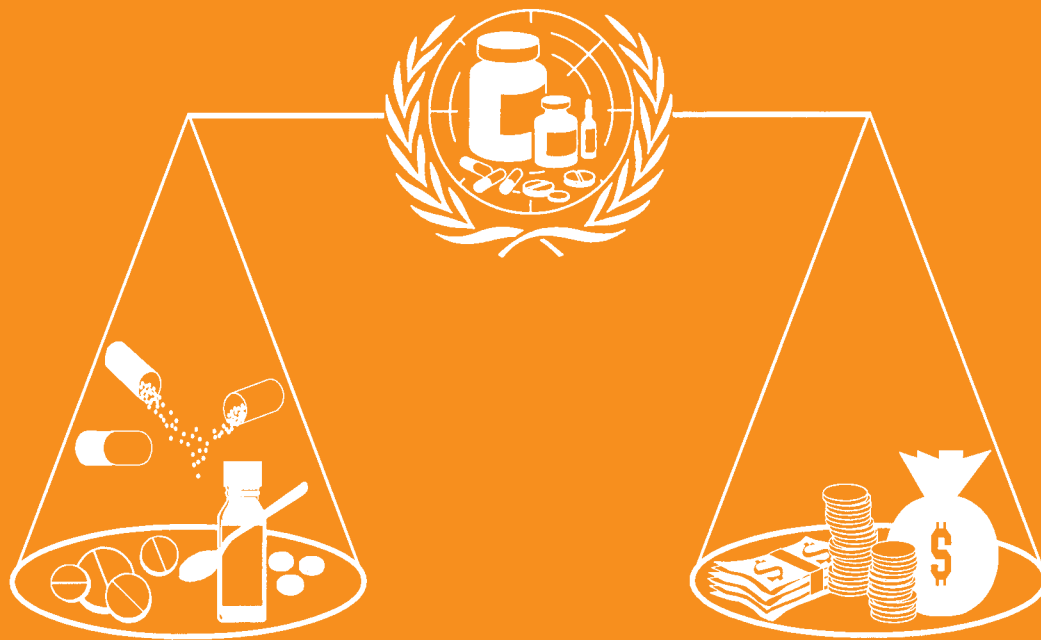


DETERMINING THE PATENT STATUS OF ESSENTIAL MEDICINES IN DEVELOPING COUNTRIES

Health Economics and Drugs
EDM Series No. 17



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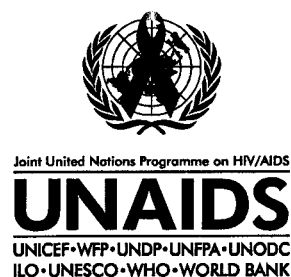
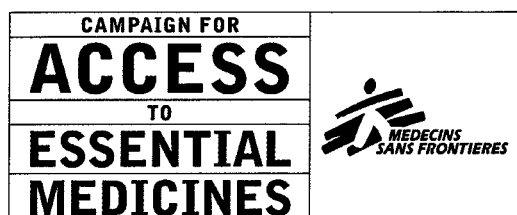


World Health Organization
Essential Drugs and Medicines Policy



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Determining the patent status of essential medicines in developing countries.
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Foreword

As the response to the HIV/AIDS epidemic is stepped up in many countries around the world, the campaign to ensure access to safe, effective, good quality antiretroviral medicines at affordable prices takes on new proportions and importance. The problem of access to medicines is not confined to HIV/AIDS alone. Millions of people, particularly in the developing world, do not have access to essential medicines.

While it may be argued that the price of medicines is just one of the several reasons for the lack of access, it is equally true to say that the debate about prices, patents and public health has been one of the most controversial and difficult. The Declaration on the TRIPS Agreement and Public Health adopted at the World Trade Organization (WTO) Ministerial Conference in Doha, November 2001 (hereinafter referred to as the Doha Declaration), was a milestone in its affirmation of the primacy of public health interests in the application of intellectual property rights protection.

Now that the Doha Declaration has confirmed the inherent flexibility within the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) that allows governments to take measures to protect public health, it is up to governments to ensure that patents do not constitute a barrier to access to medicines.

It will be important to integrate public health perspectives into national patent laws, including ensuring that the patentability requirements for pharmaceuticals are kept to the minimum required by the TRIPS Agreement. In cases where such patents have been validly granted, the use of public health safeguards, such as compulsory licences or government use authorization, are TRIPS-consistent means of facilitating access to affordable medicines.

There are, therefore, a range of policy options for countries, depending on the particular circumstances and needs. However, a crucial factor to ensure effective decision-making in such issues must be the availability of accurate and up-to-date information about the patent status of essential medicines. The question of whether or not a medicine is under patent protection is clearly of great importance for drug procurement decisions. Unfortunately, such information is not always easily accessible or available in an easily understood form.

