CA2075189	EMORY UNIVERSITY (US)							
	CA19922152269 19921221; US19890308101 19890208		CA2009637	BIOCHEM PHARMA INC. (Canada)	CN1044817 A N 1990-08-22	CN1033640C C 1996-12-25	90100612,2	1990.2.8	1996.12.25	2005.2.8	Valid
	US19910659760 19910222; US19900473318 19900201		US5210085	Emory University	CN1065065 A 1992.10.07	CN1037682C C 1998-03-11	92101981,5	1992.2.22	11/03/1998	2007.2.22	Valid
					CN1203232 A 1998.12.30	CN1084745C C 2002-05-15	98108905,4	1998.05.15	15/05/2002	2018.05.15	valid
					CN1127301 A 1996.07.24	CN1109108C C 2003-05-21	95109814,4	1995.08.18	21/05/2003	2015.08.18	valid
					CN1418966 A N 2003-05-21	Non-issued	2144033,6	2002.09.30	No patent		No patent
	US19930017820 19930216; US19910659760 19910222; US19900473318 19900201		US5814639	Emory University							
	US19950488097 19950607; US19920831153 19920212; US19910659760 19910222; US19900473318 19900201; US19910736089 19910726		US5914331	Emory University	CN1037682C C 1998-03-11 CN1065065 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 CN1418966 A N 2003-05-21						

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 (FCT) (continued)	US19950475339 19950607; US19920831153 19920212; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201		US6642245	Emory University	CN1037682C C 1998-03-11 CN1065065 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 CN1418966 A N 2003-05-21						
	US19950402730 19950313; GB19910004741 19910306; GB19910009505 19910502; US19930092248 19930715; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201		US6703396	Emory University	CN1037682C C 1998-03-11 CN1065065 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 CN1418966 A N 2003-05-21						
Tenofovir disoproxil fumarate (TDF)	US19970900746 19970725; US19960022708P 19960726		US5922695	Gilead Sciences, Inc							
	US19970900752 19970725		US5935946	Gilead Sciences, Inc	CN1554350 A N 2004-12-15	CN1251679C 2006 04 19	200410046290.x	1998.7.23	2006.4.19	2018.7.23	Valid
					CN1264387 A N 2000-08-23	Non-issued	98807435.4	1998.7.23			No patent
Tenofovir disoproxil fumarate (TDF) (continued)	US19980187763 19981106; US19970900746 19970725; US19960022708P 19960726		US5977089	Gilead Sciences, Inc.							
	US19990314606 19990519; US19970900746 19970725; US19960022708P 19960726		US6043230	Gilead Sciences, Inc							
Zidovudine/ Lamivudine (AZT/3TC)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344	CA2068790	Glaxo Group Limited	CN1068570 A N 1993-02-03	CN1045961C C 1999-10-27	92104553	1992.5.15	1999.10.27	2005.5.15	Valid
	CA19922070230 19920602; GB19910011902 19910603		CA2311988	Glaxo Group Limited							
	GB19910011902 19910603	WO9221676	US5905082	Glaxo Group Limited							
	WO1996EP01352 19960328, GB19950006489 19950330; GB19950006490 19950330	WO9630025	CA2216634	THE WELLCOME FOUNDATION LIMITED (U.K.)	CN1185110 A N 1998-06-17	CN1103593C C 2003-03-26	96194050.6	1996.3.28	2003-03-26	2016.3.28	Valid
	US19960605610 19960222; GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106; US19940219176 19940328; US19920883169 19920515		US5859021	Glaxo Group Limited	CN1045961C C 1999-10-27 CN1068570 A N 1993-02-03						

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).
Zidovudine/ Lamivudine (AZT/3TC) (continued)	US19970955635 19971023; GB19960022681 19961031; US19960029240P 19961031		US6113920	Glaxo Group Limited							
Abacavir (ABC)	US19890455201 19891222		CA2033044	THE WELLCOME FOUNDATION LIMITED (U.K.)	CN1054981 A N 1991-10-02	CN1028106C C 1995-04-05	91100671	1990.12.21	05/04/1995	2005.12.21	Valid
	GB19880015265 19880627		CA1340589 US5089500 US5034394	Burroughs Wellcome Co.							
	WO1998EP02835 19980514; GB19970009945 19970517	WO9852949	US6294540	Glaxo Wellcome Inc.	CN1263529 A 2000.08.16	CN1150194C C 2004-05-19	98807073,1	1998.5.14	19/05/2004	2018.5.14	Valid
					CN1515572 A N 2004-07-28	Non-issued	3102921,3	1998.5.14	No patent		No patent
Abacavir/ Zidovudine/ Lamivudine (ABC/AZT/3TC)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344	CA2068790	GLAXO GROUP LTD (GB)	CN1045961C C 1999-10-27 CN1068570 A N 1993-02-03						
	CA19922070230 19920602; GB19910011902 19910603		CA2311988	GLAXO GROUP LTD (GB)							
	GB19910011902 19910603	WO9221676	US5905082	Glaxo Group Limited							
	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025	US6417191	GlaxoSmithKline	CN1185110 A N 1998-06-17	CN1103593C C 2003-03-26	96194050,6	1996.3.28	26/03/2003	2016.3.28	valid
(ABC/3TC)	CA19922070230 19920602; GB19910011902 19910603		CA2311988	GLAXO GROUP LTD (GB)							
	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025	US6417191	GlaxoSmithKline	CN1103593C C 2003-03-26 CN1185110 A N 1998-06-17						
	GB19910011902 19910603	WO9221676	US5905082	Glaxo Group Limited							
Lamivudine (3TC)	GB19900009861 19900502; WO1991GB00706 19910502	WO9117159	CA2059263	IAF BIOCHEM INTERNATIONAL INC. (Canada)	CN1108655 A 1995.09.20	CN1056145C C 2000-09-06	94109429,4	1994.8.15	06/09/2000	2014.8.15	Valid
					CN1326743 A 2001.12.19	CN1154500C C 2004-06-23	99126580,7	1994.8.15	23/06/2004	2014.8.15	Valid
					CN1058214 A 1992.01.29	CN1036196C C 1997-10-22	91102778,5	1991.4.30	22/10/1997	2006.4.30	Valid
	CA19922152269 19921221; US19890308101 19890208		CA2009637 US5047407	BioChem Pharma, Inc.	CN1044817 A N 1990-08-22	CN1033640C C 1996-12-25	90100612,2	1990.2.8	25/12/1996	2005.2.8	Valid
	GB19910011902 19910603	WO9221676	CA2070230 US5905082	Glaxo Group Limited							
	GB19970006295 19970326; US19970042353P 19970324; WO1998EP01626 19980320	WO9842321	CA2286126	Glaxo Group Limited	CN1255849 A N 2000-06-07	CN1191061C C 2005-03-02	98805122,2	1998.3.20	2005-03-02	2018.3.20	Valid
	GB19910000039 19910103; GB19910009913 19910507; WO1992CA00001 19920103	WO9211852	CA2100269 (hep B) US5532246	IAF BIOCHEM INT (CA)							
	US19970042353P 19970324 GB19910011902 19910603	WO9842321	US6004968	Glaxo Wellcome Inc.	CN1191061C C 2005-03-02 CN1255849 A N 2000-06-07						
Indinavir (IDV)	US19910789508 19911108; US19920883825 19920515	WO9309096	CA2081970	Merck & Co., Inc.							

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).
Indinavir (IDV) (continued	US19930059038 19930507; US19930040729 19930331; US19920883825 19920515; US19910789508 19911108		US5413999	Merck & Co., Inc.	CN1176250 A N 1998-03-18	seen as rejected (1999.08.11)	97101853	1997.2.1	no patent		seen as rejected (1999.08.11)
					CN1126469 A N 1996-07-10	seen as rejected (1999.08.11)	94192691	1994.4.26	no patent		seen as rejected (1999.08.11)
					CN1120316 A N 1996-04-10	CN1090186C 2002 09 04	94191671	1994.3.24	2002.09.04	2014.03.24	valid
	US19980045885 19980304; US19970040158P 19970307		US6645961	Merck & Co., Inc.							
	US19950382113 19950201	WO9623509	US6689761	Merck & Co., Inc.	CN1179722 A N 1998-04-22	CN1160081C C 2004-08-04	96192910,3	1996.1.29	04/08/2004	2016.1.29	valid
Efavirenz (EFV)	US19930054805 19930427; US19920926607 19920807	WO9403440	CA2101572	Merck & Co., Inc.	CN1250652 A N 2000-04-19	Non-issued	99118108.5	1999.8.20	no patent		No patent
					CN1221608 A 1999.07.07	CN1107505C C 2003-05-07	98121309.x	1998.10.10	07/05/2003	2018.10.10	valid
					CN1090277 A 1994.08.03	CN1051767C C 2000-04-26	93117660,3	1993.8.6	26/04/2000	2013.8.6	valid
	US19950460026 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807		US5519021	Merck & Co., Inc.	CN1250652 A N 2000-04-19 CN1221608 A N 1999-07-07 CN1090277 A N 1994-08-03	CN1107505C C 2003-05-07 CN1051767C C 2000-04-26					
	US19950458528 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807		US5663169	Merck & Co., Inc.	CN1250652 A N 2000-04-19 CN1221608 A N 1999-07-07 CN1090277 A N 1994-08-03	CN1107505C C 2003-05-07 CN1051767C C 2000-04-26					
	US19970815780 19970312; US19950458529 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807		US5811423	Merck & Co., Inc.	CN1250652 A N 2000-04-19 CN1221608 A N 1999-07-07 CN1090277 A N 1994-08-03	CN1107505C C 2003-05-07 CN1051767C C 2000-04-26					
	US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408; US20010000537 20011019		US6639071	Merck & Co., Inc	CN1385425 A N 2002-12-18	CN1191242C C 2005-03-02	1122709,5	1998.2.2	2005-03-02	2018.2.2	valid
					CN1246113 A 2000.03.01	CN1073991C C 2001-10-31	98802171,4	1998.2.2	2001-10-31	2018.2.2	valid
	US20040891749 20040624; US20030447690 20030529; US20010000537 20011019; US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408		US6939964	Bristol-Myers Squibb Company	CN1385425 A N 2002-12-18 CN1246113 A N 2000-03-01	CN1191242C C 2005-03-02 CN1073991C C 2001-10-31					
	US19990286902 19990406; US19980080925P 19980407		US6238695	DuPont Pharmaceuticals Company	CN1296412 A N 2001-05-23	CN1146419C C 2004-04-21	99804801,1	1999.4.1	2004-04-21	2019.4.1	valid
	US20010824071 20010402; US19990286902 19990406; US19980080925P 19980407		US6555133	Bristol-Myers Squibb Company	CN1296412 A N 2001-05-23	CN1146419C C 2004-04-21					
Nelfinavir (NFV)	US19930133543 19931007; US19930133696 19931007; US19940190764 19940202; WO1994US11307 19941007	WO9509843	US5484926 CA2173328	Agouron Pharmaceuticals, Inc. (US)	CN1131942 A 1996.09.25	CN1046269C C 1999-11-10	94193534.5	1994.10.7	10/11/1999	2014.10.7	valid

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).
Nelfinavir (NFV) (continued)					CN1262272 A 2000.08.09	CN1195737C C 2005-04-06	99105164,5	1994.10.7	06/04/2005	2014.10.7	valid
	US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007; US19930137254 19931018; US19920995621 19921222		US5952343	Agouron Pharmaceuticals, Inc. (US)		CN1195737C C 2005-04-06	99105164,5	1994.10.7	06/04/2005	2014.10.7	valid
						CN1046269C C 1999-11-10	94193534,5	1994.10.7	1999-11-10	2014.10.7	valid
	US19990283152 19990401; US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007		US6162812	Agouron Pharmaceuticals, Inc. (US)	CN1131942 A N 1996-09-25 CN1262272 A N 2000-08-09	CN1046269C C 1999-11-10 CN1195737C C 2005-04-06					
Saquinavir (SQV)	GB19880013940 19880613; GB19890008035 19890410		CA1340588	F. Hoffmann-La Roche & Co. Aktiengesllschaft (Switzerland)							
	GB19890027913 19891211		CA2030433 US5196438	Hoffmann-La Roche Inc.	CN1052482 A 1991.06.26	CN1034805C C 1997-05-07	90109931,7	1990.12.10	07/05/1997	2015.12.10	valid
					CN1138983 A 1997.01.01	CN1066329C C 2001-05-30	96107466,3	1990.12.10	2001-05-30	2015.12.10	valid
	US19950468493 19950606; US19960616233 19960507; WO1996EP02431 19960604	WO9639142	US6008228 CA2224125	Hoffmann-La Roche Inc.	CN1186434 A N 1998-07-01	CN1092960C C 2002-10-23	96194327	1996.6.4	23/10/2002	2016.6.4	valid
	EP19980121831 19981117	WO0028942	US6352717	Hoffman-La Roche Inc.	CN1326335 A N 2001-12-12	CN1172649C C 2004-10-27	99813395,7	1999.11.11	27/10/2004	2019.11.11	valid
Enfuvirtide (T20)	US19930073028 19930607	WO9428920	US5464933	Duke University							
	US19950554616 19951106; US19930073028 19930607		US6133418	Duke University							
	US19980973952 19980529; US19950481957 19950607; WO1996US09499 19960606		US6475491	Trimeris, Inc.	CN1192688 A N 1998-09-09	rejected (2006 04 05)	96196051	1996.6.6	no patent		rejected (2006-04-05)
Amprenavir (APV)	US19920941982 19920908; WO1993US08458 19930907	WO9405639	CA2143208	Vertex Pharmaceuticals, Incorporated (USA)	CN1087347 A N 1994-06-01	CN1061339C C 2001-01-31	93117370,1	1993.9.8	31/01/2001	2013.9.8	valid
	US19930142327 19931124; US19920941982 19920908; WO1993US08458 19930907	WO9405639	US5585397	Vertex Pharmaceuticals, Incorporated (USA)	CN1225587 A N 1999-08-11	Non-issued	97193229,8	1997.3.21	no patent		
	GB19960006372 19960326; US19960013893P 19960322; US19970820848 19970320; WO1997EP01438 19970321	(WO9735587)	CA2249336	Glaxo Group Limited (U.K.)	CN1087347 A N 1994-06-01	CN1061339C C 2001-01-31	93117370,1	1993.9.8	31/01/2001	2013.9.8	valid
	US19950567199 19951205	WO9720554	US5646180	Vertex Pharmaceuticals Incorporated	CN1203530 A N 1998-12-30	seen as withdrawn (2003-8-13)	96198816,9	1996.12.5	No patent		seen as withdrawn (2003-8-13)
	US19950424819 19950419; US19950393460 19950223; US19930142327 19931124; US19920941982 19920908		US5723490 Vertex Pharmaceuticals Incorporated		CN1087347 A N 1994-06-01	CN1061339C C 2001-01-31	93117370,1	1993.9.8	31/01/2001	2013.9.8	valid
					CN1181755 A N 1998-05-13	seen as withdrawn (2001-07-25)	96193364	1996.04.18	no patent		seen as withdrawn (2001-07-25)
	US19970820848 19970320; US19960013893P 19960322		US6730679	SmithKline Beecham Corporation	CN1225587 A N 1999-08-11						

