The effects of the 2005 TRIPS implementation deadline on access to medicines

Médecins Sans Frontières Campaign for Access to Essential Medicines
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The TRIPS Agreement: Transitional arrangements for implementation.

When the World Trade Organisation’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into effect on January 1st 1995, it set out transitional periods for implementation for developed, developing and least developed countries. This allowed member countries time to introduce the various TRIPS obligations into their national legislation and regulations in order to become fully TRIPS-compliant. These obligations include granting patents for a range of products for a minimum of 20 years; compulsory licenses subject to a number of conditions; and protecting pharmaceutical test data against "unfair commercial use".

In accordance with TRIPS Art. 65.1, developed countries had to comply with all of the TRIPS provisions by 1996. Least developed countries originally had until 2006, with the possibility of a longer transition period. In 2002, the deadline for implementation under Article 66 for LDC’s TRIPS obligation for pharmaceutical products was extended until 2016. Most member countries that joined the WTO after its creation in 1995 agreed to implement TRIPS immediately after accession.

Developing countries generally had until 2000 to comply. However, in order to accommodate differing economies and the fact that a number of developing countries did not grant product patents in a particular area of technology (i.e. pharmaceutical products), a special transitional rule was included in the TRIPS Agreement: if a developing country did not provide product patent protection in a particular area of technology when the TRIPS transitional period for developing countries ran out, it had a further five years (until 2005) to introduce protection in that area.

Summary of TRIPS implementation deadlines:

- Developed countries: 1996
- Developing countries that had already granted patents for pharmaceutical products: January 1st, 2000.
- Developing countries that had not granted patents for pharmaceutical products could further delay the introduction of such until: January 1st, 2005.
- Least developed countries: initially 2006, but changed by Doha Declaration para.7, now 2016.

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1 TRIPS Article 65 & 66 set out the transitional arrangement provisions. Fifty countries are currently designated by the UN as least-developed countries (LDCs). The list is reviewed every three years. Of these, 32 countries are also members of the WTO. Source: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm
2 TRIPS Art.31.
3 TRIPS Art. 39.3.
4 The extension period took into account the instructions of Paragraph 7 of the Doha Declaration on TRIPS and Public Health that LDCs would not be obliged to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement with respect to pharmaceutical products. See (WT/MIN(01)/DEC/2)
6 TRIPS Art. 65.4
Which countries could use the 2005 transition period?

At first, approximately 13 countries, including Argentina, Brazil and India, took advantage of the extra transition period. However, some of these countries, including Argentina and Brazil, introduced pharmaceutical patent protection prior to the 2005 deadline. Others, such as Thailand, were unable to use the transitional period, as they had introduced patent protection for pharmaceutical products even before the TRIPS Agreement was signed.

In fact, India was one of the few developing countries that did not yet grant product patents for medicines, although process patents were granted for seven years. However, many developing and least developed countries that do not have pharmaceutical manufacturing capacity import affordable generic medicines from India. The 2005 deadline will therefore have a dramatic effect not only on India but also all countries relying on imports of Indian generics.

What is the "mailbox"?

The mailbox system is a TRIPS-imposed obligation on developing countries that wished to benefit from the TRIPS transitional period by delaying granting of patents for pharmaceutical products until 2005. In exchange for not granting patents, these countries had to establish a "mailbox" system for receiving and filing patent applications from the beginning of the transitional period in 1995.

In accordance with the "mailbox" provisions in TRIPS Art. 70.8, countries concerned had to provide a means by which patent applications could be filed during the transitional period. The mailbox provision allowed applicants to file for patents and thereby establish filing dates, while at the same time permitting member countries to defer the granting of the patent for pharmaceutical products. The date of filing (or, in some cases, the date of priority) is important, as it is used to assess whether or not the application meets the necessary conditions for patenting a product, i.e. novelty, inventiveness and being capable of industrial application.

The mailbox allows the patent application to remain "fresh", even though years pass between the patent application mailbox filing and its examination. Upon examination, if the application fulfils the necessary criteria for granting a patent under the new post-2005 law, the patent will be issued for a period of 20 years. For instance, if a pharmaceutical company had wanted to apply for a product patent in India in 1997, the patent application would be put in the Indian mailbox, "waiting" for the Indian patent office to start examining pending applications as of January 1st 2005. If the patent application filed in 1997 meets all the patentability criteria under new post-2005 Indian law, the patent would be granted some time after 2005, and expire at the latest in 2017.

