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Policy Brief for Parliamentarians

Without Compulsory Licensing - Patients the World Over Will Pay the Price

Patents have a major impact on the prices of drugs, by preventing competition. Following the implementation of a product patent regime as mandated in the TRIPS Agreement in India from April 2005 the Indian Patent Office has granted patents on new essential medicines, including for HIV/AIDS, hepatitis and cancer.

A patent granted *in India for an essential drug will block generic production by Indian companies and make drugs either unavailable or unaffordable (or both) across the developing world. Lack of competition from India and dramatically higher prices for newer essential drugs could mean that people in developing countries may not be able to benefit from improved treatment that is widely available in wealthy countries.*

The time has come for India to seriously consider implementing public health safeguards such as compulsory licensing, which authorises generic production in the event that patent holders fail to fulfil their obligation to make patented medicines available and affordable to patients.

India's Patents Act allows the government to implement a progressive policy on compulsory licensing in accordance with international trade rules. Public interest groups, other developing countries and people across the world will applaud India's decision to continue its longstanding tradition of placing patients before patents.

Introduction

The World Trade Organisation's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) made it mandatory for India to have a product patent regime for medicines by 2005, a commitment fulfilled by Parliament on 23 March 2005 when it amended the Patents Act, 1970. At the time, the prognosis of public interest groups reflected broader concern for patients in the developing world - the revised law had the potential to provide short-term relief, but long-term pain.

In this context, we present this policy brief on compulsory licensing for parliamentarians and policy makers, which addresses the critical issue of how to make patented drugs accessible and affordable for people in India and other developing countries. This policy brief discusses the policy measures that will be needed in the near future to ensure that generic competition remains possible in India. These measures are crucial to the millions of lives dependent on India's generic drugs around the world.

Patent regime: an overview

When the Parliament amended the patent law in 2005, patient and public health groups were relieved at the inclusion of several key safeguards including a prohibition on the patenting of insignificant or minor improvements of known medicines - section 3(d). This means that pharmaceutical companies should not be able to obtain patents in India for medicines that are not actual inventions, such as combinations or slightly modified formulations of existing medicines. Such patent applications are designed to delay generic competition that could lead to lower prices. For the first time, a country emphasised stricter patentability criteria for pharmaceuticals and included provisions in its patent law stipulating that patents should only be granted on medicines that are truly new and innovative.

While Section 3(d) should help safeguard against the granting of frivolous patents, there is still great concern about those new drugs (new chemical entities) invented after 1995 that can be patented under Indian law[1]. Under the amended law, a company holding a patent on a new drug in India can effectively prevent the generic pharmaceutical industry from producing or selling the drug in the developing world during the patent's term - which, according to WTO rules, is a minimum of 20 years. This in turn allows companies to charge high prices, because there are no competitors in the market. This monopolistic market situation is detrimental to the health needs of the country.

Patent monopolies in India will thus result in high prices for new and essential drugs putting them out of reach for the majority of Indians and those living in developing countries. Patients needing to switch to newer treatment will bear the brunt of this, particularly as resistance in current HIV/AIDS and tuberculosis medicines is growing across the world.

Box 1: Generic competition from India provides AIDS treatment to millions worldwide

AIDS treatment is an important illustration of the benefits of encouraging generic competition. It was only with the arrival of generic anti-retrovirals produced by Indian companies in the market in 2001 that prices started to reduce significantly - from $10439 to $350 for first-line AIDS treatment. Today, first-line AIDS treatment is available for as little as US$99 per patient per year 140 times lower than the price demanded by multinational pharmaceutical companies in 2001. This price reduction due to generic competition from India continues to save millions of lives of people living with HIV/AIDS.

However, India's Parliament was unwilling to rule out generic production if the abuse of a granted patent affected public health, national treatment programmes and access to essential medicines. To this end, another key safeguard in India's amended patent law is the provision of compulsory licensing, which authorises generic production in the event that patent holders fail to fulfil their duty to make patented medicines available and affordable to patients.

What is a compulsory licence (CL)?