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

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	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: Patent status (whether patent is valid or has lapsed)
Ritonavir (RTV)	US19960754390 19961121; WO1997US20794 19971112	WO9822106	Abbott Laboratories US	CA2271196	ZA9710071 A N 1998-05-25	1997/10071	1997/10071	07/11/1997	29/07/1998	07/11/2017	in force
	US19960753201 19961121; US19950572226 19951213; WO1996US20440 19961206	WO9721685	Abbott Laboratories US	US5914332 CA2238978	ZA9610475 A N 1997-07-31	1996/10475	1996/10475	12/12/1996	29/10/1997	12/12/2016	in force
	US19980207873 19981208; US19960753201 19961121; US19950572226 19951213		Abbott Laboratories US	US6284767	ZA9610475 A N 1997-07-31	1996/10475	1996/10475	12/12/1996	29/10/1997	12/12/2016	in force
	US19990393872 19990910; US19990347077 19990702; US19970966495 19971107; US199600314 63P 19961121		Abbott Laboratories US	US6521651							
	US19990347077 19990702; US19970966495 19971107; US199600314 63P 19961121		Abbott Laboratories US	US6458818							
	US20010946085 20010904; US20000230095P 20000905		Abbott Laboratories US	US6911214							
Ritonavir (RTV) / Lopinavir (LPV)	US19990061617 0 19901120; US19910746020 19910815; US19910777626 19911023		Abbott Laboratories US	CA2055670							
	US19920998114 19921229; US19930158587 19931202	WO9414436	Abbott Laboratories US	CA2135890							
	US19950000654P 19950629; US19950003849P 19950915; WO1996US11015 19960628	WO9701349	Abbott Laboratories US	CA2224738							
	US19970821609 19970320; US19950417879 19950406; US19930158587 19931202; US19920998114 19921229		Abbott Laboratories US	US5846987							
	US19950413136 19950329; US19920998114 19921229; US19930158587 19931202; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		Abbott Laboratories US	US5674882							
	US19950423387 19950425; US19930158587 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		Abbott Laboratories US	US5541206							

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: Patent status (whether patent is valid or has lapsed)
Ritonavir (RTV) / Lopinavir (LPV) (continued)	US19950417879 19950406; US19930158587 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		Abbott Laboratories US	US5635523							
	US19950410623 19950324; US19940270210 19940823; US19930121673 19930914; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		Abbott Laboratories US	US5648497							
	US20010957171 20010920; US19990387261 19990831; US19960687774 19960626; US19950000654P 19950629; US19950003849P 19950915		Abbott Laboratories US	US6703403							
	US19970966495 19971107; US19960031463P 19961121		Abbott Laboratories US	US6232333							
	US19950440277 19950512; US19940283239 19940729; US19940189021 1994012		Abbott Laboratories US	US5484801							
	US19970822071 19970320; US19950413136 19950329; US19930158587 19931202; US19920998114 19921229		Abbott Laboratories US	US5886036							
	US19950003849P 19950915; US19960687774 19960626; US19950000654P 19950629		Abbott Laboratories US	US6037157							
Nevirapine (NVP)	US19890438923 19891117; US19900579001 19900906; US19900600390 19901019			CA2030056	ZA9009246 A N 1992-07-29	1990/09246	1990/09246	19/11/1990	29/07/1992	19/11/2010	in force
	US19930091418 19930713; US19890340970 19890420; US19890372974 19890628; US19890438923 19891117; US19900579001 19900906; US19900600390 19901019; US19910740828 19910805		Boehringer Ingelheim Pharmaceuticals, Inc.	US5366972	ZA9004991 A N 1992-03-25	1990/04991	1990/04991	27/06/1990	25/03/1992	27/06/2010	in force
					ZA9009246 A N 1992-07-29	1990/09246	1990/09246	19/11/1990	29/07/1992	19/11/2010	in force
Atazanavir (ATV)	CH19960001018 19960422; CH19970000223 19970131		Novartis Finance Corporation	US5849911	ZA9703387 A N 1997-10-22	1997/03387	1997/03387	21/04/1997	31/12/1997	21/04/1997	in force
	US19980071968P 19980120; WO1998US27382 19981222	WO9936404	Bristol-Myers Squibb Company US	CA2317736	ZA9900056 A N 2000-07-05	1999/00056	1999/00056	05/01/1999	27/09/2000	05/01/2019	in force
	US19980217538 19981221; US19980071968P 19980120		Bristol-Myers Squibb Company	US6087383	ZA9900056 A N 2000-07-05	1999/00056	1999/00056	05/01/1999	27/09/2000	05/01/2019	in force
Didanosine (DDI)	US19850769016 19850826	WO8701284	US HEALTH (US)	CA1269044							
	US19900460490 19900103	WO9109605	US HEALTH (US)	CA2072573							

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: Patent status (whether patent is valid or has lapsed)
Didanosine (DDI) (continued)	US19910733547 19910722; US19920882204 19920513		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
	US19870084055 19870811; US19850769016 19850826		The United States of America as represented by the Department of Health	US4861759							
	US19910663288 19910228; US19870084055 19870811; US19890420664 19890828; US19850769016 19850826; US19860937925 19861204		U.S. Government, Dept. of Health and Human Services, c/o National	US5254539							
	US19930036043 19930430; US19910663288 19910228; US19890420664 19890828; US19870084055 19870811; US19860937925 19861204; US19850769016 19850826		The United States of America as represented by the Department of Health	US5616566							
	US19970942660 19971002; US19920882204 19920513; US19910733547 19910722		Bristol-Myers Squibb Company	US5880106	ZA9205484 A N 1993-09-13	1992/05484	1992/05484	21/07/1992	24/11/1993	21/07/2012	in force
Stavudine (D4T)	US19860942666 19861217		Yale University	CA1293447 US4978655	ZA8707171 A N 1988-03-24	1987/07171	1987/07171	23/09/1987	25/05/1988	23/09/2007	in force
Emtricitabine (FCT)	US19900473318 19900201, WO1991US00685 19910131	WO9111186	Emory University (US)	CA2075189							
	CA19922152269 19921221; US19890308101 19890208		Biochem Pharma Inc. Canada)	CA2009637	ZA9000943 A N 1990-10-31	1990/00943	1990/00943	08/02/1990	31/10/1990	08/02/2010	in force
	US19910659760 19910222; US19900473318 19900201		Emory University	US5210085	ZA9201251 A N 1993-08-20	1992/01251	1992/01251	20/02/1992	27/10/1993	20/02/2012	in force
	US19930017820 19930216; US19910659760 19910222; US19900473318 19900201		Emory University	US5814639	ZA9201251 A N 1993-08-20	1992/01251	1992/01251	20/02/1992	27/10/1993	20/02/2012	in force
	US19950488097 19950607; US19920831153 19920212; US19910659760 19910222; US19900473318 19900201; US19910736089 19910726		Emory University	US5914331	ZA9201251 A N 1993-08-20	1992/01251	1992/01251	20/02/1992	27/10/1993	20/02/2012	in force
	US19950475339 19950607; US19920831153 19920212; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201		Emory University	US6642245	ZA9201251 A N 1993-08-20	1992/01251	1992/01251	20/02/1992	27/10/1993	20/02/2012	in force
	US19950402730 19950313; GB19910004741 19910306; GB19910009505 19910502; US19930092248 19930715; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201		Emory University	US6703396	ZA9201251 A N 1993-08-20	1992/01251	1992/01251	20/02/1992	27/10/1993	20/02/2012	in force
					ZA9201658 A N 1993-09-06	1992/01658	1992/01658	05/03/1992	24/11/1993	05/03/2012	in force
Tenofovir Disoproxil fumarate (TDF)	US19970900746 19970725; US19960022708P 19960726		Gilead Sciences, Inc	US5922695							
	US19970900752 19970725		Gilead Sciences, Inc	US5935946							
	US19980187763 19981106; US19970900746 19970725; US19960022708P 19960726		Gilead Sciences, Inc.	US5977089							

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: Patent status (whether patent is valid or has lapsed)
Tenofovir Disoproxil fumarate (TDF) (continued)	US19990314606 19990519; US19970900746 19970725; US19960022708P 19960726		Gilead Sciences, Inc	US6043230							
Zidovudine (AZT) / Lamivudine (3TC)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344	Glaxo Group Limited	CA2068790	ZA9203544 A N 1993-03-31	1992/03544	1992/03544	15/05/1992	31/03/1993	15/05/2012	in force
	CA19922070230 19920602; GB19910011902 19910603		Glaxo Group Limited	CA2311988	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	GB19910011902 19910603	WO9221676	Glaxo Group Limited	US5905082	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	WO1996EP01352 19960328, GB19950006489 19950330; GB19950006490 19950330	WO9630025	The Wellcome Foundation Limited (U.K.)	CA2216634	ZA9602477 A N 1997-10-28	1996/02477	1996/02477	28/03/1996	31/12/1997	28/03/2016	in force
	US19960605610 19960222; GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106; US19940219176 19940328; US19920883169 19920515		Glaxo Group Limited	US5859021	ZA9203544 A N 1993-03-31	1992/03544	1992/03544	15/05/1992	31/03/1993	15/05/2012	in force
	US19970955635 19971023; GB19960022681 19961031; US19960029240P 19961031		Glaxo Group Limited	US6113920	ZA9709726 A N 1999-04-29	1997/09726	1997/09726	29/10/1997	28/07/1999	29/10/2017	in force
Abacavir (ABC)	US19890455201 19891222		The Wellcome Foundation Limited (U.K.)	CA2033044	ZA9010365 A N 1992-08-26	1990/10365	1990/10365	21/12/1990	26/08/1992	21/12/2010	in force
	GB19880015265 19880627		Burroughs Wellcome Co.	CA1340589 US5089500 US5034394	ZA8904837 A N 1991-03-27	1989/04837	1989/04837	26/06/1989	27/03/1991	26/06/2009	in force
	WO1998EP02835 19980514; GB19970009945 19970517	WO9852949	Glaxo Wellcome Inc.	US6294540	ZA9804083 A N 1999-11-15	1998/04083	1998/04083	14/05/1998	26/01/2000	14/05/2018	in force
					ZA9804085 A N 1999-11-15	1998/04085	1998/04085	14/05/1998	26/01/2000	14/05/2018	in force
Abacavir (ABC)/ Zidovudine (AZT) / Lamivudine (3TC)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344	Glaxo Group Ltd. (GB)	CA2068790	ZA9203544 A N 1993-03-31	1992/03544	1992/03544	15/05/1992	31/03/1993	15/05/2012	in force
	CA19922070230 19920602; GB19910011902 19910603		Glaxo Group Limited (GB)	CA2311988	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	GB19910011902 19910603	WO9221676	Glaxo Group Limited	US5905082	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025	GlaxoSmithKline	US6417191	ZA9602477 A N 1997-10-28	1996/02477	1996/02477	28/03/1996	31/12/1997	28/03/2016	in force
Abacavir (ABC)/ Lamivudine (3TC)	CA19922070230 19920602; GB19910011902 19910603		Glaxo Group Limited (GB)	CA2311988	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025	GlaxoSmithKline	US6417191	ZA9602477 A N 1997-10-28	1996/02477	1996/02477	28/03/1996	31/12/1997	28/03/2016	in force
	GB19910011902 19910603	WO9221676	Glaxo Group Limited	US5905082	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
Lamivudine (3TC)	GB19900009861 19900502; WO1991GB00706 19910502	WO9117159	IAF BioChem International Inc. (Canada)	CA2059263	ZA9103293 A N 1992-02-26	1991/03293	1991/03293	30/04/1991	26/02/1992	30/04/2001	in force
	CA19922152269 19921221; US19890308101 19890208		BioChem Pharma, Inc.	CA2009637 US5047407	ZA9000943 A N 1990-10-31						

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: Patent status (whether patent is valid or has lapsed)
Lamivudine (3TC) (continued)	GB19910011902 19910603	WO9221676	Glaxo Group Limited	CA2070230 US5905082	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	GB19970006295 19970326; US19970042353P 19970324; WO1998EP01626 19980320	WO9842321	Glaxo Group Limited	CA2286126	ZA9802367 A N 1999-09-20	1998/02367	1998/02367	19/03/1998	24/11/1999	19/03/2018	in force
	GB19910000039 19910103; GB19910009913 19910507; WO1992CA00001 19920103	WO9211852	IAF BioChem Int. (CA)	CA2100269 (hep B) US5532246							
	US19970042353P 19970324 GB19910011902 19910603	WO9842321	Glaxo Wellcome Inc.	US6004968	ZA9802367 A N 1999-09-20	1998/02367	1998/02367	19/03/1998	24/11/1999	19/03/2018	in force
Indinavir (IDV)	US19910789508 19911108; US19920883825 19920515	WO9309096	Merck & Co., Inc.	CA2081970	ZA9208563 A N 1993-05-05	1992/08563	1992/08563	06/11/1992	30/07/1993	06/11/2012	in force
	US19930059038 19930507; US19930040729 19930331; US19920883825 19920515; US19910789508 19911108		Merck & Co., Inc.	US5413999	ZA9208563 A N 1993-05-05	1992/08563	1992/08563	06/11/1992	30/07/1993	06/11/2012	in force
					ZA9402255 A N 1994-11-01	1994/02255	1994/02255	30/03/1994	28/12/1994	30/03/2014	lapsed
					ZA9403104 A N 1995-11-06	1994/03104	1994/03104	05/05/1994	27/12/1994	05/05/2014	lapsed
	US19980045885 19980304; US19970040158P 19970307		Merck & Co., Inc.	US6645961							
	US19950382113 19950201	WO9623509	Merck & Co., Inc.	US6689761	ZA9600722 A N 1996-08-26	1996/00722	1996/00722	31/01/1996	30/10/1996	31/01/2016	lapsed
Efavirenz (EFV)	US19930054805 19930427; US19920926607 19920807	WO9403440	Merck & Co., Inc.	CA2101572	ZA9305724 A N 1994-03-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force
	US19950460026 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807		Merck & Co., Inc.	US5519021	ZA9305724 A N 1994-03-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force
	US19950458528 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807		Merck & Co., Inc.	US5663169	ZA9305724 A N 1994-03-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force
	US19970815780 19970312; US19950458529 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807		Merck & Co., Inc.	US5811423	ZA9305724 A N 1994-03-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force
	US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408; US20010000537 20011019		Merck & Co., Inc	US6639071							
	US20040891749 20040624; US20030447690 20030529; US20010000537 20011019; US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408		Bristol-Myers Squibb Company	US6939964							
	US19990286902 19990406; US19980080925P 19980407		DuPont Pharmaceuticals Company	US6238695	ZA200004313 A N 2001-11-07	2000/04313	2000/04313	22/08/2000	30/01/2002	22/08/2020	in force
	US20010824071 20010402; US19990286902 19990406; US19980080925P 19980407		Bristol-Myers Squibb Company	US6555133	ZA200004313 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 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: Patent status (whether patent is valid or has lapsed)
Nelfinavir (NFV)	US19930133543 19931007; US19930133696 19931007; US19940190764 19940202; WO1994US11307 19941007	WO9509843	Agouron Pharmaceuticals, Inc. (US)	US5484926 CA2173328	ZA9407815 A N 1996-07-08	1994/07815	1994/07815	06/10/1995	28/08/1996	06/10/2015	in force
	US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007; US19930137254 19931018; US19920995621 19921222		Agouron Pharmaceuticals, Inc. (US)	US5952343	ZA9407815 A N 1996-07-08	1994/07815	1994/07815	06/10/1995	28/08/1996	06/10/2015	in force
	US19990283152 19990401; US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007		Agouron Pharmaceuticals, Inc. (US)	US6162812	ZA9407815 A N 1996-07-08	1994/07815	1994/07815	06/10/1995	28/08/1996	06/10/2015	in force
Saquinavir (SQV)	GB19880013940 19880613; GB19890008035 19890410		F. Hoffmann-La Roche & Co. Aktiengesellschaft (Switzerland)	CA1340588	ZA8904285 A N 1990-02-28	1989/04285	1989/04285	06/06/1989	28/02/1990	06/06/2009	in force
	GB19890027913 19891211		Hoffmann-La Roche Inc.	CA2030433 US5196438	ZA9009743 A N 1991-08-28	1990/09743	1990/09743	04/12/1990	28/08/1991	04/12/2010	in force
	US19950468493 19950606; US19960616233 19960507; WO1996EP02431 19960604	WO9639142	Hoffmann-La Roche Inc.	US6008228 CA2224125	ZA9604448 A N 1996-12-06	1996/04448	1996/04448	30/05/1996	26/02/1997	30/05/2016	in force
	EP19980121831 19981117	WO0028942	Hoffman-La Roche Inc.	US6352717	ZA200103891 A N 2002-08-14	2001/03891	2001/03891	14/05/2001	30/10/2002	14/05/2021	in force
Enfuvirtide (T20)	US19930073028 19930607	WO9428920	Duke University	US5464933							
	US19950554616 19951106; US19930073028 19930607		Duke University	US6133418							
	US19980973952 19980529; US19950481957 19950607; WO1996US09499 19960606		Trimeris, Inc.	US6475491							
Amprenavir (APV)	US19920941982 19920908; WO1993US08458 19930907	WO9405639	Vertex Pharmaceuticals, Incorporated (USA)	CA2143208							
	US19930142327 19931124; US19920941982 19920908; WO1993US08458 19930907	WO9405639	Vertex Pharmaceuticals, Incorporated (USA)	US5585397							
	GB19960006372 19960326; US19960013893P 19960322; US19970820848 19970320; WO1997EP01438 19970321	(WO9735587)	Glaxo Group Limited (U.K.)	CA2249336	ZA9702387 A N 1997-12-10	1997/02387	1997/02387	19/03/1997	25/02/1998	19/03/2017	in force
	US19950567199 19951205	WO9720554	Vertex Pharmaceuticals Incorporated	US5646180	ZA9610139 A N 1997-06-17	1996/10139	1996/10139	03/12/1996	27/08/1997	03/12/2016	lapsed
	US19950424819 19950419; US19950393460 19950223; US19930142327 19931124; US19920941982 19920908		Vertex Pharmaceuticals Incorporated	US5723490							
	US19970820848 19970320; US19960013893P 19960322		SmithKline Beecham Corporation	US6730679	ZA9702387 A N 1997-12-10	1997/02387	1997/02387	19/03/1997	25/02/1998	19/03/2017	in force

