



**AFFORDABILITY OF DRUGS IN THE CONTEXT  
OF THE WORLD TRADE ORGANISATION:  
THE CASE OF INDIA**

**Prepared by:**

**Di McIntyre  
Health Economics Unit, University of Cape Town**

**Aditi Iyer, Shon John, Gita Sen, Asha George  
Indian Institute of Management, Bangalore**

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## **BACKGROUND**

### **Overview of the World Trade Organisation and the TRIPS Agreement**

The World Trade Organisation (WTO) was formally established in 1995, with the mandate to reduce trade barriers between countries and to mediate disputes between countries. A key component of the WTO's rules, particularly from the health sector's perspective, is the Agreement on Trade-Related aspects of Intellectual Property rights (TRIPS). The TRIPS Agreement awarded a minimum of 20 years protection from the date of filing a patent.

What is critical about TRIPS from the perspective of drug patents is that both the manufacturing process and the final product is protected under the patent. Under the previous General Agreement on Tariffs and Trade (GATT – which preceded the establishment of the WTO), only the manufacturing process had been patent protected, which had allowed production of generic equivalents of brand-name drugs using slightly different manufacturing processes. Thus, TRIPS effectively gives multi-national pharmaceutical corporations (which undertake most of the research and development of new drugs) a 20 year monopoly on the production and sale of new drugs. Any country who is not TRIPS compliant faces trade sanctions. It is noteworthy that the TRIPS Agreement was effectively drafted by a self-appointed Intellectual Property Committee consisting of *Bristol Myers*, *DuPont*, *General Electric*, *Hewlett Packard*, *IBM*, *Johnson and Johnson*, *Merck*, *Monsanto* (a producer of genetically modified seeds), *Pfizer*, *Rockwell*, and *Time-Warner* (with multi-national pharmaceutical companies indicated in italics).

Given that it was necessary to change patents legislation within each country, industrialised countries were given one year from 1 January 1995 to become TRIPS compliant, developing countries and countries in transition were given a five year grace period, while the least developed countries were permitted up to 11 years to comply. However, when a country becomes TRIPS compliant, it has to consider all applications for patent protection that have been lodged since the beginning of 1995.

For example, faced with enormous international pressure, India changed its Patents Act to become TRIPS compliant in 2005. In terms of TRIPS Article 70.8, India had been required to establish a 'mailbox' where patent applications could be filed

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between 1995 and 2004, which would be considered by the Indian Patent Office in 2005. During this ten year period, over 4,000 drug patent applications were filed in this 'mailbox'. It is interesting to note that only a few hundred new chemical entities have been developed (i.e. 'true' new drug discoveries), which indicates that the vast majority of these applications for drugs that are already known and have been only slightly modified. India was also required to grant exclusive marketing rights to those companies introducing newly invented products.

### **Mechanisms for limiting the impact of TRIPS**

There are three key mechanisms by which the potential impact of TRIPS can be limited:

- **Compulsory licensing:** A judicial authority (e.g. Ministry of Health, Competition Board) within a country can issue a licence for the domestic manufacture of a drug still under patent, without the agreement of the patent holder (although an acceptable royalty payment must be made to the patent holder). This can be done only where the availability of that drug is critical to public health (e.g. AIDS drugs) or on the grounds of anti-competitive practices (e.g. insufficient quantity or excessively high prices).
- **Parallel importation:** This occurs when a country imports a drug from an organisation in another country rather than purchasing it directly from the manufacturer to obtain it at a cheaper price (given that pharmaceutical manufacturers sell drugs at different prices in different countries). For example, parallel importation may occur if a manufacturer indicates that they will sell a particular drug at \$100 to drug distributors in country A, but country A can purchase the identical brand-name drug from a drug distributor in country B for \$30.
- **The Bolar exception:** This allows generic manufacturers to conduct research and development for a generic equivalent of a brand-name drug which is still under patent, and to submit a registration application to a drug regulatory authority. This allows the generic manufacturer to begin production and sale of the drug immediately after the 20 year patent has expired.