Compulsory licensing is the authorisation given by the government, judiciary or even the competition commission to a third party to produce, market and supply a generic version of a patented drug, without the consent of the patent holder. Under Article 31 of the TRIPS Agreement, CLs are a legally recognised means to overcome barriers in accessing affordable medicines.

Four years after the amendment of the Patents Act, the time has come for the government to use compulsory licensing. Newer patented drugs are prohibitively expensive (see Box 5), and in the absence of generic competitors will remain out of reach for patients in India and the rest of the developing world.

Box 2: The need for compulsory licensing

Need: If patented drugs are unaffordable and/or unavailable, a CL for local production is often the only solution to solve procurement problems, increase local availability of drugs and save on costs for patients and the national health budget.

Why:

- Increase the power of the Ministry of Health to purchase medicines from sources independent of the patentee
- Increase access to affordable medicines of patients in India and other developing countries

How: CL allows generic competition. License to produce/sell is granted to a competitor to reduce prices.

While segments of India's population may be able to afford medicines priced at levels comparable to those charged in developed economies, the overwhelming majority cannot. When companies use monopoly-pricing strategies that are typically aimed at high-income markets, in India and other developing (low and middle-income) countries, then it is essential to use existing safeguards and flexibilities such as compulsory licensing.

Box 3: Compulsory license provisions in '2005' Indian Patents Act

Sec. 84 CLs initiated by generic companies who can apply when (a) the reasonable requirements of the public with respect to the patented invention have not been satisfied or (b) it is not available to the public at a reasonably affordable price and (c) the patent is not being worked. The grant of CLs to competitors such as generic companies can be an effective measure to make patented drugs affordable and available. However, the provisions impose a three-year waiting period from the date of the grant of the patent before a generic company can make an application for a CL.

Sec. 92 Notification by central government in the official gazette that a CL needs to be issued for public non-commercial use, national emergency or extreme urgency. After the notification, the Patent Controller can grant a compulsory license to a generic company so that the drug is made available to the public at an affordable price.

Sec. 92A CL to generic company when another country wants to import drugs. This provision is important, as Indian generic manufacturers play a key role in supplying medicines to developing countries with insufficient manufacturing capacity.

Sec. 100 Government use license, which will apply in situations where the government needs to manufacture, procure, distribute and sell the patented drug on a non-commercial basis.

The "emergency myth"

The Indian government is free under its own legislation and under international trade law to issue CLs when required. However, in an attempt to prevent the law on compulsory licensing from taking effect, the multinational pharmaceutical industry[2] and its proponents in the US and EU argue that compulsory licensing is reserved only for emergencies.

This is a misguided reading of India's patent law and certainly not a requirement of domestic or international trade law[3].

All governments who are members of the WTO - including the US - agreed to these terms in the 2001 WTO Doha Declaration on TRIPS and Public Health (Doha Declaration), which clearly states that "***Each Member has***

the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."

Anticipating the eventual need for compulsory licensing to ensure access to affordable medicines, the Indian parliament included several CL provisions in the revised Patents Act.

Box 4: Excerpts from World Health Organisation's report on *Public Health, Innovation and Intellectual Property Rights (CIPIH)*

One of the key recommendations of this report for governments of developing countries was to *make use of compulsory licensing provisions, where this will promote innovation or access to medicines*. The report states:

"The Doha Declaration clarifies the right of governments to use compulsory licensing as a means of resolving tensions that may arise between public health and intellectual property, and to determine the grounds for using it." (Pg.120 of the report)

"Countries which have adequate technological and manufacturing capacity may use these mechanisms to lower prices, remedy anti-competitive practices, create a sustainable supply or for other reasons, as determined by national laws." (Pg.117 of the report)

Compulsory licenses can, thus, be issued to generic producers if patented drugs are not available or unaffordable, or if countries that lack production capacity order drugs from India. The government can equally notify drugs on which CLs are needed for public non-commercial use and in situations of national emergency or extreme urgency. And, of course, CLs can be issued for government use.

Therefore compulsory licensing under Indian law is not reserved only for emergencies. Ultimately, the assessment of whether a CL is needed or not should be made, not by pharmaceutical companies, but by the Patent Office in consultation with patient groups, public health experts and the Health Ministry.