In 2000, WHO and UNAIDS jointly published a report, "Patent Situation of HIV/AIDS-related Drugs in 80 Countries". The aim of the report was to assess the patent situation of HIV/AIDS-related medicines in countries for which data was available.

Since the publication of this report, a number of new medicines have become vital in the treatment of HIV/AIDS, as well as the treatment of opportunistic infections. The patent table in this report is an attempt to update the previous work.

In the interests of facilitating the availability of up-to-date information, WHO and the UNAIDS Secretariat are exploring the possibilities of taking such work further within their respective mandates.

Acknowledgements

This report has been compiled and prepared by Médecins Sans Frontières (MSF), with the support of WHO and the UNAIDS Secretariat.

The patent table in this report (pages 11-14) was compiled and first published by MSF, as an annex to its publication, "*Drug Patents under the Spotlight*", in May 2003.

Data in the patent table were obtained from and cross-checked between a variety of sources including the local patent offices and a number of free web sites, based on search by generic name, chemical formula and/or priority dates. Patent searches can be difficult for many reasons and the information contained in the patent table cannot be considered as a complete and official source of patent information. Further checks on the patent status with the national patent office are strongly advised prior to drug procurement or manufacture in a specific country. Given these reasons, WHO, the UNAIDS Secretariat and MSF cannot be liable for the use of these data.

The text accompanying the patent table was prepared by Pascale Boulet and Ellen 't Hoen of MSF. The authors gratefully acknowledge Christopher Garrison, MSF; Laura Hakokongas, MSF; Julian Fleet, UNAIDS; Cecilia Oh and Germán Velásquez of the WHO Department of Essential Drugs and Medicines Policy for their comments and input.

Any views expressed in this report are the views of the authors and do not necessarily reflect the views of WHO or the UNAIDS Secretariat. The authors are solely responsible for the opinions expressed herein.

Pharmaceutical patents in the context of TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health

Patents have become one of the most hotly debated topics when discussing access to essential medicines since the creation of the WTO and the conclusion of the TRIPS Agreement in 1994. Patents are by no means the only barriers to access to life-saving medicines, but they can play a significant, or even determinant, role in that they grant the patent holder a monopoly on a medicine for the number of years the patent is in force. During this time-limited monopoly, the patent holder's ability to determine prices can result in medicines being unaffordable to the majority of people living in developing countries.

The TRIPS Agreement sets out the minimum standards for patent protection with which all WTO Members must abide. Unlike in the days before the TRIPS Agreement, WTO Members can no longer rule out granting patents in particular fields of technology, such as the pharmaceutical sector. Now, all inventions in the pharmaceutical sector fall within the scope of the patentability requirements of the TRIPS Agreement and national authorities must provide patent protection for a minimum term of 20 years, provided that the invention is new, inventive and capable of industrial application.¹

Much of the debate surrounding pharmaceutical patents and access to medicines has thus far been focused on the safeguards in the TRIPS Agreement, the use of which would enable countries to address the negative effect of patent monopolies. Much less attention has been directed at the question of the granting of the pharmaceutical patents themselves. Although the TRIPS Agreement sets out the minimum standards for patent protection, it still allows some room for WTO Members to make decisions, such as for which sort of inventions they will grant patents. The patentability of pharmaceutical inventions is an important issue, as developing country WTO Members assess their options for implementing the provisions of the TRIPS Agreement in ways that best suit their needs. This issue is discussed in further detail in a number of publications.²

In respect of safeguards, the TRIPS Agreement provides for a number of measures that countries may use. WTO Members can incorporate several safeguard measures into their patent laws, for example, compulsory licence and government use provisions, in order to remedy the negative effect of patent monopolies and enable generic competition.

Such measures were clearly reaffirmed in the now famous Doha Declaration. This Declaration unequivocally recognizes that access to medicines should have primacy over commercial interests and encourages countries to interpret and implement the

¹ As per Article 27.1 of the TRIPS Agreement.

² See, for example, Correa, C. *Integrating Public Health Concerns into Patent Legislation in Developing Countries*. Geneva, South Centre, 2000.

TRIPS Agreement in a manner that would protect public health and promote access to medicines for all.

Despite the fact that this flexibility in the TRIPS Agreement is now widely recognized, most developing countries have not made use of the safeguard measures. For instance, while compulsory licences in respect of pharmaceutical and other patents are routinely granted in developed countries, there have been very few, if any, in the developing countries.

The UK Commission on Intellectual Property Rights³ identified the absence, or lack, of an appropriate administrative and legal infrastructure in many developing countries as one of the reasons for the lack of use of compulsory licences and other safeguard measures. The effective use of safeguard measures would often require an efficient and coordinated decision-making process involving different government agencies, including the health, trade and intellectual property agencies, in a particular country. The decision-making process with regard to the use of safeguard measures would have to take into account various issues related to procurement, such as therapeutic needs and options, prices and availability or supply, in order to facilitate access to essential medicines.

