

Patent situation of HIV/AIDS-related drugs in 80 countries

Geneva, January 2000



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Acknowledgements

The authors are very grateful to Dr J.D. Quick (WHO/EDM), Dr M. Scholtz (WHO/HTP) and G. Velásquez (WHO/EDM) for their constructive comments. Professor C.M. Correa (University of Buenos Aires), Mr A. Otten (WTO), Mr R. Wilder (WIPO) and Ms S. Zarilli (UNCTAD) are also acknowledged for their technical review and contributions to the document.

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Introduction

More than 95% of all HIV-infected people now live in the developing world, which has likewise experienced 95% of all deaths to date from AIDS. Most of these deaths occurred among young adults who would normally be in their peak productive and reproductive years.

In developed countries, the introduction of highly active antiretroviral treatment and the availability of drugs for opportunistic infections and malignancies (PCP, cytomegalovirus disease, herpes, tuberculosis) led to a substantial reduction in AIDS mortality. In developing countries, however, access to these drugs is seriously lacking.

Several interrelated factors determine access to essential drugs, including drugs to treat HIV and opportunistic infections. Among them are appropriate use, supply management, economic issues, drug selection, legislation and regulation, manufacturing, research and development decisions. A number of WHO Member States have expressed the opinion that affordability is a major factor contributing to lack of access to drugs.

As HIV/AIDS is quite recent in medical history, most of the drugs created especially to treat HIV infection are proprietary (i.e. under patent). This renders the treatment less affordable than drugs for which generic alternatives exist. Since patent protection allows exclusive rights to an invention and prevents generic competition, it is one of the possible reasons for limited availability and affordability of drugs.

As for drugs to treat or prevent opportunistic infections and malignancies, a number of anti-infective agents (foscarnet, itraconazole, fluconazole, etc) needed by people living with HIV/AIDS also remain under patent in many countries.

Therefore, the question whether a drug is under patent protection is of significant importance for drug procurement. The present document assesses the patent situation of HIV/AIDS related drugs in countries for which data are available. Data for some countries are difficult to get, and as this field is in constant evolution, the data are **indicative**. When planning procurement, it is recommended to check the patent status locally, i.e. at the patent office of the country where the drug will be used.

What are patents and how are they regulated internationally?

The objective of the patent system is to encourage inventive activity as well as technology transfer and activities associated with the commercialisation or marketing of an invention.

A patent is a title granted by the State in a specific country that gives exclusive rights over the manufacture and use of an invention to the owner of this invention in that country, in exchange of the disclosure of the invention to the public. A patent is **national** and applications for patents must be filed in every country (or regional offices, where they exist) where protection is desired for a specific invention. There is no international patent.

The criteria for a patent to be granted is that the invention must be new, involve an inventive step and be capable of industrial application. The novelty criterion implies that the invention should not be part of the "state of the art" world-wide, but be a genuine

innovation. Because of this novelty criterion, a system was instituted under the Paris Convention (1883, as revised) to allow companies to protect the same invention in various countries. When a company invents a new product or process, the Paris Convention (now managed by the World Intellectual property Organization - WIPO) allows this company a year to file patent applications for this invention in any other Member State of the Paris convention. This one-year period is a juridical artifice to preserve the novelty of the invention during the time the company decides in which countries it wants to seek patent protection. It gives the company a right of priority over any party which would file a patent application for the same invention during this one year in any Member country of the Paris Convention. In other words, the right of priority "keeps" the novelty of an invention in time, and preserves the novelty criterion necessary for a patent to be granted.

Some patent offices such as the United States Patent Office and the European Patent Office, make a broad preliminary international search before granting a patent, to assess that the invention for which a patent is requested is not already part of the state of the art. Basically, they look at all published patents and articles to check that the knowledge was not made publicly available before the application of the patent. This does not prevent patents from being challenged, especially in developed countries. Other patent offices, mostly those in developing countries, only rely on these data to base a decision to grant a national patent. In some developing countries, because patent offices do not have the human, technical and financial means to carry out this search, it is only if the patent is challenged before courts that the search will be done to assess whether the patent is indeed valid.

