MSF Comments on intellectual property provisions in the final agreement of India-EFTA Agreement concerning the impact on access to medicines

On March 10, 2024, it was announced that India and the European Free Trade Association (EFTA) signed the free trade agreement (FTA).[1] While a number of provisions that undermined generic competition from India were removed from the main text of the final agreement, MSF is concerned about certain clauses contained in the Annex 8[2] and the Record of Understanding[3] of the final trade deal; these are clauses related to intellectual property which could dilute TRIPS flexibilities (the health safeguards) in Indian patent laws that encourage generic competition needed to increase access to affordable treatments for Medecins Sans Frontieres (MSF) and people in India and other developing countries.

Summary of key provisions that undermine TRIPS Flexibilities

Pre-grant opposition

Multinational pharmaceutical corporations, including those based in Switzerland, have long been seeking a more extensive granting of patents on improvements, modifications, and new forms of known medicines. The IP provisions in the FTA could potentially affect people's right to file pre-grant oppositions on such patent claims.

The corporations have been pressuring India to weaken the examination process for such patent claims. This process currently allows anyone (patients, individuals, organisations, or generic manufacturers) to legally challenge patent applications before a decision is made (pre-grant oppositions) by the patent office on whether to grant or reject a monopoly on a medicine.

Article 11.7 of the annex 8 on IP of the signed FTA requires swift rejection of pre-grant opposition by the competent authority on the vague ground that they may be *prima facie* unfounded. This vague provision puts an arbitrary power in the hands of the Controller of patents (the competent authority) to reject pre-grant oppositions without following due process. It is well settled through judicial precedents in India that the Controller is required to hear all persons who have filed pre-grant opposition and consider the opposition as per Indian patent law at the time of examination of the patent claims. The prima facie rejection of patent oppositions will only make it easier for patents to be granted on known medicines with minor modifications or improvements. Similar concerns have been raised by patient groups and health organizations while criticizing the Draft Patent Amendment Rules 2023.[4]

[1] Full text of the India-EFTA Free Trade Agreement: https://www.efta.int/sites/default/files/documents/legal-texts/free-trade-relations/india/1.%20Main%20Agreement.pdf

[2] Annex 8 on Intellectual Property of India-EFTA Free Trade Agreement: https://www.efta.int/sites/default/files/documents/legal-texts/free-trade-relations/india/8.A%20-%20Protection%20of%20Intellectual%20Property.pdf

[3] Record of understanding on Intellectual Property: https://www.efta.int/sites/default/files/documents/legal-texts/free-trade-relations/india/Record%20of%20Understanding%20on%20IPR.pdf

For instance, two survivors of tuberculosis filed a pre-grant opposition against the secondary patent application for the DR-TB medicine bedaquiline. They presented evidence and were heard by the Controller of Patents on the merits of their submission to show that the patent application filed by the drug company J&J was frivolous. It is only because of such hearing on the merits of the opposition, that such frivolous secondary patent application could be rejected by the patent office. The rejection led to the generic supply starting immediately after the 20-year monopoly on the compound expired in July 2023, reducing prices by more than 50%. If such oppositions were rejected at the initial stage at the time of filing by the patent controller that would hinder efforts to challenge such unjustified patents.

Working of Patents

Patents are a social contract, and a monopoly is granted in exchange for making the patented drug available to the public, i.e. the patent must be worked on to ensure that the patented medicines are available in the country where it exists.

However, the IP text in the final agreement undermines an important flexibility contained in the India Patent Act, that is the requirement for providing data annually on the working of a patent on medicines. The patent working information was instrumental in granting India's initial compulsory license for the cancer drug Sorafenib using updated annual information.[5]

The same article in the agreement in the name of confidential information tries to curtail information on important aspects that are needed to establish whether a patent on a medicine is being worked properly. Annual reporting of the working of the patents has acted as an important tool for helping to ensure the availability of medicines. For instance, the information about pharmaceutical corporation Otsuka not working the patents on delamanid - a new drug used for the treatment of drug-resistant tuberculosis - has encouraged civil society to pressure Otsuka who held the patent monopoly on delamanid into seeking marketing approval and supplying the drug to the TB programme in India.

Article 12 in the annex 8 of the final trade agreement further requires that a patented invention may not be considered as not worked merely because the product was imported. However, it is important to note that to establish working of the patent, it should be shown that needs of the public have been met at a reasonable price.

The lack of crucial patent information such as registration, pricing, quantity imported, availability and whether it has been licensed to Indian manufacturers can hinder compulsory licensing from addressing high prices and lack of availability for Indian patients and beyond.

TRIPS Plus requirements in EFTA-India FTA

The Parties to the agreement have agreed that a Party may provide for enforcement measures at a level that is beyond what is provided in the TRIPS Agreement. This requires more analysis on whether it could lead to barriers in legitimate trade in medicines and curb judicial discretion to balance the right to life and access to medicines for patients in cases of IP enforcement before the courts.

The Joint EFTA-India Committee comprising senior government officials established under the agreement will be a form of continuous pressure on India to dilute TRIPS flexibilities and to adopt TRIPS-plus measures like data exclusivity.

Data Exclusivity

Multinational pharmaceutical corporations, including those based in Switzerland, have also been pushing for more restrictive TRIPS-plus provisions like data exclusivity through the FTA since the beginning. Though data exclusivity is not immediately adopted in the final text, according to the Record of Understanding on Intellectual Property.[6] the parties have agreed to enter into consultations, one year after entry into force of this agreement, to discuss issues relating to the protection of undisclosed information from unfair commercial use. This could be a tool for Switzerland and other EFTA members to keep continuously pressuring India to adopt TRIPS-plus measures like data exclusivity.

Data exclusivity is a backdoor way for multinational pharmaceutical companies to get or maintain a monopoly and charge high drug prices, even when their drug has been found to not deserve a patent,[7] or the patent has expired – DE would apply to all drugs and not just patented ones. DE is also a way of getting around the public health safeguards India built into its patent law in 2005, which have long vexed the multinational pharmaceutical industry. There has been ample evidence established on the detrimental effects of DE on access to medicines from other countries who have signed such FTAs.[8]