

Impact of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement on India as a Supplier of Generic Antiretrovirals

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ABSTRACT: This is a commentary on how the trade-related aspects of intellectual property rights (TRIPS) agreement has impacted India as a supplier of generic antiretrovirals (ARVs). We provide a systematic review of the issues related to the TRIPS agreement that affects India. This includes discussion around (a) the legal landscape underpinning India as a supplier of generic ARVs; (b) supply of second-line ARVs; and (c) the future of generic drug production in India. The proclamation into force of TRIPS-compliant intellectual property law in India is likely to affect its position as a supplier of affordable ARVs, especially drugs brought to market after 2005. Currently, mechanisms exist for the generic production of almost all ARVs in India, including second-line drugs; however, the manufacture of these drugs by generic pharmaceutical companies may require additional market incentives. Compulsory licensing may emerge as an additional mechanism by which India can provide affordable versions of patented drugs to Least Developed Countries (LDCs). © 2010 Wiley-Liss, Inc. and the American Pharmacists Association *J Pharm Sci* 100:816–821, 2011

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INTRODUCTION: THE IMPORTANCE OF GENERIC ANTIRETROVIRALS

The World Health Organization (WHO) estimates indicate that one third of the world lacks regular access to essential medicines,¹ defined as those drugs and diagnostics necessary for a basic health care system.² The 16th WHO model list of essential medicines for adults³ includes medicines used to treat chronic diseases, such as antihypertensives and anti-inflammatory drugs, as well as anti-infectives, including 14 antiretrovirals (ARVs) and five fixed-dose combinations (FDCs), used for treating patients infected with HIV. Conservative estimates indicate that 10 million lives could be saved annually by promoting better access to these existing essential medicines.⁴

Although intellectual property rights are granted to reward and promote innovation, they can impede

patients' ability to access the medicines they need to stay healthy. Barriers to access can arise when one manufacturer, holding one or more patents to a drug, exerts a monopoly over its production and sales for the duration of the patent(s), selling it at a high price; as a result, the drug may stay out of reach of low-income patients, especially in developing countries.

It is important to note that patents for most drugs on the WHO list of essential medicines have already expired, permitting legal generic production all over the world. Nevertheless, intellectual property considerations are of particular importance in the context of increasing patients' ability to access HAART (highly active antiretroviral therapy). ARVs used to treat HIV are a relatively new class of drugs, and are still under patent in many countries with the manufacturing capacity to produce them. While the patents for selected older ARVs, including stavudine (d4t), zidovudine (AZT), didanosine (ddI), and abacavir (ABC) have expired,⁵ select patents on newer, second-line medications including lopinavir/ritonavir and raltegravir will expire as late as 2020 and 2023, respectively.⁶

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Generic production of affordable ARVs has historically been a major contributor to patients' ability to access treatment. One example that illustrates this concept is the price drop of the first-line combination of stavudine (d4t), lamivudine (3TC), and nevirapine (NVP). In 2000, the lowest originator price⁷ of this combination was \$10439 pppy, a sum completely out of reach of most patients living in resource-limited settings. In the same year, patient and civil society groups fought for the release of the patent on stavudine in South Africa, which ultimately allowed for the import of this combination from generic manufacturers. As early as February 2001, the humanitarian organization MSF had negotiated with the Indian generic pharmaceutical company, Cipla, a price⁸ of \$350 pppy, which represented a 30-fold drop over the originator price in South Africa. By 2008, the price⁷ of the same combination had dropped to \$87 pppy, supplied by a different Indian generic drugmaker, Hetero drugs.

However, this price drop is the first of many battles to be won in promoting access to HAART for people living in poor countries. Since 2001, new evidence has emerged indicating the health risks of stavudine, including its long-term, irreversible side effects. In light of these findings, the WHO recommended in 2009 that countries phase out the use of stavudine as first-line treatment.⁹

Currently, there are 24 different antiretroviral drugs on the market for treating HIV, and many more fixed-dose combinations of these drugs have been approved.⁶

Since the battle to make stavudine more affordable to patients, newer drugs have emerged with greater potency (including against resistant strains of HIV) and fewer side effects. These drugs have the potential to dramatically improve the quality of patients' lives. Will they be affordable to anyone but the wealthy minority of the world?

In the late 20th century, India was well-poised as a supplier of affordable generic medicines to the world. In part because of its patent laws that allowed for the reverse-engineering of medicinal compounds, the generics industry thrived, and India acted as a "pharmacy for the developing world." In 2005 to 2006, exports comprised approximately 40% of total pharmaceutical industry production¹⁰ and approximately 350,000 people worldwide, half of all people in the developing world, who received ARV treatment, used ARVs produced in India.¹¹ MSF uses ARVs manufactured by Indian generic manufacturers to treat 70% of the patients in its HIV/AIDS project.