Once a patent is granted, the patentee has the right to **prevent** others from "using, offering for sale, selling, or importing" the invention without his permission. Thus, this is a "negative" right.

Review of patent expiry dates of HIV/AIDS drugs

The following table provides indication on expiry dates of the basic substance patent protecting some HIV/AIDS related drugs, as well as countries in which this patent has been applied for and granted. However, some caveats apply.

In the pharmaceutical sector, patents may be granted for different kinds of inventions. The invention may concern a new pharmaceutical substance, or a new manufacturing process for a known pharmaceutical substance, or a new use or indication of a known pharmaceutical substance, or a new formulation. Therefore, looking for patents related to a specific drug is a huge task since a drug may be protected by dozens of patents in different countries. A pharmaceutical company which owns an invention, either through its own R&D or in-licensing of patents from other inventors (i.e. other companies, public institutions, etc) will file or enforce patent protection in countries where there is a market for such invention or where potential competitors could use the invention for their product development.

To get an approximate idea of the date on which generic competition can start for a specific drug, the most useful approach is to locate the date of application for the first patent, usually protecting the basic substance of the drug. Then, if one adds 20 years to this date, taking into account the one-year period of priority ("20 + 1"), one gets an approximate idea of when the same patent granted for the same drug in other countries will expire - since those patents for the same invention should have been filed within the one-year priority period. As from this expiry date of the substance patent, copies of the basic substance of this drug may be

produced, although other patents may protect a manufacturing process, a formulation or an indication. But the basic substance at least is in the public domain. This applies only to countries where a patent has been granted and where the patentee regularly pays the maintenance fees to keep the patent "alive". Depending on the specific patent and country, patent owners may not file or maintain all patents.

Finally, with regard to the patent expiry date provided in the table, it is possible to obtain patent extension beyond 20 years in some countries, to compensate for time spent in R&D or the registration process to obtain marketing authorization.

In the table, the *patent priority date* column corresponds to the date of the first patent application for the drug in question, and which was referred to as the priority date by the company seeking for the same patent protection in other countries.

The *20-year patent protection* column gives an idea of the latest date around which the same patent should expire in other countries. Note that this date may not be valid in countries where patent extensions are possible (such as Australia, EU, Japan, Korea, Mexico and the US).

The next two columns provide for the expiry date of the first patent in the US and in Europe (as a regional patent) or France.

The last column gives some of the countries where a similar patent has been applied for or granted (with reference to the priority date), whether for the protection of a product or process. Data mainly originates from the European Patent Office website, which provides patent data originating from about 64 patent offices, including regional patent offices (Argentina, ARIPO¹, Australia, Brazil, Bulgaria, Canada, China, Croatia, Cuba, Cyprus, Czech Republic, Egypt, EPO², Eurasian Patent Office³, Hong Kong, Hungary, India, Israel, Japan, Korea, Latvia, Lithuania, Mexico, Moldova, Mongolia, New Zealand, Norway, OAPI⁴, Philippines, Poland, Romania, Russia, Singapore, Slovakia, Slovenia, South Africa, Turkey, Vietnam, Yugoslavia). However, the European Patent Office warns that the information provided is not exhaustive, often refers to published patent applications only and that this service cannot be considered as a complete and official source of patent information.

Recourse was also made to Derwent database which provides data on whether a patent has indeed been granted following the application, but only covers 40 countries (Argentina, Australia, Brazil, Canada, China, Czech Republic, EPO, Hungary, Israel, Japan, Korea, Mexico, Norway, New Zealand, Philippines, Romania, Russia, Singapore, South Africa, Slovakia, Taiwan, and the USA).

¹ The ARIPO patents granted by the Office of the African Regional Industrial Property Organization (ARIPO, Harare) may have effect in 14 African countries (Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Sierra Leone, Somalia, Sudan, Swaziland, Uganda, United Republic of Tanzania, Zambia, Zimbabwe).

² European patents, granted by the European Patent Office (Munich) may have effect in up to 18 European countries (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland, United Kingdom).

