

# **NEGOTIATION OF A FREE TRADE AGREEMENT EUROPEAN UNION-INDIA: WILL INDIA ACCEPT TRIPS-PLUS PROTECTION?**

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## Introduction

India and the European Union (EU) are embarked in the negotiation of a free trade agreement (FTA) that includes – in line with the policies deployed by the EU and the United States in the last ten years – a comprehensive chapter on intellectual property rights (IPRs).

The need to integrate IPRs into broader development policies has been widely recognized in authoritative reports<sup>1</sup> and in international fora<sup>2</sup>. The ‘Objectives’ of the IPRs chapter in the proposed FTA<sup>3</sup> overlook the differences in the levels of development of India and the EU. The stated objectives are limited to facilitating the production and commercialization of ‘innovative and creative products between the Parties’ and to achieving ‘an adequate and effective level of protection and enforcement’ of IPRs. They seem to view IPRs as an end in themselves, rather than as an instrument to be applied in a way that permits countries to address their development constraints and needs. The absence of objectives outside the protection of IPRs in itself is noteworthy in the light of the involvement of both India and the EU in the discussion of the Development Agenda within WIPO.<sup>4</sup>

Despite the European Parliament’s repeated calls on the European Commission not to seek TRIPS-plus standards of protection in developing countries, particularly as they may affect access to medicines,<sup>5</sup> article 2.1 of the EU-India draft FTA indicates that ‘this chapter shall complement and further specify the rights and obligations between the Parties *beyond* those under the TRIPS Agreement and other international treaties in the field of intellectual property to which they are parties’.<sup>6</sup> Hence, the intention to exceed the TRIPS standards is explicit. This approach ignores that India, notwithstanding its recent economic performance and the expansion of its research and development capabilities, is the home to one of the largest populations of poor people in the world.<sup>7</sup> Higher

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<sup>1</sup> See, e.g., Commission on Intellectual Property Rights, Integrating intellectual property rights and development policy, available at [http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm).

<sup>2</sup> The World Intellectual Property Organization (WIPO) has adopted, in particular, a ‘Development Agenda’. See <http://www.wipo.int/ip-development/en/agenda/>.

<sup>3</sup> This analysis refers to the draft IPR chapter of the EU-India FTA in its status before the 6<sup>th</sup> round of negotiations held from 17 to 19 March 2009 in Delhi. See, e.g., [http://bilaterals.org/article.php3?id\\_article=14864](http://bilaterals.org/article.php3?id_article=14864).

<sup>4</sup> See, e.g. Martin Khor, *Strong support from South for WIPO development agenda*, available at <http://www.twinside.org.sg/title2/twr171c.htm>.

<sup>5</sup> See, e.g., the European Parliament Resolution of 12 July 2007 on the TRIPS Agreement and access to medicines which calls on the European Council ‘to meet its commitments to the Doha Declaration and to restrict the Commission’s mandate so as to prevent it from negotiating pharmaceutical-related TRIPS-plus provisions affecting public health and access to medicines, such as data exclusivity, patent extensions and limitation of grounds of compulsory licences, within the framework of the EPA negotiations with the ACP countries and other future bilateral and regional agreements with developing countries’ (para. 11), available at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0353+0+DOC+XML+V0//EN>.

<sup>6</sup> Emphasis added.

<sup>7</sup> Around 30% (i.e. about 300 million) of the Indian population is below the poverty line (see [http://ddp-ext.worldbank.org/ext/ddpreports/ViewSharedReport?&CF=1&REPORT\\_ID=9147&REQUEST\\_TYPE=VIEWADVANCED&HF=N&WSP=N](http://ddp-ext.worldbank.org/ext/ddpreports/ViewSharedReport?&CF=1&REPORT_ID=9147&REQUEST_TYPE=VIEWADVANCED&HF=N&WSP=N)).

standards of IPRs protection can only aggravate the exclusion of the poor from access to essential products, such as medicines and inputs for agricultural production, the very basis for the survival of the largest part of Indian population.

