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How India's Trade Agreements May Price Out Affordable Medicines

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India's free trade agreements are progressively undermining access to affordable medicines. The government must resist big pharma's narrative that stronger IP protection drives investment and innovation, and instead heed health advocacy groups that say healthcare costs for the poor will balloon.

Over the past three to four years, India's rush to conclude free trade agreement (FTA) negotiations with some of the largest economies has been making headlines. However, what has not been adequately discussed is how India's recent FTAs could erode hard-won flexibilities under the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, thereby raising medicine prices significantly and undermining affordable access.

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The contested issues include compulsory licensing and disclosure related to the working of patents. Data exclusivity and India's criteria related to patentability could also come under contestation in future trade deals. What has happened on these issues in the FTAs? Why does it matter?

The TRIPS Agreement mandates countries to protect patents for at least 20 years. During this period, the patent holder has the exclusive right to prevent third parties from making, using, selling, or importing the patented product without consent, and production and supply remain largely under the patent holder's control. The patent holder can also arrange for these activities through voluntary licensing agreements with contract manufacturers.

Under voluntary licensing agreements, the patent holder retains control over the technology and know-how, and therefore over production and supply as well. Most such agreements are shrouded in secrecy, with very little information available in the public domain regarding their terms, duration, volume, or the countries to be supplied.

Voluntary agreements often artificially limit production and supply, enabling patent holders to charge high prices and profiteer from multiple health crises. Voluntary licensing therefore does not provide a reliable basis for ensuring access to affordable medicines.

As an alternative, the TRIPS Agreement contains compulsory licensing as a built-in flexibility for public health purposes. If the price of a patented medicine is very high, or the product is not available in sufficient quantities, a government can issue a compulsory licence to an entity to manufacture it or import its generic version. The generic drug can then be made available to patients cheaply, often at a fraction of the price of the patented medicine. The patent holder is required to be paid adequate remuneration in lieu of compulsory licensing.

After securing most of its commercial interests through the TRIPS Agreement, the pharmaceutical industry in developed countries-commonly referred to as big pharma-has continued to lobby hard for eroding TRIPS flexibilities and seeking more stringent intellectual property protection through FTA negotiations. It has also lobbied aggressively to prevent countries from making rightful use of TRIPS flexibilities. Any policy intervention that might even remotely affect its profits is sought to be immediately countered.

When the AIDS crisis was wreaking havoc in many parts of the world, big pharma legally challenged, in 2001, the South African government's attempts to invoke TRIPS flexibilities to make available low-priced generic versions of exorbitantly priced patented antiretroviral medicines. It also sought to dissuade developing countries from resorting to TRIPS flexibilities, including compulsory licensing.

In response, collective efforts by health advocacy groups and governments in developing countries resulted in the WTO adopting the Doha Declaration on TRIPS and Public Health in 2001, which reaffirmed the rights of WTO members to resort to TRIPS flexibilities, including compulsory licensing. Brazil, India, and South Africa were at the forefront of this struggle.

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This empowered many developing countries to stand up to big pharma's opposition to their efforts at invoking TRIPS flexibilities, and many countries subsequently resorted to compulsory licensing to make medicines accessible at affordable prices.

Big pharma is now fighting back against compulsory licensing and other flexibilities, and appears to be gradually winning through FTA negotiations. A relevant example is a provision on patents in the recently concluded India-UK Comprehensive Economic and Trade Agreement (CETA). Article 13.6 of the CETA states that the parties have recognised voluntary mechanisms, such as voluntary licensing, as the preferable route to promote access to medicines. While this provision may appear innocuous, it should be viewed in the context of persistent efforts by big pharma to prevent developing countries from resorting to compulsory licensing.

Having stood by patients in securing a reaffirmation of compulsory licensing and other TRIPS flexibilities in 2001, India has, through the CETA, bent decisively in favour of voluntary licensing. While compulsory licensing may continue to exist in India's patent rulebook, the future direction of government policy appears clear: a preference for voluntary licensing over compulsory licensing.

Disturbing signals in this direction were already visible during the Covid-19 pandemic. In response to a writ petition (March 2021) before the Supreme Court regarding the distribution of essential services and supplies during the pandemic, the central government stated, through an affidavit in May 2021, that any discussion or mention of the exercise of statutory powers for implementing TRIPS flexibilities and the Doha Declaration-whether for essential drugs or vaccines-would have "serious, severe and unintended adverse consequences".

The CETA provision appears to have further confirmed the government's reluctance to invoke compulsory licensing. It is now uncertain whether India will successfully resist pressure from big pharma and invoke compulsory licensing, even if a future health crisis demands it.

Various assertions and creative arguments have been put forward by some experts and think-tanks in support of the CETA provision on voluntary licensing. It has been argued that since India has used compulsory licensing just once in the past 20 years, the provision merely reflects reality. It has also been contended that since very few countries have granted compulsory licences for pharmaceuticals, voluntary licensing should be seen as global best practice.

Another argument in favour of voluntary licensing is that most manufacturers of generic medicines in India are now manufacturing patented medicines through voluntary licences, and would therefore have little interest in compulsory licensing, even if the government were to resort to it.