³ Eurasian patents granted by the Eurasian Patent Office (Moscow), which have effect in 9 countries (Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Republic of Moldova, Russian Federation, Tajikistan, Turkmenistan).

⁴ Patents granted by the African Intellectual Property Organization (OAPI, Yaoundé) have effect in 14 African countries (Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Gabon, Guinea, Mali, Mauritania, Niger, Senegal, Togo).

Thus, the data presented here cover only approximately 80 countries. No reliable patent information is available from the others. Taking into account the caveats of this study, it is therefore strongly advised to check the patent status at the national patent office before planning drug procurement or manufacture in a specific country.

Further readings

Information on broader aspects of access to HIV/AIDS related drugs and further information on intellectual property rights for pharmaceuticals are available in the following links and references.

- Questions and Answers on pharmaceuticals and the WTO TRIPS Agreement
- <http://www.who.int/medicines/>
- <http://www.unaids.org/>

Access to HIV/AIDS-related drugs

- *Technical Up-date: Access to drugs* addressing the main obstacles and challenges in improving access to drugs for people living with HIV. (UNAIDS Best practice Collection, 1998).
- *Model Prescribing Information for the use of the drugs used in HIV-related infections.* (WHO/DMP/DSI/99.2)
- *Guidelines on Standard treatments and Essential Drugs for HIV-related conditions- Access to HIV-related Drugs* (WHO/DAP, December 1997).
- *“The implications of antiretroviral treatment”* organised by WHO and UNAIDS (April 1997)
- Modules technical and policy guidance modules on antiretroviral treatments for health planners and policy makers (WHO/ASD/98.1, UNAIDS/98/7).

Intellectual property rights and pharmaceuticals

- WHO/EDM. *Globalization, patents and drugs – an annotated bibliography.* Health Economics and Drugs EDM Series No. 9. Geneva: World Health Organization; 1999 (WHO/EDM/PAR/99.6).
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- Otten A. The implications of the TRIPS Agreement for the protection of pharmaceutical inventions. *WHO Drug Information.* 1997(11): 1.
- UNCTAD. *The TRIPS Agreement and developing countries.* Geneva: United Nations Conference on Trade and Development; 1996. UNCTAD/ITE/1.
- South Centre. *The TRIPs Agreement - a guide for the South.* Geneva: South Centre; 1997.
- IFPMA. *The Question of patents.* Geneva: International Federation of Pharmaceutical Manufacturers Associations; 1998.
- Health Action International. *Power, patents and pills - an examination of GATT/WTO policies and essential drug policies. Seminar Report.* Amsterdam: HAI-Europe; 1997.

Drug	Patent owner	Basic Patent priority date	Max. 20 years patent protection	US patent expiry date	French or Europ. patent expiry date	Countries where similar patents have been filed or granted ⁵
Anti-infective drugs						
albendazole	SmithKline	19 Jun 74	19 Jun 1995	19 Jun 94, but excl. marketing rights until 11 Jun 2003 (as an orphan drug)	N/A	Australia, Belgium , Canada , Cyprus, Denmark , Finland, France, Germany , Hong Kong, Hungary, Ireland, Israel, Italy , Japan , Kenya, Luxembourg, Malaysia, Mexico, Netherlands , Norway, Philippines, Portugal, USSR , South Africa , Sweden, Switzerland , UK , US, Yugoslavia
azythromycin	Pliva	6 Mar 81	6 Mar 2002	14 May 2002, ext. until Nov 2005 (+ 1267 days)	Fr 1 Mar 2002, ext. until 3 Apr 2006 (MA)	Austria, Belgium , Canada , Czech Rep., France , Germany , Hungary, Italy , Japan , Poland, Slovakia, Sweden , Switzerland , UK , US , USSR , Yugoslavia
	Pfizer	9 July 87	9 July 2008	N/A	EP 28 Jun 2008	ARIPO , Australia, Bosnia, Canada , China, Cyprus, Czech Rep., Denmark , EP (AT, BE, CH, DE, ES, FR, GB, IT, LI, LU, NL, SE) , Finland, Hong Kong, Hungary, Ireland, Israel, Japan , Korea , Latvia, Mexico, New Zealand, Norway , OAPI , Portugal, Romania , Russia , Singapore, South Africa , Yugoslavia
ceftriaxone	Roche	30 May 78	30 May 1999	27 Apr. 99	EP 30 May 1999	Australia, Brazil, Canada , Cuba, Cyprus, Czechoslovakia, Denmark, EP⁶ (AT, BE, CH, DE, FR, IT, LU, NL, SE) , Finland, Greece, Hong Kong, Hungary, Korea, Ireland, Israel, Japan , Kenya, Latvia, Lithuania, Malta, Malaysia, Monaco, Netherlands, New Zealand,

