



Damaging provisions for access to medicines in the leaked UK-India FTA negotiation text

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 more affordable, quality-assured generic medicines produced in India to treat many people, including those with tuberculosis (TB), malaria, HIV/AIDS and other infections that affect some of the most vulnerable communities. Competition among generic producers brings medicines prices down and saves lives, but it is constantly under threat from free trade agreements (FTAs) that expand monopolies on medicines.

India is currently negotiating FTAs with several countries and trading blocs. The FTA negotiation between the United Kingdom (UK) and India was formally launched in January 2022 and is progressing rapidly. On 31 October 2022, [a draft proposal from the UK of the UK-India FTA's Chapter of Intellectual Property](#) (IP chapter) was leaked. The leaked text shows that the UK has tabled harmful IP provisions that threaten to tighten the screws on producing, supplying and exporting affordable generic medicines from India. This fact sheet analyses the provisions in the draft text against the current Indian IP law, highlighting their damaging consequences.

When India and other developing countries joined the World Trade Organization (WTO), they became obligated to start granting patents on medicines, where before they had not, in order to be compliant with the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).¹ Least-developed countries were given a grace period and still are not required to grant patents on medicines. But the draft provisions in this leaked chapter go beyond the obligations enshrined in the TRIPS Agreement. If adopted, they could significantly affect a series of essential public health safeguards under the current Indian laws and impede the supply of more affordable generic lifesaving medicines in India and other developing countries. Aggressive IP proposals will, in the long run, undermine the constitutional right to life, dismantle health safeguards in national laws, and significantly reduce the local capacity to produce affordable generic medicines. Yet FTAs attract little public attention, as they are negotiated in secret, and lack a process of consultation with affected communities, health organisations and parliamentary scrutiny.

As a medical humanitarian organisation working in nearly 70 countries, MSF calls on the Indian government to reject provisions that will harm the supply of affordable generic medicines and to exclude IP provisions from current and future FTA negotiations altogether. MSF also calls on the UK government to withdraw the IP chapter and refrain from introducing 'TRIPS-plus' provisions in FTA negotiations that may have an impact on the supply of lifesaving essential medical products.

Issues of concern	Articles in the leaked text	Comments
<p>Risk of introducing substantive IP harmonisation</p> <p>WHAT THIS MEANS: <i>India will not be able to balance private IP rights with people's right to health</i></p>	<p>Article B.2.1.h Article B.2.2.b Article B.3 Article B.4.1, 3</p>	<p>India's 2005 patent law was welcomed globally for balancing the need to implement the TRIPS obligation of introducing product patents with the need to safeguard generic manufacturing critical to supplying essential medicines and vaccines. Substantive harmonisation with the UK's demands can undermine several vital provisions of India's patent system. In the race to harmonise, important TRIPS flexibilities are continuously diluted, including those that are critical to preventing patent 'evergreening', and preserving the independence of the judiciary in dealing with IP disputes.</p> <p>Article B.2.1.h of the leaked IP chapter suggests both parties cooperate in application procedures, obtaining and maintaining IP rights, reducing IP infringement and enforcing IP. Article B.2.2.b stipulates that both parties "shall" endeavour to cooperate in fostering international harmonisation and enforcement of IP. Furthermore, Articles B.4.1 and 3 specify that both parties shall endeavour to cooperate in streamlining and simplifying the process for examination and granting of patents.</p> <p>In the past, cooperation with developed countries has rarely supported India's stricter patentability criteria, and these provisions might impact India's strict procedures of patent examination, leading to the more lenient granting of unmerited patents in the longer term. It also opens the door for substantive harmonisation of IP, reducing national discretion and existing flexibilities in India's IP law.</p> <p>Harmonisation of enforcement provisions can harm the availability of and trade in generic medicines and affect how Indian courts can handle disputes over IP rights. If India agrees to these clauses, the Indian judiciary will have its hands tied and will no longer be able to balance IP rights with people's right to health. This directly contradicts a country's right to place public health above IP rights.</p> <p>The Working Group on IP Rights under Article B3 of the leaked IP chapter could create a mechanism of continuous pressure and negotiations with India's Department for Promotion of Industry and Internal Trade (DPIIT), which administers the Patents Act and patent offices.</p>
<p>Lowering the bar of patentability</p> <p>WHAT THIS MEANS: <i>India would be required to allow patenting on new use or obvious modifications of existing medicines.</i></p>	<p>Article E.2.2</p>	<p>Patents on new therapeutic compounds eventually run out – but not if pharmaceutical corporations 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 Patents Act. Preventing patents from being granted too easily for new uses or on obvious improvements of existing drugs has protected generic competition in many therapeutic areas, including HIV, TB and cancer.</p> <p>Article E.2.2 of the leaked IP chapter stipulates that each party "shall" allow a new medical use of a known medicine to be patentable and shall not require a patent applicant to prove the enhancement of efficacy of a new medical use or a new form of a known substance or composition as the precondition for patenting.</p> <p>The Indian patent law, under the well-known Section 3(d), categorically denies patents on new medical use or medical indications and does not grant patents on new forms of a known substance unless there is an enhanced therapeutic efficacy.</p>