Where the infrastructure and procedures for coordination and the provision of relevant information are lacking, it is not surprising that countries may be reluctant to make use of safeguard measures, given the risk of sanctions and potential litigation.

Another crucial aspect of the decision-making process is the availability of accurate and up-to-date information about the patent status of essential medicines. However, such information is often not easily accessible or available in an easily understood form. For these reasons, there have been calls for such patent data to be collected and presented in a transparent and public form.

The patent table below is a contribution to this call, in the hope that it will be a starting point upon which further work can build. WHO and the UNAIDS Secretariat are exploring the possibilities of taking this work further within their respective mandates.

³ *Integrating Intellectual Property Rights and Development Policy*, Report of the Commission on Intellectual Property Rights. London, September 2002, p. 44.

Scope and limits of the patent table

The patent table was compiled by MSF, as part of its study on the patent status of certain medicines in the context of its own procurement activities. Therefore, the table only provides data regarding a selected number of medicines and countries. The medicines chosen are essential medicines for which patents already constitute a barrier to access or might do so in the coming years. The countries selected are countries where MSF has, or is planning to open, field projects.

For each medicine/country, the table provides information on whether or not there is a patent and, where there is, the estimated expiry date of the identified patent, as well as the patent number in the country. Patents are granted on a country-to-country basis, sometimes on a regional basis. The duration is typically 20 years from the filing of the patent application, but this term may vary.⁴

For various reasons, it is common for products to be patented in certain countries but not in others. In some cases, the patent application was still under examination at the time of data collection and users of the table are therefore encouraged to request the local patent office to clarify whether a particular patent application has indeed resulted in a patent or has been rejected.

It should be noted that the patent table sometimes lists several entries for one medicine. This is because patents are granted to protect *inventions*, not products per se. In the pharmaceutical sector, the subject matter of patents will seldom be a medicine, but rather the basic molecule of a medicine, a special form, or a combination. A single medicine is generally protected by a number of patents, and it should be noted that the patent table may not include all of them.

The patent table focuses on patents protecting the basic molecule of a given medicine (usually including a manufacturing process) or, in the case of old molecules, the target therapeutic use of this medicine, such as the prevention or treatment of HIV/AIDS. This is mainly because the patent related to the active ingredient of a medicine is generally the first that was applied for and therefore the first one to expire. This does not mean however that no additional patent has been granted later on to protect, for example, a different manufacturing process, an improved formulation with fewer side-effects, or a new combination. The lack of or the expiry of a patent in a given country, as provided in the table, does not necessarily mean that one can import or manufacture generic versions of the medicine without the risk of being sued by a potential patent holder.

⁴ Expiry dates were calculated on the basis of the national patent law in force at the time of collection of the data. These can only be estimates because the law may be revised to change the patent term and/or the patent owner may decide to abandon the patent (i.e. to stop paying the annual maintenance fees).

