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Trading Away Health:
What to Watch Out for in Free Trade Agreements

More than eight million people living with HIV/AIDS are on treatment today. This is largely thanks to affordable medicines produced in India, as generic competition brought the price of life-saving HIV drugs down by 99% in the course of the last decade and enabled treatment scale-up on a massive scale. India's contribution to the health of the developing world cannot be underestimated: more than 90% of the donor-funded medicines for HIV programmes are sourced from Indian generic companies.

Generic competition saves lives. High medicine prices hurt patients and restrict the capacity of governments and other treatment providers to respond to medical needs. As a medical treatment provider, Médecins Sans Frontières / Doctors Without Borders (MSF) relies on affordable, quality generic medicines produced in India to treat many diseases, including tuberculosis, malaria, HIV/AIDS and other infections that affect the poorest and most vulnerable populations.

Yet today, medicines remain a luxury for too many people in developing countries. Free trade agreement (FTA) negotiations between India and certain developed countries threaten to tighten the screws on the production and export of affordable essential medicines, so that they are once more priced out of reach.

While India's discussions with the US are still at the inception stage, several rounds of talks have been completed with European Free Trade Association (EFTA), and negotiations with the European Union (EU) are now at an advanced stage. In each of these FTAs, the US, the EU and EFTA (led by Switzerland) have tabled or are planning to table harmful intellectual property (IP) provisions which threaten to limit the production of affordable medicines in India and their use across the developing world.

Aggressive IP proposals will in the long run undermine the constitutional right to life; dismantle public health safeguards enshrined in national laws, and significantly reduce the local capacity to produce price-lowering generic medicines. Yet FTAs attract little public attention, as they are negotiated in secret, despite repeated requests from public interest groups to open them to public debate and parliamentary scrutiny.

Governments like India have a responsibility to ensure that public health interests are not trampled by commercial interests, and must resist pressures to erode hard-won legal flexibilities under international law and trade rules that are crucial to safeguard public health as they represent a lifeline for people in developing countries.

As a medical humanitarian organisation working in nearly 70 countries, Médecins Sans Frontières / Doctors Without Borders (MSF) calls on India to reject provisions that will harm the production, registration and supply of affordable generic medicines and to exclude intellectual property provisions from current or future FTA negotiations altogether.

Some of the most harmful provisions in FTAs threatening access to medicines are highlighted in the table below:

Proposed Provision	Impact on Access to Medicines
Lowering the bar of patentability. → **WHAT THIS MEANS:** India would be required to patent new use or obvious modifications of existing medicines. → **PROPOSAL TABLED IN WHICH FTA:** • US (anticipated if US FTA negotiations start with India) • EFTA (currently being negotiated)	Patents eventually run out – but not if pharmaceutical companies are provided opportunities to perpetually extend or renew monopolies. By applying for patents on obvious modifications and 'new use' of existing medicines, companies try to obtain patents on known substances all over again. India currently limits this practice, known as "evergreening," under section 3(d) of the Patent Act. Preventing patents from being granted too easily on new use or on obvious improvements of existing drugs has protected generic competition in many therapeutic areas including HIV, TB and cancer. Both the US and the Swiss negotiators are likely to ask for the removal of section 3(d) safeguards with the aim to get the legal framework for examining patent applications in India relaxed. Without such provisions, multinational pharmaceutical companies are likely to obtain patents far more widely in India, effectively blocking generic competition.
Prohibiting pre-grant oppositions. → **WHAT THIS MEANS:** India would have to forbid challenges to weak or invalid patents until after they have been granted. → **PROPOSAL TABLED IN WHICH FTA:** • US (anticipated if negotiations start with India)	Under Section 25 of the Indian Patent Act, third parties are also allowed to provide information to the patent office setting out why a patent should not be granted. These initiatives are known as 'pre-grant' patent oppositions. Given the large volume of patent applications on pharmaceuticals, examiners often miss information related to a patent application under consideration. If attention is drawn to information that shows the patent application is, for example, for a 'derivative' or a 'new use' of a known drug, the likelihood of a patent being wrongly granted is reduced. As such, patent oppositions have provided an important public health safeguard with a number of applications on key second-line medicines for HIV such as darunavir, lopinavir and ritonavir being rejected by the Indian patent office. Once negotiations start, the US is likely to ask for the removal of this system, as without opposition from patient groups and generic competitors, US companies are likely to obtain patents far more widely in India, effectively blocking generic competition.
Introducing data exclusivity.	Data exclusivity would mean that the Drugs Controller General of India (DCGI) is prohibited from registering a generic medicine as long as the exclusivity lasts over the clinical trial data