The "HIV/AIDS" myth

Compulsory licenses can be used for a range of diseases. Circumstances requiring the issuance of CLs in India and other developing countries may vary, ranging from well recognised public health crises like HIV/AIDS and tuberculosis to widespread chronic illnesses such as cancer, heart disease, diabetes and asthma. Without discrimination, compulsory licensing can address problems of access to affordable quality drugs, diagnostics and vaccines for a range of diseases and illnesses.

Box 5: Drugs patented in India

Valganciclovir is an important treatment for active cytomegalovirus retinitis (CMV) infection that people living with HIV are susceptible to. Without treatment the infection can lead to blindness. *CMV can be effectively treated with oral doses of valganciclovir consisting usually of 264 tablets given over four months.* If not available it has to be substituted with *invasive, painful and far from ideal injections of* ganciclovir *directly into the affected eye of the patient or intravenous, twice-daily treatment requiring a long stay in hospital.*	A patent on *valganciclovir* was granted to Roche in India in June 2007. The grant of the patent **(IN207232)** nevertheless prevents the marketing of generic versions of valganciclovir, leaving Roche - the sole source for the drug - free to continue charging exorbitant prices in India and other developing countries. *The international aid organization Medecins Sans Frontieres has reported facing tremendous difficulty in getting this drug at affordable prices for its patients in China and is looking to India for affordable generics.* **MRP in India** Rs. 1040/450mg tablet (per dose). The four-month treatment will cost approximately **Rs. 2,74,560** per patient.
Pegylated interferon (peg-IFN) in combination with ribavirin is the current standard of treatment for Hepatitis C. For people living with HIV/AIDS, hepatitis C (HCV) is a growing concern. Without HCV treatment, liver damage can be rapid and antiretroviral (ARV) treatment may also be compromised. HCV-related liver disease is a major cause of death among people living with HIV/HCV co-infection. The duration of treatment for HIV/HCV co-infected patients with pegylated interferon and ribavirin is 48 weeks. If pegylated interferon is not accessible it has to be substituted with far from ideal therapy with interferon that is injected three times a week. It is not as effective in fighting HCV (viral clearance from the blood).	A patent **(IN98952)** on *pegylated interferon alpha-2a* was granted to Roche in 2006 and prevents Indian generic companies from developing and marketing a more affordable version of the drug till 2017. A key reason that makes HCV treatment inaccessible is the exorbitant price of pegylated interferon. Pegylated interferon alpha-2a is a liquid that comes in a vial and is stored in the refrigerator. Everyone uses the same dose regardless of his or her weight -180 mcg of pegylated interferon alfa-2a once a week. **MRP in India:** Rs. 18,200 for a single vial of 180 mcg. The lack of generic alternatives means that the cost of pegylated interferon alone will be approximately **Rs. 8,73,600** for a patient who has HIV/HCV co-infection and is undergoing treatment for a standard 48-week course.
Availability: *All the above-patented drugs have been imported into India; the drug has to be ordered by the patient from a particular dealer.*	

Paragraph 4 of the Doha Declaration is very clear on this: no limits in terms of disease range. Therefore, all countries have the right to issue CLs, to produce/import those generic drugs that the country considers essential, for all diseases, including - but not limited to - HIV/AIDS. Similarly under Indian law, the government has the discretion to notify in the official gazette any essential drug on which a CL is needed for public non-commercial use, national emergency or extreme urgency. The Patent Offices also have wide powers to grant CLs to generic producers on a range of diseases. All the WTO requires is that developing countries "promptly" notify the patent owner when it issues a CL and provide reasonable remuneration/royalty for the use of the patent. These conditions can be fulfilled by India.

The issuance of CLs should not be restricted to HIV/AIDS drugs. In the last two years, the government of Thailand has issued compulsory licenses to produce, import and procure generic drugs for HIV/AIDS, heart disease and cancer, as its public health insurance schemes cannot afford to provide expensive patented medicines to citizens eligible for government healthcare.

Will compulsory licenses affect investments in medical R&D?