INN(s)	Originator's Trade mark	Patent holder(s) (manufacturer)	Basic patent priority date	International patent application	Representative European corresponding patent	Expected(o) patent expiry date (patent number) in															
						Brazil (3)	Cambodia (4)	China (5)	Guatemala (6)	Kenya	Malawi (7)	OAPI (8)	Peru (9)	South Africa	Thailand (10)	Uganda (11)	Ukraine	Zambia(7)	Zimbabwe		
Abacavir (racemic mixture)	Ziagen	Wellcome (GSK)	27.06.1988 (GB8815265)	No	EP0349242	27.06.08 (BR1100288)	No	No	No	No	26.06.09 (AP101)	26.06.05 (AP101)	No	No	25.06.09 (ZA8904837)	No	23.10.05 (AP101)	No	26.06.05 (AP101)	26.06.09 (AP101)	
Abacavir (enantiomer)		Wellcome (GSK)	22.12.1989 (US455201)	No	EP0434450	No	No	21.12.10 (CN1054981)	No	No	21.12.10 (AP196)	21.12.06 (AP196)	No	No	20.12.10 (ZA9010365)	No	30.06.07 (AP196)	21.12.10 (UA29382)	21.12.06 (AP196)	21.12.10 (AP196)	
Didanosine - ddl improved oral formulation	Videx	USA Gov (BMS)	26.08.1985 (US769016)	WO87/01284	EP0216510	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	
Efavirenz	Stocrin/Sustiva	BMS	22.07.1991 (US733547)	No	EP0524579	No	No	21.07.12 (CN1068739)	No	No	No	No	No	No	20.07.12 (ZA9205484)	07.07.12 (7600)	No	No	No	No	
		Merck (MSD, BMS)	07.08.1992 (US926607)	WO94/03440	EP0582455	07.08.12 (BR1100250)	No	No	06.08.13 (CN1090277)	No	No	No	No	No	06.08.13 (ZA9305724)	30.07.13 (11367)	No	06.08.13 (UA42699)	No	No	
Indinavir (including sulfate) (related) Indinavir	Crixivan	Merck (MSD)	08.11.1991 (US789508)	WO93/09096	EP0541168	No	No	No	No	No	No	No	No	06.11.12 (ZA9208563)	No	No	03.11.12 (UA45945)	No	No	No	
		Merck	07.05.1993 (US059038)	WO94/26717	EP0696277 (withdrawn)	No	No	under examination (CN1126469)	No	No	WO94/26717?	WO94/26717?	No	No	05.05.14 (ZA9403104)	under examination (16620)	No	No	No	No	
Lamivudine - 3TC (including enantiomer) enantiomer crystalline form	Epivir	IAF Biochem (GSK)	08.02.1989 (US308101)	No	EP0382526	No	No	08.02.10 (CN1044817)	No	08.02.10 (AP136)	08.02.06 (AP136)	08.02.10 (OA 9193)	No	07.02.10 (ZA9000943)	No	05.08.06 (AP136)	No	08.02.06 (AP136)	08.02.10 (AP136)		
		IAF Biochem	02.05.1990 (GB9009861)	WO91/17159	EP0625150 (rejected)	No	No	30.04.11 (CN1058214)	No	02.05.11 (AP182)	02.05.07 (AP182)	02.05.11* (OA9559)	No	30.04.11 (ZA9103293)	?	30.06.07 (AP182)	No	02.05.07 (AP182)	02.05.11 (AP182)		
		Glaxo	03.06.1991 (GB911902)	WO92/21676	EP0517145	No	No	No	No	02.06.12 (AP300)	02.06.08 (AP300)	02.06.12* (OA9913)	No	02.06.12 (ZA9204007)	?	20.01.09 (AP300)	02.06.12 (UA41265)	02.06.08 (AP300)	02.06.12 (AP300)		
Nelfinavir mesylate	Viracept	Agouron (Roche)	07.10.1993 (US133543)	WO95/09843	EP0722439	07.10.13 (BR1100166)	No	07.10.14 (CN1131942)	No	07.10.14 (AP600)	07.10.14 (AP600)	07.10.14* (OA10718)	No	07.10.14 (ZA9407815)	No	No	No	No	No		
Nevirapine Syrup formulation	Viramune	Boehringer	17.11.1989 (US438923)	No	EP0429987	No	No	?	Potentially in the mailbox	16.11.10 (AP179)	16.11.06 (AP179)	16.11.10 (OA9852)	No	18.11.10 (ZA9009246)	No	30.04.07 (AP179)	17.11.09 (UA34420)	16.11.06 (AP179)	16.11.10 (AP179)		
		Boehringer	25.08.1997 (US60/056803)	?	?	?	?	?	?	?	?	?	?	?	?	?	11.08.18 (UA44370)	?	?		
Ritonavir Combination w/ lopinavir	Norvir Kaletra	Abbott	29.12.1992 (US998114)	WO94/14436	EP0674513	No	No	under examination (CN1208405)	No	No	No	No	No	No	No	No	?	?	No	No	
		Abbott	13.12.1995 (US572226)	WO97/21685	EP0882024	No	No	No	Potentially in the mailbox	No	No	No	No	No	11.12.16 (ZA9610475)	04.12.16 (13302)	No	?	?	No	
Saquinavir	Fortovase	Hoffmann-La Roche	11.12.1989 (GB8927913)	No	EP0432695	No	No	10.12.10 (CN1052482)	No	No	18.11.06 (MW9088)	11.12.10 (OA9334)	No	03.12.10 (ZA9009743)	No	No	?	No	13.11.10 (ZW90174)		
Stavudine - d4T Pro-drug	Zerit	Yale Univ. (BMS)	17.12.1986 (US942666)	No	EP0273277	No	No	No	No	No	No	No	No	22.09.07 (ZA8707171)	No	No	No	No	No		
		BMS	06.05.1988 (US190809)	No	EP0340778 (withdrawn)	No	No	No	No	No	No	No	No	No	04.05.09 (ZA8903348)	No	No	No	No		
Zidovudine - AZT	Retrovir	Glaxo Wellcome	16.03.1985 (GB8506869)	No	EP0196185	No	No	No	No	14.03.06 (AP11)	14.03.02 (AP11)	No	No	13.03.06 (ZA8601933)	No	22.12.02 (AP11)	?	14.03.02 (AP11)	14.03.06 (AP11)		
AZT - 3TC combination Tablet formulation	Combivir	Glaxo Wellcome	16.05.1991 (GB9110624)	WO92/20344	EP0513917	No	No	15.05.12 (CN1068570)	No	No	WO92/20344?	11.05.12* (OA10058)	No	15.05.12 (ZA9203544)	No	No	No	No	No		
		Glaxo Wellcome	31.10.1996 (GB9622681)	WO98/18477	EP0941100 (expected grant 28.05.03)	under examination (BR9712614)	No	No	under examination (CN1241142)	Potentially in the mailbox	29.10.17 (AP1067)	29.10.13 (AP1067)	29.10.17* (OA11038)	under examination (965-1997)	29.10.17 (ZA9709726)	under examination (37164/opp. filed)	01.05.17 (AP1067)	No	No	29.10.17 (AP1067)	
AZT + 3TC + abacavir Tablet formulation	Trizivir	Glaxo Wellcome	30.03.1995 (GB9506490)	WO96/30025	EP0817637	under examination (BR9607851)	No	under examination (CN1185110)	Potentially in the mailbox	28.03.16* (AP652)	28.03.12* (AP652)	WO96/30025 ?	No	27.03.16 (ZA9602477)	under examination (28828)	19.06.13* (AP652)	WO96/30025 ?	No	28.03.16* (AP652)		
		Glaxo Wellcome	29.04.1998 (GB9809213)	WO99/55372	EP1083932 (under examination)	under examination (BR9910071)	No	No	under examination (BR9910071)	Potentially in the mailbox	WO99/55372 ?	WO99/55372 ?	WO99/55372 ?	No	WO99/55372 ?	?	WO99/55372 ?	WO99/55372 ?	No	WO99/55372 ?	