		<p>This has ensured that old and repurposed drugs are not eligible for monopoly protection again, and made it harder for pharmaceutical corporations to obtain additional patents on trivial changes to known medicines.</p> <p>Article E.2.2 of the leaked IP chapter could substantively nullify Section 3(d) of India's patent law, going against India's Supreme Court judgement in the Novartis case, which upheld Section 3(d) as a bulwark against patent abuse in Indian law.²</p>
<p>Prohibiting pre-grant oppositions</p> <p>WHAT THIS MEANS: India would not be able to forbid challenges to weak or invalid patents until after they have been granted.</p>	Article E.10	<p>Under Section 25(1) of the Indian Patent Act, after the publication of a patent application, third parties, including patients and health organisations, can provide information to the patent office about why a patent should not be granted. These initiatives are known as ‘pre-grant’ patent oppositions. Given the enormous volume of patent applications on pharmaceuticals, examiners often miss technical 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, pre-grant patent oppositions have provided an essential safeguard with several critical medicines for HIV, TB and viral hepatitis going into generic production and supply after the Indian Patent Office rejected patent claims on the basis of pre-grant oppositions.</p> <p>Article E.10 of the leaked IP chapter stipulates that both parties “shall not” make patent opposition proceedings available <u>BEFORE</u> the grant of a patent. In effect, this provision applies only to India as the UK does not have a pre-grant opposition system.³</p> <p>This goes directly against the current Indian patent law, which allows patent opposition proceedings both before and after the grant of a patent.</p>
<p>Introducing patent term extension</p> <p>WHAT THIS MEANS: India would be required to extend 20-year patent monopolies by several years, leading to delay in introducing price-lowering generic competitions.</p>	Article E.12.2	<p>Currently, patents on drugs in most countries last for 20 years from the filing date. Extending the life of a drug's patent beyond 20 years is the easiest way to extend a corporation’s monopoly over the drug. This would allow the patent holder to continue to charge artificially high prices for the drug, free from generic competition.</p> <p>Article E.12.2 of the leaked IP chapter states that each party “shall” provide either a special period of protection or an extension of the patent term to compensate for time spent to get market approval for medicines.</p> <p>The argument that patent term extension is necessary to compensate for the time taken in regulatory processes has been found flawed.⁴</p> <p>Demands for patent term extensions were raised during the negotiation of the TRIPS Agreement at the WTO. As a result, all member countries of the WTO had to provide a minimum of 20-year patent term from the filing date compared to much shorter terms provided by many countries earlier. India only provided seven-year monopolies for process patents in pharmaceuticals before the transition. The current Indian patent law was amended in 2005 to provide a 20-year patent term in all technology fields as required under the TRIPS Agreement. The introduction of a 20-year term for product patents and significant extension from seven to 20 years to the term for process patents has already made it more difficult to introduce new medicines and generic competition from India. If India agrees to patent term extension demands, it will further harm access to medicines, including for key diseases such as TB.</p>