Data collected from CIPRO 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	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)
Ritonavir (RTV)	US19960754390 19961121; WO1997US20794 19971112	WO9822106	Abbott Laboratories US	CA2271196							
	US19960753201 19961121; US19950572226 19951213; WO1996US20440 19961206	WO9721685	Abbott Laboratories US	US5914332 CA2238978							
	US19980207873 19981208; US19960753201 19961121; US19950572226 19951213	0	Abbott Laboratories US	US6284767							
	US19990393872 19990910; US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121	0	Abbott Laboratories US	US6521651							
	US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121	0	Abbott Laboratories US	US6458818							
	US20010946085 20010904; US20000230095P 20000905	0	Abbott Laboratories US	US6911214							
Ritonavir (RTV) / Lopinavir (LPV)	US19900616170 19901120; US19910746020 19910815; US19910777626 19911023	0	Abbott Laboratories US	CA2055670							
	US19920998114 19921229; US19930158587 19931202	WO9414436	Abbott Laboratories US	CA2135890							
	US19950000654P 19950629; US19950003849P 19950915; WO1996US11015 19960628	WO9701349	Abbott Laboratories US	CA2224738							
	US19970821609 19970320; US19950417879 19950406; US19930158587 19931202; US19920998114 19921229	0	Abbott Laboratories US	US5846987							
	US19950413136 19950329; US19920998114 19921229; US19930158587 19931202; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523	0	Abbott Laboratories US	US5674882							
	US19950423387 19950425; US19930158587 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523	0	Abbott Laboratories US	US5541206							

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)
Ritonavir (RTV) / Lopinavir (LPV) (continued)	US19950417879 19950406; US19930158587 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523	0	Abbott Laboratories US	US5635523							
	US19950410623 19950324; US19940270210 19940823; US19930121673 19930914; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523	0	Abbott Laboratories US	US5648497							
	US20010957171 20010920; US19990387261 19990831; US19960687774 19960626; US19950000654P 19950629; US19950003849P 19950915	0	Abbott Laboratories US	US6703403							
	US19970966495 19971107; US19960031463P 19961121	0	Abbott Laboratories US	US6232333							
	US19950440277 19950512; US19940283239 19940729; US19940189021 1994012	0	Abbott Laboratories US	US5484801							
	US19970822071 19970320; US19950413136 19950329; US19930158587 19931202; US19920998114 19921229	0	Abbott Laboratories US	US5886036							
	US19950003849P 19950915; US19960687774 19960626; US19950000654P 19950629	0	Abbott Laboratories US	US6037157							
Nevirapine (NVP)	US19890438923 19891117; US19900579001 19900906; US19900600390 19901019	0		CA2030056							
	US19930091418 19930713; US19890340970 19890420; US19890372974 19890628; US19890438923 19891117; US19900579001 19900906; US19900600390 19901019; US19910740828 19910805	0	Boehringer Ingelheim Pharmaceuticals, Inc.	US5366972		2485/DEL/1998		24/08/1998			Under examination, pre grant opposition filed
Atazanavir (ATV)	CH19960001018 19960422; CH19970000223 19970131	0	Novartis Finance Corporation	US5849911		807/MAS/1997		21.04.1997			Under examination, pre grant Opposition filed
	US19980071968P 19980120; WO1998US27382 19981222	WO9936404	Bristol-Myers Squibb Company US	CA2317736							
	US19980217538 19981221; US19980071968P 19980120	0	Bristol-Myers Squibb Company	US6087383							
Didanosine (DDI)	US19850769016 19850826	WO8701284	US HEALTH (US)	CA1269044							
	US19900460490 19900103	WO9109605	US HEALTH (US)	CA2072573							
	US19910733547 19910722; US19920882204 19920513	0	SQUIBB BRISTOL MYERS CO (US)	CA2074215							

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)	US19870084055 19870811; US19850769016 19850826	0	The United States of America as represented by the Department of Health	US4861759							
	US19910663288 19910228; US19870084055 19870811; US19890420664 19890828; US19850769016 19850826; US19860937925 19861204	0	U.S. Government, Dept. of Health and Human Services, c/o National	US5254539							
	US19930056043 19930430; US19910663288 19910228; US19890420664 19890828; US19870084055 19870811; US19860937925 19861204; US19850769016 19850826	0	The United States of America as represented by the Department of Health	US5616566							
	US19970942660 19971002; US19920882204 19920513; US19910733547 19910722	0	Bristol-Myers Squibb Company	US5880106							
Stavudine (D4T)	US19860942666 19861217	0	Yale University	CA1293447 US4978655							
Emtricitabine (FCT)	US19900473318 19900201, WO1991US00685 19910131	WO9111186	EMORY UNIVERSITY (US)	CA2075189							
	CA19922152269 19921221; US19890308101 19890208	0	BIOCHEM PHARMA INC. (Canada)	CA2009637							
	US19910659760 19910222; US19900473318 19900201	0	Emory University	US5210085							
	US19930017820 19930216; US19910659760 19910222; US19900473318 19900201	0	Emory University	US5814639							
	US19950488097 19950607; US19920831153 19920212; US19910659760 19910222; US19900473318 19900201; US19910736089 19910726	0	Emory University	US5914331							
	US19950475339 19950607; US19920831153 19920212; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201	0	Emory University	US6642245							
	US19950402730 19950313; GB19910004741 19910306; GB19910009505 19910502; US19930092248 19930715; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201	0	Emory University	US6703396							
Tenofovir Disoproxil fumarate (TDF)	US19970900746 19970725; US19960022708P 19960726	0	Gilead Sciences, Inc	US5922695							
	US19970900752 19970725	0	Gilead Sciences, Inc	US5935946	IN190780 A N 2003-08-23	896/DEL/2002 A		09/04/2002			Under Examination, pre grant Opposition filed
	US19980187763 19981106; US19970900746 19970725; US19960022708P 19960726	0	Gilead Sciences, Inc.	US5977089							
	US19990314606 19990519; US19970900746 19970725; US19960022708P 19960726	0	Gilead Sciences, Inc	US6043230							
Zidovudine (AZT) / Lamivudine (3TC)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344	Glaxo Group Limited	CA2068790							

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)
Zidovudine (AZT) / Lamivudine (3TC) (continued)	CA19922070230 19920602; GB19910011902 19910603	0	Glaxo Group Limited	CA2311988							
	GB19910011902 19910603	WO9221676	Glaxo Group Limited	US5905082							
	WO1996EP01352 19960328, GB19950006489 19950330; GB19950006490 19950330	WO9630025	The Wellcome Foundation Limited (U.K.)	CA2216634							
	US19960605610 19960222; GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106; US19940219176 19940328; US19920883169 19920515	0	Glaxo Group Limited	US5859021							
	US19970955635 19971023; GB19960022681 19961031; US19960029240P 19961031	0	Glaxo Group Limited	US6113920		2044/CAL/1997		28/10/1997			Withdrawn, Application Rejected
Abacavir (ABC)	US19890455201 19891222	0	The Wellcome Foundation Limited (U.K.)	CA2033044							
	GB19880015265 19880627	0	Burroughs Wellcome Co.	CA1340589 US5089500 US5034394							
	WO1998EP02835 19980514; GB19970009945 19970517	WO9852949	Glaxo Wellcome Inc.	US6294540		872/CAL/1998		14/05/1997			Under examination, pre grant Opposition filed
Abacavir (ABC)/ Zidovudine (AZT) / Lamivudine (3TC)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344	Glaxo Group Ltd. (GB)	CA2068790							
	CA19922070230 19920602; GB19910011902 19910603	0	Glaxo Group Ltd. (GB)	CA2311988							
	GB19910011902 19910603	WO9221676	Glaxo Group Limited	US5905082							
	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025	GlaxoSmithKline	US6417191							
Abacavir (ABC)/ Lamivudine (3TC)	CA19922070230 19920602; GB19910011902 19910603	0	Glaxo Group Ltd. (GB)	CA2311988							
	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025	GlaxoSmithKline	US6417191							
	GB19910011902 19910603	WO9221676	Glaxo Group Limited	US5905082							
Lamivudine (3TC)	GB19900009861 19900502; WO1991GB00706 19910502	WO9117159	IAF BioChem International Inc. (Canada)	CA2059263							
	CA19922152269 19921221; US19890308101 19890208	0	BioChem Pharma, Inc.	CA2009637 US5047407							
	GB19910011902 19910603	WO9221676	Glaxo Group Limited	CA2070230 US5905082							
	GB19970006295 19970326; US19970042353P 19970324; WO1998EP01626 19980320	WO9842321	Glaxo Group Limited	CA2286126							
	GB19910000039 19910103; GB19910009913 19910507; WO1992CA00001 19920103	WO9211852	IAF BioChem Int. (CA)	CA2100269 (hep B) US5532246							
	US19970042353P 19970324 GB19910011902 19910603	WO9842321	Glaxo Wellcome Inc.	US6004968		479/CAL/1998		23/03/1998 A			No opposition have been filed yet, no request for examination filed.

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)
Indinavir (IDV)	US19910789508 19911108; US19920883825 19920515	WO9309096	Merck & Co., Inc.	CA2081970							
	US19930059038 19930507; US19930040729 19930331; US19920883825 19920515; US19910789508 19911108	0	Merck & Co., Inc.	US5413999							
	US19980045885 19980304; US19970040158P 19970307	0	Merck & Co., Inc.	US6645961							
	US19950382113 19950201	WO9623509	Merck & Co., Inc.	US6689761							
Efavirenz (EFV)	US19930054805 19930427; US19920926607 19920807	WO9403440	Merck & Co., Inc.	CA2101572							
	US19950460026 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807	0	Merck & Co., Inc.	US5519021							
	US19950458528 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807	0	Merck & Co., Inc.	US5663169							
	US19970815780 19970312; US19950458529 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807	0	Merck & Co., Inc.	US5811423							
	US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408; US20010000537 20011019	0	Merck & Co., Inc	US6639071							
	US20040891749 20040624; US20030447690 20030529; US20010000537 20011019; US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408	0	Bristol-Myers Squibb Company	US6939964							
	US19990286902 19990406; US19980080925P 19980407	0	DuPont Pharmaceuticals Company	US6238695							
	US20010824071 20010402; US19990286902 19990406; US19980080925P 19980407	0	Bristol-Myers Squibb Company	US6555133							
Nelfinavir (NFV)	US19930133543 19931007; US19930133696 19931007; US19940190764 19940202; WO1994US11307 19941007	WO9509843	Agouron Pharmaceuticals, Inc. (US)	US5484926 CA2173328							
	US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007; US19930137254 19931018; US19920995621 19921222	0	Agouron Pharmaceuticals, Inc. (US)	US5952343							
	US19990283152 19990401; US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007	0	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)
Saquinavir (SQV)	GB19880013940 19880613; GB19890008035 19890410	0	F. HOFFMANN-LA ROCHE & CO. AKTIENGESELLSCHAFT (Switzerland)	CA1340588							
	GB19890027913 19891211	0	Hoffmann-La Roche Inc.	CA2030433 US5196438	IN172553 A N 1993-09-25						
	US19950468493 19950606; US19960616233 19960507; WO1996EP02431 19960604	WO9639142	Hoffmann-La Roche Inc.	US6008228 CA2224125	IN192899 A N 2004-05-29						
	EP19980121831 19981117	WO0028942	Hoffman-La Roche Inc.	US6352717							
Enfuvirtide (T20)	US19930073028 19930607	WO9428920	Duke University	US5464933							
	US19950554616 19951106; US19930073028 19930607	0	Duke University	US6133418							
	US19980973952 19980529; US19950481957 19950607; WO1996US09499 19960606	0	Trimeris, Inc.	US6475491							
Amprenavir (APV)	US19920941982 19920908; WO1993US08458 19930907	WO9405639	Vertex Pharmaceuticals, Incorporated (USA)	CA2143208							
	US19930142327 19931124; US19920941982 19920908; WO1993US08458 19930907	WO9405639	Vertex Pharmaceuticals, Incorporated (USA)	US5585397							
	GB19960006372 19960326; US19960013893P 19960322; US19970820848 19970320; WO1997EP01438 19970321	(WO9735587)	GLAXO GROUP LIMITED (U.K.)	CA2249336		727/Del/1997		21/03/1997			Under Examination, Pre grant Opposition filed
	US19950567199 19951205	WO9720554	Vertex Pharmaceuticals Incorporated	US5646180							
	US19950424819 19950419; US19950393460 19950223; US19930142327 19931124; US19920941982 19920908	0	Vertex Pharmaceuticals Incorporated	US5723490							
	US19970820848 19970320; US19960013893P 19960322	0	SmithKline Beecham Corporation	US6730679		727/Del/1997		21/03/1997			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 datatbasesfor 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)	Kaletra	US19990325826 19990604		Abbott Laboratories US		WO0074677		IN/PCT/2001/01312/ MUM		22/10/2001			Has been abandoned
Efavirenz	A Process for Preparing Form 1 of Crystalline Efavirenz	60/088,981 19980611, WO1999US13199 19990610	US19980088981P 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	60/088,981 19980611, WO1999US13199 19990610	US19980088981P 19980611	Bristol Myers Squibb Pharma Company Ltd.		WO9964405		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 Efvirenz	US19980088981 19980611 US19990329421 19990610 US19990329421 US6673372	US19980088981P 19980611	Bristol Myers Squibb Pharma Company Ltd.		WO9964405		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)	US19990603291 9991019 US20000226171 20000817 US20001019 US20040024981	US19990603291P 19991019 US20000226171P 20000817	Bristol Myers Squibb Pharma Company Ltd.		WO0129037		IN/PCT/2002/00570/ MUM (PCT/ CA01/00890)		05/06/2002			No request for examination has been made
Nevirapine (Improvement)	Non Nucleoside Reverse Transcriptase Inhibitors	US20000212329 20000616 US20000256638 US20001218 US20020288071	US20000212329P 20000616; US20000256638P 20001218	Boerhinger Ingelheim Ltd.		WO0196338		IN/PCT/2002/01622/ MUM (PCT/ CA01/00890)		22/10/2002			Awaiting information from Mumbai patent office
Ritonavir (RTV) (Polymorph)	Ritonavir (RTV)	US19981193451 9980720, US19990326093 19990604	US19980119345 19980720; US19990326093 19990604	Abbott Laboratories US		WO0004016		PCT/2001/00018/ MUM		03/04/2005			FER issued on11.10.2006, 2 oppositions have been filed
Lopinavir (Crystalline form)	Lopinavir (Product Patent)	US20005382571 20000330, US20010793536 20010227	US20000538257 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		259/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 espacenet for the PCT applications	Assignee	Patent numbers Health Canada Orange Book	WIPO (WO)	Information sourced by EPO internal datatbasesfor 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.
Fosamprenavir	Lexiva (Calcium (3S) Tetrahydro-3-Funaryl (1S,2R)-3-[[(4-Aminophenyl) Sulphonyl] (Isobutyl) Amino]-1-Benzyl-2(Phosphonooxy) Propylcarbamate)	9815567.4 (WO1999EP04991 19990715; GB19980015567 19980718)	GB19980015567 19980718	Glaxo Group Limited		WO0004033		IN/PCT/2001/00039		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)	CA2271196	Abbott Laboratories US	US19960754390 19961121; WO1997US20794 19971112	WO9822106 A Y 1998-05-28		BR9714310 A N 2000-05-02	CN1248914 A N 2000-03-29					ZA9710071 A N 1998-05-25
	US5914332 CA2238978	Abbott Laboratories US	US19960753201 19961121; US19950572226 19951213; WO1996US20440 19961206	WO9721683 A Y 1997-06-19 WO9721685 A Y 1997-06-19		BR1100397 A N 2000-04-11	CN1207288C C 2005-06-22 CN1208405 A N 1999-02-17					ZA9610475 A N 1997-07-31
	US6284767	Abbott Laboratories US	US19980207873 19981208; US19960753201 19961121; US19950572226 19951213	WO9721683 A Y 1997-06-19 WO9721685 A Y 1997-06-19		BR1100397 A N 2000-04-11	CN1207288C C 2005-06-22 CN1208405 A N 1999-02-17					ZA9610475 A N 1997-07-31
	US6521651	Abbott Laboratories US	US19990393872 19990910; US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121		no family found							
	US6458818	Abbott Laboratories US	US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121		no family found							
	US6911214	Abbott Laboratories US	US20010946085 20010904; US20000230095P 20000905		no family found							
Ritonavir (RTV) / Lopinavir (LPV)	CA2055670	Abbott Laboratories US	US19900616170 19901120; US19910746020 19910815; US19910777626 19911023									
	CA2135890	Abbott Laboratories US	US19920998114 19921229; US19930158587 19931202	WO9414436 A Y 1994-07-07								
	CA2224738	Abbott Laboratories US	US19950000654P 19950629; US19950003849P 19950915; WO1996US11015 19960628	WO9701349 A Y 1997-01-16								
	US5846987	Abbott Laboratories US	US19970821609 19970320; US19950417879 19950406; US19930158587 19931202; US19920998114 19921229	WO9414436 A Y 1994-07-07		BR1100661 A N 2000-04-11						
	US5674882	Abbott Laboratories US	US19950413136 19950329; US19920998114 19921229; US19930158587 19931202; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523	WO9414436 A Y 1994-07-07								
	US5541206	Abbott Laboratories US	US19950423387 19950425; US19930158587 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523	WO9414436 A Y 1994-07-07								