Footnotes:

(o) Except when stated differently, this expiry date is 20 years from the filing date, but note that the patent may expire before if the patent holder abandons it (i.e. stops paying the annual fees).

(1) Patents may be granted to protect the basic molecule of a medicine, but also, e.g. to protect the manufacturing process, a specific therapeutic indication, or a specific formulation of the said molecule. Note that a product patent usually covers also a manufacturing process.

(2) Note that only the first patent holder is named where there are more than one.

(3) In Brazil, patent protection for pharmaceuticals was only introduced on 14 May 1997. However, between 15 May 1996 and 15 May 1997 it was possible to register a preexisting foreign patent or pending patent application in Brazil in order to obtain pipeline patent protection, i.e. patent protection for medicines which are patent protected abroad but which have not been marketed yet.

(4) There was no patent law in force in Cambodia until early 2003. In the new patent law, pharmaceutical products are excluded from patent protection until 2016, in accordance with the Doha Declaration on TRIPS and Public Health.

(5) Note that some Chinese patents may only protect manufacturing processes as China did not grant patents on pharmaceutical products before 1 January 1993.

(6) Guatemala only introduced patent protection for pharmaceuticals on 1 November 2000.

(7) In Malawi and Zambia, patents are granted for an initial term of 16 years from the filing date, with a possible extension.

(8) OAPI patents are effective in the 16 member States of the Organisation Africaine de la Propriété Intellectuelle (Benin, Burkina Faso, Cameroon, Central African Rep., Chad, Congo, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Ivory Coast, Mali, Mauritania, Niger, Senegal, and Togo).

(9) Patent protection for pharmaceutical products was only introduced on 11 December 1991 in Peru, as in all other members of the Andean Community (Bolivia, Colombia, Ecuador, and Venezuela).

(10) Patent protection for pharmaceutical products has only been available in Thailand since 30 September 1992, including pending applications at this date.

(11) In Uganda, patents are granted for 15 years from the date of grant, and may be extended for 5 additional years if the patent is worked locally.

WO refers to patent applications filed under the system of the Patent Cooperation Treaty (PCT). The PCT allows patent applicants to file a kind of "worldwide" patent application, by designating countries among PCT Member States in which they intend to obtain a patent. However, the applicant must then confirm this wish in each designated country/region and the patent can only be granted by the patent office of the said country/region.

WO? means that we don't know if the PCT application has been confirmed at national level.

* There is an error in the published patent document with regard to the filing date. The estimated patent expiry date is therefore based on the assumed correct filing date.

Where '?' appears, the information was not available.

In addition, other important data have been included in the table that readers may provide to their patent offices to find out if a similar patent has been granted in their country:

- The date and number of the main priority patent application (the priority patent application is the first patent application that is filed in a country to protect an invention). Other patent applications filed to protect the same invention in other countries will very likely include a reference to the priority date and number. Priority data are therefore key to obtaining information from the patent office on whether a patent protecting the same invention has been granted in the country concerned.
- The number of the related international patent application (where there is one). Although patents only have national, not international, effect (notwithstanding the function of some regional intellectual property authorities, a patent issued in one country has no validity or effect in another country), and "international patents" do not exist, it has been possible since 1970 to file "international" patent applications to apply for a patent in several countries at the same time. It must be noted however that an international patent application will only cover countries that have signed the Patent Cooperation Treaty.⁵
- The number of the equivalent European patent.