This is a key concern raised by a number of policy makers, but recent studies have found little evidence that pharmaceutical patents boost innovation for diseases, which mainly affect people in less developed economies. The statistics speak volumes: only 1.3% of drugs reaching the market between 1975 and 2006 were developed for neglected diseases such as kala-azar, malaria and tuberculosis[4]. This is also one of the key findings of the 2006 report of the Commission on Innovation, Public Health and Intellectual Property, published by the WHO, where it is stated that *"There is very little real evidence, one way or the other, on how the availability or possible use of compulsory licenses will affect willingness or reticence to invest in R&D."*

Absence of royalty/remuneration guidelines will delay compulsory licenses

In order to issue CLs, the Patent Office must first determine royalty/remuneration to be paid to the patentee. The Patents Act provides for the payment of a 'reasonable' royalty to the patent holder, but with little guidance on what would be considered reasonable.

It is important that the government notify royalty guidelines under the Patents Act. This will reduce complexity and provide guidance to the Indian Patent Offices, as well as increasing transparency and predictability. In the absence of such guidelines, the patent holder is also likely to legally contest the royalty proposed by the generic company or laid down by the Patent Office. In South Africa, GlaxoSmithKline charge 30% royalty for the generic production of zidovudine and laimivudine from Aspen Pharmacare until activists and the Competition Commission intervened. The royalty was reduced to a maximum 5% royalty rate[5].

The necessary royalty guidelines can be notified as Rules to Section 90 of the Patents Act. However, the amount of the royalty should not present a barrier to accessibility of medicines, and the guidelines should lay down a maximum limit or a cap on the amount of royalty. International norms for royalties are in the range of 3-4% of net sales of the generic versions. Several countries have provided for royalty caps. Canada has placed a cap of 4% of the cost of a generic medicine produced under a compulsory licence for export.

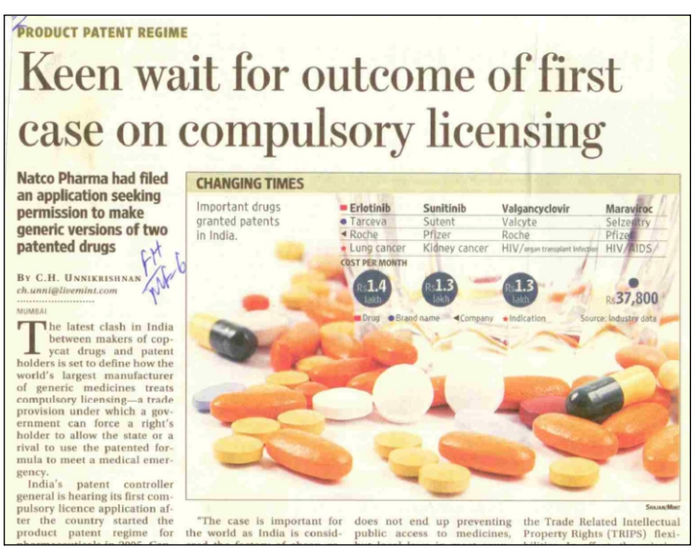
The Canadian guidelines even prescribe a royalty that is in some cases far lower than the 4% norm, as it is tied to the United Nations' Human Development Index - i.e. based on the paying capacity of the country importing the drugs. India should not only adopt a similar cap of 4% for the drugs that are supplied to the domestic market and the government under a CL, but also a reduced rate of royalty for low-income countries to whom it supplies essential medicines. This will ensure that India continues the supply of generic drugs to developing countries at affordable prices.

The WHO's *"Remuneration guidelines for non-voluntary use of a patent on medical technologies"*[6] provide guidance on this issue to developing countries such as India.

Patent law restrictions on compulsory licensing are TRIPS Plus

Compulsory licensing is not only important for the government, which takes responsibility for ensuring the sustainability of national HIV/AIDS and tuberculosis programmes, but also for people who access treatment in the private sector, e.g. cancer patients.