Unquestionably, India has the expertise and the negotiating capacity to address the IPRs issues in a way consistent with its national interests and with its position in international fora. While the EU may, expectedly, condition certain trade concessions of interest to India to India's acceptance of higher standards of IPRs protection, it will be up to the Indian government to assess whether the possible trade benefits (often ephemeral in the light of changing competitive conditions) actually offset the permanent constraints on development and costs to Indian society that such higher standards may generate. Coherence with the position that India has so far maintained in WIPO, WTO and other fora would suggest that India will endeavor to avoid TRIPS-plus commitments in the context of the agreement with the EU. There might be, however, exceptions notably when there is a declared interest in TRIPS-plus standards as it is the case in relation to geographical indications, or when the proposed additional standards would not have a social or economic impact nor require substantial changes in the domestic legal system. It should be borne in mind, in any case, that as a result of the Most-Favoured-Nation clause, any TRIPS-plus standard agreed upon with the EU should be extended automatically and unconditionally to other WTO members without any trade concession from them.

The negotiating texts so far known do indicate that India is resisting many aspects of the EU demands of higher IPRs standards. While in some cases, India has apparently rejected some particular EU proposals (e.g. extension of the patent term, data exclusivity), in other cases its strategy has apparently been to accept certain obligations but only to the extent admissible under 'existing' or 'applicable' laws (e.g. articles 6.3, 6.4, 12, 13, 16, 17, 18) or where the proposed measures are deemed 'appropriate' by the relevant authorities (e.g. articles 14, 15, 16). Many provisions proposed by the EU, particularly in the area of trademarks have been simplified. In the area of enforcement, many provisions with mandatory intent ('the Parties shall...') have apparently been redrafted by India as facultative ('the Parties may...') (e.g., article 13, 14, 16, 18, 19, 20, 21, 23) or converted into a best effort obligation ('the Parties shall endeavor...') (e.g. articles 17 and 22). In the following sections a more detailed analysis of some of the provisions under discussion is made.

### **Coverage of the IPRs chapter**

The EU-India draft FTA practically covers all areas of IPRs. The EU attempts in article 2.2 to embark India in the protection of 'non original databases'. Apparently rejected by the Indian government, the *sui generis* protection of such databases, as contained in the Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases, creates rights (including what is termed the 'extraction right') that may generate a significant obstacle to access to knowledge in the public domain. Access to collected data is essential in an information-based society. Curiously, this EU demand comes after a critical evaluation by the European Commission that casts serious doubts about the necessity of the *sui generis* protection established by said Direc-

tive.<sup>8</sup> Even the United States, which has championed the protection of IPRs, has refused so far to extend protection to non original databases, a possibility strongly resisted by the scientific and librarian communities in that country.

Article 2.2 also makes it clear EU's intention, as discussed below, of creating *sui generis* exclusive rights for a particular set of empirical data: those obtained as a result of clinical trials to demonstrate the efficacy and safety of a drug or agrochemical product.<sup>9</sup>

## Transfer of technology

The impact of strengthened and broadened standards of IPRs protection on transfer of technology is a concern of many developing countries, including India. Soon after the adoption of the TRIPS Agreement, India noted the absence of disciplines in the TRIPS Agreement to ensure an effective transfer of technology on fair and reasonable terms.<sup>10</sup> Such disciplines are notoriously absent in the EU-India draft FTA. There is nothing therein that would enhance technology flows from Europe to India.

Article 3.1 of the draft EU-India FTA limits itself to the Parties' 'exchange of views and information on their domestic and international policies affecting transfer of technology' and to the creation of an 'enabling environment for technology transfer in the host countries, including issues such as the relevant legal framework and development of human capital'. This general declaration seems to put on India the burden of creating the appropriate conditions for the transfer of technology to occur, without any substantial obligation on the EU.