		<p>The UK's implementation of the Supplementary Protection Certificate (SPC) mechanism, one type of patent term extension, under the European Patent Convention has been criticised and there are several calls for reform.⁵</p>
<p>Introducing data exclusivity</p> <p>WHAT THIS MEANS: <i>India would have to delay the registration of generic versions of medicines - even when there is no patent on that medicine.</i></p>	<p>Article F.2.1</p>	<p>The TRIPS Agreement only requires the protection of undisclosed data against unfair competition in the context of commercialisation.⁶ Under such an arrangement, regulators can assess and approve a generic product by relying on data submitted by the originator corporation without disclosing it publicly.</p> <p>However, data exclusivity is a TRIPS-plus requirement which prohibits regulatory agencies from relying on test data submitted by the originator corporation to assess and approve generic medicines. Under data exclusivity, a generic medicine may be introduced upon expiry of the exclusivity, or through the submission of independent clinical trial data by generic companies. Generic introduction under data exclusivity would therefore be either unjustifiably delayed, or need a clinical trial to be repeated all over again, which has serious ethical and financial implications.</p> <p>Exclusivity is triggered when a pharmaceutical corporation submits data to a drug regulatory authority on a new drug, on any new use or formulation of an old medicine. As long as a competitor drug cannot be registered as a result of exclusive rights over pharmaceutical test data, pharmaceutical corporations can enjoy monopolies on a large number of medicines, and can thus charge high prices - even when a drug is derived from traditional knowledge, when no primary patent of the drug has been filed in a country or it has been found not to deserve a patent, or when a patent has expired.</p> <p>Article F.2.1 of the leaked IP chapter introduces a data exclusivity regime of six years by obliging both parties not to permit marketing of generic or biosimilar products based on test data or other data submitted first on a new pharmaceutical product.</p> <p>The current Indian law protects undisclosed data but does not allow exclusivity or prevent reliance on test data submitted for regulatory approval. This practice is in full compliance with obligations under the TRIPS Agreement. Data exclusivity provisions, if introduced, would prohibit the Drugs Controller General of India (DCGI) from registering a generic medicine for six years.</p> <p>As pointed out by the World Health Organization (WHO), test data submitted to regulatory agencies for them to perform a public health duty does not constitute “unfair competition”.⁶ Data exclusivity under FTA provisions has led to increased drug prices in developing countries, and has therefore proved detrimental to access to medicines.^{7,8}</p>
<p>Diluting local patent working requirements</p>	<p>Article E.11</p>	<p>Article E.11 of the leaked IP chapter removes the requirement for a patent owner to provide periodic disclosure of information concerning the working of a patent. Such disclosures can take various forms, including, but not limited to, disclosing information on whether a patented medicine is adequately meeting the needs of the people, supply sufficiency, affordability, and status of licensing and transfer of technologies for local production.</p> <p>This directly goes against current Indian law and practices, which requires disclosure of such information by a patent owner every six months via the Form 27 mechanism under Section 146 of the Indian patent law. The Form 27 mechanism played a crucial role in the grant of India's first compulsory license on a medicine.⁹ Removal of the information disclosure requirement on the working of a patent could reduce transparency and impede competitors' ability to ask for a voluntary or compulsory license based on the evidence of non-working of the patent.</p>