It is also advisable to first ask the patent office, or the World Intellectual Property Organization (WIPO), the date from which patents on medicines have been available in a particular country. If the country, like Guatemala or Peru, did not allow patenting of pharmaceuticals until relatively recently, it is likely that patents with an earlier filing date will not be valid in that country, subject to any transitional provisions. There would then be no need to initiate a patent search on these medicines in the local patent office.

It must be stressed that the information presented in the patent table cannot be regarded as complete. For example, it has already been mentioned that the patent table only provides data regarding a selected number of medicines in a number of countries. In addition, the patents in the table are primarily those protecting the basic molecule of a given medicine. The table does not provide information for all of the patents that may protect a particular medicine – there could be a large number in each country. Thus, it should be reiterated that the information contained in the patent table merely provides a starting point to making comprehensive patent searches.

INN(1)	Originator's Trade mark	Patent holder(2) (manufacturer)	Basic patent priority date (number)	International patent application	Representative European corresponding patent	Expected(o) patent expiry date (patent number) in														
						Brazil(3)	Cambodia(4)	China(5)	Guatemala(6)	Kenya	Malawi(7)	OAPI(8)	Peru(9)	South Africa	Thailand(10)	Uganda(11)	Ukraine	Zambia(7)	Zimbabwe	
Amphotericin B liposomal	Fungizone	Olin Mathieson (Bristol Myers Squibb)	28.12.1954 (US478014)	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
	Ambisome	Vestar (Gilead-NeXstar)	12.11.1987 (US119518)	No	EP0317120	No	No	No	No	No	No	?	No	No	No	No	No	No	No	No
Arthemeter+ Lumefantrine (benflutemol)	Coartem/Riamet(13)	Ciba-Geigy (Novartis)	08.08.1990 (CN106722)	WO92/02217	EP0500823	No	No	abandoned? (CN1058717)	No	12.06.11 (AP231)	12.06.07 (AP231)	?	No	12.06.11 (ZA9104490)	No	31.01.08 (AP231)	?	12.06.07 (AP231)	12.06.11 (AP231)	
Azithromycin crystalline dihydrate	Sumamed	Pliva (+Pfizer)	06.03.1981 (YU592)	No	GB2094293	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
	Zithromax	Pfizer	09.07.1987 (PCT/US87/01612)	WO89/00576	EP298650	No	No	08.07.08 (CN1030422)	No	15.06.08 (AP44)	15.06.04 (AP44)	abandoned (OA8743)	No	07.07.08 (ZA8804925)	No	27.07.04 (AP44)	?	15.06.04 (AP44)	15.06.08 (AP44)	
Ciprofloxacin tablet formulation(12)	Cipro, Ciproxin	Bayer	03.09.1980 (DE3033157)	No	EP0049355	No	No	No	No	expired 21.08.01 (KE3545)	No	No	No	expired 01.09.01 (ZA8106080)	No	No	No	No	No	
	Cipro, Ciproxin	Bayer	21.01.1986 (DE3601566)	No	EP0230881	No	No	abandoned? (CN1013839)	No	No	No	No	No	No	No	No	No	No	No	
Fluconazole (general)		ICI	02.06.1980 (GB8017959)	No	EP0044605	No	No	No	No	expired 14.05.01 (KE3733)	No	No	No	expired 19.05.01 (ZA8103354)	No	No	No	No	No	
	specific	Diffucan	Pfizer	06.06.1981 (GB8117379)	No	EP0069442	No	No	No	expired 22.04.02 (KE3771)	No	No	No	expired 04.06.02 (ZA8203934)	No	No	expired 01.06.02 (UA8019)	No	No	

Footnotes:

- (o) Except when stated differently, this expiry date is 20 years from the filing date, but note that the patent may expire before if the patent holder abandons it (i.e. stops paying the annual fees).
- (1) Patents may be granted to protect the basic molecule of a medicine, but also, e.g. to protect the manufacturing process, a specific therapeutic indication, or a specific formulation of the said molecule. Note that a product patent usually covers also a manufacturing process.
- (2) Note that only the first patent holder is named where there are more than one.
- (3) In Brazil, patent protection for pharmaceuticals was only introduced on 14 May 1997. However, between 15 May 1996 and 15 May 1997 it was possible to register a preexisting foreign patent or pending patent application in Brazil in order to obtain pipeline patent protection, i.e. patent protection for medicines which are patent protected abroad but which have not been marketed yet.
- (4) There was no patent law in force in Cambodia until early 2003. In the new patent law, pharmaceutical products are excluded from patent protection until 2016, in accordance with the Doha Declaration on TRIPS and Public Health.
- (5) Note that some Chinese patents may only protect manufacturing processes as China did not grant patents on pharmaceutical products before 1 January 1993.
- (6) Guatemala only introduced patent protection for pharmaceuticals on 1 November 2000.
- (7) In Malawi and Zambia, patents are granted for an initial term of 16 years from the filing date, with a possible extension.