Interestingly, developing countries involved in the negotiation of the CARIFORUM-European Partnership Agreement (EPA) succeeded in incorporating more substantive

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<sup>8</sup> The European Commission has noted that '[T]he economic impact of the "sui generis" right on database production is unproven. [...] Is "sui generis" protection therefore necessary for a thriving database industry? The empirical evidence, at this stage, casts doubts on this necessity' (see DG INTERNAL MARKET AND SERVICES WORKING PAPER, *First evaluation of Directive 96/9/EC on the legal protection of databases*, Brussels, 12 December 2005, available at [http://ec.europa.eu/internal\\_market/copyright/docs/databases/evaluation\\_report\\_en.pdf](http://ec.europa.eu/internal_market/copyright/docs/databases/evaluation_report_en.pdf). See also 'Program Schedules, Event Data and Telephone Subscriber Listings under the Database Directive. The 'Spin-Off' Doctrine in the Netherlands and elsewhere in Europe', paper presented at Fordham University School of Law, Eleventh Annual Conference on International IP Law & Policy, New York, 14 to 25 April 2003, available at <http://www.ivir.nl/publications/hugenholtz/spinofffordham.html>.

<sup>9</sup> Article, 2.2, in effect, refers to the 'protection of undisclosed information' as separate from 'the protection against unfair competition as referred to in article 10bis of the Paris Convention for the Protection of Industrial Property (Stockholm Act 1967). The TRIPS Agreement, however, subjects such information to the discipline of unfair competition (see paragraphs 1 and 3 of article 39).

<sup>10</sup> 'One of the important objectives of the WTO Agreement, as mentioned in its preamble, is the need for positive efforts designed to ensure that developing countries secure a share in the growth in international trade commensurate with the needs of their economic development. However, the TRIPS Agreement in its current form might tempt IPR holders to charge exorbitant and commercially unviable prices for transfer or dissemination of technologies held through such IPRs. It is important, therefore, to build disciplines for effective transfer of technology at fair and reasonable costs to developing countries so as to harmonize the objectives of the WTO Agreement and the TRIPS Agreement' (WT/GC/W/147, 18 February 1999, available at [www.commerce.nic.in/D644e.doc](http://www.commerce.nic.in/D644e.doc)).

provisions on transfer of technology than those currently in the EU-India draft text.<sup>11</sup> Although said EPA does not contain any specific obligation for the transfer of technologies originating from Europe (which are overwhelmingly under private control) it requires Parties to ‘take measures, as appropriate, to prevent or control licensing practices or conditions pertaining to intellectual property rights which may adversely affect the international transfer of technology and that constitute an abuse of intellectual property rights by right holders or an abuse of obvious information asymmetries in the negotiation of licences’ (article 142.2). In addition, it is established that the ‘EC Party shall facilitate and promote the use of incentives granted to institutions and enterprises in its territory for the transfer of technology to institutions and enterprises of the CARIFORUM States in order to enable the CARIFORUM States to establish a viable technological base (article 142.3).

It might be argued that the differences between the CARIFORUM EPA and the EU-India draft FTA in this area could be explained by the considerable industrial and innovative strength of India,<sup>12</sup> and the likely reluctance of the EU to foster the technological capabilities of a low cost, growingly sophisticated global competitor. However, the strengthening of IPRs protection sought by the EU may contribute to limit rather than to foster Indian industrial and technological development which – like developed countries earlier – substantially relied on a flexible IPRs regime. A good illustration is the strong development *before* the introduction of pharmaceutical product patents in 2005 of the Indian pharmaceutical industry, which has become a major world supplier of pharmaceutical active ingredients and medicines.