The availability of essential drugs in the public health system is poor. Drugs and medicines therefore form a



PRODUCT PATENT REGIME

Keen wait for outcome of first case on compulsory licensing

Natco Pharma had filed an application seeking permission to make generic versions of two patented drugs

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MUMBAI

The latest clash in India between makers of copycat drugs and patent holders is set to define how the world's largest manufacturer of generic medicines treats compulsory licensing—a trade provision under which a government can force a right's holder to allow the state or a rival to use the patented formula to meet a medical emergency.

India's patent controller general is hearing its first compulsory licence application after the country started the product patent regime for

"The case is important for the world as India is consid-

does not end up preventing public access to medicines,

the Trade Related Intellectual Property Rights (TRIPS) flexi-

CHANGING TIMES

Important drugs granted patents in India.

	Erlotinib	Sunitinib	Valgancyclovir	Maraviroc
	Tarceva	Sutent	Valcyte	Selzentry
	Roche	Pfizer	Roche	Pfizer
	Lung cancer	Kidney cancer	HIV/organ transplant infection	HIV/AIDS
COST PER MONTH	₹1.4 lakh	₹1.3 lakh	₹1.3 lakh	₹37,800

Drug · Brand name · Company · Indication · Source: Industry data

substantial proportion of household health expenditures. The Government's own Commission on Macroeconomics and Health has pointed out that the cost of buying medicines in India comprises 70-80% of out of pocket treatment costs.

Whether patients who do not receive treatment in the public health system can access low cost versions of patented drugs will depend on a generic company filing for a compulsory licence under Section 84 of the patent law.

However, Section 84 requires generic companies to wait for three years after the granting of a patent before applying for a compulsory license. This requirement goes far beyond what is required under the TRIPS Agreement.

In accordance with the provisions of the Paris Convention, referenced in the TRIPS Agreement, India's international obligations require a three-year waiting period for a CL only in the case of the non-working of an invention. This has been provided for in Section 84 (c) of the patent law. However Section 84 also extends this three year waiting period to other specified grounds, namely where the reasonable requirements of the public have not been met or where the invention is not available to the public at a reasonable price (S.84 (a) & (b)).

After three years, the issuance of the license will again be delayed by further procedural and legal requirements, such as the patent holder's opposition to the application for a CL. Such an opposition has the potential of delaying by several years, access to low cost versions of patented drugs, even when these drugs are unavailable or unaffordable.

Lastly, the Patents Act prohibits CLs for purposes of importation (S.90(2)). This could prevent the importation of active pharmaceutical ingredients (raw materials) required for the manufacture of some medicines in India. This restriction can be waived by an order of the Central Government (S.92(3)). However the need to obtain authorisation by the Central Government may further delay the supply of affordable essential medicines to the public. This restriction is surprising, as the TRIPS Agreement does not impose such restrictions on importations under CLs.

Price negotiations fail to make patented drugs affordable

Before examining the effectiveness of price negotiations with patent holders, it is important to understand the legal framework provided in Indian law to reduce prices of patented drugs.

India's patent law does not require the government to enter into any prior price negotiation with the patent holder before a CL is issued. If a patented medicine is priced beyond the reach of patients, a CL should be issued to remedy the abuse of the monopoly granted by the Indian Patent Office.

As opposed to the legal framework provided in its patent law, India is currently considering price negotiations with patent holders to make drugs affordable. A '*Committee on Price Negotiations for Patented Drugs & Medical Devices*' has been established to make recommendations in this matter[7].

This is not surprising, since pharmaceutical companies, their associations, the US, the European Commission and the Swiss government have been pressurising developing countries to engage in prior negotiation with patent owners before issuing CLs. However, there is no legal requirement under WTO rules for the government to enter into such negotiations.

Under TRIPS there is a requirement to negotiate - not the price - but a license with the patent holder, and even this condition is waived when the government is issuing CLs for public non-commercial use, government use or issued in a situation of national emergency, extreme urgency or to remedy anti-competitive practices. Under the TRIPS agreement, prior negotiations for a license with the patent holder are required only when a generic company wishes to apply for a CL on grounds other than those mentioned above. If the negotiations fail, then the generic company can still apply for a compulsory license.