- (8) OAPI patents are effective in the 16 member States of the Organisation Africaine de la Propriété Intellectuelle (Benin, Burkina Faso, Cameroon, Central African Rep., Chad, Congo, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Ivory Coast, Mali, Mauritania, Niger, Senegal, and Togo).
- (9) Patent protection for pharmaceutical products was only introduced on 11 December 1991 in Peru, as in all other members of the Andean Community (Bolivia, Colombia, Ecuador, and Venezuela).
- (10) Patent protection for pharmaceutical products has only been available in Thailand since 30 September 1992, including pending applications at this date.
- (11) In Uganda, patents are granted for 15 years from the date of grant, and may be extended for 5 additional years if the patent is worked locally.
- (12) Note that other patents protect aqueous solutions and flavoured-masqued compositions of ciprofloxacin.
- (13) Coartem: name in poor countries / Riamet: name in rich countries.
- WO refers to patent applications filed under the system of the Patent Cooperation Treaty (PCT). The PCT allows patent applicants to file a kind of "worldwide" patent application, by designating countries among PCT Member States in which they intend to obtain a patent. However, the applicant must then confirm this wish in each designated country/region and the patent can only be granted by the patent office of the said country/region.
- Where '?' appears, the information was not available.

⁵ List of country members available on the Internet at <http://www.wipo.org/pct/en/index.html>

How to overcome patent barriers in procurement activities aimed at accessing medicines at the lowest possible price

First, it is important to keep in mind that not all patents that are granted are valid. For example, some countries do not allow in their patent law the granting of new use patents or patents on compositions of existing molecules. Still, at times, national authorities may improperly grant such patents despite the fact that the law does not allow it.⁶ These patents are very likely to be judged invalid if challenged, and should therefore not be considered as definite barriers to generic competition.

Secondly, least developed countries (LDCs), which benefit from a special provision since the adoption of the Doha Declaration are not required to grant or enforce patents for pharmaceutical products until 2016 at least and can take whatever action is required to import or produce generic pharmaceutical products until then.

LDCs: a special case

The Doha Declaration granted the LDC Members of the WTO special treatment with regard to pharmaceutical patents. Paragraph 7 of the Doha Declaration provides a special extension of the TRIPS transitional period for pharmaceutical products. LDCs do not have “to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016”. This means that LDCs do not have to grant patents for pharmaceutical products, provide protection of undisclosed test data⁷ or enforce patents or data exclusivity rights that have already been granted until at least 2016. In LDCs therefore, neither patents nor data protection should be a barrier to purchasing or producing generic versions of medicines. LDCs have enormous flexibility to ensure that patents and data protection rules are not barriers to the purchase of lowest priced medicines, and they are encouraged to use this flexibility, including by the major multilateral donors (such as the World Bank and the Global Fund to Fight AIDS, Tuberculosis and Malaria).⁸

⁶ See MSF Report *Drug patents under the spotlight* (2003) for a detailed explanation on this point.

⁷ WTO Members are obliged to protect undisclosed tests or other data, required by drug regulatory authorities for the registration of a new medicine, against unfair commercial use (Article 39.3 of the TRIPS Agreement).

⁸ See, for example, the World Bank Technical Guide *HIV/AIDS Medicines and Related Supplies: Contemporary Context and Procurement* (2004)

<http://siteresources.worldbank.org/INTPROCUREMENT/Resources/Technical-Guide-HIV-AIDS.pdf>

Other countries may take one or more of the following actions:

a) Compulsory licensing and government use

An important tool for developing country governments and their procurement authorities in dealing with potential obstacles presented by patents is a "compulsory licensing" or "government use" authorization.

A patent is a government grant that permits its holder to exclude third parties from the market for a product. A "compulsory licence" is an authorization by the government to itself or to a third party to use the patented invention without the permission of the patent holder. This enables the compulsory licensee to use, manufacture, import, sell and export (with some limitations) the product under patent. Most, if not all, countries – developed and developing – allow the government to make use of patented inventions for public purposes with fewer bureaucratic obstacles than those applied to the private sector. A compulsory licence authorizing the government to use the patent for its own purposes is also referred to as a "government use" authorization. An obligation remains to pay the patent holder adequate remuneration in the circumstances of compulsory licensing or government use, taking into account the economic value of the authorization.