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) / Lopinavir (LPV) (continued)	US5635523	Abbott Laboratories US	US19950417879 19950406; US19930158587 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523	WO9414436 A Y 1994-07-07								
	US5648497	Abbott Laboratories US	US19950410623 19950324; US19940270210 19940823; US19930121673 19930914; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523									
	US6703403	Abbott Laboratories US	US20010957171 20010920; US19990387261 19990831; US19960687774 19960626; US19950000654P 19950629; US19950003849P 19950915	WO9701349 A Y 1997-01-16								
	US6232333	Abbott Laboratories US	US19970966495 19971107; US19960031463P 19961121									
	US5484801	Abbott Laboratories US	US19950440277 19950512; US19940283239 19940729; US19940189021 1994012	WO9520384 A Y 1995-08-03								
	US5886036	Abbott Laboratories US	US19970822071 19970320; US19950413136 19950329; US19930158587 19931202; US19920998114 19921229	WO9701349 A Y 1997-01-16								
	US6037157	Abbott Laboratories US	US19950003849P 19950915; US19960687774 19960626; US19950000654P 19950629	WO9701349 A Y 1997-01-16								
Nevirapine (NVP)	CA2030056		US19890438923 19891117; US19900579001 19900906; US19900600390 19901019		AP179 A N 1992-04-30				OA9852 A - 1994-08-15	RU2040527 C N 1995-07-25		ZA9009246 A N 1992-07-29
	US5366972	Boehringer Ingelheim Pharmaceuticals, Inc.	US19930091418 19930713; US19890340970 19890420; US19890372974 19890628; US19890438923 19891117; US19900579001 19900906; US19900600390 19901019; US19910740828 19910805		AP189 A N 1992-05-04 AP179 A N 1992-04-30				OA9852 A - 1994-08-15 OA9741 A N 1993-11-30	RU2024522 C N 1994-12-15 RU2040527 C N 1995-07-25		ZA9004991 A N 1992-03-25 ZA9009246 A N 1992-07-29
Atazanavir (ATV)	US5849911	Novartis Finance Corporation	CH19960001018 19960422; CH19970000223 19970131	WO9740029 A Y 1997-10-30		BR9701877 A N 1998-09-29	CN1082508C C 2002-04-10 CN1193010C C 2005-03-16 CN1216539 A N 1999-05-12 CN1319587 A N 2001-10-31 CN1616453 A N 2005-05-18					ZA9703387 A N 1997-10-22
	CA2317736	Bristol-Myers Squibb Company US	US19980071968P 19980120; WO1998US27382 19981222	WO9936404 A Y 1999-07-22		BR9814736 A N 2000-10-24	CN1283188 A 2001-02-07 CN1116282C C N 2003-07-30			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)	Aripo(AP)	Brazil (BR)	China (CN)	India (IN)	OAPI (OA)	Russian Federation (RU)	Ukraine (UA)	South Africa (ZA)
Atazanavir (ATV) (continued)	US6087383	Bristol-Myers Squibb Company	US19980217538 19981221; US19980071968P 19980120	WO9936404 A Y 1999-07-22		BR9814736 A N 2000-10-24	CN1283188 A 2001-02-07 CN1116282C C N 2003-07-30			RU2186070 C N 2002-07-27		ZA9900056 A N 2000-07-05
Didanosine (DDI)	CA1269044	US Health	US19850769016 19850826	WO8701284 A Y 1987-03-12								
	CA2072573	US Health (US)	US19900460490 19900103	WO9109605 A Y 1991-07-11								
	CA2074215	Squibb Bristol Myers Co. (US)	US19910733547 19910722; US19920882204 19920513				CN1042299C C 1999-03-03 CN1068739 A N 1993-02-10			RU2089193 C N 1997-09-10		ZA9205484 A N 1993-09-13
	US4861759	The United States of America as represented by the Department of Health	US19870084055 19870811; US19850769016 19850826	WO8701284 A Y 1987-03-12								
	US5254539	U.S. Government, Dept. of Health and Human Services, c/o National	US19910663288 19910228; US19870084055 19870811; US19890420664 19890828; US19850769016 19850826; US19860937925 19861204	WO8701284 A Y 1987-03-12								
	US5616566	The United States of America as represented by the Department of Health	US19930056043 19930430; US19910663288 19910228; US19890420664 19890828; US19870084055 19870811; US19860937925 19861204; US19850769016 19850826	WO8701284 A Y 1987-03-12								
	US5880106	Bristol-Myers Squibb Company	US19970942660 19971002; US19920882204 19920513; US19910733547 19910722				CN1042299C C 1999-03-03 CN1068739 A N 1993-02-10			RU2089193 C N 1997-09-10		ZA9205484 A N 1993-09-13
Stavudine (D4T)	CA1293447 US4978655	Yale University	US19860942666 19861217									ZA8707171 A N 1988-03-24
Emtricitabine (FCT)	CA2075189	Emory University (US)	US19900473318 19900201, WO1991US00685 19910131	WO9111186 A Y 1991-08-08						RU2125558 C N 1999-01-27		
	CA2009637	BioChem Pharma Inc. (Canada)	CA19922152269 19921221; US19890308101 19890208		AP136 A N 1991-08-05		CN1033640C C 1996-12-25 CN1044817 A N 1990-08-22		OA9193 A N 1992-06-30	RU2092485 C N 1997-10-10		ZA9000943 A N 1990-10-31
	US5210085	Emory University	US19910659760 19910222; US19900473318 19900201	WO9111186 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 CN1065065 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 CN1418966 A N 2003-05-21			RU2125558 C N 1999-01-27		ZA9201251 A N 1993-08-20

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Emtricitabine (FCT) (continued)	US5814639	Emory University	US19930017820 19930216; US19910659760 19910222; US19900473318 19900201	WO9111186 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 CN1065065 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 CN1418966 A N 2003-05-21			RU2125558 C N 1999-01-27		ZA9201251 A N 1993-08-20
	US5914331	Emory University	US19950488097 19950607; US19920831153 19920212; US19910659760 19910222; US19900473318 19900201; US19910736089 19910726	WO9111186 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 CN1065065 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 CN1418966 A N 2003-05-21			RU2125558 C N 1999-01-27 RU2235724 C N 2004-09-10		ZA9201251 A N 1993-08-20
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	US6703396	Emory University	US19950402730 19950313; GB19910004741 19910306; GB19910009505 19910502; US19930092248 19930715; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201	WO9111186 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 CN1065065 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 CN1418966 A N 2003-05-21			RU2116789 C N 1998-08-10 RU2125558 C N 1999-01-27		ZA9201251 A N 1993-08-20 ZA9201658 A N 1993-09-06
Tenofovir Disoproxil fumarate (TDF)	US5922695 (CA2261619)	Gilead Sciences, Inc	US19970900746 19970725; US19960022708P 19960726	WO9804569 A Y 1998-02-05								
	US5935946	Gilead Sciences, Inc	US19970900752 19970725	WO9905150 A Y 1999-02-04		BR9811045 A N 2000-08-22	CN1554350 A N 2004-12-15 CN1264387 A N 2000-08-23 CN1745755	IN190780 A N 2003-08-23				
	US5977089	Gilead Sciences, Inc.	US19980187763 19981106; US19970900746 19970725; US19960022708P 19960726	WO9804569 A Y 1998-02-05								

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Tenofovir Disoproxil fumarate (TDF) (continued)	US6043230	Gilead Sciences, Inc	US19990314606 19990519; US19970900746 19970725; US1996022708P 19960726	WO9804569 A Y 1998-02-05								
Zidovudine (AZT) / Lamivudine (3TC)	CA2068790	Glaxo Group Limited	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344 A Y 1992-11-26			CN1045961C C 1999-10-27 CN1068570 A N 1993-02-03		OA10058 A N 1996-10-14	RU2139059 C N 1999-10-10		ZA9203544 A N 1993-03-31
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	US5905082	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
	CA2216634	THE WELLCOME FOUNDATION LIMITED (U.K.)	WO1996EP01352 19960328, GB19950006489 19950330; GB19950006490 19950330	WO9630025 A Y 1996-10-03	AP652 A N 1998-06-19	BR9607851 A N 1998-07-21	CN1103593C C 2003-03-26 CN1185110 A N 1998-06-17		OA10616 A N 2001-03-15			ZA9602477 A N 1997-10-28
	US5859021	Glaxo Group Limited	US19960605610 19960222; GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106; US19940219176 19940328; US19920883169 19920515	WO9220344 A Y 1992-11-26			CN1045961C C 1999-10-27 CN1068570 A N 1993-02-03		OA10058 A N 1996-10-14	RU2139059 C N 1999-10-10		ZA9203544 A N 1993-03-31
	US6113920	Glaxo Group Limited	US19970955635 19971023; GB19960022681 19961031; US1996029240P 19961031	WO9818477 A Y 1998-05-07	AP1067 A N 2002-05-01	BR9712614 A N 1999-10-26			OA11038 A N 2002-02-06		UA64725 C N 1999-12-29	ZA9709726 A N 1999-04-29
Abacavir (ABC)	CA2033044	The Wellcome Foundation Limited (U.K.)	US19890455201 19891222		AP196 A N 1992-06-30		CN1054981 A N 1991-10-02 CN1028106C C 1995-04-05			RU2068849 C N 1996-11-10 RU2091386 C N 1997-09-27		ZA9010365 A N 1992-08-26
	CA1340589 US5089500 US5034394	Burroughs Wellcome Co.	GB19880015265 19880627		AP101 A N 1990-10-23							ZA8904837 A N 1991-03-27
	US6294540	Glaxo Wellcome Inc.	WO1998EP02835 19980514; GB19970009945 19970517	WO9852570 A Y 1998-11-26 WO9852571 A Y 1998-11-26 WO9852949 A Y 1998-11-26		BR9809124 A N 2000-08-01 BR9809126 A N 2000-08-01 BR9809127 A N 2000-08-01	CN1150194C C 2004-05-19 CN1263529 A N 2000-08-16 CN1515572 A N 2004-07-28		OA11304 A N 2003-10-22			ZA9804083 A N 1999-11-15 ZA9804085 A N 1999-11-15
Abacavir (ABC)/ Zidovudine (AZT) / Lamivudine (3TC)	CA2068790	Glaxo Group Limited (GB)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344 A Y 1992-11-26			CN1045961C C 1999-10-27 CN1068570 A N 1993-02-03		OA10058 A N 1996-10-14	RU2139059 C N 1999-10-10		ZA9203544 A N 1993-03-31
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Abacavir (ABC)/ Lamivudine (3TC)	CA2311988	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		ZA9204007 A N 1993-04-28
	US6417191	GlaxoSmithKline	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025 A Y 1996-10-03	AP652 A N 1998-06-19	BR9607851 A N 1998-07-21	CN1103593C C 2003-03-26 CN1185110 A N 1998-06-17		OA10616 A N 2001-03-15			ZA9602477 A N 1997-10-28
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Lamivudine (3TC)	CA2059263	Iaf Biochem International Inc. (Canada)	GB19900009861 19900502; WO1991GB00706 19910502	WO9117159 A Y 1991-11-14	AP182 A N 1992-06-30		CN1056145C C 2000-09-06 CN1058214 A N 1992-01-29 CN1108655 A N 1995-09-20 CN1154500C C 2004-06-23 CN1326743 A N 2001-12-19 CN1036196C C 1997-10-22		OA9559 A N 1993-01-31	RU2099338 C N 1997-12-20		ZA9103293 A N 1992-02-26
	CA2009637 US5047407	BioChem Pharma, Inc.	CA19922152269 19921221; US19890308101 19890208		AP136 A N 1991-08-05		CN1044817 A N 1990-08-22 CN1033640C C 1996-12-25		OA9193 A N 1992-06-30	RU2092485 C N 1997-10-10		ZA9000943 A N 1990-10-31
	CA2070230 US5905082	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
	CA2286126	Glaxo Group Limited	GB19970006295 19970326; US19970042353P 19970324; WO1998EP01626 19980320	WO9842321 A Y 1998-10-01	AP1141 A N 2003-01-29	BR9808060 A N 2000-03-08	CN1191061C C 2005-03-02 CN1255849 A N 2000-06-07					ZA9802367 A N 1999-09-20
	CA2100269 (hep B) US5532246	Iaf Biochem Int (CA)	GB19910000039 19910103; GB19910009913 19910507; WO1992CA00001 19920103	WO9211852 A Y 1992-07-23								
	US6004968	Glaxo Wellcome Inc.	US19970042353P 19970324 GB19910011902 19910603	WO9842321 A Y 1998-10-01	AP1141 A N 2003-01-29	BR9808060 A N 2000-03-08	CN1191061C C 2005-03-02 CN1255849 A N 2000-06-07					ZA9802367 A N 1999-09-20
Indinavir (IDV)	CA2081970	Merck & Co., Inc.	US19910789508 19911108; US19920883825 19920515	WO9309096 A Y 1993-05-13						RU2171254 C N 2001-07-27 RU2131416 C N 1999-06-10		ZA9208563 A N 1993-05-05
	US5413999	Merck & Co., Inc.	US19930059038 19930507; US19930040729 19930331; US19920883825 19920515; US19910789508 19911108	WO9309096 A Y 1993-05-13 WO9422480 A Y 1994-10-13 WO9426717 A Y 1994-11-24		BR9406576 A N 1996-01-30 BR9406503 A N 1996-01-02	CN1176250 A N 1998-03-18 CN1126469 A N 1996-07-10 CN1120316 A N 1996-04-10 CN1090187C C 2002-09-04			RU2171254 C N 2001-07-27 RU2139052 C N 1999-10-10 RU2131416 C N 1999-06-10		ZA9208563 A N 1993-05-05 ZA9402255 A N 1994-11-01 ZA9403104 A N 1995-11-06
	US6645961	Merck & Co., Inc.	US19980045885 19980304; US19970040158P 19970307		no family found							
	US6689761	Merck & Co., Inc.	US19950382113 19950201	WO9623509 A Y 1996-08-08		BR9607714 A N 1998-01-13	CN1179722 A N 1998-04-22 CN1160081C C 2004-08-04					ZA9600722 A N 1996-08-26
Efavirenz (EFV)	CA2101572	Merck & Co., Inc.	US19930054805 19930427; US19920926607 19920807	WO9403440 A Y 1994-02-17			CN1250652 A N 2000-04-19 CN1221608 A N 1999-07-07 CN1107505C C 2003-05-07 CN1090277 A N 1994-08-03 CN1051767C C 2000-04-26			RU2186775 C N 2002-08-10		ZA9305724 A N 1994-03-03