⁵ Countries in bold are those where a patent was granted (Derwent database), as compared with other countries where data are available regarding patent applications only (Derwent + European Patent Office website).

⁶ European patents, granted by the European Patent Office (Munich) may have effect in up to 18 European countries (Austria - AT, Belgium - BE, Denmark - DK, Finland - FI, France - FR, Germany - DE, Greece - GR, Ireland - IE, Italy - IT, Liechtenstein - LI, Luxembourg - LU, Monaco - MO, Netherlands - NL, Portugal - PT, Spain - ES, Sweden - SE, Switzerland - CH, United Kingdom - GB).

Drug	Patent owner	Basic Patent priority date (origin)	Max. 20 years patent protection	US patent expiry date	French or Europ. patent expiry date	Countries where similar patents have been filed or granted
						Norway, OAPI , Philippines, Poland, Portugal, Romania, Singapore, Slovenia, South Africa , Sweden, UK, US, USSR , Yugoslavia.
cidofovir	Czech. Academy	18 Jul 86	18 Jul 2007	26 June 2010 (14 years after MA)	EP 17 Jul 2007	Australia, Brazil, Czechoslovakia, Denmark , EP (AT, BE, CH, DE, ES, FR, GB, GR, IT, LI, LU, NL, SE), Finland, Ireland, Israel, Japan , Korea, New Zealand, Portugal, South Africa, US
ciprofloxacin	Bayer	3 Sept 80	3 Sept 2001	9 Dec 2003 (?)	EP 21 Aug 2001 Fr ext. until 29 Oct 2004	Australia, Cyprus, Denmark, EP (AT, BE, CH, DE, FR, GB, IT, LI, NL, SE), Hong Kong, Ireland, Japan , Kenya, Korea , Malaysia, Singapore, South Africa, US
clarithromycin	Taisho	4 Jun 80	4 Jun 2001	19 Jun 2001, ext. until Jun 2005 (+ 1465 days)	EP 27 May 2001 Fr ext. until 26 May 2008 (7 years)	EP (AT, BE, CH, DE, FR, GB, IT, LI, NL, SE), Japan, US
fluconazole	Pfizer	6 Jun 1981	6 Jun 2002	1 Jun 2002, ext. until 29 Jan 2004 (14 years after MA)	EP 22 Apr 2002, Fr ext. until 7 Mar 2005 (MA)	Australia, Bosnia, Canada , Czechoslovakia, Denmark, EP (AT, BE, CH, DE, FR, GB, IT, LI, LU, NL, SE), Finland, Greece, Hong Kong, Hungary, Ireland, Israel, Japan , Kenya, Malaysia, Mexico, New Zealand, Norway, Philippines, Portugal, Singapore, Slovenia, South Africa, US, USSR Yugoslavia
foscarnet	Astra	1 Jul 76	1 Jul 1997	29 Jul 97, ext. until 6 June 2000 (+ 1042 days)	Fr 30 Jun 97, ext. until 29 Jun 2002 (5 years)	Australia, Austria, Belgium , Bulgaria, Canada , Denmark, Finland, France, Germany , Hong Kong, Ireland, Italy, Japan , Luxembourg, Mexico, Malaysia, Netherlands , Norway, UK , Singapore, Sweden, Switzerland, US