Box 6: Experience of Thai 'Working Group for Price Negotiation of Patented Essential Drugs'

Even without the need for prior negotiation and discussion, the Thai Ministry of Public Health used multiple mechanisms between 2004 and 2006 to discuss and negotiate with patent holders. In April 2005, a Working Group to negotiate for price reduction on patented drugs was established with representation from the relevant departments in the Ministry of Public Health, Thai Food and Drug Administration (FDA) and the Ministry of Commerce.

The working group received little cooperation from the patent holders to provide adequate information on drug pricing structures for the negotiation. After one year, a report of the working group concluded the failure of their work to reduce the price of the patented drugs.

Furthermore, the Department of Disease Control - the biggest purchaser of antiretrovirals (ARVs) in Thailand - had several meetings with the patent holders in 2004 and 2005, as well as some official communications to request reduction in prices of patented ARVs. They also reported failures in achieving any significant price reduction.

Ultimately, Thailand concluded that exercising a CL by the government would be the most effective measure of price reduction and issued CLs on two AIDS drugs, Efavirenz (2006), Lopinavir/Ritonavir (2007), and a heart disease drug, Clopidogrel (2007).

- Facts & Evidence on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand,

http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf, p.5

Before adopting price negotiations with patent holders, it is important to assess whether these measures have succeeded in making patented drugs affordable for the public in other developing countries.

Both Brazil and Thailand have negotiated prices with patent holders. After more than two years of negotiations to reduce the price of three patented drugs, Thailand's Ministry of Public Health concluded, *"Prior negotiation with the patent holders is not an effective measure and only delays the improvement of access to essential medicines…. Those who advocate for prior negotiation should realise these facts. The attempt to push for prior negotiation only delays improvement in access to patented essential medicines and puts more lives in less healthy or even dangerous situations."*[8]

Brazil has in the last decade used price negotiations with multinational pharmaceutical companies to lower the price of newer patented antiretrovirals. For the AIDS drug Lopinavir/Ritonavir (LPV/r), Brazil has been negotiating with Abbott Laboratories. After price negotiations in 2003, Abbott agreed to a price of US $3241 per patient per year.

In June 2005, Brazil again negotiated the price of this drug, but the Brazilian's government's tactic of negotiation was based on the threat of issuing CLs without ever doing so. This was losing credibility. Abbott offered a price of US$1518, and the government accepted. In addition, the Brazilian government accepted a number of conditions demanded by Abbott, which included restricting the use of the compulsory license to authorise the local production or importation of generic LPV/r, and a moratorium on future price negotiations until 2011.

Given that the World Health Organisation estimates that the drug costs less than US$400 to manufacture, this was a price far higher than if the drug was produced by Brazil's public sector company, FarManguinhos under a CL. In relying on negotiations, Brazil has also suffered from stunted local manufacturing capacity as is reflected in the fact that no new generic AIDS drug has been produced in Brazil since 2002.[9]

In comparison, Thailand recognised the failure of price negotiations with patent holders in 2006. When Abbott's best price after negotiation was as high as $2967 per patient per year, Thailand issued a CL compulsory license allowing the country to either legally import the drug or produce it locally. After the CL was issued, Abbott offered to reduce prices - but with conditions (no further price reduction and withdrawal of the LPV/r compulsory license), which were, similar to those imposed on Brazil. Thailand's Ministry of Public Health found them unacceptable. Thanks to generic competition, treating that same patient with a second-line drug regimen containing LPV/r cost the Thai government $695 per patient per year as compared to the earlier cost of $2967 per patient per year for just LPV/r. With compulsory licensing, Thailand obtained substantial price reductions in just one year.

The experiences of the governments of Brazil and Thailand show that negotiations with pharmaceutical companies largely fail to secure affordable prices for the government. While discounts on the prices of patented drugs may appear impressive, governments should also be careful that the prices obtained are actually affordable for patients and are not higher than the price reductions possible through generic competition.

In Brazil, Gilead sells Tenofovir (TDF) for US$1,387 (Rs. 59,571) per patient per year, in comparison to the US price of more than $5000 per patient per year. When the price of TDF in Brazil is compared with the generic version manufactured in India, it is evident that Brazilians are paying 9 times more than the generic price. TDF manufactured by Indian generic companies costs only US$ 158 (Rs. 6770) per patient per year.

