The Intellectual Property and Investment Chapters of the EU-India FTA: Implications for Health

Since 2007, the European Union (EU) and India have been negotiating a bilateral Free Trade Agreement (FTA). Negotiations are expected to finish by the end of 2011.

Classified as a lower middle-income developing country, and with 35 per cent of the population living on less than USD 1 a day and 80 per cent living on less than USD 2 a day, India is home to more poor people than the twenty-six countries of sub-Saharan Africa put together.

India is also home to a large and sophisticated generic pharmaceutical industry. Because the country produces the vast majority of quality generic medicines used in developing countries to treat diseases like HIV/AIDS, malaria, cancer, and heart disease, India is often referred to as the “pharmacy of the developing world.” A 2010 study found that 80 per cent of the AIDS medicines used by donor-funded programmes were sourced from India.\(^1\) A report published by UNICEF in 2009 shows that India is the largest supplier to UNICEF of essential supplies for children, including life-saving products such as vaccines, essential medicines, and health commodities.\(^2\) In fact, the dependence of health systems and donor programmes in developing countries is such that their sustainability will depend to a large extent on India’s ability to remain a major producer of affordable and quality generic medicines.

The vital role of Indian generics companies in supplying the developing world with affordable medicines can be attributed to the intellectual property (IP) policies enacted by the Indian government. First, India’s 1970s Patents Act did not allow product patents on pharmaceuticals. Second, India was one of the few developing countries that made full use of the transition period allowed under the TRIPS Agreement, delaying implementation of World Trade Organization (WTO) minimum standards for IP protection until 2005. And, third, India made use of TRIPS flexibilities and incorporated key safeguards in its national patent law, thereby ensuring space for generic production once the country implemented the TRIPS Agreement in 2005.

However, India’s role as pharmacy of the developing world is now under threat because of the EU-India Free Trade Agreement.

1. **The Intellectual Property Chapter**

According to publicly available negotiating texts, the EU is pushing for the introduction in the FTA intellectual property chapter of measures of IP protection that go beyond those required under TRIPS. So-called “TRIPS-plus” provisions upset the already precarious balance that exists in that agreement between public interests and the interests of IP holders. TRIPS-plus provisions in FTAs have been demonstrated to reduce the availability of generic medicines, thus raising medicines prices.\(^3\) The enactment of TRIPS-plus provisions in India would reduce the production, domestic sale, and export of generic medicines, thereby undermining access to affordable quality treatment for millions of people - not just in India, but across the developing world.

The following TRIPS-plus provisions have been included in past drafts of the EU-India FTA:

- Language requiring India to provide "data exclusivity," which would act like a backdoor to monopoly status by prohibiting India’s medicines regulatory authority from registering generic medicines on the basis of existing clinical data, whether the medicine deserved a patent or not;
- Language requiring India to extend the length of a patent term beyond 20 years, which would keep medicines unaffordable for a longer duration;
Public outrage at the impact the FTA would have on the worldwide availability of affordable generic medicines has contributed, first, to the withdrawal of the draft provisions on patent term extension and, more recently, to a reported agreement to remove data exclusivity provisions from the FTA. While this cannot be confirmed until an updated text becomes available, the announcement is grounds for cautious optimism.

Despite this development, the following TRIPS-plus provisions still present a significant threat to access to affordable medicines, and to health regulation more broadly:

- The introduction of TRIPS-plus IP enforcement measures, based on EU regulations. For instance, the EU is pushing for measures that would grant draconian powers to customs officials to seize and even destroy products that are in transit or intended for export, including legitimate generic medicines, at the behest of multinational pharmaceutical companies or on their own authority. Despite the documented, negative impact of the EU regulations, the EU is pushing India – where many quality generics originate - to adopt similar regulations. This would give companies the right to lodge requests with Indian customs authorities to detain, suspend the release, or destroy shipments of generic medicines on the basis of allegations of IP infringement (whether trademarks or patents) without judicial review or even notification of the patent holder.

In addition to the threat posed by IP enforcement measures in the IP chapter, other parts of the draft EU-India FTA, and notably the investment chapter, are problematic from a health perspective.

2. The Investment Chapter

The draft investment chapter of the EU-India FTA poses a direct threat to health-related regulation and would compromise, in particular, the ability of either Party to take action to promote the production, registration, supply, import, and export of generic medicines.

The problematic provisions in the draft investment chapter are the following:

- An expansive definition of “investment” which includes “intellectual property rights (IPR), including good will, technical processes and know-how as conferred by law;”
- Broad language prohibiting “any measures of expropriation;”
- An investor-to-state arbitration mechanism;
- Additional investment protections, for instance a “fair and equitable treatment” standard without any exceptions;
- Market access provisions; and
- Provisions which expand on the terms included in existing bilateral trade agreements between some European countries and India.