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Efavirenz (EFV) (continued)	US5519021	Merck & Co., Inc	US19950460026 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807	WO9403440 A Y 1994-02-17 WO9520389 A Y 1995-08-03			CN1250652 A N 2000-04-19 CN1221608 A N 1999-07-07 CN1107595C C 2003-05-07 CN1090277 A N 1994-08-03 CN1051767C C 2000-04-26			RU2186775 C N 2002-08-10		ZA9305724 A N 1994-03-03
	US5663169	Merck & Co., Inc	US19950498528 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807	WO9403440 A Y 1994-02-17 WO9520389 A Y 1995-08-03			CN1250652 A N 2000-04-19 CN1221608 A N 1999-07-07 CN1107595C C 2003-05-07 CN1090277 A N 1994-08-03 CN1051767C C 2000-04-26			RU2186775 C N 2002-08-10		ZA9305724 A N 1994-03-03
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	US6933964	Bristol-Myers Squibb Company	US20040891749 20040624; US20030447690 20030529; US20010000537 20011019; US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408	WO9833782 A Y 1998-08-06			CN1385425 A N 2002-12-18 CN1246113 A N 2000-03-01 CN1191244C C 2005-03-02 CN1073991C C 2001-10-31					
	US6238695	DuPont Pharmaceuticals Company	US19990286902 19990406; US19980080925P 19980407	WO9951239 A Y 1999-10-14		BR9908810 A N 2000-12-19	CN1196412 A N 2001-05-23 CN1146419C C 2004-04-21				UA72207 C N 2001-02-15	ZA200004313 A N 2001-11-07
	US6555133	Bristol-Myers Squibb Company	US20010824071 20010402; US19990286902 19990406; US19980080925P 19980407	WO9951239 A Y 1999-10-14		BR9908810 A N 2000-12-19	CN1196412 A N 2001-05-23 CN1146419C C 2004-04-21				UA72207 C N 2001-02-15	ZA200004313 A N 2001-11-07
Nelfinavir (NFV)	US5484926 CA2173328	Agouron Pharmaceuticals, Inc. (US)	US19930135343 19931007; US19930136961 19931007; US19940190764 19940202; WO1994US11307 19941007	WO9509843 A Y 1995-04-13	AP600 A N 1997-07-23	BR9407782 A N 1997-03-18	CN1046269C C 1999-11-10 CN1131942 A N 1996-09-25 CN1195737C C 2005-04-06 CN1262272 A N 2000-08-09		OA10718 A N 2001-11-02	RU2139280 C N 1999-10-10		ZA9407815 A N 1996-07-08

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Nelfinavir (NFV) (continued)	US5952343	Agouron Pharmaceuticals, Inc. (US)	US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007; US19930137254 19931018; US19920995621 19921222	WO9509843 A Y 1995-04-13	AP600 A N 1997-07-23	BR9407782 A N 1997-03-18 BR9305161 A N 1994-11-01	CN1262272 A N 2000-08-09 CN1195737C 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)	US19990283152 19990401; US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007	WO9509843 A Y 1995-04-13	AP600 A N 1997-07-23	BR9407782 A N 1997-03-18	CN1046269C C 1999-11-10 CN1131942 A N 1996-09-25 CN1195737C C 2005-04-06 CN1262272 A N 2000-08-09		OA10718 A N 2001-11-02	RU2139280 C N 1999-10-10		ZA9407815 A N 1996-07-08
Saquinavir (SQV)	CA1340588	F. Hoffmann-La Roche & Co. Aktiengesellschaft (Switzerland)	GB19880013940 19880613; GB19890008035 19890410									ZA8904285 A N 1990-02-28
	CA2030433 US5196438	Hoffmann-La Roche Inc.	GB19890027913 19891211		Zimbawe ZW17490 A N 1992-06-17	BR9006264 A N 1991-09-24	CN1034805C C 1997-05-07 CN1052482 A N 1991-06-26 CN1066329C C 2001-05-30 CN1138983 A N 1997-01-01	IN172553 A N 1993-09-25	OA9334 A N 1992-09-15	RU2071470 C N 1997-01-10		ZA9009743 A N 1991-08-28
	US6008228 CA2224125	Hoffmann-La Roche Inc.	US19950468493 19950606; US19960616233 19960507; WO1996EP02431 19960604	WO9639142 A Y 1996-12-12		BR9610842 A N 1999-07-13	CN1186434 A N 1998-07-01 CN1092960C C 2002-10-23	IN192899 A N 2004-05-29	OA10546 A N 2002-05-29			ZA9604448 A N 1996-12-06
	US6352717	Hoffman-La Roche Inc.	EP19980121831 19981117	WO0028942 A Y 2000-05-25		BR9915444 A N 2001-08-07	CN1326335 A N 2001-12-12 CN1172649C C 2004-10-27			RU2219911 C N 2003-12-27		ZA200103891 A N 2002-08-14
Enfuvirtide (T20)	US5464933	Duke University	US19930073028 19930607	WO9428920 A Y 1994-12-22								
	US6133418	Duke University	US19950554616 19951106; US19930073028 19930607	WO9428920 A Y 1994-12-22								
	US6475491	Trimeris, Inc.	US19980973952 19980529; US19950481957 19950607; WO1996US09499 19960606	WO9640191 A Y 1996-12-19		BR9609152 A N 1999-05-04	CN1192688 A N 1998-09-09					
Amprenavir (APV)	CA2143208	Vertex Pharmaceuticals, Incorporated (USA)	US19920941982 19920908; WO1993US08458 19930907	WO9405639 A Y 1994-03-17	AP390 A N 1995-08-02	BR1100824 A N 1999-08-31	CN1061339C C 2001-01-31 CN1087347 A N 1994-06-01			RU2135496 C N 1999-08-27		
	US5585397	Vertex Pharmaceuticals, Incorporated (USA)	US19930142327 19931124; US19920941982 19920908; WO1993US08458 19930907	WO9405639 A Y 1994-03-17	AP390 A N 1995-08-02	BR1100824 A N 1999-08-31	CN1087347 A N 1994-06-01 CN1061339C C 2001-01-31			RU2135496 C N 1999-08-27		
	CA2249336	Glaxo Group Limited (U.K.)	GB19960006372 19960326; US19960013893P 19960322; US19970820848 19970320; WO1997EP01438 19970321	WO9735587 A Y 1997-10-02	AP1150 A N 2003-03-14	BR9708238 A N 1999-08-03	CN1225587 A N 1999-08-11		OA10880 A N 2001-10-11		UA67723 C N 2004-07-15	ZA9702387 A N 1997-12-10

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Amprenavir (APV) (continued)	US5646180	Vertex Pharmaceuticals Incorporated	US19950567199 19951205	WO9720554 A Y 1997-06-12	AP864 A N 2000-08-11	BR9611861 A N 1999-05-18	CN1203530 A N 1998-12-30		OA10691 A N 2001-05-04	RU2203658 C N 2003-05-10	UA61902 C N 2003-12-15	ZA9610139 A N 1997-06-17
	US5723490	Vertex Pharmaceuticals Incorporated	US19950424819 19950419; US19950393460 19950223; US19930142327 19931124; US19920941982 19920908	WO9405639 A Y 1994-03-17 WO9633184 A Y 1996-10-24	AP950 A N 2001-03-28 AP390 A N 1995-08-02	BR9608032 A N 1999-01-12 BR1100824 A N 1999-08-31	CN1181755 A N 1998-05-13 CN1087347 A N 1994-06-01 CN1061339C C 2001-01-31			RU2135496 C N 1999-08-27		
	US6730679	SmithKline Beecham Corporation	US19970820848 19970320; US19960013893P 19960322	WO9735587 A Y 1997-10-02	AP1150 A N 2003-03-14	BR9708238 A N 1999-08-03	CN1225587 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 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)	US19960754390 19961121; WO1997US20794 19971112	WO9822106	CA2271196	Abbott Laboratories US	CN1248914 A N 2000-03-29	CN1250219C 2006-04-12	97199780,2	1997.11.12	2006.04.12	2017.11.12	valid
	US19960753201 19961121; US19950572226 19951213; WO1996US20440 19961206	WO9721685	US5914332 CA2238978	Abbott Laboratories US	CN1208405 A N 1999-02-17	CN1207288C C 2005-06-22	96199904,7	1996.12.6	2005.6.22	2016.12.6	valid
	US19980207873 19981208; US19960753201 19961121; US19950572226 19951213		US6284767	Abbott Laboratories US	CN1208405 A N 1999-02-17	CN1207288C C 2005-06-22					
	US19990393872 19990910; US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121		US6521651	Abbott Laboratories US							
	US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121		US6458818	Abbott Laboratories US							
	US20010946085 20010904; US20000230095P 20000905		US6911214	Abbott Laboratories US							
Ritonavir/ Lopinavir (RTV/ LPV)	US19900616170 19901120; US19910746020 19910815; US19910777626 19911023		CA2055670	Abbott Laboratories US							
	US19920998114 19921229; US19930158587 19931202	WO9414436	CA2135890	Abbott Laboratories US							
	US19950000654P 19950629; US19950003849P 19950915; WO1996US11015 19960628	WO9701349	CA2224738	Abbott Laboratories US							
	US19970821609 19970320; US19950417879 19950406; US19930158587 19931202; US19920998114 19921229		US5846987	Abbott Laboratories US							
	US19950413136 19950329; US19920998114 19921229; US19930158587 19931202; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		US5674882	Abbott Laboratories US							
	US19950423387 19950425; US19930158587 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		US5541206	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/ Lopinavir (RTV/ LPV) (continued)	US19950417879 19950406; US19930158587 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		US5635523	Abbott Laboratories US							
	US19950410623 19950324; US19940270210 19940823; US19930121673 19930914; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		US5648497	Abbott Laboratories US							
	US20010957171 20010920; US19990387261 19990831; US19960687774 19960626; US19950000654P 19950629; US19950003849P 19950915		US6703403	Abbott Laboratories US							
	US19970966495 19971107; US19960031463P 19961121		US6232333	Abbott Laboratories US							
	US19950440277 19950512; US19940283239 19940729; US19940189021 1994012		US5484801	Abbott Laboratories US							
	US19970822071 19970320; US19950413136 19950329; US19930158587 19931202; US19920998114 19921229		US5886036	Abbott Laboratories US							
	US19950003849P 19950915; US19960687774 19960626; US19950000654P 19950629		US6037157	Abbott Laboratories US							
Nevirapine (NVP)	US19890438923 19891117; US19900579001 19900906; US19900600390 19901019		CA2030056	Boehringer Ingelheim Pharma (DE); Thomae GmbH DR K (DE)							
	US19930091418 19930713; US19890340970 19890420; US19890372974 19890628; US19890438923 19891117; US19900579001 19900906; US19900600390 19901019; US19910740828 19910805		US5366972	Boehringer Ingelheim Pharmaceuticals, Inc.							
Atazanarir (ATV)	CH19960001018 19960422; CH19970000223 19970131		US5849911	Novartis Finance Corporation	CN1216539 A 1999.05.12	CN1082508C C 2002-04-10	97194025,8	1997.4.14	2002.4.10	2017.4.14	Valid
					CN1319587A 2001-10-31	CN1193010C C 2005-03-16	1103494,7	1997.4.14	2005.3.16	2017.4.14	Valid
					CN1616453 A N 2005-05-18	Non-issued	200410079187.5;	missing data	No patent		No patent
	US19980071968P 19980120; WO1998US27382 19981222	WO9936404	CA2317736	Bristol-Myers Squibb Company US	CN1283188 A 2001-02-07	CN1116282C C N 2003-07-30	98812741,5	1997.4.14	2003.7.30	2017.4.14	Valid

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.
Atazanarir (ATV) (continued)	US19980217538 19981221; US19980071968P 19980120		US6087383	Bristol-Myers Squibb Company	CN1283188 A 2001-02-07 CN1116282C C N 2003-07-30						
Didanosine (DDI)	US19850769016 19850826	WO8701284	CA1269044	US Health (US)							
	US19900460490 19900103	WO9109605	CA2072573	US Health (US)							
	US19910733547 19910722; US19920882204 19920513		CA2074215	Squibb Bristol Myers Co. (US)	CN1068739 A N 1993-02-10	CN1042299C C 1999-03-03	92108657,1	1992.7.21	1999.3.3	2007.7.21	Valid
	US19870084055 19870811; US19850769016 19850826		US4861759	The United States of America as represented by the Department of Health							
	US19910663288 19910228; US19870084055 19870811; US19890420664 19890828; US19850769016 19850826; US19860937925 19861204		US5254539	U.S. Government, Dept. of Health and Human Services, c/o National							
	US19930056043 19930430; US19910663288 19910228; US19890420664 19890828; US19870084055 19870811; US19860937925 19861204; US19850769016 19850826		US5616566	The United States of America as represented by the Department of Health							
	US19970942660 19971002; US19920882204 19920513; US19910733547 19910722		US5880106	Bristol-Myers Squibb Company	CN1042299C C 1999-03-03 CN1068739 A N 1993-02-10						
Stavudine (D4T)	US19860942666 19861217		CA1293447 US4978655	Yale University							
Emtricitabine (FCT)	US19900473318 19900201, WO1991US00685 19910131	WO9111186	CA2075189	Emory University (US)							
	CA19922152269 19921221; US19890308101 19890208		CA2009637	BioChem Pharma Inc. (Canada)	CN1044817 A N 1990-08-22	CN1033640C C 1996-12-25	90100612,2	1990.2.8	1996.12.25	2005.2.8	Valid
	US19910659760 19910222; US19900473318 19900201		US5210085	Emory University	CN1065065 A 1992.10.07	CN1037682C C 1998-03-11	92101981,5	1992.2.22	11/03/1998	2007.2.22	Valid
					CN1203232 A 1998.12.30	CN1084745C C 2002-05-15	98108905,4	1998.05.15	15/05/2002	2018.05.15	valid
					CN1127301 A 1996.07.24	CN1109108C C 2003-05-21	95109814,4	1995.08.18	21/05/2003	2015.08.18	valid
					CN1418966 A N 2003-05-21	Non-issued	2144033,6	2002.09.30	No patent		No patent
	US19930017820 19930216; US19910659760 19910222; US19900473318 19900201		US5814639	Emory University							
	US19950488097 19950607; US19920831153 19920212; US19910659760 19910222; US19900473318 19900201; US19910736089 19910726		US5914331	Emory University	CN1037682C C 1998-03-11 CN1065065 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 CN1418966 A N 2003-05-21						