Drug	Patent owner	Basic Patent priority date (origin)	Max. 20 years patent protection	US patent expiry date	French or Europ. patent expiry date	Countries where similar patents have been filed or granted
ganciclovir	Syntex	21 May 81	21 May 2002	21 May 2001, ext. until 23 Jun 2003 (14 years after MA)	EP 19 May 2002	Australia, Brazil, Canada , Czechoslovakia, Denmark, EP (AT, BE, CH, DE, FR, GB, IT, LI, LU, NL, SE) , Finland, Greece, Hong Kong, Hungary, Ireland, Israel, Japan , Korea , Malaysia, New Zealand, Norway, Philippines, Portugal, Romania, USSR , Singapore, South Africa , Spain , US
itraconazole	Janssen	23 Jun 78	23 Jun 99	23 Jun 98, ext. until 23 Jun 2000 (2 years)	EP 13 Jun 99 Fr ext. until 12 Jun 2006 (7 years)	Australia, Bosnia, Bulgaria, Canada , Cyprus, Czechoslovakia, Denmark, EP (AT, BE, CH, DE, FR, GB, IT, LU, LI, SE) , Finland, Greece, Hong Kong, Hungary, Israel, Ireland, Japan , New Zealand, Norway, Philippines, Poland, Portugal, Romania, USSR , Singapore, South Africa , US , Yugoslavia
ivermectin	Merck	16 Dec 74	16 Dec 95	Expired ?	N/A	Australia, Austria, Belgium , Canada , Czechoslovakia, Denmark , France, Finland, Germany , Hungary, Ireland, Israel, Japan , Luxembourg, Netherlands , New Zealand, Norway, OAPI , Philippines, South Africa , Sweden, Switzerland , UK , US , Yugoslavia
rifabutin	Archifar	13 Jun 75	13 Jun 96	26 Aug 97, ext. until July 2000 (+ 1406 days)	Fr 14 Jun 96, ext. until 13 June 2001 (5 years)	Australia, Austria, Belgium , Canada , Czechoslovakia, Denmark, Finland, France , Germany , Hong Kong, Hungary, Ireland, Israel, Italy , Japan , Netherlands , Norway, Portugal, USSR , South Africa , Sweden, Switzerland , UK , US , Yugoslavia
Antiretrovirals						
delavirdine	Upjohn	28 Dec 89	28 Dec 2010	8 Oct 2013 (17 years, numerous patents)	EP 24 Dec 2010	Australia , Canada , EP (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE) , Hong Kong, Hungary, Japan , Latvia, Mexico, Russia , US

Drug	Patent owner	Basic Patent priority date (origin)	Max. 20 years patent protection	US patent expiry date	French or Europ. patent expiry date	Countries where similar patents have been filed or granted
didanosine	Wellcome Found	15 May 85	15 May 2006		EP 14 May 2006	Australia, Canada , Denmark, EP (AT, BE, CH, DE, FR, GB, IT, LI, LU, NL, SE) , Finland, Greece, Hungary, Japan , New Zealand, Portugal, South Africa , Spain, US
	US Gov.	26 Aug 85	26 Aug 2006	29 Aug 2006 (17 years)	EP 21 Aug 2006 Fr ext. until 4 May 2009	Australia, Canada , Cyprus, EP (AT, BE, CH, DE, FR, GB, IT, LI, LU, NL, SE) , Hong Kong, Ireland , Israel, Japan , Mexico, New Zealand, Singapore, US
efavirenz	Merck	7 Aug 92	7 Aug 2013	7 Aug 2012	EP 3 Aug 2013?	Australia , Bulgaria, Brazil, Canada , China, Croatia, Czech Rep., EP, Finland, Hungary, Israel, Japan , Mexico, New Zealand , Norway , Poland, Romania , Singapore, Slovakia, Slovenia, South Africa , US
indinavir	Merck	8 Nov 91	8 Nov 2012	7 May 2013 (20 years)	EP 2 Nov 2012	Australia , Brazil, Bulgaria, Canada , China, Czech Rep, EP (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LI, LU, NL, PT, SE) , Finland, Hong Kong, Hungary, Israel, Japan , Latvia, New Zealand , Norway , Poland, Singapore, Slovakia , South Africa , Taiwan, US
lamivudine	IAF Biochem.	8 Feb 89	8 Feb 2010	8 Feb 2009	EP 8 Feb 2010 Fr ext. until 7 Aug 2011 (15 years after MA)	ARIPO , Australia, Brazil, Canada , China, Croatia, Cyprus, Czech Rep. , EP (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE) , Finland, Hong Kong, Hungary , Ireland , Israel, Japan , Korea , Mexico, Norway , New Zealand , OAPI , Portugal, Russia , Singapore, Slovakia , Slovenia, South Africa , US , Yugoslavia
nelfinavir	Agouron	7 Oct 93	7 Oct 2014	7 Oct 2013	EP 7 Oct 2014	Australia , ARIPO , Bulgaria, Brazil, Canada, China, Czech Rep., EP, Finland, Hungary, Japan , New Zealand , Norway, Poland, Singapore, Slovakia, South Africa , US