(2.1) Expansive Definition of “Investment”

The investment chapter of the draft FTA includes “intellectual property rights, goodwill, technical processes and know-how as conferred by law” in the definition of what constitutes an “investment.” The central consequence of this is that it would grant foreign IP owners the investment protections set out in the investment chapter in addition to the extensive protections set forth in the IP chapter.

This broadens the range of government actions that could be challenged as expropriation by companies or their respective governments to include actions that foreign companies claim affect their intellectual property. Companies have already filed such claims against governments.

And while the demands in the IP chapter would require changes in national patent and drug regulatory laws, the investment chapter would enable investors, including IP owners, to bypass
national courts - even high courts - entirely. If included in the final agreement, the draft investment chapter would subject the Parties’ health policies, including their use of IP safeguards to promote access to medicines, to challenges in international arbitration by foreign companies or their respective governments.

**(2.2) Measures of “Expropriation”**

The draft investment chapter contains broad language prohibiting parties from taking “measures of expropriation,” and the EU is seeking language that explicitly prohibits “indirect” nationalization or expropriation. Indirect expropriation refers to regulatory actions that may interfere with enjoyment of an investment, including profits, and which may therefore be considered by an investor to be tantamount to outright expropriation. This could encompass many different regulatory actions. For instance, measures to promote generic competition - by enhancing flexibilities in the national IP system, or enacting regulations that favour low-cost generics over more expensive branded medicines – could be perceived to undermine the companies’ enjoyment of their IP, including profits and even “goodwill” associated with their trademarks.

On the basis of the expansive definition of investment, Indian or European pro-health measures could be challenged by foreign companies seeking compensation for indirect, or regulatory, expropriation of their IP. The broad coverage of the provisions in the chapter allows challenges not only to government laws and policies but also court decisions and judgments.

Indian courts have sought to carefully balance India’s human rights and constitutional obligations regarding the right to life and health, on the one hand, and its obligations under the TRIPS Agreement, on the other hand.

Pharmaceutical companies have demonstrated their willingness to challenge governments for pursuing pro-health measures such as the granting of compulsory licenses, on the grounds of “expropriation of intellectual property.” For instance, in 2007, the Brazilian government issued a compulsory license for efavirenz, an antiretroviral medicine. In response, Merck issued a press release expressing “profound disappointment” and calling this an “expropriation of intellectual property.”

In addition, the draft FTA text contains weak or no safeguards to challenges of expropriation. The draft investment text contains language that shields compulsory licenses from challenge to some extent, by saying that if a compulsory license is consistent with the TRIPS Agreement then the article on expropriation will not apply. However, the protection provided is inadequate and, at the same time, raises questions as to whether an arbitration tribunal has jurisdiction to determine consistency of a measure with the TRIPS Agreement, since the jurisdiction to interpret consistency with TRIPS rests exclusively with WTO panels. Most importantly, the protection provided only applies to use of compulsory licensing. It does not extend to the wide range of other regulatory measures that could be used to promote access to affordable medicines, or to improve public health more broadly. Vague protection – in brackets – is provided to regulation in the public interest in a separate part of the draft text; however, because the provision specifies that measures must be in any event “consistent with this Chapter,” it is of limited usefulness.

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**Does the European Commission have the mandate to negotiate the investment chapter?**

With the enactment of the Lisbon Treaty, exclusive competence to handle matters related to foreign direct investment was transferred to the European Union, becoming part of the common commercial policy.

On 20 January 2011, the European Commission requested that the EU Council of Ministers modify and extend its negotiating mandate for the EU-India FTA in order to be authorised to negotiate investment protection on behalf of the Union. The Commission sought authorisation to negotiate...
extensive protections for foreign investment, in addition to comprehensive provisions to liberalise cross-border investment. It proposed that such negotiations be conducted on the basis of an expansive definition of “investment” which includes intellectual property rights. At the same time, the Commission also requested that it be authorised to negotiate the inclusion of an investor-to-state arbitration mechanism in the FTA.

The Commission’s request remains under consideration by the Council of Ministers.

Meanwhile, the European Parliament (EP) has adopted a formal position on the direction of EU investment negotiations. On 6 April 2011, it passed a resolution that incorporates some elements of the Commission’s request, while insisting that any investment provisions negotiated by the Commission not negatively impact the production of generic medicines and “respect the TRIPS exceptions for public health”. An additional EP resolution regarding the EU-India FTA, adopted on 11 May 2011, also called on the Commission “to ensure that provisions on investment protection do not lessen the parties’ ability to issue compulsory licenses or undermine other public health policies.”