Compulsory licence: an example

French law provides that, "where the interests of public health demand", patents issued for medicines may be subject to a special regime of compulsory licences ("licence d'office") whereby any qualified person may request a licence from the relevant Minister. The law authorizes this procedure when the patented medicines are "being made available to the public in insufficient quantity or quality or at abnormally high prices".⁹

Government use for procurement of generic antiretrovirals in Cameroon

Cameroon is a developing country and a Member of the African Intellectual Property Organization (OAPI in French). The OAPI patent office grants patents on a regional basis that are valid in all OAPI member countries. A significant number of antiretroviral medicines are currently protected by OAPI patents. However, some of the patented antiretrovirals are available at lower prices from generic manufacturers than from the originator pharmaceutical company. In order to make the best possible use of its limited resources, the Ministry of Health of Cameroon, in 2000, authorized the public procurement agency to buy antiretrovirals from generic sources, when these are priced cheaper than the originator.

Article 31 of the TRIPS Agreement authorizes governments to grant compulsory licences without restriction as to purpose or grounds. This authority was confirmed in paragraph 5(b) of the Doha Declaration.

⁹ See Article L.613-16 of the Code on Intellectual Property.

The TRIPS Agreement establishes certain procedural requirements for granting a compulsory licence. For instance, a party seeking a compulsory licence must first have tried to obtain a voluntary licence from the patent holder on reasonable commercial terms and conditions and show that such efforts have not been successful within a reasonable period of time.

However, this procedural requirement can be significantly minimized. Prior negotiations with the patent holder before granting of compulsory licences are not required in the case of a national emergency, other circumstances of extreme urgency or when the licence is intended for public non-commercial use. Countries are free to determine what they consider a national emergency. The TRIPS Agreement does not prescribe any procedure for using the emergency safeguard; for example a declaration of emergency is not required. Countries are also free to define what is "public non-commercial use" – this can be defined as procurement or production of health care products for use in the public sector, for example.

In practice, this means that a procurement authority in a country can start purchasing generic versions of needed medicines without prior negotiations with the patent holder. The patent holder will be informed of the decision to make government use of the patent and the government will have to offer the patent holder adequate compensation, the level of which is to be decided by the government.

b) Parallel importation

"Parallel importation" refers to the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country. The sale of the patented medicine in the exporting country is deemed to "exhaust" the patent holder's right in the importing country. Parallel importation in general refers to the import of the branded product and can be useful when the patent holder has put the product on the market elsewhere at a lower price. A country that allows parallel importation from any other country has an "international exhaustion regime". A country adopting a "regional exhaustion regime" would only allow parallel importation from other countries that are members of the same regional trade agreement or arrangement. An international exhaustion regime will be more helpful than a regional exhaustion regime in this respect as prices within a region will probably be similar. Paragraph 5(d) of the Doha Declaration clarified the fact that countries are free to determine their exhaustion regimes:

"The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4."

There are no procedural or remuneration requirements in the case of parallel importation. The extent to which parallel importation is possible depends on the regime of exhaustion adopted in the national legislation (although the marketing of the product will be subject to national drug regulatory requirements).

Annex 1 – Declaration on the TRIPS Agreement and Public Health

**WORLD TRADE
ORGANIZATION**

WT/MIN(01)/DEC/2
20 November 2001

(01-5860)

**MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 – 14 November 2001**

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

- (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
- (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
- (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Annex 2 – Least developed country Members of the WTO¹⁰

The WTO does not define "developed" or "developing" countries and recognizes as least developed countries (LDCs) those countries which have been designated as such by the United Nations. Developing countries in the WTO are designated on the basis of self-selection although this is not necessarily automatically accepted in all WTO bodies.

Angola
Bangladesh
Benin
Burkina Faso
Burundi
Central African Republic
Chad
Democratic Republic of the Congo
Djibouti
Gambia
Guinea
Guinea-Bissau
Haiti
Lesotho
Madagascar
Malawi
Maldives
Mali
Mauritania
Mozambique
Myanmar
Nepal
Niger
Rwanda
Senegal
Sierra Leone
Solomon Islands
Togo
Uganda
United Republic of Tanzania
Zambia

Nine other least developed countries are in the process of accession to the WTO. They are: Bhutan, Cambodia, Cape Verde, Ethiopia, Lao People's Democratic Republic, Samoa, Sudan, Vanuatu and Yemen.

¹⁰ World Trade Organization website: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm

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The WHO Department of Essential Drugs and Medicines Policy (EDM) seeks to ensure that all people, wherever they may be, are able to obtain the drugs they need at a price that they and their country can afford; that these drugs are safe, effective and of good quality; and that they are prescribed and used rationally. It provides operational support to countries in the development and implementation of national drug policies based on the concept of essential drugs and it promotes the rational use of drugs at every level.

Health economics is of increasing relevance in the formulation and development of national drug policies that promote equity and rationalize the use of community and state resources. In many countries the new economic context and the global increase in pharmaceutical prices has highlighted the socio-economic aspects of drug use and accessibility. In this process, national drug policies have evolved from a primarily technical and pharmacological focus to encompass social and economic dimensions.

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