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Emtricitabine (FCT) (continued)	US19950475339 19950607; US19920831153 19920212; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201		US6642245	Emory University	CN1037682C C 1998-03-11 CN1065065 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 CN1418966 A N 2003-05-21						
	US19950402730 19950313; GB19910004741 19910306; GB19910009505 19910502; US19930922448 19930715; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201		US6703396	Emory University	CN1037682C C 1998-03-11 CN1065065 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 CN1418966 A N 2003-05-21						
Tenofovir disoproxil fumarate (TDF)	US19970900746 19970725; US19960022708P 19960726		US5922695	Gilead Sciences, Inc							
	US19970900752 19970725		US5935946	Gilead Sciences, Inc	CN1554350 A N 2004-12-15	CN1251679C 2006-04-19	200410046290.x	1998.7.23	2006.4.19	2018.7.23	Valid
					CN1264387 A N 2000-08-23	Non-issued	98807435.4	1998.7.23			No patent
	US19980187763 19981106; US19970900746 19970725; US19960022708P 19960726		US5977089	Gilead Sciences, Inc.							
	US19990314606 19990519; US19970900746 19970725; US19960022708P 19960726		US6043230	Gilead Sciences, Inc							
Zidovudine/ Lamivudine (AZT/3TC)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344	CA2068790	Glaxo Group Limited	CN1068570 A N 1993-02-03	CN1045961C C 1999-10-27	92104553	1992.5.15	1999.10.27	2005.5.15	Valid
	CA19922070230 19920602; GB19910011902 19910603		CA2311988	Glaxo Group Limited							
	GB19910011902 19910603	WO9221676	US5905082	Glaxo Group Limited							
	WO1996EP01352 19960328, GB19950006489 19950330; GB19950006490 19950330	WO9630025	CA2216634	The Wellcome Foundation Limited (U.K.)	CN1185110 A N 1998-06-17	CN1103593C C 2003-03-26	96194050.6	1996.3.28	2003-03-26	2016.3.28	Valid
	US19960605610 19960222; GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106; US19940219176 19940328; US19920883169 19920515		US5859021	Glaxo Group Limited	CN1045961C C 1999-10-27 CN1068570 A N 1993-02-03						
	US19970955635 19971023; GB19960022681 19961031; US19960029240P 19961031		US6113920	Glaxo Group Limited							

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.
Abacavir (ABC)	US19890455201 19891222		CA2033044	The Wellcome Foundation Limited (U.K.)	CN1054981 A N 1991-10-02	CN1028106C C 1995-04-05	91100671	1990.12.21	05/04/1995	2005.12.21	Valid
	GB19880015265 19880627		CA1340589 US5089500 US5034394	Burroughs Wellcome Co.							
	WO1998EP02835 19980514; GB19970009945 19970517	WO9852949	US6294540	Glaxo Wellcome Inc.	CN1263529 A 2000.08.16	CN1150194C C 2004-05-19	98807073,1	1998.5.14	19/05/2004	2018.5.14	Valid
					CN1515572 A N 2004-07-28	Non-issued	3102921,3	1998.5.14	No patent		No patent
Abacavir/ Zidovudine/ Lamivudine (ABC/AZT/3TC)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344	CA2068790	Glaxo Group Ltd. (GB)	CN1045961C C 1999-10-27 CN1068570 A N 1993-02-03						
	CA19922070230 19920602; GB19910011902 19910603		CA2311988	Glaxo Group Ltd. (GB)							
	GB19910011902 19910603	WO9221676	US5905082	Glaxo Group Limited							
	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025	US6417191	GlaxoSmith Kline	CN1185110 A N 1998-06-17	CN1103593C C 2003-03-26	96194050,6	1996.3.28	26/03/2003	2016.3.28	valid
(ABC/3TC)	CA19922070230 19920602; GB19910011902 19910603		CA2311988	Glaxo Group Ltd. (GB)							
	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025	US6417191	GlaxoSmith Kline	CN1103593C C 2003-03-26 CN1185110 A N 1998-06-17						
	GB19910011902 19910603	WO9221676	US5905082	Glaxo Group Limited							
Lamivudine (3TC)	GB19900009861 19900502; WO1991GB00706 19910502	WO9117159	CA2059263	IAF BioChem Int. (Canada)	CN1108655 A 1995.09.20	CN1056145C C 2000-09-06	94109429,4	1994.8.15	06/09/2000	2014.8.15	Valid
					CN1326743 A 2001.12.19	CN1154500C C 2004-06-23	99126580,7	1994.8.15	23/06/2004	2014.8.15	Valid
					CN1058214 A 1992.01.29	CN1036196C C 1997-10-22	91102778,5	1991.4.30	22/10/1997	2006.4.30	Valid
	CA19922152269 19921221; US19890308101 19890208		CA2009637 US5047407	BioChem Pharma, Inc.	CN1044817 A N 1990-08-22	CN1033640C C 1996-12-25	90100612,2	1990.2.8	25/12/1996	2005.2.8	Valid
	GB19910011902 19910603	WO9221676	CA2070230 US5905082	Glaxo Group Limited							
	GB19970006295 19970326; US19970042353P 19970324; WO1998EP01626 19980320	WO9842321	CA2286126	Glaxo Group Limited	CN1255849 A N 2000-06-07	CN1191061C C 2005-03-02	98805122,2	1998.3.20	2005-03-02	2018.3.20	Valid
	GB19910000039 19910103; GB19910009913 19910507; WO1992CA00001 19920103	WO9211852	CA2100269 (hep B) US5532246	IAF BioChem Int. (CA)							
	US19970042353P 19970324 GB19910011902 19910603	WO9842321	US6004968	Glaxo Wellcome Inc.	CN1191061C C 2005-03-02 CN1255849 A N 2000-06-07						
Indinavir (IDV)	US19910789508 19911108; US19920883825 19920515	WO9309096	CA2081970	Merck & Co., Inc.							
	US19930059038 19930507; US19930040729 19930331; US19920883825 19920515; US19910789508 19911108		US5413999	Merck & Co., Inc.	CN1176250 A N 1998-03-18	seen as rejected (1999.08.11)	97101853	1997.2.1	no patent		seen as rejected (1999.08.11)
					CN1126469 A N 1996-07-10	seen as rejected (1999.08.11)	94192691	1994.4.26	no patent		seen as rejected (1999.08.11)

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.
Indinavir (IDV) (continued)					CN1120316 A N 1996-04-10	CN1090186C 2002-09-04	94191671	1994.3.24	2002.09.04	2014.03.24	valid
	US19980045885 19980304; US19970040158P 19970307		US6645961	Merck & Co., Inc.							
	US19950382113 19950201	WO9623509	US6689761	Merck & Co., Inc.	CN1179722 A N 1998-04-22	CN1160081C C 2004-08-04	96192910.3	1996.1.29	04/08/2004	2016.1.29	valid
Efavirenz (EFV)	US19930054805 19930427; US19920926607 19920807	WO9403440	CA2101572	Merck & Co., Inc.	CN1250652 A N 2000-04-19	Non-issued	99118108.5	1999.8.20	no patent		No patent
					CN1221608 A 1999.07.07	CN1107505C C 2003-05-07	98121309.x	1998.10.10	07/05/2003	2018.10.10	valid
					CN1090277 A 1994.08.03	CN1051767C C 2000-04-26	93117660.3	1993.8.6	26/04/2000	2013.8.6	valid
	US19950460026 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807		US5519021	Merck & Co., Inc.	CN1250652 A N 2000-04-19 CN1221608 A N 1999-07-07 CN1090277 A N 1994-08-03	CN1107505C C 2003-05-07 CN1051767C C 2000-04-26					
	US19950458528 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807		US5663169	Merck & Co., Inc.	CN1250652 A N 2000-04-19 CN1221608 A N 1999-07-07 CN1090277 A N 1994-08-03	CN1107505C C 2003-05-07 CN1051767C C 2000-04-26					
	US19970815780 19970312; US19950458529 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807		US5811423	Merck & Co., Inc.	CN1250652 A N 2000-04-19 CN1221608 A N 1999-07-07 CN1090277 A N 1994-08-03	CN1107505C C 2003-05-07 CN1051767C C 2000-04-26					
	US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408; US20010000537 20011019		US6639071	Merck & Co., Inc	CN1385425 A N 2002-12-18	CN1191242C C 2005-03-02	1122709.5	1998.2.2	2005-03-02	2018.2.2	valid
					CN1246113 A 2000.03.01	CN1073991C C 2001-10-31	98802171.4	1998.2.2	2001-10-31	2018.2.2	valid
	US20040891749 20040624; US20030447690 20030529; US20010000537 20011019; US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408		US6939964	Bristol-Myers Squibb Company	CN1385425 A N 2002-12-18 CN1246113 A N 2000-03-01	CN1191242C C 2005-03-02 CN1073991C C 2001-10-31					
	US19990286902 19990406; US19980080925P 19980407		US6238695	DuPont Pharmaceuticals Company	CN1296412 A N 2001-05-23	CN1146419C C 2004-04-21	99804801.1	1999.4.1	2004-04-21	2019.4.1	valid
	US20010824071 20010402; US19990286902 19990406; US19980080925P 19980407		US6555133	Bristol-Myers Squibb Company	CN1296412 A N 2001-05-23	CN1146419C C 2004-04-21					
Nelfinavir (NFV)	US19930133543 19931007; US19930133696 19931007; US19940190764 19940202; WO1994US11307 19941007	WO9509843	US5484926 CA2173328	Agouron Pharmaceuticals, Inc. (US)	CN1131942 A 1996.09.25	CN1046269C C 1999-11-10	94193534.5	1994.10.7	10/11/1999	2014.10.7	valid
					CN1262272 A 2000.08.09	CN1195737C C 2005-04-06	99105164.5	1994.10.7	06/04/2005	2014.10.7	valid
	US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007; US19930137254 19931018; US19920995621 19921222		US5952343	Agouron Pharmaceuticals, Inc. (US)		CN1195737C C 2005-04-06	99105164.5	1994.10.7	06/04/2005	2014.10.7	valid

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.
Nelfinavir (NFV) (continued)						CN1046269C C 1999-11-10	94193534.5	1994.10.7	1999-11-10	2014.10.7	valid
	US19990283152 19990401; US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007		US6162812	Agouron Pharmaceuticals, Inc. (US)	CN1131942 A N 1996-09-25 CN1262272 A N 2000-08-09	CN1046269C C 1999-11-10CN1195737C C 2005-04-06					
Saquinavir (SQV)	GB19880013940 19880613; GB19890008035 19890410		CA1340588	F. Hoffmann-La Roche & Co. Aktiengesellschaft (Switzerland)							
	GB19890027913 19891211		CA2030433 US5196438	Hoffmann-La Roche Inc.	CN1052482 A 1991.06.26	CN1034805C C 1997-05-07	90109931,7	1990.12.10	07/05/1997	2015.12.10	valid
					CN1138983 A 1997.01.01	CN1066329C C 2001-05-30	96107466.3	1990.12.10	2001-05-30	2015.12.10	valid
	US19950468493 19950606; US19960616233 19960507; WO1996EP02431 19960604	WO9639142	US6008228 CA2224125	Hoffmann-La Roche Inc.	CN1186434 A N 1998-07-01	CN1092960C C 2002-10-23	96194327	1996.6.4	23/10/2002	2016.6.4	valid
	EP19980121831 19981117	WO0028942	US6352717	Hoffman-La Roche Inc.	CN1326335 A N 2001-12-12	CN1172649C C 2004-10-27	99813395,7	1999.11.11	27/10/2004	2019.11.11	valid
Enfuvirtide (T20)	US19930073028 19930607	WO9428920	US5464933	Duke University							
	US19950554616 19951106; US19930073028 19930607		US6133418	Duke University							
	US19980973952 19980529; US19950481957 19950607; WO1996US09499 19960606		US6475491	Trimeris, Inc.	CN1192688 A N 1998-09-09	rejected (2006-04-05)	96196051	1996.6.6	no patent		rejected (2006 04 05)
Amprenavir (APV)	US19920941982 19920908; WO1993US08458 19930907	WO9405639	CA2143208	Vertex Pharmaceuticals, Incorporated (USA)	CN1087347 A N 1994-06-01	CN1061339C C 2001-01-31	93117370,1	1993.9.8	31/01/2001	2013.9.8	valid
	US19930142327 19931124; US19920941982 19920908; WO1993US08458 19930907	WO9405639	US5585397	Vertex Pharmaceuticals, Incorporated (USA)	CN1225587 A N 1999-08-11	Non-issued	97193229,8	1997.3.21	no patent		
	GB19960006372 19960326; US19960013893P 19960322; US19970820848 19970320; WO1997EP01438 19970321	(WO9735587)	CA2249336	Glaxo Group Ltd. (GB)	CN1087347 A N 1994-06-01	CN1061339C C 2001-01-31	93117370,1	1993.9.8	31/01/2001	2013.9.8	valid
	US19950567199 19951205	WO9720554	US5646180	Vertex Pharmaceuticals Incorporated	CN1203530 A N 1998-12-30	seen as withdrawn (2003-8-13)	96198816,9	1996.12.5	No patent		seen as withdrawn (2003-8-13)
	US19950424819 19950419; US19950393460 19950223; US19930142327 19931124; US19920941982 19920908		US5723490	Vertex Pharmaceuticals Incorporated	CN1087347 A N 1994-06-01	CN1061339C C 2001-01-31	93117370,1	1993.9.8	31/01/2001	2013.9.8	valid
					CN1181755 A N 1998-05-13	seen as withdrawn (2001-07-25)	96193364	1996.04.18	no patent		seen as withdrawn (2001-07-25)
	US19970820848 19970320; US19960013893P 19960322		US6730679	SmithKline Beecham Corporation	CN1225587 A N 1999-08-11						

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

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 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 lapsed.
Ritonavir (RTV)	US19960754390 19961121; WO1997US20794 19971112	WO9822106	Abbott Laboratories US	CA2271196	ZA9710071 A N 1998-05-25	1997/10071	1997/10071	07/11/1997	29/07/1998	07/11/2017	in force
	US19960753201 19961121; US19950572226 19951213; WO1996US20440 19961206	WO9721685	Abbott Laboratories US	US5914332 CA2238978	ZA9610475 A N 1997-07-31	1996/10475	1996/10475	12/12/1996	29/10/1997	12/12/2016	in force
	US19980207873 19981208; US19960753201 19961121; US19950572226 19951213		Abbott Laboratories US	US6284767	ZA9610475 A N 1997-07-31	1996/10475	1996/10475	12/12/1996	29/10/1997	12/12/2016	in force
	US19990393872 19990910; US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121		Abbott Laboratories US	US6521651							
	US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121		Abbott Laboratories US	US6458818							
	US20010946085 20010904; US20000230095P 20000905		Abbott Laboratories US	US6911214							
Ritonavir (RTV) / Lopinavir (LPV)	US19900616170 19901120; US19910746020 19910815; US19910777626 19911023		Abbott Laboratories US	CA2055670							
	US19920998114 19921229; US19930158587 19931202	WO9414436	Abbott Laboratories US	CA2135890							
	US19950000654P 19950629; US19950003849P 19950915; WO1996US11015 19960628	WO9701349	Abbott Laboratories US	CA2224738							
	US19970821609 19970320; US19950417879 19950406; US19930158587 19931202; US19920998114 19921229		Abbott Laboratories US	US5846987							
	US19950413136 19950329; US19920998114 19921229; US19930158587 19931202; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		Abbott Laboratories US	US5674882							
	US19950423387 19950425; US19930158587 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		Abbott Laboratories US	US5541206							