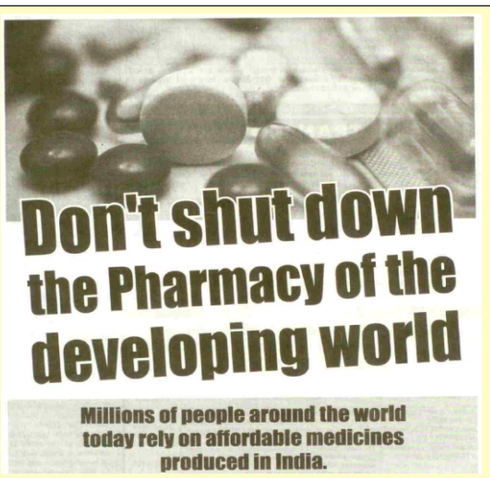
Political will to implement compulsory licensing

It is clear that policy makers involved in the regulation of the patent system (Department of Industrial Policy and Promotion, Ministry of Commerce)[10] have reserved compulsory licensing as a measure of last resort, to be used only in the event of an emergency. These views are also evident amongst policy makers involved in drug pricing (Department of Chemicals & Fertilisers).

Box 7: India The Pharmacy of the Developing World

India is the main supplier of essential medicines to developing countries.

- **67%** of medicines exported from India go to **developing countries**.
- Approximately **50%** of the essential medicines that **UNICEF** distributes in developing countries come from India
- **75-80%** of all medicines distributed by the **International Dispensary Association (IDA)** are manufactured in India.
- **80%** of ARVs that **Medecins Sans Frontieres** uses are purchased in India and are distributed in treatment projects in over 30 countries.



List of compulsory licenses issued by other countries[11]:

Country	Date	Drug/drugs
Israel	October 1995	**Hepatitis B vaccine**
Zimbabwe	May 2002	To **make or use** any patented drug, including **any antiretroviral drug**, used in the treatment of persons living with from HIV/AIDS or HIV/AIDS related conditions To import any generic drug used in the treatment of persons living with from HIV/AIDS or HIV/AIDS related conditions
Mozambique	April 5, 2004	**Lamivudine** (medicine used in the treatment of HIV/AIDS)
Mozambique	April 5, 2004	**Stavudine** (medicine used in the treatment of HIV/AIDS)
Mozambique	April 5, 2004	**Nevirapine** (medicine used in the treatment of HIV/AIDS)
Zambia	September 21, 2004	**Lamivudine** (medicine used in the treatment of HIV/AIDS)
Zambia	September 21, 2004	Sta**vudine** (medicine used in the treatment of HIV/AIDS)
Zambia	September 21, 2004	**Nevirapine** (medicine used in the treatment of HIV/AIDS)
Malaysia	September 29, 2004	**Didanosine** (medicine used in the treatment of HIV/AIDS)
Malaysia	September 29, 2004	**Zidovudine** (medicine used in the treatment of HIV/AIDS)
Malaysia	September 29, 2004	Fixed dose combination **lamivudine/zidovidine** (medicine used in the treatment of HIV/AIDS)
Indonesia	October 5, 2004	**Lamivudine** (medicine used in the treatment of HIV/AIDS)
Indonesia	October 5, 2004	**Nevirapine** (medicine used in the treatment of HIV/AIDS)
Cameroon	January 2005	Fixed dose combination **lamivudine/zidovidine** (medicine used in the treatment of HIV/AIDS)
Cameroon	January 2005	**Nevirapine** (medicine used in the treatment of HIV/AIDS)
Cameroon	January 2005	**Lamivudine** (medicine used in the treatment of HIV/AIDS)
Eritrea	June 5, 2005	Generic **HIV-AIDS medicines**
Italy	June 21, 2005	Italian Competition Authority obliges Merck to license Manufacture of the antibiotic **imipenem/cilastatine** (antibiotic)
Ghana	October 26, 2005	Generic **HIV-AIDS medicines**
Italy	February 26, 2006	**Sumatripan succinate** (medicine for migraine headaches)
Canada	July 2006	**Oseltamivir** (medicine for influenza)
Thailand	November 29, 2006	**Efavirenz** (medicine used in the treatment of HIV/AIDS)
Thailand	January 25, 2007	**Lopinavir/ritonavir** (medicine used in the treatment of HIV/AIDS)
Thailand	January 2007	**Clopidogrel** (medicine used in the treatment of heart disease)
Italy	March 26, 2007	Italian Competition Authority rules Merck must grant free licenses for the active ingredient **finasteride** (medicine for prostate enlargement)
Brazil	May 4, 2007	**Efavirenz** (medicine used in the treatment of HIV/AIDS)
Thailand	January 2008	**Docetexel** (used in the treatment of lung & breast cancer)
Thailand	January 2008	**Letrozole** (used in the treatment of breast cancer)
Thailand	January 2008	**Erlotinib** (used in the treatment of lung cancer)