<p>WHAT THIS MEANS: India would not know how well a patent is working.</p>		<p>In 2017, based on Form 27, health groups highlighted that the Japanese corporation Otsuka Pharmaceuticals had not initiated the process of making its delamanid available in the Indian market. The non-working of the patents on delamanid was adversely affecting people living with multidrug-resistant (MDR)- and extensively drug-resistant (XDR)-TB who needed the medicine.¹⁰ Otsuka subsequently filed for registration.</p>
<p>Removing the failure to disclose information on the status of foreign patent applications as grounds for patent opposition or revocation</p> <p>WHAT THIS MEANS: India would lose the ability to track and enforce a key transparency requirement, and therefore risk missing critical evidence in patent examination, opposition and revocation proceedings.</p>	<p>Article E.9</p>	<p>The current Indian law, under Sections 8(1) and (2), requires patentees and applicants to disclose all related foreign applications and developments. The failure to disclose this information can be grounds for patent opposition [Sections, 25(1)(h) & 25(2)(h)] or revocation [Section 64(m)]. This is recognised as good practice to enhance transparency and accountability in the patent system.</p> <p>Article E.9 of the leaked IP chapter states that while a party may require a patent applicant to disclose information about its corresponding foreign patent applications and grants, failing to disclose this information “shall not” constitute grounds for a patent opposition, revocation or refusal to grant. This substantively goes against the provisions under current Indian law.</p> <p>Removing the legal consequences of failing to disclose information would reduce the enforceability of transparency requirements in India’s patent law. As the information required by the current Indian patent law can also help the patent offices consider the grounds for refusing a similar patent application in a different country, reducing the information disclosure requirement may increase the chances of granting unmerited patents.</p> <p>This move also goes against the international consensus of promoting transparency in the context of access to medicines, including on patent information, as stipulated under the 72nd World Health Assembly resolution on transparency, and in the report from the United Nations Secretary General’s High-Level Panel on Access to Medicines.^{11,12}</p>
<p>Enforcement Section</p> <p>WHAT THIS MEANS: Excessive IP enforcement measure could hinder legitimate generic medicines from being shipped from India to other countries and interfere with judicial discretion in India.</p>	<p>Section J, Article J.1 to Article J.39</p>	<p>The current leaked IP chapter proposal includes enforcement provisions on all forms of IP. Excessive enforcement provisions could have a range of harmful effects on the production of and trade in generic medicines and how Indian courts handle disputes over IP rights. For instance, Article J.11 of the leaked IP chapter includes patents under Border Measures, which may allow multinational pharmaceutical corporations to claim that their patents are being infringed upon and request customs officials to block legitimate medicines from leaving India on their way to people in developing countries, leading to delayed access for people in need.¹³</p> <p>Furthermore, Article J.5 and J.7 prescribe how courts should adjudicate IP disputes, which could impact judicial discretion and courts’ ability to take into consideration the right to health in deciding infringement cases. Under Article J.5, third parties—such as treatment providers like MSF— could potentially become subject to legal action simply for buying or distributing generic medicines.</p>

MSF RECOMMENDATIONS

Increase transparency

FTA negotiations that affect public health and the right to health must be conducted with adequate levels of transparency and public scrutiny, and access to the negotiating texts and positions in advance of negotiating rounds must be increased. We request both the UK and the Indian government to publish the most updated version of the negotiating positions from now on, and allow sufficient time for parliamentary and public scrutiny of the negotiation text at each stage of the negotiation.

Reject and withdraw the IP chapter

Indian negotiators from the Commerce Ministry have already rejected measures that prescribe overly broad IP enforcement, lenient criteria of patentability, patent term extension and data exclusivity in other FTA negotiations (RCEP, previous EU-India FTA).¹⁴ For the ongoing UK-India FTA, negotiators should stick to their earlier negotiating position and eliminate barriers to affordable medicines by excluding provisions contained in the leaked IP chapter as mentioned above. Removal of IP from the scope of FTA negotiations is the most efficient mechanism of avoiding pressure on such provisions in trade deals.

The UK should withdraw the IP chapter, recognising the importance of preserving generic competition and health safeguards in national laws of developing countries.

Keep previous commitment on 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 the FTA is aligned with the objective of safeguarding access to affordable medicines and the right to life.

The UK should ensure that, as a result of this FTA, neither party is required to amend their IP laws and policies in relation to medical technologies, including devices, pharmaceuticals and biological medical products. Higher prices for medicines would ironically also impact the UK National Health Service (NHS) itself, and undermine previous commitments from the UK government that stated they would not “accept any provisions that would increase the cost of medicines for the NHS”.¹⁵ Furthermore, the UK has previously committed to protect utilisation of policy space for all available TRIPS flexibilities for public health and access to medicines.¹⁵

Conduct health impact assessment

As recommended by the United Nations Secretary General’s High-Level Panel on Access to Medicines [recommendation 2.6.1 (e)], before engaging in bilateral FTA negotiations, it is important to assess the health impact of the IP provisions that are likely to be tabled by negotiating countries such as those contained in the leaked IP chapter tabled by the UK in this negotiation. All negotiating countries should make health impact assessment accessible for civil society organisations, patients and health organisations who would be directly affected.¹²

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