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Despite the fact that all three of these mechanisms are fully consistent with the TRIPS Agreement, enormous pressure has been exerted (primarily by the US government who were lobbied by the American Pharmaceutical Manufacturers Association - PhRMA) on low- and middle-income countries to outlaw compulsory licensing and parallel importation. Thus, several countries have been encouraged to amend their patent legislation, or not implement legislation that explicitly allows compulsory licensing and parallel importation, so that these entirely legitimate mechanisms to limit the impact of TRIPS cannot be used (called 'TRIPS-Plus'). For example, South Africa faced enormous pressure when it attempted to introduce the Medicines and Related Substances Control Amendment Act of 1997, which potentially allowed for compulsory licensing and parallel importation. Multinational pharmaceutical companies launched a court case against the South African Ministry of Health in 1998. At the same time, South Africa was placed on the US Trade Representative's special 'Watch List', which meant that the US withheld preferential tariff treatment on some South African exports. Ultimately, the US government withdrew its 'Watch List' pressures in 1999, in no small way due to mass demonstrations by AIDS treatment activists during the 1999 US Presidential elections, and the pharmaceutical companies settled out of court with the Ministry of Health in 2001. In both cases, South Africa simply had to agree to honour its commitments under the TRIPS Agreement.

### **The Indian Patents Act amendments**

India revised its Patent Act to become TRIPS compliant in 2005. On the one hand, there was considerable pressure from WTO and high-income country governments to meet the 2005 deadline. On the other hand, major concerns were vociferously expressed by Indian and global civil society groups. An important reason for global concern is that India is the world's leading supplier of generic medicines, with two-thirds of its exports going to developing countries. With respect to the AIDS epidemic facing many low- and middle-income countries, Indian production of generic antiretroviral medicines has reduced the price of these drugs by as much as 98%.

Key areas of concern about the proposed amendments to the Indian Patents Act, which would effectively impose a 'TRIPS-Plus' policy in India, include:

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- The proposed amendments to the Patents Act potentially allowed for manufacturers to apply for patents on ‘new-use’ products (i.e. for a drug that already exists but which will now be used to treat a different disease to that for which it was initially developed). This process is known as ‘ever-greening’ where a patent is repeatedly extended beyond the initial 20 year period to prevent generic production of the drug. TRIPS does not require approval of ‘new-use’ patent applications.
- The draft amendments would not permit the export of compulsorily licensed medicines from India to certain other countries. In terms of this amendment, in order to import generics produced in India under a compulsory license, the importing country must itself have a patent on the originator (brand-name) drug in force and have granted a compulsory licence for the generic drug. Once again, such a provision is not in line with the WTO General Council decision on implementing paragraph 6 of the Doha Declaration for countries that lack sufficient domestic pharmaceutical manufacturing capacity.
- Within India, compulsory licensing would be allowed only under exceptional circumstances; when there is a national (health) emergency, for instance, or if the drug is meant for public non-commercial use. The existing process in India for granting compulsory licences was seen as very cumbersome which could significantly delay the process of issuing compulsory licences.

### **Indian health system context**

The impact of the amendments to the Indian Patent Act should be considered within the context of the Indian health system. There are very low levels of government funding for health care in India, with less than 4% of total government resources being allocated to health services. Less than a quarter of health care expenditure is funded by the government while nearly 80% of expenditure is funded privately, mostly through out-of-pocket payments. Thus, the burden for funding health care falls heavily on households. Most (70%) of these out-of-pocket payments are attributable to the purchase of drugs and doctors’ fees (doctors dispense medicines and charge a single fee).

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### **THE TASK**

You are asked to divide up into 4 groups which will represent:

- Multi-national drug manufacturers
- Indian generic drug manufacturers
- Civil society and human rights advocacy groups
- Households

The Indian Parliament has invited interested groups to make verbal presentations on the proposed amendments to the Patent Act. Parliament has indicated that it is particularly interested in hearing suggestions on how the affordability of drugs, particularly for the poorest households, can be ensured while still fulfilling their commitment to become TRIPS compliant. Each group will be provided with an information sheet that may assist you in preparing the argument you will present to the parliament on behalf of the group you represent. You will be allowed a maximum of 10 minutes for your presentation to Parliament. In your presentation, you should briefly indicate what amendments to the Patent Act should be introduced and why, and identify specific strategies for ensuring the affordability of drugs in India. When you are preparing for your presentation, you may wish discuss strategy with another group if you feel that you could create an alliance with them.

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