The patent lifetime only runs from the filing date, however: this means that a portion (up to half) of what would have been the patent life expires while the patent application is in the mailbox.

What are exclusive marketing rights?

In return for being able to delay the granting of product patents for up to ten years, a WTO member also had to provide "exclusive marketing rights" (EMRs). In theory, these could reduce the benefit of the transitional provision.

EMRs were supposed to apply in case the product "waiting for a patent in the mailbox" obtained marketing approval before the mailbox is opened and a decision is made on whether or not to grant the patent. In such a case, the manufacturer could request exclusive marketing rights for up to five years or until a decision is made on the patent application.

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7 See, WTO fact sheet: [http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm)
8 Thailand introduced patent protection for pharmaceutical products in 1992.
9 According to the WTO, to the best of its knowledge there are now six countries using the extra transition period: India, Cuba, Egypt, Pakistan, Qatar and United Arab Emirates. See WTO Fact Sheet September 2003, [TRIPS and Pharmaceutical Patents](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm).
10 For further details about the patentability criteria, See MSF report May 2003: [Drug Patent under the spotlight - Sharing practical knowledge about Pharmaceutical patents](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm).
11 TRIPS Art. 70.9.
rendered on the patentability of the product, whichever is shorter. However, exclusive marketing rights were subject to two preconditions: a patent should have been granted for the same product in another WTO member country after 1995 (the date of entry into force of TRIPS), and marketing approval should have been obtained for this product in the other member country. EMRs were supposed to prevent others coming onto the market until the patent would be granted or rejected. Yet, in practice, the granting of exclusive marketing rights seems to have been quite rare.

Returning to the previous example of India, if the product had obtained market approval in India in 2000, and if the manufacturer could demonstrate that they were granted a patent and market approval for this product in another WTO member country, they could apply to the Indian patent office for an EMR. If all the conditions were met, the EMR would be granted until 2005 when the mailbox in India is opened and the patent application examined under the new Indian patent law. If an EMR were granted, generic competition with that product would therefore be stifled in India until 2005.

**What will change after 2005? How will it affect drugs already on the market?**

The great majority of medicines that are currently available in generic form will not be affected because patents cannot be "retroactively" granted for products that are in the public domain. However, this general rule will suffer some exceptions because of the mailbox system. On January 1st 2005, countries not yet granting patents for pharmaceutical products, such as India, opened the mailbox, started examining the pending patent applications - together with other new patent applications filed after January 1st 2005 - to grant or reject patents in accordance with their own patentability conditions. (Note that the "mailbox system" relates only to patent applications filed between 1995 and 2005. Patent applications filed prior to 1995 will not be affected by the opening of the mailboxes, and the status of related products (patented or not) will therefore not change.)

In India, for example, there are more than 6,000 patent applications pending in the mailbox. This does not mean that the floodgates opened on January 1st 2005 and that 6,000 patents will be granted suddenly. Rather, at the beginning of the year, the Indian patent office opened the mailbox and started to examine the various patent applications and decide whether or not to grant relevant patents. This will take time, and the effect of the 2005 deadline will therefore be progressive.

Since patents are often filed at an early stage in the development of medicines, the majority of patent applications pending in the mailbox are likely to relate to medicines not yet marketed, or only recently marketed, i.e. medicines for which generic firms have not yet produced their own versions. Only a few drugs which are already available in generic form are likely to have a patent application pending in the mailbox. One such case is the fixed-dose antiretroviral combination AZT+3TC, which is currently available from various generic manufacturers in India. A patent application on the combination was filed in many countries in 1997. It is therefore very likely that this patent application is pending in the Indian mailbox.