Drug	Patent owner	Basic Patent priority date (origin)	Max. 20 years patent protection	US patent expiry date	French or Europ. patent expiry date	Countries where similar patents have been filed or granted
nevirapine	Boehringer	17 Nov 89	17 Nov 2010	22 Nov 2011 (17 years, numerous patents)	EP 16 Nov 2010	Australia, ARIPO , Canada , EP (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE) , Finland, Hungary, Israel, Ireland , Japan , Mexico , New Zealand , Norway , OAPI, Portugal, Russia , Singapore, US , South Africa
ritonavir	Abbott	29 Dec 92	29 Dec 2013	29 Dec 2012	EP 16 Dec 2013	Australia , Brazil, Canada , EP (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LI, LU, NL, PT, SE) , Hong Kong, Hungary, Israel, Japan , Korea, Mexico , New Zealand , US
saquinavir	Roche	11 Dec 89	11 Dec 2010	19 Nov 2010 (20 years)	EP 10 Dec 2010 Fr ext. until 3 Oct 2011 (15 years after MA)	Australia , Brazil, Canada , Czech Rep. , China, Croatia, EP (AT, BE, CH, DE, DK, ES, FR, GR, IT, LI, LU, NL, SE) , Finland, Hong Kong, Hungary , Korea , Ireland , Israel, Japan , Latvia, Malawi, Mexico, Malta, Monaco, New Zealand , Norway , OAPI, Philippines , Portugal, Romania , Russia , Singapore, Slovakia , Slovenia, South Africa , UK , US , Zimbabwe
stavudine	Yale University	17 Dec 86	17 Dec 2007	25 Jun 2008 (ext. /MA)	EP 11 Dec 2007 Fr ext. until 8 May 2011 (15 years from MA)	Australia, Canada , Denmark, Egypt, EP (AT, BE, CH, DE, ES, FR, GB, GR, IT, LI, LU, NL, SE) , Finland, Hong Kong, Ireland, Israel, Japan , Korea , New Zealand, Philippines , Portugal, US , South Africa
zalcitabine	US Gov.	26 Aug 85	26 Aug 2006	7 Nov 2006 (17 years)	EP 21 Aug 2006 Fr ext. until 1 Dec 2008 (15 years from MA)	Australia, Canada , EP (AT, BE, CH, DE, FR, GB, IT, LI, LU, NL, SE) , Hong Kong, Ireland , Israel, Japan , New Zealand, US
zidovudine	Glaxo	16 Mar 85	16 Mar 2006	17 Sept 2005 (20 years)	EP 14 Mar 2006	ARIPO , Australia, Canada , Cyprus, Czechoslovakia, Denmark , EP (AT, BE, CH, DE, FR, GB, IT, LI, LU, NL, SE) , Finland, Hong Kong, Hungary, Ireland , Israel, Japan , Korea , Latvia, Monaco, New Zealand, Philippines , Portugal, Singapore, South Africa , US