In considering the request of the Commission for an extended negotiating mandate the Council should be mindful of the potential impact on access to affordable medicines in India and throughout the developing world, in addition to the potential impact of the agreement on EU regulations.

### (2.3) Investor-to-state Arbitration Mechanism

Possibly the most problematic feature of the investment chapter in the draft EU-India FTA is an investor-state dispute provision that gives foreign investors the right to sue governments for damages, if laws, policies, or other actions interfere with the enjoyment of their investments - even if the laws are in the public interest.

This mechanism would give investors, including IPR holders, the right to circumvent normal legal processes - particularly those before domestic courts that would balance IP with constitutional and human rights - and to bring a claim directly to a secret international arbitral tribunal instead. Investors could challenge state actions before arbitral tribunals whenever they perceive that their “investment,” as defined in the trade agreement, is threatened by an action or policy of the host government. This mechanism would allow foreign pharmaceutical companies to challenge Indian actions and measures in support of generic medicines directly through private arbitration tribunals, without first having to use administrative and judicial channels in India. Inclusion of investor-to-state arbitration in the final FTA is a key negotiating goal of the Commission.

In the context of other Bilateral Investment Treaties (BITs) and FTAs, investor-to-state arbitration has generated rulings that favour the interests of investors over government actions in the public interest, including actions taken by host countries to fulfil their domestic human rights obligations. Moreover, investor-to-state arbitration can result in interpretations of public health measures that differ sharply from declarations by the WTO membership, and rulings on WTO IP rules that have been issued under WTO dispute settlement. For instance, although the right to use all TRIPS flexibilities was unanimously confirmed by WTO members in 2001, an investor-to-state arbitral tribunal may find the use of such flexibilities to constitute indirect expropriation of a foreign investment. In addition, the cost of defending a measure in international arbitration is significant – even when a case is dismissed.

### (2.4) Fair and Equitable Treatment

The European Commission is seeking an expanded mandate to negotiate additional investment protections. The Commission recommends that the investment chapter ensure that each Party accords to investors of the other Party “fair and equitable treatment,” along with “full protection and security.”
The fair and equitable treatment requirement aims to provide a minimum level of protection to foreign investors. In other words, regardless of the treatment given to a state’s own investors, the treatment of foreign investors must not fall below a minimum threshold. However, because “fair and equitable treatment” is a relatively recent feature of international agreements providing investor protections, and many treaties containing this requirement do not define it, it is unclear what exactly is required of governments.

Arbitral tribunals have enjoyed considerable discretion when determining, on a case-by-case basis, which government actions are not “fair” or “equitable.” In certain cases, broad interpretations of these terms by arbitrators have formed the basis for rulings against governments seeking to regulate in the public interest.

Moreover, foreign investors may threaten to sue for breach of the fair and equitable standard in an effort to influence regulators. In June 2002, Philip Morris, a company qualifying as a foreign investor in Canada, made a submission to the Canadian government, threatening to bring a case that under the investor state dispute mechanism contained in Chapter 11 of North American Free Trade Agreement (NAFTA). The potential case centred on proposed health legislation banning terms such as ‘light’ and ‘mild’ from cigarette labels. Philip Morris argued that enactment of this legislation would constitute unfair and inequitable treatment of foreign investors by creating a barrier to the possible sale or licensing in Canada of popular brands sold elsewhere under trademarks containing similar descriptive terms.

The European Commission has indicated that it would not want any public interest exception to the fair and equitable treatment requirement, even for public health.

(2.5) Market Access Provisions
The investment chapter commits the Parties to grant significant market access to foreign investors, and requires the application of the principles of “national treatment” and “most favoured nation” (MFN) to foreign investments. India will not be able to treat European investors any less favourable than its own domestic investors, and European investors will be entitled to receive, at a minimum, the same benefits and treatment as the investors of any country with which India has an investment agreement.

These provisions will restrict India’s policy space, curbing its ability to support domestic investors through preferential treatment or other schemes and limiting India’s flexibility in future agreements to grant differential market access to different trading partners. Beyond market opening, national treatment, and MFN, the EC has pushed for language applying all investor protections to so-called “pre-establishment;” this language, which is included in the draft text, would enable foreign investors to sue even before they have made an investment in India. Last but not least, the EC has stated its intention to seek restrictions on “performance requirements” on foreign investors; this would forbid India from requiring investors to use local inputs, such as local personnel, which could reduce FDI-related benefits such as transfer of technology and know-how.