These arguments miss many crucial points. The fact that India has resorted to compulsory licensing just once does not reduce its utility as a policy instrument. If the government is seen to have the ability and will to use it, the mere threat of compulsory licensing can be effective in containing, to some extent, the high prices charged by big pharma.

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Having signalled a preference for voluntary licensing, the government would now be seen as unlikely to invoke compulsory licensing. This would embolden big pharma to raise the already high prices of patented medicines even further. Moreover, while many manufacturers of generic medicines in India may have become contract manufacturers for big pharma, some have not. These could be relied upon to implement compulsory licensing, were the need to arise.

We turn now to another issue related to FTAs and access to medicines: the compliance obligations of patentees and licensees in India related to the working of patents. Under the Indian Patents Act, 1970, and the patent rules thereunder, the Statement of Working (Form 27) provides information on the extent to which a patented invention has been worked on a commercial scale in India, and whether the patented product is accessible at a reasonable price. Information obtained from Form 27 can serve as a useful basis for invoking compulsory licensing, as was the case when India granted its sole compulsory licence.

In March 2024, India made certain crucial changes to the patent rules governing Form 27. First, patentees and licensees would henceforth be required to file Form 27 once every three years, rather than annually. Second, under the revised Form 27, the patentee is no longer required to disclose value or sales data. These changes are expected to weaken transparency on patented products and hinder efforts to confront the abuse of patent monopoly.

While the changes to filing frequency and disclosure requirements have ostensibly been made to ease the compliance burden on patentees and licensees, the resulting opacity would create significant hurdles to ensuring access to affordable generics.

It is important to note that these changes to Form 27 were made in parallel with India's FTA with the European Free Trade Association (EFTA) in 2024, which contained similar obligations related to the working of patents. While this agreement was signed on 10 March 2024, the changes to Form 27 followed almost immediately, on 15 March.

Similar provisions related to the working of patents are also contained in the India-UK CETA. There is little doubt that, through these provisions, big pharma has further tilted the odds against generic pharmaceutical companies in India.

In addition to these two specific changes already made to India's patent regime, there are at least two other issues on which big pharma is seeking to advance its commercial interests through India's trade agreements. These relate to data exclusivity and criteria related to patentability.

Under the TRIPS Agreement, protection against unfair commercial use is required for undisclosed data on new chemical entities submitted to market regulators for pharmaceutical and agrochemical products. The agreement leaves it to individual countries to determine the mechanism for protecting such undisclosed information.

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India ensures that this data is never disclosed, either to the public or to an individual company, so that no unfair commercial advantage is gained. However, the drug marketing regulator is permitted to rely on information already in its possession, from data submitted by the originator, to grant regulatory approval to a second applicant for the same product, usually a generic manufacturer. This serves the public health interest by allowing generics to enter the market faster, while preserving the confidentiality of the data.

Developed countries, including the US and the European Union (EU), interpret and implement the relevant TRIPS Agreement provision differently. In these countries, data submitted to the regulator cannot be relied upon by the regulator to approve a second applicant's product for a certain period of time. This is commonly referred to as data exclusivity or fixed-term data protection.

If the period of data exclusivity extends beyond the period of patent protection-as could happen if the clock for data exclusivity starts ticking near the end of the 20-year patent period-it would create additional barriers to the entry of generic medicines.

India has been under considerable pressure from developed countries, including in FTA negotiations, to provide at least a five-year term of data exclusivity. This would compel generic pharmaceutical companies to generate their own data through clinical trials to obtain marketing approval during the data exclusivity period. This would not only be costly and time-consuming; it would also be against the public interest.

Media reports suggest that, as part of the review of the implementation of its FTA with the EFTA countries, India was actively considering the possibility of introducing data exclusivity. Timely intervention by health advocacy groups, and a strong stand taken against it by certain government departments, stopped this ill-conceived move. However, big pharma can be expected to push for data exclusivity in India's future trade negotiations.

Turning to the criteria for patentability, Section 3(d) of the Indian Patents Act sets the bar high. It seeks to prevent the evergreening of patents, a stratagem deployed by big pharma whereby patent protection is claimed even for small changes to existing medicines without any enhancement of known efficacy.

In contrast, the US and other developed countries keep the threshold for the grant of a patent low. The US has on many occasions articulated strong reservations against Section 3(d) of the Indian Patents Act, which has so far been effective in curbing the evergreening of patents and facilitating the timely entry of generics into the market. It cannot be ruled out that this issue will come

under intense negotiation as part of the India-US Bilateral Trade Agreement talks.

In conclusion, in the battle of patents over patients, the Indian government must come down on the side of patients and ensure access to affordable medicines. It must not buy into the narrative being promoted by big pharma and its supporters that stronger protection of intellectual property rights-through changes to Section 3(d) or the introduction of data exclusivity-would attract foreign investment and make India an innovation-based economy.

The government must change course by heeding what credible health advocacy groups have to say about how India's FTAs are progressively undermining access to affordable medicines. Failure to do so would surely result in ballooning healthcare costs for the poor and the sick.

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The views expressed are personal.