→ **WHAT THIS MEANS:** India would have to delay the registration of generic versions of medicines - even when there is no patent on that medicine. → **PROPOSAL TABLED IN WHICH FTA:** • US (anticipated if negotiations start) • EFTA (currently being negotiated) • Was also tabled initially as a part of the EU FTA negotiations, but withdrawn under public pressure	(usually 5 to 10 years). In addition to bio-equivalence data that is currently required, domestic producers will additionally have to submit their own safety and efficacy data to register the generic medicines. This will oblige them to repeat clinical trials—something that takes years and involves costs that the generic companies usually cannot afford. But more importantly, the repetition of clinical trials raises serious ethical concerns. Exclusivity is triggered when a pharmaceutical company submits data to the Drug Regulatory Authority on a new drug but also most often on any new formulation of an old medicine. As long as a competitor cannot be registered as a result of exclusive rights over pharmaceutical test data, pharmaceutical companies can enjoy monopolies on a large number of medicines, and can thus charge high prices - even when the drug has been found not to deserve a patent or the patent has expired.
Extending patent term durations. → **WHAT THIS MEANS:** India would be required to extend 20-year patent monopolies by at least 5 years to compensate for delays in the regulatory process. → **PROPOSAL TABLED IN WHICH FTA:** • US (anticipated if negotiations start) • Was also tabled initially as a part of the EU – India FTA negotiations, but withdrawn under public pressure	At present, patents on drugs in most countries last for 20 years from the date of filing. There is no more straight-forward way to extend a company's monopoly over a drug than to extend the life of the drug's patent beyond 20 years. The extra years added to the patent are extra years in which the patent holder can maintain a monopoly position and continue to charge artificially high prices for the drug, free from generic competition.
Introducing patent linkage. → **WHAT THIS MEANS:** India's drug regulatory authority (the Drug Controller of India) would be forced to link regulatory approval of generic medicines with the patent status of the medicine, and would be prohibited from approving generic	At present a drug's patent status and its registration status are two separate things. Linking patent status and the registration of medicines means that the drug regulatory authority is required to withhold marketing approval to a generic version of a patented drug regardless of whether the patent granted is valid or not. The DCGI lacks the necessary resources and expertise to assess whether a drug is patented or not, the patent is valid or would not be infringed and would thus be more likely to enforce all

medicines until patents have expired. → **PROPOSAL TABLED IN WHICH FTA:** • US (anticipated if negotiations start)	patents including invalid ones – turning the Indian Drug Regulator into a Patent Police, wasting public resources that are much needed for ensuring the safety and efficacy of medicines in India. Patent linkage also undermines the Bolar provision - Section 107A of the patent law that allows generic producers to manufacture a generic version of a patented drug, conduct all tests and obtain necessary marketing approval (or registration) in advance, so that a more affordable generic can be put on the market as soon as the patent expires. It can also undermine the use of a compulsory licence as such a licence would not automatically lift the bar on registration by the drug regulatory authority until the patent term has ended.
Introducing new forms of IP enforcement. → **WHAT THIS MEANS:** By giving multinational pharmaceutical companies a free rein to demand abusive enforcement of intellectual property rights, the Indian judiciary would be unable to balance intellectual property rights with the people's right to health → **PROPOSAL TABLED IN WHICH FTA:** • EU (currently being negotiated) • US (anticipated if negotiations start)	Enforcement provisions have a range of harmful effects on the production of and trade in generic medicines by affecting how the Indian courts can handle disputes over intellectual property rights. The impact is broad-ranging: multinational pharmaceutical companies could claim that their IP is being infringed upon and block legitimate medicines from leaving India on their way to people in developing countries; third parties—such as treatment providers like MSF— could become subject to legal action simply for buying or distributing generic medicines. If India agrees to these clauses, the Indian judiciary will have its hands tied and will no longer be able to balance intellectual property rights with people's right to health. This is in direct contravention to a country's right to place public health above IP rights.
Introducing investment clauses. → **WHAT THIS MEANS:** The investor-to-state dispute mechanism hidden in these agreements is effectively used by corporations to sue governments, seeking damages over domestic health policies outside of domestic courts.	The investment chapter of FTAs would expand multinational companies' ability to sue the Indian government when it regulates health in the public interest. India could thereby be prevented from rejecting, overriding or revoking a drug patent to increase access to a medicine, or from implementing drug price controls. Investor-to-State dispute mechanisms hidden in the investment chapter can be effectively used to sue outside of domestic courts, with large sums of damages being claimed in investor-friendly arbitration forums (such as the ICC, ICSID, UNCITRAL) to generate rulings that favour the claims of multinational companies over the government's right and need to regulate public

→ **PROPOSAL TABLED IN WHICH FTA:** • US (anticipated as part of the US- India bilateral investment treaty negotiations) • EU (currently being negotiated)	health. Several such disputes have already been filed by corporations against governments, in order to force a reversal of governmental public health policies and judicial decisions on patentability (for example tobacco company Phillip Morris vs. Uruguay, Phillip Morris vs Australia and drug company Eli Lilly vs. Canada). Key countries like South Africa and Australia have already announced their intention to exclude investor-to-state dispute mechanisms from future international trade deals.

MSF RECOMMENDATIONS:

Increase transparency

FTA negotiations that affect public health must be conducted with adequate levels of transparency and public scrutiny, and access to the negotiating texts must be increased. Certain industry associations and lobby groups have privileged access to the draft text tabled in the negotiations, but this is withheld from public interest organisations.

For FTAs under negotiation: reject harmful measures

For the **EU-India FTA**, Indian negotiators from the Commerce Ministry have already rejected patent term extension and data exclusivity; they should reject overly broad intellectual property enforcement measures from the intellectual property chapter. They should remove "intellectual property rights (IPR)" from the definition of "investment" in the investment chapter of the proposed EU-India FTA; and remove the "investor-to-state" arbitration mechanism from the investment chapter. In the **EFTA negotiations**, negotiators should eliminate barriers to affordable medicines by excluding provisions on lowering the criteria of patentability, data exclusivity and intellectual property enforcement measures from the intellectual property chapter.

For future FTA negotiations: intellectual property should be excluded

Before engaging in bilateral FTA negotiations, it is important to assess the impact of the extremely restrictive IP provisions that are likely to be tabled by countries like the US. Negotiations on the IP chapter will open up pressure on negotiators to include clauses harmful to the health of people in developing countries.

Recognise previous commitments to access to medicines

India should ensure it can fulfil its role as the key global player in the supply of affordable medicines to the developing world, and ensure that the final text of FTAs are aligned with the objective of safeguarding access to affordable medicines and the right to life. India should honour its commitments, including the 2001 WTO Doha Declaration on TRIPS and Public Health, and the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property.