If included in the final agreement, the combination of these elements would curb the abilities of the Parties to regulate in support of health, and to take actions to promote availability of affordable generic medicines. They could lead to challenges of governments seeking to promote access to medicines by pharmaceutical companies claiming their IPR have been affected. Pharmaceutical companies could allege that health regulations undermine enjoyment of their IP-related “investments,” and therefore constitute indirect expropriation or unfair and inequitable treatment. The risk that they may have to compensate foreign investors for regulatory actions, on the basis of an arbitral award, could undermine governments’ willingness to regulate. A “chilling effect” could be
created, diminishing the willingness of governments to use IP flexibilities or to interpret TRIPS in a manner that protects health and access to medicines.

This is unacceptable from a public health perspective - particularly in the case of India, given its critical role as supplier of affordable quality medicines for poor people worldwide.

This is not a theoretical threat to health regulation. In addition to threats to sue in Canada, Philip Morris has challenged a public health measure enacted by Uruguay illustrates the risk posed by investment agreements that include the combination of an expansive definition of investment, a prohibition on indirect expropriation, and an investor-to-state arbitration mechanism. In February 2010, tobacco company Philip Morris used the investor-state dispute mechanism under a Switzerland-Uruguay Bilateral Investment Treaty to file a case against Uruguay's decision to increase the size of tobacco warning labels on cigarette packets. Philip Morris argues that requirements that health warnings be larger and that branding be at least partially removed from cigarette packets is "expropriation" of its trademarks, abuse of its investment rights, and a breach of bilateral trade agreements and the TRIPS Agreement.

What does the draft EU-India FTA mean for existing bilateral trade agreements between India and European countries?

The EC proposal to include an investment chapter in the FTA will expand the reach of existing investment treaties, including BITs, between some European countries and India to cover all 27 members of the European Union. The chapter will also set a precedent for all future FTAs negotiated by the EU, including with developing countries that do not have bilateral agreements with European countries. The existing BITs are currently under discussion and there is some movement to consolidate all investment treaties at the EU level.

Over twenty years has passed since developing countries began signing BITs, and there is an emerging awareness amongst developing countries of the extent to which foreign companies can use BITs to challenge their domestic policies and regulations. Countries that have been targeted by US and European companies for claims related to local laws, policies, regulations, and other actions in the public interest include Argentina, Bolivia, Ecuador, Egypt, Lebanon, Pakistan, Peru, South Africa, and Tanzania.

Not only does the proposed investment chapter in the EU-India FTA not seek to reform existing investment agreements, it specifically preserves and reinforces them, thus creating multiple platforms for foreign companies as well as governments to challenge domestic regulation and limit developing countries’ policy space. Importantly, even if the final India-EU FTA includes safeguards in the investment chapter that protect measures enacted for the protection of public health and other public interests, there remains a threat from the existing bilateral agreements between India and European countries, which do not contain such safeguards. Thus, an investor could challenge any health regulation on the basis of a BIT and the regulation would not be protected by public health exceptions in the EU-India FTA.

3. Recommendations

Investment provisions that continue to hold governments to ransom over health and other public interest regulations, and in particular the investor-to-state dispute mechanism have drawn sharp criticism and increasing calls for a global rethink and reform.

As a first step, the EU Council of Ministers, as is considers the European Commission's request for an expansion of the FTA negotiating mandate on investment, could follow the example of the Australian government. In April 2011, the Australian government issued a Trade Policy Statement
rejecting investor-to-state dispute settlement mechanisms in FTA negotiations, noting that this approach gives foreign companies far greater legal rights than those available to domestic businesses while also constraining the ability of host governments to enact laws on social, environmental and economic matters. The Australian government’s concern for health regulation was highlighted in its statement: “The Government has not and will not accept provisions that limit its capacity to put health warnings or plain packaging requirements on tobacco products or its ability to continue the Pharmaceutical Benefits Scheme.”

The statement also noted the impact of such a provision on its developing country partners, stating that “in the past, Australian Governments have sought the inclusion of investor-state dispute resolution procedures in trade agreements with developing countries at the behest of Australian businesses. The Gillard Government will discontinue this practice. If Australian businesses are concerned about sovereign risk in Australian trading partner countries, they will need to make their own assessments about whether they want to commit to investing in those countries.”