This is contrary to Indian law, and the Indian Parliament should be closely involved in ensuring that the government makes full use of compulsory licensing to encourage generic production and ensure access to affordable essential medicines in India and across the developing world.

Production of low cost drugs by Indian pharmaceutical industry is critical

In the long run, a system of compulsory licensing will be the only way to ensure access to affordable medicines. Indian policy makers must therefore preserve the right to allow time-tested generic competition, which will solve procurement problems, increase local availability and affordability of drugs and save on costs for patients and the national health budget. This legal responsibility to safeguard the public's right to access affordable medicines extends to India's global responsibility of making affordable generic medicines available to the world in the event that patent holders choose profits over patients.

Selected References:

[1] Three of the newer antiretrovirals, etravirine (NNRTI), maraviroc (entry inhibitor) and raltegravir (integrase inhibitor), have already been patented in India. The impact of these patents on access to treatment by people living with HIV/AIDS is likely to be considerable, as these newer antiretrovirals, patent-protected in India will remain out of generic production unless the Indian government grants compulsory licenses. Indeed, low cost, quality generic versions of antiretrovirals manufactured domestically in India have played a major role HIV/AIDS treatment scale-up by developing countries.

[2] A story in Mint quoted the Swiss pharma company Novartis as saying that the move (compulsory licensing) was unjustified in the absence of an emergency for which compulsory licensing is designed. *Drug makers worry over compulsory licensing*, mint, February 4, 2008, available at: *http://www.livemint.com/2008/02*

[3] *Frequently Asked Questions: Compulsory licensing of pharmaceuticals and TRIPS*. Geneva, WTO, 2006. Published by the WTO explaining the current WTO rules for issuing compulsory licenses. Available at: *http://www.wto.org/english/tratop_e/trips*

[4] For more information see *What is wrong with R&D today?*, available at: *http://www.accessmed-msf.org/main/medical-innovation*

[5] Competition Commission Settlement Agreements Secure Access to Affordable Life-Saving Antiretroviral Medicines. TAC Newsletter, December 2003 Available at: *http://www.tac.org.za/newsletter/2003.*

[6] *Remuneration guidelines for non-voluntary use of a patent on medical technologies*, Health Economics and Drugs TCM Series No. 18, WHO and UNDP, Geneva, 2005. Available at: *http://www.who.int/medicines/areas*

[7] Information regarding the *Committee on Price Negotiations for Patented Drugs & Medical Devices* available at: *http://chemicals.nic.in/ptdmd.doc*

[8] *Facts & Evidence on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand*, By the Ministry of Public Health and the National Health Security Office, Thailand, February 2007, Pg 6, available at: *http://www.moph.go.th*

[9] *Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand*. 2007, 21 Suppl 4:S21-9 AIDS, available at: *http://fieldresearch.msf.org/msf*

[10] Govt may use compulsory licensing for drug companies only in emergency, The Economic Times, 3 April 2008, available at: *http://economictimes.indiatimes.com/News*

[11] Information on compulsory licenses issued by different countries is available at: *http://www.cptech.org/ip/health/cl*

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Without Compulsory Licensing - Patients the World Over Will Pay the Price

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