If so, there are many different possible scenarios regarding this patent application after 2005: it may be rejected if it does not meet all the patentability criteria of the new Indian patent law, or the patent may be granted. If the patent is granted, there are three possible options for generic manufacturers: they can reach a licensing agreement with the patent owner to remain on the market in exchange for compensation; they can

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12 Although there has been a notable case recently in India going through the courts involving imatinib mesylate (Gleevec). For more information on this case see: [http://economictimes.indiatimes.com/cms.dll/%3E/articleshow/842919.cms](http://economictimes.indiatimes.com/cms.dll/%3E/articleshow/842919.cms)
14 TRIPS Art. 70.9.
16 Supra, note 13 at 28-31.
17 It is impossible to know at the date of writing this report how the patentability criteria will be applied by the India patent office, but the patentability of "combinations" is a much debated question. Indeed, it could be argued that some combinations of known molecules are not inventive enough to justify granting of a patent. In the case of the patent application related to the AZT-3TC combination, it is worth noting that a written opinion (the "international preliminary examination report") requested under the Patent Cooperation Treaty (PCT) managed by the World Intellectual Property Organization concluded in 1999 that none of the claims involved an inventive step, which suggests that this patent application should be rejected.
request a compulsory license to the competent authorities; or they can remove their products from the market upon notice of infringement from the patent owner.

What effect will 2005 have on new drugs?

Following the full implementation of the TRIPS Agreement in 2005 in India and the few other developing countries not yet granting pharmaceutical patents, access to new drugs may be expected to become more difficult. All new drugs may be subject to at least 20 years of patent protection in all but the least developed countries and the occasional non-WTO country such as Somalia, Palestine and Macedonia.

As this will affect producers in key manufacturing countries, such as India, and other countries that are dependent on India for raw materials, it will keep prices up and will likely make new medicines inaccessible for the majority of the population in developing and least developed countries. Generic producers will also be blocked from developing fixed-dose combinations until the relevant patents on the individual components of the combinations expire. In other words, the current situation could change dramatically in the coming years.

Overcoming new challenges after 2005

Faced with these new challenges, the public health safeguards affirmed in the Doha Declaration, such as compulsory licensing or government use, will become even more important. It is imperative that producing countries such as Brazil, Thailand and India routinely make use of compulsory licenses or "government use" provisions to allow generic competition to drive prices down. Strong political resolve will be needed to do this.

Developing countries with pharmaceutical manufacturing capacity will also need to include provisions in their national patent laws to ensure that products produced under compulsory license can be exported, as outlined in the WTO August 30th 2003 decision on the implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health. In India, for example, the government has included in the draft Patent (Amendment) Ordinance 2004 a provision that would allow the granting of compulsory licenses, not only for the domestic market, but also to supply pharmaceutical products to countries with no manufacturing capacity.

All least developed countries should take measures to benefit from the transition period outlined in paragraph 7 of the Doha Declaration, in order to avoid granting or enforcing patents for pharmaceutical products or providing data protection before January 2016.

Unfortunately, since the signing of the Doha Declaration on TRIPS and Public Health, the safeguards confirmed in the declaration have been eroded in recently concluded bilateral and regional free trade agreements (FTAs). In several cases, these free trade agreements include provisions which go way beyond the TRIPS Agreement, and which will undermine the capacity to lower prices by restricting the entry of generic competitors. Countries currently negotiating FTAs must reject the inclusion of any provisions that are not required by the TRIPS Agreement.

To conclude, countries will face many new challenges after 2005. Countries must be encouraged to implement the longer transitional periods and make use of the public health safeguards acknowledged in the Doha Declaration in order to respond to the anticipated high cost of new medicines after 2005. However, it remains to be seen whether the existing flexibilities of the TRIPS agreement will be sufficient to counter the long-term effects of pharmaceutical product patenting in every country.

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18 Although section 92A of the Patent (Amendment) Ordinance 2004 is a bit more restrictive than the August 30, 2003 decision on Para.6 of the Doha Declaration on TRIPS and Public Health.

19 To find out more about how LDCs can implement the 2016 deadline, see "Battling HIV/AIDS - A Decision Maker’s guide to the Procurement of Medicines and Related Supplies", World Bank, 2004, pp. 112-115. This publication is available at http://www-wds.worldbank.org/servlet/WDS_IBank_Servlet?pcont=details&eid=000090341_20040730152040

20 These TRIPS+ provisions are also included in bilateral/regional trade agreements currently being negotiated.

21 For further information on the impact of bilateral trade agreements on access to medicines, see: MSF Briefing Note (May 2004) "Access to Medicines at Risk Across the Globe: What to watch out for in free trade agreements with the United States."