In order to ensure that the EU-India FTA will not curtail the abilities of the EU or India to regulate in the public interest, including in support of health and access to medicines, the additional threat posed by the investment chapter must be addressed. The undersigned organisations recommend the Parties:

- eliminate barriers to affordable medicines by excluding both data exclusivity and overly broad intellectual property enforcement measures from the intellectual property chapter;
- remove “intellectual property rights (IPR), including good will, technical processes and know-how as conferred by law” from the definition of “investment” in the investment chapter of the proposed EU-India FTA;
- remove the “investor-to-state” arbitration mechanism from the investment chapter;
- restrict the scope of the investment chapter to cooperation activities, so that binding rules on market access, investment protection, and expropriation are excluded;
- immediately review and reform all existing BITs between European countries and India to effect the same changes recommended above.

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1 A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries; Brenda Waning, Ellen Diedrichsen and Suerie Moon. Journal of the International AIDS Society 2010, 13:35
4 On 7 April 2011, Commissioner De Gucht gave a response to a written parliamentary question on data exclusivity that indicated that the EU is no longer pushing for the inclusion of DE in the FTA. He stated that, “in the context of the negotiations of a Free Trade Agreement (FTA) with India, the EU requests India to grant national treatment to EU pharmaceutical producers in case India were to adopt legislation providing for data exclusivity.” http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=P-2011-002242&language=HU.
5 These enforcement measures, already in place in the European Union, have led to the seizures of at least 19 shipments of generic medicines from India and China that were intended for other developing countries. India and Brazil initiated dispute settlement proceedings at the WTO as a result of these seizures; the Parties continue to engage in “consultations.” While the EU has said that it will amend its own regulations, which form the basis for the enforcement provisions in the draft FTA text, there has been no detail provided or a timetable for change.
The European Commission is requesting permission to negotiate text that forbids “directly or indirectly” nationalising or expropriating the investment of companies. Paragraph 3(d), Recommendations from the Commission. To review the European Commission’s request for a new, extended negotiating mandate on investment, please see “Recommendations from the Commission” available at http://ec.europa.eu/governance/impact/planned_ia/docs/2011_trade_002_recomm_regarding_investment_en.pdf [accessed 16 May 2011].


9 Art. 207 of the Treaty on the Functioning of the EU.


11 See Henning Grosse Ruse – Khan: Protecting Intellectual Property under BITs, FTAs, and TRIPS: conflicting regimes or mutual coherence?, Max Planck Institute for Intellectual Property and Competition Law Research Paper No.11-02


14 Although bilateral investment agreements are not circumscribed into the WIPO context, this organization has an experience in arbitration for IPR conflict resolution. See WIPO Arbitration and Mediation Center [online]. Available at http://arbiter.wipo.int/arbitration/why-is-arb.html for the main differences between IP disputes in court litigation and in arbitration. A distinction should be drawn between controversies among particulars and controversies among states (as in the WTO dispute-settlement procedures).

15 Paragraph 8, Recommendations from the Commission.


18 A frivolous case brought in 2010 by Commerce Group, on the basis of CAFTA investment provisions, against environmental regulations enacted by the government of El Salvador was dismissed. Nonetheless, based on decision by the ICSID arbitral tribunal, El Salvador was responsible for paying more than USD 800,000 in legal fees. Statement of Lori Wallach, Director of Public Citizen’s Global Trade Watch, 15 March 2011, available at http://citizen.typepad.com/eyesontrade/cafta/ [accessed 16 May 2011].

19 On 20 January 2011, the European Commission requested that the EU Council of Ministers modify and extend its negotiating mandate for the EU-India FTA in order to be authorized to negotiate investment protection on behalf of the Union. The Commission sought authorization to negotiate extensive protections for foreign investment, in addition to comprehensive provisions to liberalize cross-border investment. 2010/TRADE/040; http://www.bilaterals.org/spip.php?article18960.

20 Paragraph 3(a), Recommendations from the Commission.


22 See 2000 ruling in the ICSID (additional facility) arbitration between Metalclad Corporation and the United Mexican States, Case no. ARB(AF)/97/1. Text of the ruling is available at http://icsid.worldbank.org.


24 Paragraph 4, Recommendations from the Commission.


26 http://www.iareporter.com/articles/20100303

27 See submission of Phillip Morris International in response to the request for comments (by USTR) concerning the proposed Trans-Pacific Partnership Trade Agreement.


29 For a more detailed understanding of the interplay between the BITs and the FTA see he following document which looks at the EU-CARIFORUM FTA and existing BITs between the CARIFORUM and European countries. The European Union and the United States Approach to International Investment Agreements with Developing Countries: Free Trade Agreements and Bilateral Investment Treaties; South Centre, April 2010.


32 Emphasis added.