However, the patent landscape in India changed in 2005 with amendments made to the *Indian Patent Act* in order to comply with the World Trade Organization (WTO) trade-related aspects of intellectual property rights (TRIPS) agreement, which India signed

in 1995. Will the more stringent patent laws prevent India from supplying affordable second-line HIV medicines to the world?

THE LEGAL LANDSCAPE UNDERPINNING INDIA AS A SUPPLIER OF GENERIC ARVS

From 1970 to 1995, India recognized process patents, but not product patents for pharmaceuticals.¹² This allowed generic manufacturers to replicate the drugs produced by originator pharmaceutical companies, as long as they did not use a manufacturing process patented in India. This legal landscape promoted competition among generic manufacturers and incentivized the search for greater efficiencies in the processes used to make the drugs.

India joined the WTO¹³ in 1995, and by doing so became a signatory on 18 international trade-related agreements, including TRIPS. Developing countries in which product patent protection was not recognized prior to TRIPS were given until 2005 to amend their patent laws,¹⁴ which India did¹² in March 2005 (Least Developed Countries were given until 1 January 2016). The TRIPS agreement requires WTO members to provide protection for a minimum term of 20 years from the filing date of a patent application for any invention, including for a pharmaceutical product or process.¹⁴ Under the *Indian Patent Act 1970* (enacted 1972) until 2005, patents in India were valid from 7 years from the filing date or 5 years from the date of grant, whichever was shorter.¹⁵

In summary, from 1970 to 1995, it was legally permissible for Indian manufacturers to produce generic versions of all medicines, as long as the processes used were not patented in India. Drugs introduced after 2005 are granted the same patent protection in India as in most developed countries, with some exceptions (for example, to patent new versions of existing medicines, manufacturers must demonstrate increased efficacy¹⁶).

What about drugs introduced in India during the period of 1995 to 2005? It is particularly interesting to consider how this period was treated in Indian patent law, because it marked a boom in the introduction of new ARVs; 71 of a current total of 93 patents on ARVs were filed in the US during this time.⁶

Article 70.8 of TRIPS¹⁷ addresses situations, where there is a delay between countries joining the WTO, and amending their patent laws to conform to TRIPS. In the case of India, it applies to the period of 1995 to 2005. Article 70.8 states that countries must provide, as from their date of entry into the WTO, a means by which patent applications can be filed, and later examined once new patent laws are in effect. The application of this article in India,¹² known as the "mailbox provision," allowed inventors to file patent applications prior to the coming into force of a TRIPS

compliant *Patent Act* (in 2005). Once the new Act was in place, the patents would be considered and if granted, they would be valid for 20 years from the date of submission of the application to the mailbox.

The “mailbox period” of 1995 to 2005 was highlighted by a dramatic increase in new ARVs brought to market. In fact, 21 of the 31 ARVs and fixed-dose combinations currently approved by the US Food and Drug Administration were introduced to the world during that period.⁶ Generic manufacturers were free to produce those drugs in India until 2005, at which point decisions on the granting of product patents to originator companies came into force. It would be reasonable to conclude that, if granted a patent(s), the originators would hold a monopoly over the production of the relevant drugs from 2005 until the date of expiration of the patent, 20 years after the application was submitted to the “mailbox.”

However, under the new *Indian Patent Act*, section 11A(7) provides that in cases where specific drugs were being produced and marketed in India prior to January 2005, the patent holder would only be entitled to receive “reasonable royalty” from such enterprises, without being able to institute infringement proceedings.¹² In short, generic companies are able to continue to produce the drugs, as long as they pay royalties to the patentee(s).

In summary, Indian patent law allows for the continued generic production of drugs brought to market prior to 1995. Drugs that were introduced to India between 1995 to 2005 may still be produced by generic manufacturers, as long as “reasonable royalties” are paid to the patent holder(s). Generic production of drugs that were introduced after 2005 can start only once the patents pertaining to the drugs have expired.

At first glance, the picture looks promising. In theory, legal mechanisms exist permitting the generic production of ARVs introduced in India prior to 2005; all but five ARVs currently on the market.⁶ But do these possibilities translate into low-priced drugs that patients can take? Will the progress made in increasing access to ARVs by eliminating intellectual property barriers continue for drugs patented after 2005?