## Parallel imports

Parallel imports are an important mechanism to prevent market fragmentation and allow access to IPRs-protected products. They may be essential in areas such as pharmaceuticals, as the possibility of parallel importing products cheaper than those locally available may allow access to medicines that may be otherwise unaffordable. While article 4 (‘Exhaustion’) of the EU-India draft FTA seems to confirm the Parties’ right to provide for

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<sup>11</sup> In addition, the CARIFORUM EPA contains some provisions regarding the promotion of innovation. See e.g., Sisule Musungu, (2008), *Innovation and Intellectual Property in the EC-CARIFORUM EPA: Lessons for other ACP Regions*. A Study Commissioned by GTZ, available at [www.gtz.de/en/themen/laendliche-entwicklung/24568.htm](http://www.gtz.de/en/themen/laendliche-entwicklung/24568.htm).

<sup>12</sup> India has been considered in recent literature as an ‘innovative developing country’ (IDC), as it invests in R&D relatively more than other developing countries, there is a greater involvement of the private sector, and the interactions between public institutions and private companies and with innovation agents in developed countries are more frequent than it is generally the case in such countries. See Morel, Carlos, Tara Acharya, Denis Broun, Ajit Dangi, Christopher Elias, N. K. Ganguly, Charles A. Gardner, R. K. Gupta, Jane Haycock, Anthony D. Heher, Peter J. Hotez, Hannah E. Kettler, Gerald T. Keusch, Anatole F. Krattiger, Fernando T. Kreutz, Sanjaya Lall, Keun Lee, Richard Mahoney, Adolfo Martinez-Palomo, R. A. Mashelkar, Stephen A. Matlin, Mandi Mzimba, Joachim Oehler, Robert G. Ridley, Pramilla Senanayake, Peter Singer, and Mikyung Yun, (2005). ‘Health Innovation Networks to Help Developing Countries Address Neglected Diseases’, *Science*, Vol. 309, 15 July.

parallel imports (under the principle known as ‘exhaustion of rights’),<sup>13</sup> the final proviso (‘subject to the provision of the TRIPS Agreement’) raises some concerns, since article 6 of the Agreement exempts exhaustion, as contemplated under national laws, from any challenge under the WTO dispute settlement mechanism. The referred to final proviso seems to subordinate each Party’s right to establish its ‘own regime for exhaustion’ to unspecified provisions of the Agreement, in contradiction with the broad exemption conferred under article 6 of the Agreement, subject only to the provisions of Articles 3 and 4 thereof.

## Copyright and related rights

As in other EU trade agreements, in the EU-India draft FTA the EU requests the accession by India to a number of international conventions on IPRs that India has not ratified so far. The EU demand shows the complementarity of plurilateral and bilateral efforts by the EU to increase the levels of protection of IPRs in foreign countries.

Indian legislation in the area of copyright and related rights provides a considerably high level of protection. Some copyright-based industries, such as the film and the software industries, generate significant income for the country. However, India has not ratified the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (Rome Convention), nor the more recent WIPO Copyrights Treaty and the WIPO Performances and Phonograms Treaty.

Interestingly, the TRIPS Agreement does not obligate all WTO members to comply with the Rome Convention despite that it pre-existed the TRIPS Agreement negotiation. This probably was a result of the US reluctance to accept obligations under a Convention it had not adhered to, and may be explained by the differences between the continental and common law approaches towards copyright ‘neighbouring’ or ‘related’ rights.

India has apparently not accepted so far the obligation to adhere to such conventions, nor many of the provisions proposed by the EU in the area of copyright, as discussed below.

The copyright section of the EU-India draft FTA reflects the trend, promoted by developed countries, towards the extension of the term for copyright protection. As noted by Prof. Boyle, ‘copyright term limits are now absurdly long. The most recent retrospective extensions, to a term which already offered 99% of the value of a perpetual copyright, had the practical effect of helping a tiny number of works that are still in print, or in circulation. Estimates are between 1% and 4%’.<sup>14</sup>

In apparently agreed texts, India and EU commit themselves to recognize authors’ rights for 60 years *post mortem auctoris*<sup>15</sup> (this is also the current term of protection recognized

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<sup>13</sup> See, in particular, the Doha Declaration on the TRIPS Agreement and Public Health (available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)), which explicitly confirmed the right of WTO members to apply such a principle.