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 lapsed.
Ritonavir (RTV) / Lopinavir (LPV) (continued)	US19950417879 19950406; US19930158587 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		Abbott Laboratories US	US5635523							
	US19950410623 19950324; US19940270210 19940823; US19930121673 19930914; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523		Abbott Laboratories US	US5648497							
	US20010957171 20010920; US19990387261 19990831; US19960687774 19960626; US19950000654P 19950629; US19950003849P 19950915		Abbott Laboratories US	US6703403							
	US19970966495 19971107; US19960031463P 19961121		Abbott Laboratories US	US6232333							
	US19950440277 19950512; US19940283239 19940729; US19940189021 1994012		Abbott Laboratories US	US5484801							
	US19970822071 19970320; US19950413136 19950329; US19930158587 19931202; US19920998114 19921229		Abbott Laboratories US	US5886036							
	US19950003849P 19950915; US19960687774 19960626; US19950000654P 19950629		Abbott Laboratories US	US6037157							
Nevirapine (NVP)	US19890438923 19891117; US19900579001 19900906; US19900600390 19901019			CA2030056	ZA9009246 A N 1992-07-29	1990/09246	1990/09246	19/11/1990	29/07/1992	19/11/2010	in force
	US19930091418 19930713; US19890340970 19890420; US19890372974 19890628; US19890438923 19891117; US19900579001 19900906; US19900600390 19901019; US19910740828 19910805		Boehringer Ingelheim Pharmaceuticals, Inc.	US5366972	ZA9004991 A N 1992-03-25	1990/04991	1990/04991	27/06/1990	25/03/1992	27/06/2010	in force
					ZA9009246 A N 1992-07-29	1990/09246	1990/09246	19/11/1990	29/07/1992	19/11/2010	in force
Atazanavir (ATV)	CH19960001018 19960422; CH19970000223 19970131		Novartis Finance Corporation	US5849911	ZA9703387 A N 1997-10-22	1997/03387	1997/03387	21/04/1997	31/12/1997	21/04/1997	in force
	US19980071968P 19980120; WO1998US27382 19981222	WO9936404	Bristol-Myers Squibb Company US	CA2317736	ZA9900056 A N 2000-07-05	1999/00056	1999/00056	05/01/1999	27/09/2000	05/01/2019	in force
	US19980217538 19981221; US19980071968P 19980120		Bristol-Myers Squibb Company	US6087383	ZA9900056 A N 2000-07-05	1999/00056	1999/00056	05/01/1999	27/09/2000	05/01/2019	in force
Didanosine (DDI)	US19850769016 19850826	WO8701284	US HEALTH (US)	CA1269044							
	US19900460490 19900103	WO9109605	US HEALTH (US)	CA2072573							

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 lapsed.
Didanosine (DDI) (continued)	US19910733547 19910722; US19920882204 19920513		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
	US19870084055 19870811; US19850769016 19850826		The United States of America as represented by the Department of Health	US4861759							
	US19910663288 19910228; US19870084055 19870811; US19890420664 19890828; US19850769016 19850826; US19860937925 19861204		U.S. Government, Dept. of Health and Human Services, c/o National	US5254539							
	US19930056043 19930430; US19910663288 19910228; US19890420664 19890828; US19870084055 19870811; US19860937925 19861204; US19850769016 19850826		The United States of America as represented by the Department of Health	US5616566							
	US19970942660 19971002; US19920882204 19920513; US19910733547 19910722		Bristol-Myers Squibb Company	US5880106	ZA9205484 A N 1993-09-13	1992/05484	1992/05484	21/07/1992	24/11/1993	21/07/2012	in force
Stavudine (D4T)	US19860942666 19861217		Yale University	CA1293447 US4978655	ZA8707171 A N 1988-03-24	1987/07171	1987/07171	23/09/1987	25/05/1988	23/09/2007	in force
Emtricitabine (FCT)	US19900473318 19900201, WO1991US00685 19910131	WO9111186	Emroy University (US)	CA2075189							
	CA19922152269 19921221; US19890308101 19890208		BioChem Pharma Inc. (Canada)	CA2009637	ZA9000943 A N 1990-10-31	1990/00943	1990/00943	08/02/1990	31/10/1990	08/02/2010	in force
	US19910659760 19910222; US19900473318 19900201		Emory University	US5210085	ZA9201251 A N 1993-08-20	1992/01251	1992/01251	20/02/1992	27/10/1993	20/02/2012	in force
	US19930017820 19930216; US19910659760 19910222; US19900473318 19900201		Emory University	US5814639	ZA9201251 A N 1993-08-20	1992/01251	1992/01251	20/02/1992	27/10/1993	20/02/2012	in force
	US19950488097 19950607; US19920831153 19920212; US19910659760 19910222; US19900473318 19900201; US19910736089 19910726		Emory University	US5914331	ZA9201251 A N 1993-08-20	1992/01251	1992/01251	20/02/1992	27/10/1993	20/02/2012	in force
	US19950475339 19950607; US19920831153 19920212; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201		Emory University	US6642245	ZA9201251 A N 1993-08-20	1992/01251	1992/01251	20/02/1992	27/10/1993	20/02/2012	in force
	US19950402730 19950313; GB19910004741 19910306; GB19910009505 19910502; US19930922448 19930715; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201		Emory University	US6703396	ZA9201251 A N 1993-08-20	1992/01251	1992/01251	20/02/1992	27/10/1993	20/02/2012	in force
					ZA9201658 A N 1993-09-06	1992/01658	1992/01658	05/03/1992	24/11/1993	05/03/2012	in force
Tenofovir Disoproxil fumarate (TDF)	US19970900746 19970725; US19960022708P 19960726		Gilead Sciences, Inc	US5922695							
	US19970900752 19970725		Gilead Sciences, Inc	US5935946							
	US19980187763 19981106; US19970900746 19970725; US19960022708P 19960726		Gilead Sciences, Inc.	US5977089							

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 lapsed.
Tenofovir Disoproxil fumarate (TDF) (continued)	US19990314606 19990519; US19970900746 19970725; US19960022708P 19960726		Gilead Sciences, Inc	US6043230							
Zidovudine (AZT) / Lamivudine (3TC)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344	Glaxo Group Limited	CA2068790	ZA9203544 A N 1993-03-31	1992/03544	1992/03544	15/05/1992	31/03/1993	15/05/2012	in force
	CA19922070230 19920602; GB19910011902 19910603		Glaxo Group Limited	CA2311988	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	GB19910011902 19910603	WO9221676	Glaxo Group Limited	US5905082	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	WO1996EP01352 19960328, GB19950006489 19950330; GB19950006490 19950330	WO9630025	The Wellcome Foundation Limited (U.K.)	CA2216634	ZA9602477 A N 1997-10-28	1996/02477	1996/02477	28/03/1996	31/12/1997	28/03/2016	in force
	US19960605610 19960222; GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106; US19940219176 19940328; US19920883169 19920515		Glaxo Group Limited	US5859021	ZA9203544 A N 1993-03-31	1992/03544	1992/03544	15/05/1992	31/03/1993	15/05/2012	in force
	US19970955635 19971023; GB19960022681 19961031; US19960029240P 19961031		Glaxo Group Limited	US6113920	ZA9709726 A N 1999-04-29	1997/09726	1997/09726	29/10/1997	28/07/1999	29/10/2017	in force
Abacavir (ABC)	US19890455201 19891222		The Wellcome Foundation Limited (U.K.)	CA2033044	ZA9010365 A N 1992-08-26	1990/10365	1990/10365	21/12/1990	26/08/1992	21/12/2010	in force
	GB19880015265 19880627		Burroughs Wellcome Co.	CA1340589 US5089500 US5034394	ZA8904837 A N 1991-03-27	1989/04837	1989/04837	26/06/1989	27/03/1991	26/06/2009	in force
	WO1998EP02835 19980514; GB19970009945 19970517		Glaxo Wellcome Inc.	US6294540	ZA9804083 A N 1999-11-15	1998/04083	1998/04083	14/05/1998	26/01/2000	14/05/2018	in force
		WO9852949			ZA9804085 A N 1999-11-15	1998/04085	1998/04085	14/05/1998	26/01/2000	14/05/2018	in force
Abacavir (ABC)/ Zidovudine (AZT) / Lamivudine (3TC)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344	Glaxo Group Limited (GB)	CA2068790	ZA9203544 A N 1993-03-31	1992/03544	1992/03544	15/05/1992	31/03/1993	15/05/2012	in force
	CA19922070230 19920602; GB19910011902 19910603		Glaxo Group Limited (GB)	CA2311988	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	GB19910011902 19910603	WO9221676	Glaxo Group Limited	US5905082	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025	GlaxoSmithKline	US6417191	ZA9602477 A N 1997-10-28	1996/02477	1996/02477	28/03/1996	31/12/1997	28/03/2016	in force
Abacavir (ABC)/ Lamivudine (3TC)	CA19922070230 19920602; GB19910011902 19910603		Glaxo Group Limited (GB)	CA2311988	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025	GlaxoSmithKline	US6417191	ZA9602477 A N 1997-10-28	1996/02477	1996/02477	28/03/1996	31/12/1997	28/03/2016	in force
	GB19910011902 19910603	WO9221676	Glaxo Group Limited	US5905082	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
Lamivudine (3TC)	GB19900009861 19900502; WO1991GB00706 19910502	WO9117159	IAF BioChem International Inc.(Canada)	CA2059263	ZA9103293 A N 1992-02-26	1991/03293	1991/03293	30/04/1991	26/02/1992	30/04/2001	in force
	CA19922152269 19921221; US19890308101 19890208		BioChem Pharma, Inc.	CA2009637 US5047407	ZA9000943 A N 1990-10-31						

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 lapsed.
Lamivudine (3TC) (continued)	GB19910011902 19910603	WO9221676	Glaxo Group Limited	CA2070230 US5905082	ZA9204007 A N 1993-04-28	1992/04007	1992/04007	02/06/1992	28/04/1993	02/06/2012	in force
	GB19970006295 19970326; US19970042353P 19970324; WO1998EP01626 19980320	WO9842321	Glaxo Group Limited	CA2286126	ZA9802367 A N 1999-09-20	1998/02367	1998/02367	19/03/1998	24/11/1999	19/03/2018	in force
	GB19910000039 19910103; GB19910009913 19910507; WO1992CA00001 19920103	WO9211852	IAF BioCHem Int. (CA)	CA2100269 (hep B) US5532246							
	US19970042353P 19970324 GB19910011902 19910603	WO9842321	Glaxo Wellcome Inc.	US6004968	ZA9802367 A N 1999-09-20	1998/02367	1998/02367	19/03/1998	24/11/1999	19/03/2018	in force
Indinavir (IDV)	US19910789508 19911108; US19920883825 19920515	WO9309096	Merck & Co., Inc.	CA2081970	ZA9208563 A N 1993-05-05	1992/08563	1992/08563	06/11/1992	30/07/1993	06/11/2012	in force
	US19930059038 19930507; US19930040729 19930331; US19920883825 19920515; US19910789508 19911108		Merck & Co., Inc.	US5413999	ZA9208563 A N 1993-05-05	1992/08563	1992/08563	06/11/1992	30/07/1993	06/11/2012	in force
					ZA9402255 A N 1994-11-01	1994/02255	1994/02255	30/03/1994	28/12/1994	30/03/2014	lapsed
					ZA9403104 A N 1995-11-06	1994/03104	1994/03104	05/05/1994	27/12/1994	05/05/2014	lapsed
	US19980045885 19980304; US19970040158P 19970307		Merck & Co., Inc.	US6645961							
	US19950382113 19950201	WO9623509	Merck & Co., Inc.	US6689761	ZA9600722 A N 1996-08-26	1996/00722	1996/00722	31/01/1996	30/10/1996	31/01/2016	lapsed
Efavirenz (EFV)	US19930054805 19930427; US19920926607 19920807	WO9403440	Merck & Co., Inc.	CA2101572	ZA9305724 A N 1994-03-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force
	US19950460026 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807		Merck & Co., Inc.	US5519021	ZA9305724 A N 1994-03-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force
	US19950458528 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807		Merck & Co., Inc.	US5663169	ZA9305724 A N 1994-03-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force
	US19970815780 19970312; US19950458529 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807		Merck & Co., Inc.	US5811423	ZA9305724 A N 1994-03-03	1993/05724	1993/05724	06/08/1993	28/04/1994	06/08/2013	in force
	US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408; US20010000537 20011019		Merck & Co., Inc	US6639071							
	US20040891749 20040624; US20030447690 20030529; US20010000537 20011019; US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408		Bristol-Myers Squibb Company	US6939964							
	US19990286902 19990406; US19980089025P 19980407		DuPont Pharmaceuticals Company	US6238695	ZA200004313 A N 2001-11-07	2000/04313	2000/04313	22/08/2000	30/01/2002	22/08/2020	in force
	US20010824071 20010402; US19990286902 19990406; US19980089025P 19980407		Bristol-Myers Squibb Company	US6555133	ZA200004313 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 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 lapsed.
Nelfinavir (NFV)	US19930133543 19931007; US19930133696 19931007; US19940190764 19940202; WO1994US11307 19941007	WO9509843	Agouron Pharmaceuticals, Inc. (US)	US5484926 CA2173328	ZA9407815 A N 1996-07-08	1994/07815	1994/07815	06/10/1995	28/08/1996	06/10/2015	in force
	US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007; US19930137254 19931018; US19920995621 19921222		Agouron Pharmaceuticals, Inc. (US)	US5952343	ZA9407815 A N 1996-07-08	1994/07815	1994/07815	06/10/1995	28/08/1996	06/10/2015	in force
	US19990283152 19990401; US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007		Agouron Pharmaceuticals, Inc. (US)	US6162812	ZA9407815 A N 1996-07-08	1994/07815	1994/07815	06/10/1995	28/08/1996	06/10/2015	in force
Saquinavir (SQV)	GB19880013940 19880613; GB19890008035 19890410		F. Hoffmann-La Roche & Co. Aktiengesellschaft (Switzerland)	CA1340588	ZA8904285 A N 1990-02-28	1989/04285	1989/04285	06/06/1989	28/02/1990	06/06/2009	in force
	GB19890027913 19891211		Hoffmann-La Roche Inc.	CA2030433 US5196438	ZA9009743 A N 1991-08-28	1990/09743	1990/09743	04/12/1990	28/08/1991	04/12/2010	in force
	US19950468493 19950606; US19960616233 19960507; WO1996EP02431 19960604	WO9639142	Hoffmann-La Roche Inc.	US6008228 CA2224125	ZA9604448 A N 1996-12-06	1996/04448	1996/04448	30/05/1996	26/02/1997	30/05/2016	in force
	EP19980121831 19981117	WO0028942	Hoffman-La Roche Inc.	US6352717	ZA200103891 A N 2002-08-14	2001/03891	2001/03891	14/05/2001	30/10/2002	14/05/2021	in force
Enfuvirtide (T20)	US19930073028 19930607	WO9428920	Duke University	US5464933							
	US19950554616 19951106; US19930073028 19930607		Duke University	US6133418							
	US19980973952 19980529; US19950481957 19950607; WO1996US09499 19960606		Trimeris, Inc.	US6475491							
Amprenavir (APV)	US19920941982 19920908; WO1993US08458 19930907	WO9405639	Vertex Pharmaceuticals, Incorporated (USA)	CA2143208							
	US19930142327 19931124; US19920941982 19920908; WO1993US08458 19930907	WO9405639	Vertex Pharmaceuticals, Incorporated (USA)	US5585397							
	GB19960006372 19960326; US19960013893P 19960322; US19970820848 19970320; WO1997EP01438 19970321	(WO9735587)	Glaxo Group Limited (U.K.)	CA2249336	ZA9702387 A N 1997-12-10	1997/02387	1997/02387	19/03/1997	25/02/1998	19/03/2017	in force
	US19950567199 19951205	WO9720554	Vertex Pharmaceuticals Incorporated	US5646180	ZA9610139 A N 1997-06-17	1996/10139	1996/10139	03/12/1996	27/08/1997	03/12/2016	lapsed
	US19950424819 19950419; US19950393460 19950223; US19930142327 19931124; US19920941982 19920908		Vertex Pharmaceuticals Incorporated	US5723490							
	US19970820848 19970320; US19960013893P 19960322		SmithKline Beecham Corporation	US6730679	ZA9702387 A N 1997-12-10	1997/02387	1997/02387	19/03/1997	25/02/1998	19/03/2017	in force