SUPPLY OF SECOND-LINE ANTIRETROVIRALS

In 2009, the WHO undertook a study investigating the worldwide distribution and use of first-line and second-line antiretroviral treatments. Antiretroviral therapy reached 42% of people in need in low- and middle-income countries, the vast majority (98%) of whom received first-line regimens.¹⁸ The most common first-line therapy is still d4t + 3TC + NVP, which has a low cost of approximately \$87 pppy, manufactured by Hetero drugs of India.⁷ However, population health research indicates that up to 30% of

patients taking this combination require second-line treatment after 12 months.¹⁹

The most commonly used¹⁸ second-line regimen is a fixed-dose combination of tenofovir, lamivudine or emtricitabine, and lopinavir/ritonavir (TDF + 3TC + LPV/r or TDF + FTC + LPV/r). However, this regimen is considerably more expensive than the standard first-line combination, its median cost ranging from \$819 in low-income countries to \$1677 in upper-middle income countries (country income classification defined by the World Bank). It remains unclear why this combination is not produced in India as a FDC, although all of its individual components are made by generic producers.⁶

Taking into consideration that switching patients from the standard first-line regimen of d4t + 3TC + NVP to the standard second-line combination TDF + 3TC/FTC + LPV/r would increase the cost of their therapy ninefold, at best, it is not surprising that only 2% of all patients receiving HAART in developing countries are on second-line regimens.

The Clinton Health Access Initiative (CHAI), formerly the Clinton HIV/AIDS initiative, has historically been an instrumental player in reducing the prices of ARVs worldwide. In 2003, the prices of first-line therapies were reduced by 30% to 50% after negotiations with Indian generic companies, which agreed to supply the drugs at reduced prices to governments of countries in Africa and the Caribbean.²⁰ For example, the widely used fixed-dose combination of 3TC + d4t + NVP dropped in price²¹ from the lowest originator price of \$562 pppy to \$140 pppy. Currently, CHAI makes ARVs affordable to patients living in 69 nations which are members of its the procurement consortium, and works on-the-ground in 20 countries to enable scale-up of treatment. CHAI agreements provide lifesaving antiretroviral therapy to more than 2 million people living with HIV/AIDS,²² that is, half of all patients who currently receive treatment.¹⁸ The next challenge in the push to scale-up lifesaving antiretroviral therapy will involve increasing the supply of second-line ARVs, such as the TDF + FTC/3TC + LPV/r combination, at prices patients in developing countries can afford. Bulk procurement consortia such as CHAI have the opportunity to play a big role in advancing access to newer medicines by negotiating lower prices for large-scale orders of drugs from generic producers, as well as requesting the production of new FDCs, where patent regulations allow.

THE FUTURE OF GENERIC DRUG PRODUCTION IN INDIA

Although legal mechanisms exist for the production of most ARVs generically in India, one author²³ notes, “TRIPS provisions have been implemented in a setting already adversely affected by poverty. Any rise

in price due to the new patent laws exacerbates an already difficult scenario". Indeed, the introduction and strengthening of intellectual property barriers, even if surmountable, indirectly discourages generic competition and impedes the resulting drop in price of drugs, as well as directly prevents generic competition for drugs patented after 2005.

Other research suggests that while the main focus of Indian pharmaceutical companies has changed with the introduction of TRIPS---from reverse engineering patented compounds to investing more in R&D of new chemical entities---the impact of TRIPS on India's exports of low-cost generics is in all likelihood minimal.²⁴ This is likely to change as new drugs introduced in India after the adoption of the 2005 patent law are subject to much longer periods of market monopoly by the originator(s).

It is important to understand India's low-cost production of generics in the context of tiered pricing offered by multinational pharmaceutical companies to select low- and middle-income countries. In some cases, the lowest cost generic version is in fact more expensive than some discounted prices charged by the patent holder. One example⁷ is Saquinavir (SQV), one of five boosted protease inhibitors recommended by the WHO for second-line treatment. SQV is sold for \$1825 pppy by Cipla, but is provided for \$1223 pppy by Roche to Category 1 countries, which includes all sub-Saharan African countries as well as all countries classified as least-developed by the UN. While most⁷ major pharmaceutical companies offer some version of tiered pricing to low-income countries for purchasing ARVs, these discounts are frequently negotiated on a case-by-case basis, and frequently leave out China and India itself, which are home to 3.1 million people living with HIV/AIDS, many of them in poverty.²⁵ Multinational pharmaceutical companies should be applauded for their commitment to providing low-cost ARVs to people living in poor countries, but it is widely recognized that competition among generic producers, alongside bulk purchasing by organizations like CHAI, is the most efficient, systematic way to ensure access to affordable medicines for people living in all poor countries. Success in driving down the cost of medicines by purchasing them in bulk from generic manufacturers is evidenced by the 2008 pppy prices⁷ of many important antiretroviral FDCs; for example, d4t/3TC/NVP (\$331 lowest originator price / \$87 CHAI price); AZT/3TC/NVP (\$444 lowest originator price/\$153 CHAI price) and ABC/3TC (\$484 lowest originator price / \$243 CHAI price).

It is interesting to note that Section 25(1) of India's new *Patent Act* permits individuals to oppose a patent before it is granted on the grounds of novelty, inventive steps and exclusions from patentability. This mechanism has already been used successfully.