<sup>14</sup> Boyle, J. (2004) ‘A Manifesto on WIPO and the future of intellectual property’, Duke Law & Technology Review No. 9, available at <http://www.law.duke.edu/journals/dltr/articles/PDF/2004DLTR0009.pdf>

<sup>15</sup> The minimum term is 70 years in the case of the EU proposals for Central American and Andean countries.

in India). 50 years is the minimum term requested by the EU (and apparently accepted by India, except for broadcasts)<sup>16</sup> for related rights, counted from the date of performance, fixation of a phonogram or film and the first broadcast. Disagreement seems to exist, however, regarding the EU TRIPS-plus proposal to eventually count the 50 year term from a different date (such as the first publication or communication of a performance or of a phonogram) with the ensuing extension of the term of protection.<sup>17</sup> No agreement seems either to exist regarding a complex provision (article 5.5) proposed by the EU on ‘Broadcasting and Communication to the Public’ which would significantly reinforce related rights. Notably, the EU proposal would oblige the Parties to ensure that the relevant performers and phonogram producers share the remuneration charged for the broadcasting by wireless means or the communication to the public of the content of a phonogram.

The EU has also proposed (apparently with relative success)<sup>18</sup> a provision on *Cooperation on collective management of rights* (article 5.4) which notably aims at ‘ensuring mutual transfer of royalties for use of the Parties’ works or other protected subject matters’. Given the reference to the TRIPS Agreement in article 1 of the draft FTA, this provision might be interpreted as ensuring the application of the principle of national treatment to right-holders with regard to royalty payments by collecting societies, an issue that generated a strong controversy between the USA and the European Communities during the Uruguay Round.

One important innovation in the EU proposal submitted to India<sup>19</sup> (but apparently not agreed upon) is a provision obligating the Parties to recognize a ‘resale right’ for original works of art. Such a right is recognized in India but subject to certain limitations (section 53A of the Copyright Act, 1957) that the proposed provision would contribute to eliminate.

Finally, the copyright section contains two detailed provisions (still apparently in brackets, pending an Indian opinion on them) about protection of technological measures (article 5.7) and ‘Rights Management information’ (article 5.8).

Providing protection to digital works – currently under consideration at the national level in India – requires the determination of a delicate balance between public and private interests and, in particular, to ensure that the public domain is preserved from illegitimate appropriations. The provisions proposed by the EU, such as regarding ‘technology pro-

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<sup>16</sup> The TRIPS Agreement established a 50 year minimum term for related rights, but only 20 years for broadcasts (article 14.5).

<sup>17</sup> Interestingly, this proposal has apparently not been made by the EU to the Andean and Central American countries.

<sup>18</sup> An identical provision is contained in both the EU proposals for the Andean and Central American countries (but apparently it has not been accepted so far by the latter). The CARIFORUM EPA is less explicit on the subject (‘...so that right holders are adequately rewarded for the use of such content’ (article 143.2)).

<sup>19</sup> A corresponding provision is not included in the CARIFORUM EPA nor in the proposals to the Andean and Central American countries.

tection'<sup>20</sup> and, particularly, 'anti-circumvention' measures<sup>21</sup>, may limit the use of copyrighted works even for legitimate purposes. This type of measures, if broadly defined, may drastically limit access to knowledge and put a significant obstacle to the implementation of educational policies.

Measures designed to prevent third parties from unauthorized access to and use of digital works may, in effect, permit right-holders to control, monitor and meter every possible use of a work. If strengthened by the legal prohibition to defeat them, such measures may prevent fair use and other legitimate acts. An operative set of exceptions to the exclusive rights granted under copyright is essential in a country like India, where millions of people may be deprived of access to copyrighted work for education and general information.

