DETERMINING THE PATENT STATUS
OF ESSENTIAL MEDICINES
IN DEVELOPING COUNTRIES

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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

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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.

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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.
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 Rights\(^1\) 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.

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### Scope and limits of the patent table

The patent table was compiled by SEP, as part of its study on the status of certain medicines in the context of the new procurement activities. Therefore, the table only provides data regarding a selected number of medicines and countries. The results chosen are the essential medicines for which patents already constitute a barrier to access or might do so in the coming years. The countries selected are those where SEP 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 grouped in a country-

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Country</th>
<th>Patent Status</th>
<th>Estimated Expiry Date</th>
<th>Patent Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine A</td>
<td>Country 1</td>
<td>Patent</td>
<td>2025</td>
<td>P12345</td>
</tr>
<tr>
<td>Medicine B</td>
<td>Country 2</td>
<td>Patent</td>
<td>2026</td>
<td>P54321</td>
</tr>
</tbody>
</table>

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 outstanding at the time of data collection and some of the columns are therefore intended to request the latest information on the status of whether a particular patent application has been granted or a patent has been rejected.

It should be noted that the public may sometimes have second entries for one medicine. This is because patents are granted to prevent transactions, not produced per se, and that for the same medicine the subject matter of any further patent will always be for the same medicine, but neither the basic molecule of a medicinal, a special form, or a continued. 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 medicinal form, including a name for the medicinal form or medicine. The table does not include information about other forms, such as the treatment regimen, the dosage form, or the delivery system. SEP has decided to update the list of medicines in the third column, which will be updated as new information arises or as all relevant information becomes available. The updated list will be made available on the SEP website, and the list will be updated periodically. SEP also acknowledges that the list of medicines is not exhaustive and that it may be necessary for users to search for additional information for a specific product or product combination. SEP will work with the relevant authorities to ensure that the list is accurate and up-to-date.
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. 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 data 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).

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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).
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.

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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

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 WTO

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.

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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.

The Health Economics Series provides an orientation and an analysis of key issues. It aims to provide drug policy makers, planners and managers with the information and practical tools needed for policy development within this wider context.