Patent applications on gefitinib²⁶ (a tyrosine kinase inhibitor used to treat non-small cell lung cancer), imatinib²⁷ (used to treat chronic myeloid leukemia) and ARVs nevirapine,²⁸ tenofovir,²⁹ and darunavir²⁹ were rejected following pre-grant oppositions filed by generic pharmaceutical companies and civil society groups. This may pave the way for opposition to the granting of patents on new ARV therapies, including FDCs. However, product patents have been granted to two new ARVs (maraviroc³⁰ in 2007 and etravirine³¹ in 2008), signaling a start to the implementation of more stringent and widely-encompassing intellectual property protection laws in India, which in the long-term may preclude the production of new medicines at prices that patients in developing countries can afford.

After the granting of a patent, the *Patent Act* provides that any person can apply to the controller alleging that public needs with respect to the patented invention have not been met, or that it is not available at a reasonable price, and request a compulsory license.¹²

Although the WTO-sanctioned Doha declaration³² reaffirms the rights of members to grant domestic compulsory licenses on drugs in order to protect public health, countries may face immense political pressure from foreign governments and pharmaceutical industry lobby groups against the use of compulsory licensing. As an example, Thailand has issued two compulsory licenses³³ so far, on ARVs efavirenz, marketed as Stocrin by Merck, and lopinavir/ritonavir, marketed as Kaletra by Abbott. In response to the issuance of the second compulsory license, Abbott decided to stop launching new drugs in Thailand,³⁴ including a heat-stable version of Kaletra.³⁵ Furthermore, the US government downgraded Thailand's trade status to a country with poor intellectual property protection.³³

The WTO decision of 30 August 2003 (Article 31bis of TRIPS) expands the potential use of compulsory licensing,³⁶ allowing the manufacture of generic versions of patented drugs for exports to least-developed countries. However, the provisions of this agreement are cumbersome and effectively deter countries with no pharmaceutical manufacturing capacity from applying to import generic medicines. To date, only one Indian generic pharmaceutical company has applied to the patent controller for a compulsory license for export, which was rejected.³⁷ In this example, Natco applied to produce and export two anti-cancer drugs to Nepal: erlotinib (marketed by Roche as Tarceva), and sunitinib (marketed by Pfizer under the trade name Sutent). Jillian Clare Kohler argues that the sparse language pertaining to compulsory licenses in Indian patent law has created ambiguities that patent holders were able to exploit in order to argue against the issuance of a compulsory license.³⁷

By contrast, Canada's Access to Medicines Regime has been described as lengthy and cumbersome, but has provided a legal framework supporting the first use of TRIPS Article 31bis to export a generic drug to a least-developed country. In this instance, the generic company Apotex Canada has successfully used compulsory licensing to export two shipments of a FDC containing AZT + 3TC + NVP to Rwanda. It is important to note that it took four years of sustained effort by a generic manufacturer to achieve a single use of the August 30th decision; not surprisingly, Apotex has indicated its reluctance to use the process again in its current form.³⁸ Richard Elliott suggests several ways by which Canadian legislation permitting compulsory licensing may be made more workable.³⁸ It is likely that other countries, including India, could benefit from incorporating these into domestic legislation.

Of note is that India has recently entered into negotiations with the EU regarding signing a free-trade agreement,³⁹ which would extend its intellectual property protection laws beyond the requirements of TRIPS. In addition to data exclusivity provisions proposed by the EU (which would delay or prevent generic manufacturers from using clinical test data demonstrating safety and efficacy of a drug in an application for registering a generic version), a particularly troubling aspect of this agreement is the inclusion of border measures⁴⁰ that seek to detain imports or exports of goods suspected of infringing intellectual property rights. If implemented, this measure would have far-reaching impacts on the export of generic drugs from India to African markets, and would strongly undermine India's ability to serve as a medicines provider to low income countries, potentially putting hundreds of thousands of lives at risk by cutting off the supply of affordable ARVs to people living with HIV/AIDS.

CONCLUSIONS

The proclamation into force of TRIPS-compliant intellectual property law in India is likely to undermine its position as a supplier of affordable new ARVs, while having minimal impact on the generic production of medicines registered in India before the law was passed in 2005. Currently, legal mechanisms exist for the generic production of almost all ARVs in India, including some second-line drugs developed since the 2005 patent law; however, the manufacture of these drugs by generic pharmaceutical companies may require additional market incentives, such as a commitment to bulk purchasing by HIV/AIDS treatment funders, including CHAI, UNITAID and the US President's Emergency Plan for AIDS Relief. Compulsory licensing may emerge as an additional mechanism by which India can provide affordable versions of patented drugs to LDCs, while the proposed India-

EU free trade agreement is likely to have a deleterious impact on India's ability to supply affordable essential medicines to the world.

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