## **Trademarks**

In pursuing the aforementioned policy of expanding the membership of existing IPRs Conventions, the EU draft requires accession to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (1989), and to comply with the Singapore Treaty on the Law of Trade Marks (2006) and the Trademark Law Treaty (1994). India seems to go along with the obligation to comply with the latter treaties, but only wish to commit to 'endeavor to encourage accession' to the referred to Protocol. Accession to the latter may limit the intervention of the national office in the registration of marks of foreign origin, and is resisted in many countries by local trademark agents. The amendments proposed by India to articles 6.3 ('Well-known trademarks') and article 6.4 ('Exceptions to the rights conferred by a trademark') illustrate the approach mentioned above, as the alternative texts would refer to what is required under 'existing laws'. Article 6.4 addresses an issue of particular interest to the EU, as it recognizes that a geographical indication may exceptionally coexist, as a 'descriptive term' with a trademark.

## **Geographical indications**

Not surprisingly, the EU draft contains detailed provisions on the protection of geographical indications, including for the mutual recognition and protection of a number of listed EU and Indian geographical indications (GIs). The possible enhancement of GIs protection has divided developed and developing countries alike at the WTO, where disagreement persists regarding the establishment of an international registry for GIs relating to wines and spirits. Largely induced by the concerns about the use in foreign countries of the generic name of 'basmati' rice, India has been a proponent of an elevation of GIs protection in the TRIPS Agreement.

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<sup>20</sup> 'Technology protection measures' are legal remedies against acts aiming at removing or altering any digital rights management information, that is, access control technologies used by publishers and other copyright holders to limit usage of digital media or devices without authority.

<sup>21</sup> These measures prevent a person from utilizing technologies and equipment in order to bypass technical protections, such as encryption methods.

So far, no agreement seems to exist between the EU and India on GIs protection, despite the fact that Indian Geographical Indications of Goods (Registration and Protection) Act, 1999, allows the government to confer a TRIPS Article 23-type protection to all GIs of Indian origin (that is, Indian law already is TRIPS-plus in this respect). The government has established the Geographical Indications Registry, where around 30 GIs of Indian origin have been registered (more Indian GIs are in the pipeline for registration).<sup>22</sup>

The proposed text includes (in addition to the recognition of specific GIs for agricultural products and foodstuffs, wines, aromatized wines and spirits) a mechanism for the addition of new GIs, as well as provisions on the use of GIs in Internet and organizational matters. Incorporating this kind of TRIPS-plus provisions in this FTA will represent a significant achievement for European countries, who concentrate the world largest number of GIs, and who have consistently championed an expansion of the international protection of GIs. In the case of India, given the scarcity of research-based inputs on the impact of GIs protection, it has been recommended ‘a more prudent approach on the part of India’ and to ‘go slow’ in accepting international obligations on the matter.<sup>23</sup>

## Patents

Unlike the US FTAs, the EU proposal contains a relative small number of provisions on patent law.

Article 9.1 obligates the Parties to comply with certain provisions of three conventions:

- a) the Patent Cooperation Treaty (Washington, 1970, last modified in 1984) which is in force in India since December 1998.
- b) the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977, amended in 1980), which is in force in India since December 2001.
- c) the Patent Law Treaty (Geneva, 2000) which harmonizes certain procedural aspects of patent law and which has not been adhered to by India. A similar provision is present in the EU proposal for the Central American countries. However, in the CARIFORUM EPA and in the EU proposal for the Andean countries a softer requirement is established: CARIFORUM countries ‘shall endeavour to accede’ to said Treaty (article 147.1.3) while Andean countries ‘shall make all reasonable efforts to comply with’ it (article 9.1). This suggests that the EU may show some flexibility with regard to this treaty, which so far has attracted a low number of contracting parties (only 19). Should India accept this requirement, it may face difficulties to implement the obligation – currently imposed by the Indian Patent Act – to disclose the origin of claimed biological material (§ 10(a)(4)(d)(ii)(D)).<sup>24</sup>

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<sup>22</sup> See Kasturi Das, *Protection of Geographical Indications: An Overview of Select Issues with Particular Reference to India*, CENTAD, available at [http://www.centad.org/cwp\\_10.asp](http://www.centad.org/cwp_10.asp).