Data collected from CIPRO 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 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: enforcement status indicating if, according to Indian patent office requirements, the patent is enforced or lapsed. For applications: as applicable.
Ritonavir (RTV)	US19960754390 19961121; WO1997US20794 19971112	WO9822106	Abbott Laboratories US	CA2271196							
	US19960753201 19961121; US19950572226 19951213; WO1996US20440 19961206	WO9721685	Abbott Laboratories US	US5914332 CA2238978							
	US19980207873 19981208; US19960753201 19961121; US19950572226 19951213	0	Abbott Laboratories US	US6284767							
	US19990393872 19990910; US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121	0	Abbott Laboratories US	US6521651							
	US19990347077 19990702; US19970966495 19971107; US19960031463P 19961121	0	Abbott Laboratories US	US6458818							
	US20010946085 20010904; US20000230095P 20000905	0	Abbott Laboratories US	US6911214							
Ritonavir (RTV) / Lopinavir (LPV)	US19990616170 19901120; US19910746020 19910815; US19910777626 19911023	0	Abbott Laboratories US	CA2055670							
	US19920998114 19921229; US19930158587 19931202	WO9414436	Abbott Laboratories US	CA2135890							
	US19950000654P 19950629; US19950003849P 19950915; WO1996US11015 19960628	WO9701349	Abbott Laboratories US	CA2224738							
	US19970821609 19970320; US19950417879 19950406; US19930158587 19931202; US19920998114 19921229	0	Abbott Laboratories US	US5846987							
	US19950413136 19950329; US19920998114 19921229; US19930158587 19931202; US19910777626 19911023; US19910746020 19910815; US19990616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523	0	Abbott Laboratories US	US5674882							
	US19950423387 19950425; US19930158587 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19990616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523	0	Abbott Laboratories US	US5541206							

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: enforcement status indicating if, according to Indian patent office requirements, the patent is enforced or lapsed. For applications: as applicable.
Ritonavir (RTV) / Lopinavir (LPV) (continued)	US19950417879 19950406; US19930158587 19931202; US19920998114 19921229; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523	0	Abbott Laboratories US	US5635523							
	US19950410623 19950324; US19940270210 19940823; US19930121673 19930914; US19910777626 19911023; US19910746020 19910815; US19900616170 19901120; US19900518730 19900509; US19890456124 19891222; US19890405604 19890908; US19890355945 19890523	0	Abbott Laboratories US	US5648497							
	US20010957171 20010920; US19990387261 19990831; US19960687774 19960626; US19950000654P 19950629; US19950003849P 19950915	0	Abbott Laboratories US	US6703403							
	US19970966495 19971107; US19960031463P 19961121	0	Abbott Laboratories US	US6232333							
	US19950440277 19950512; US19940283239 19940729; US19940189021 1994012	0	Abbott Laboratories US	US5484801							
	US19970822071 19970320; US19950413136 19950329; US19930158587 19931202; US19920998114 19921229	0	Abbott Laboratories US	US5886036							
	US19950003849P 19950915; US19960687774 19960626; US19950000654P 19950629	0	Abbott Laboratories US	US6037157							
Nevirapine (NVP)	US19890438923 19891117; US19900579001 19900906; US19900600390 19901019	0		CA2030056							
	US19930091418 19930713; US19890340970 19890420; US19890372974 19890628; US19890438923 19891117; US19900579001 19900906; US19900600390 19901019; US19910740828 19910805	0	Boehringer Ingelheim Pharmaceuticals, Inc.	US5366972		2485/DEL/1998		24/08/1998			Under examination, pre grant opposition filed
Atazanavir (ATV)	CH19960001018 19960422; CH19970000223 19970131	0	Novartis Finance Corporation	US5849911		807/MAS/1997		21.04.1997			Under examination, pre grant Opposition filed
	US19980071968P 19980120; WO1998US27382 19981222	WO9936404	Bristol-Myers Squibb Company US	CA2317736							
	US19980217538 19981221; US19980071968P 19980120	0	Bristol-Myers Squibb Company	US6087383							
Didanosine (DDI)	US19850769016 19850826	WO8701284	Us Health (US)	CA1269044							
	US19900460490 19900103	WO9109605	Us Health (US)	CA2072573							

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: enforcement status indicating if, according to Indian patent office requirements, the patent is enforced or lapsed. For applications: as applicable.
Didanosine (DDI) (continued)	US19910733547 19910722; US19920882204 19920513	0	Squibb Bristol Myers Co (US)	CA2074215							
	US19870084055 19870811; US19850769016 19850826	0	The United States of America as represented by the Department of Health	US4861759							
	US19910663288 19910228; US19870084055 19870811; US19890420664 19890828; US19850769016 19850826; US19860937925 19861204	0	U.S. Government, Dept. of Health and Human Services, c/o National	US5254539							
	US19930056043 19930430; US19910663288 19910228; US19890420664 19890828; US19870084055 19870811; US19860937925 19861204; US19850769016 19850826	0	The United States of America as represented by the Department of Health	US5616566							
	US19970942660 19971002; US19920882204 19920513; US19910733547 19910722	0	Bristol-Myers Squibb Company	US5880106							
Stavudine (D4T)	US19860942666 19861217	0	Yale University	CA1293447 US4978655							
Emtricitabine (FCT)	US19900473318 19900201, WO1991US00685 19910131	WO9111186	Emory University (US)	CA2075189							
	CA19922152269 19921221; US19890308101 19890208	0	Biochem Pharma Inc. (Canada)	CA2009637							
	US19910659760 19910222; US19900473318 19900201	0	Emory University	US5210085							
	US19930017820 19930216; US19910659760 19910222; US19900473318 19900201	0	Emory University	US5814639							
	US19950488097 19950607; US19920831153 19920212; US19910659760 19910222; US19900473318 19900201; US19910736089 19910726	0	Emory University	US5914331							
	US19950475339 19950607; US19920831153 19920212; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201	0	Emory University	US6642245							
	US19950402730 19950313; GB19910004741 19910306; GB19910009505 19910502; US19930922248 19930715; US19910736089 19910726; US19910659760 19910222; US19900473318 19900201	0	Emory University	US6703396							
Tenofovir Disoproxil fumarate (TDF)	US19970900746 19970725; US19960022708P 19960726	0	Gilead Sciences, Inc	US5922695							
	US19970900752 19970725	0	Gilead Sciences, Inc	US5935946	IN190780 A N 2003-08-23	896/DEL/2002 A		09/04/2002			Under Examination, pre grant Opposition filed
	US19980187763 19981106; US19970900746 19970725; US19960022708P 19960726	0	Gilead Sciences, Inc.	US5977089							

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: enforcement status indicating if, according to Indian patent office requirements, the patent is enforced or lapsed. For applications: as applicable.
Tenofovir Disoproxil fumarate (TDF) (continued)	US19990314606 19990519; US19970900746 19970725; US19960022708P 19960726	0	Gilead Sciences, Inc	US6043230							
Zidovudine (AZT) / Lamivudine (3TC)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344	Glaxo Group Limited	CA2068790							
	CA19922070230 19920602; GB19910011902 19910603	0	Glaxo Group Limited	CA2311988							
	GB19910011902 19910603	WO9221676	Glaxo Group Limited	US5905082							
	WO1996EP01352 19960328, GB19950006489 19950330; GB19950006490 19950330	WO9630025	The Wellcome Foundation Limited (U.K.)	CA2216634							
	US19960605610 19960222; GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106; US19940219176 19940328; US19920883169 19920515	0	Glaxo Group Limited	US5859021							
	US19970955635 19971023; GB19960022681 19961031; US19960029240P 19961031	0	Glaxo Group Limited	US6113920		2044/CAL/1997		28/10/1997			Withdrawn, Application Rejected
Abacavir (ABC)	US19890455201 19891222	0	The Wellcome Foundation Limited (U.K.)	CA2033044							
	GB19880015265 19880627	0	Burroughs Wellcome Co.	CA1340589 US5089500 US5034394							
	WO1998EP02835 19980514; GB19970009945 19970517	WO9852949	Glaxo Wellcome Inc.	US6294540		872/CAL/1998		14/05/1997			Under examination, pre grant Opposition filed
Abacavir (ABC)/ Zidovudine (AZT) / Lamivudine (3TC)	GB19910010624 19910516; GB19910021381 19911008; GB19910023581 19911106	WO9220344	Glaxo Group Ltd (GB)	CA2068790							
	CA19922070230 19920602; GB19910011902 19910603	0	Glaxo Group Ltd (GB)	CA2311988							
	GB19910011902 19910603	WO9221676	Glaxo Group Limited	US5905082							
	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025	GlaxoSmithKline	US6417191							
Abacavir (ABC)/ Lamivudine (3TC)	CA19922070230 19920602; GB19910011902 19910603	0	Glaxo Group Ltd (GB)	CA2311988							
	WO1996EP01352 19960328; GB19950006489 19950330; GB19950006490 19950330	WO9630025	GlaxoSmithKline	US6417191							
	GB19910011902 19910603	WO9221676	Glaxo Group Limited	US5905082							
Lamivudine (3TC)	GB19900009861 19900502; WO1991GB00706 19910502	WO9117159	Iaf Biochem International Inc. (Canada)	CA2059263							
	CA19922152269 19921221; US19890308101 19890208	0	BioChem Pharma, Inc.	CA2009637 US5047407							

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: enforcement status indicating if, according to Indian patent office requirements, the patent is enforced or lapsed. For applications: as applicable.
Lamivudine (3TC) (continued)	GB19910011902 19910603	WO9221676	Glaxo Group Limited	CA2070230 US5905082							
	GB19970006295 19970326; US19970042353P 19970324; WO1998EP01626 19980320	WO9842321	Glaxo Group Limited	CA2286126							
	GB19910000039 19910103; GB19910009913 19910507; WO1992CA00001 19920103	WO9211852	Iaf Biochem Int (CA)	CA2100269 (hep B) US5532246							
	US19970042353P 19970324 GB19910011902 19910603	WO9842321	Glaxo Wellcome Inc.	US6004968		479/CAL/1998		23/03/1998 A			No opposition have been filed yet, no request for examination filed.
Indinavir (IDV)	US19910789508 19911108; US19920883825 19920515	WO9309096	Merck & Co., Inc.	CA2081970							
	US19930059038 19930507; US19930040729 19930331; US19920883825 19920515; US19910789508 19911108	0	Merck & Co., Inc.	US5413999							
	US19980045885 19980304; US19970040158P 19970307	0	Merck & Co., Inc.	US6645961							
	US19950382113 19950201	WO9623509	Merck & Co., Inc.	US6889761							
Efavirenz (EFV)	US19930054805 19930427; US19920926607 19920807	WO9403440	Merck & Co., Inc.	CA2101572							
	US19950460026 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807	0	Merck & Co., Inc.	US5519021							
	US19950458528 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807	0	Merck & Co., Inc.	US5663169							
	US19970815780 19970312; US19950458529 19950602; US19940188005 19940128; US19930054805 19930427; US19920926607 19920807	0	Merck & Co., Inc.	US5811423							
	US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408; US20010000537 20011019	0	Merck & Co., Inc	US6639071							
	US20040891749 20040624; US20030447690 20030529; US20010000537 20011019; US19990282744 19990331; US19980008824 19980120; US19970037385P 19970205; US19970042807P 19970408	0	Bristol-Myers Squibb Company	US6939964							
	US19990286902 19990406; US19980080925P 19980407	0	DuPont Pharmaceuticals Company	US6238695							
	US20010824071 20010402; US19990286902 19990406; US19980080925P 19980407	0	Bristol-Myers Squibb Company	US6555133							

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: enforcement status indicating if, according to Indian patent office requirements, the patent is enforced or lapsed. For applications: as applicable.
Nelfinavir (NFV)	US19930133543 19931007; US19930133696 19931007; US19940190764 19940202; WO1994US11307 19941007	WO9509843	Agouron Pharmaceuticals, Inc. (US)	US5484926 CA2173328							
	US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007; US19930137254 19931018; US19920995621 19921222	0	Agouron Pharmaceuticals, Inc. (US)	US5952343							
	US19990283152 19990401; US19950481831 19950607; US19940190764 19940202; US19930133543 19931007; US19930133696 19931007	0	Agouron Pharmaceuticals, Inc. (US)	US6162812							
Saquinavir (SQV)	GB19880013940 19880613; GB19890008035 19890410	0	F. Hoffmann-La Roche & Co. Aktiengesellschaft (Switzerland)	CA1340588							
	GB19890027913 19891211	0	Hoffmann-La Roche Inc.	CA2030433 US5196438	IN172553 A N 1993-09-25						
	US19950468493 19950606; US19960616233 19960507; WO1996EP02431 19960604	WO9639142	Hoffmann-La Roche Inc.	US6008228 CA2224125	IN192899 A N 2004-05-29						
	EP19980121831 19981117	WO0028942	Hoffman-La Roche Inc.	US6352717							
Enfuvirtide (T20)	US19930073028 19930607	WO9428920	Duke University	US5464933							
	US19950554616 19951106; US19930073028 19930607	0	Duke University	US6133418							
	US19980973952 19980529; US19950481957 19950607; WO1996US09499 19960606	0	Trimeris, Inc.	US6475491							
Amprenavir (APV)	US19920941982 19920908; WO1993US08458 19930907	WO9405639	Vertex Pharmaceuticals, Incorporated (USA)	CA2143208							
	US19930142327 19931124; US19920941982 19920908; WO1993US08458 19930907	WO9405639	Vertex Pharmaceuticals, Incorporated (USA)	US5585397							
	GB19960006372 19960326; US19960013893P 19960322; US19970820848 19970320; WO1997EP01438 19970321	(WO9735587)	Glaxo Group Limited (U.K.)	CA2249336		727/Del/1997		21/03/1997			Under Examination, Pre grant Opposition filed
	US19950567199 19951205	WO9720554	Vertex Pharmaceuticals Incorporated	US5646180							
	US19950424819 19950419; US19950393460 19950223; US19930142327 19931124; US19920941982 19920908	0	Vertex Pharmaceuticals Incorporated	US5723490							
	US19970820848 19970320; US19960013893P 19960322	0	SmithKline Beecham Corporation	US6730679		727/Del/1997		21/03/1997			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 datatbasesfor 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)	Kaletra	US19990325826 19990604		Abbott Laboratories US		WO0074677		IN/PCT/2001/01312/MUM		22/10/2001			Has been abandoned
Efavirenz	A Process for Preparing Form 1 of Crystalline Efavirenz	60/088,981 19980611, WO1999US13199 19990610	US19980088981P 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	60/088,981 19980611, WO1999US13199 19990610	US19980088981P 19980611	Bristol Myers Squibb Pharma Company Ltd.		WO9964405		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 Efvirenz	US19980088981 19980611 US19990329421 19990610 US19990329421 US6673372	US19980088981P 19980611	Bristol Myers Squibb Pharma Company Ltd.		WO9964405		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)	US19990603 29 19991019 US20000226171 20000817 US20001019 US20040024 98	US19990160329P 19991019 US20000226171P 20000817	Bristol Myers Squibb Pharma Company Ltd.		WO0129037		IN/PCT/2002/00570/MUM (PCT/CA01/00890)		05/06/2002			No request for examination has been made
Nevirapine (Improvement)	Non Nucleoside Reverse Transcriptase Inhibitors	US20000212329 20000616 US20000256638 US20001218 US20020288 07	US20000212329P 20000616; US20000256638P 20001218	Boerhinger Ingelheim Ltd.		WO0196338		IN/PCT/2002/01622/MUM (PCT/CA01/00890)		22/10/2002			Awaiting information from Mumbai patent office
Ritonavir (RTV) (Polymorph)	Ritonavir (RTV)	US19981193 45 19980720, US19990326093 19990604	US19980119345 19980720; US19990326093 19990604	Abbott Laboratories US		WO0004016		PCT/2001/00018/MUM		03/04/2005			FER issued on11.10.2006, 2 oppositions have been filed
Lopinavir (Crystalline form)	Lopinavir (Product Patent)	US20005382 57 20000330, US20010793536 20010227	US20000538257 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		259/MUMNP/2003 A		24/02/2003			Request for examination has been filed on 29/12/2005
Fosamprenavir	Lexiva (Calcium (3S) Tetrahydro-3-Funaryl (1S,2R)-3-[[(4-Aminophenyl) Sulphonyl] (Isobutyl) Amino]-1-Benzyl-2 (Phosphonooxy) Propylcarbamate)	9815567.4 (WO1999EP04991 19990715; GB19980015567 19980718)	GB19980015567 19980718	Glaxo Group Limited		WO0004033		IN/PCT/2001/00039		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.

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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