<sup>23</sup> Ibidem.

<sup>24</sup> Under Indian law, non-disclosure or wrongful disclosure of the origin of a biological material can result in denial or revocation of the patent. The Patent Law Treaty limits the grounds for revocation or invalida-

An interesting aspect of the EU-India draft FTA is the recognition of the ‘importance of the Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 by the Ministerial Conference of the WTO’ (article 9.2.1). This Declaration confirmed a number of ‘flexibilities’ available under the TRIPS Agreement and, in particular, ‘that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to ‘medicines for all’ (paragraph 4).

Moreover, the EU-India draft FTA provides, on the one hand, that ‘[I]n interpreting and implementing the rights and obligations under this Chapter, the Parties shall ensure consistency with this Declaration’ (article 9.2.1, second sentence). This provision, notoriously absent in the chapter on intellectual property of the CARIFORUM EPA, is a positive feature, as it means that the Declaration should be applied for interpretative purposes in the case that a dispute arises between the Parties.

On the other hand, article 9.2.2 of the draft stipulates that the Parties ‘shall contribute to the implementation and respect’ of the WTO Decision of August 30, 2003 – which allows for the exportation of pharmaceutical products under compulsory licenses to countries without manufacturing capacity in pharmaceuticals – and agree to take the necessary steps to accept the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005.<sup>25</sup> It further provides that ‘[N]othing in this Agreement shall be construed as to impair the capacity of the Parties to promote access to medicines’. This is also an interesting provision,<sup>26</sup> whose precise implications need to be determined yet.

It is to be noted, however, that the EU proposal does include two clearly TRIPS-plus provisions (apparently not accepted by India) which, if adopted, may significantly limit access to drugs:

-Article 9.3 would compel India to extend the monopoly accorded by a patent for up to five additional years in order to compensate for the time required for the marketing approval of a medicinal product.<sup>27</sup> This provision is modeled on the concept of ‘supplementary protection certificate’ applied in the European context.<sup>28</sup> The grant of such certificates would in practice extend the monopoly conferred by a patent and delay the entry of generic competition, which reduces prices and increases the affordability of drugs.

-Article 10 would impose on India the obligation to create a *sui generis* protection for test data submitted for the approval of pharmaceutical (and agrochemical products) a form of protection, not required by the TRIPS Agreement, that India has refused to grant. This

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tion of a patent (Article 10 “*Validity of Patent; Revocation*”) in a way that may exclude the possibility of taking these measures in case of lack of disclosure ‘except where the non-compliance with the formal requirement occurred as a result of a fraudulent intention’.

<sup>25</sup> Both the EU and India have already accepted this amendment and enacted legislation to implement the WTO Decision on the subject of 30 August, 2003.

<sup>26</sup> A similar text is not found in the draft FTAs submitted by the EU to the Andean and the Central American countries.

<sup>27</sup> The same position would apply to ‘plant protection products’.

<sup>28</sup> Although there is no explicit text in the EU proposal about the patenting of second pharmaceutical indications (that is, of a known medicine for which a new therapeutic use is found) article 9.3.3 of the draft suggests that India should extend the duration of patents on the ‘pediatric use’ of pharmaceutical products.

type of protection would create market exclusivity after the approval of a product, thereby isolating it from generic competition. The EU draft provision does not specify yet the duration of the proposed exclusive right on test data. Such a protection lasts for ten years in the EU, with a possible additional year (i.e. a total of eleven years) if new indications for a known product have been found. If this provision were adopted, Indian consumers may be deprived during the test data exclusivity period of access to low-priced drugs, even in the absence of a patent on the respective product.

## **Breeders' rights**

In using the flexibility allowed by the TRIPS Agreement (article 27.3.b), India protects plant varieties through breeders' rights generally in line with the standards of the Convention on the Protection of Plant Varieties (UPOV) as revised in 1978. Deliberately, India (as well as other developing countries) have adhered to or followed the standards of the 1978 Act of UPOV, since the Act adopted in 1991 is perceived as altering the balance attained in the 1978 Act between breeders' and farmers' rights. In addition, the Indian Protection of Plant Varieties and Farmers' Rights Act contains elements absent in the UPOV context, such as the registration of extant and farmers' varieties and benefit sharing provisions to compensate farmers' for their innovations.

The EU-India draft FTA obligates the Parties 'to co-operate to promote and reinforce the protection of plant varieties based' on UPOV 1991 (article 11).<sup>29</sup> It makes a specific reference to the possibility (article 15(2) of UPOV 1991) of introducing an exception for the use, in their own exploitation, of seeds saved by farmers (a right explicitly recognized under Indian law). Given the sensitivity of the issue of plant varieties protection in India, it is unlikely that this clarification – legally superfluous – would be sufficient to change India's resistance to expand the protection accorded to plant varieties in line with UPOV 1991, even if it were not required to formally adhere to this Act of the Convention.

## **Enforcement**

The EU has become in the last five years highly active in the field of enforcement of IPRS both for the internal market and internationally. It adopted the Enforcement Directive 2004/48/EC in order to address the disparities between the systems of the Member States as regards the means of enforcing IPRs, and the 'Strategy for the Enforcement of Intellectual Property Rights (IPR) in Third Countries', which aims at enhancing IPRs enforcement outside the European Union<sup>30</sup>. The European Commission is also a strong

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<sup>29</sup> The corresponding provision of the EU draft FTA for Central America is more flexible, as it reproduces the wording of TRIPS article 27.3(b) (article 10). It is to be noted, however, that Central American countries already accepted, under the free trade agreement signed with the USA (RD-CAFTA), an obligation to adhere to UPOV 1991 and to 'undertake all reasonable efforts' to make patent protection for plants available (article 15.9.2).

<sup>30</sup> See Carlos Correa (2009), *The Push for Stronger IPRs Enforcement Rules: Implications for Developing Countries*. ICTSD, Geneva, available at <http://ictsd.net/i/publications/42762/>

supporter of the negotiation of a new ‘Anti-Counterfeiting Trade Agreement’ (ACTA).<sup>31</sup> It is not surprising, hence, that the longest and more detailed section of the EU FTA proposal (articles 12-28) incorporates different types of enforcement measures.

The EU FTA proposal contains a number of TRIPS ‘complementary measures, procedures and remedies’ (article 12). For the most part, however, India has apparently not accepted these provisions. The EU proposal determines various categories of possible applicants of enforcement measures (article 13), specifies the type of evidence (including banking, financial or commercial documents) that the opposing party may be ordered to communicate (article 14), requires the Parties to grant, ‘if necessary’ *inaudita altera parte*, measures to preserve a detailed set of pieces of evidence (article 15), introduces in great detail information that the alleged infringer may be ordered to provide (article 16), provides for provisional and precautionary measures to prevent ‘the continuation’ of an alleged infringement (article 17), requires that judges be authorized to order, *inter alia*, the destruction of infringing goods, even in cases of non-intentional infringement (article 18), extends the applicability of permanent injunctions to ‘intermediaries whose services are used’ to infringe IPRs (article 19), provides for pecuniary compensation for cases where infringement was ‘non-intentional and without negligence’ (article 20), stipulates about the determination of damages (article 21), imposes legal costs and other expenses on the unsuccessful party (article 22), requires the publication of judicial decisions (article 23), provides for a presumption of ownership in the case of enforcement of copyright and related rights (article 24), regulates the liability of intermediary service providers (article 26), and obligates the Parties to adopt expansive border measures (article 27), to encourage the development of codes of conducts aimed at contributing towards the enforcement of intellectual property rights and to enter into forensic cooperation (article 28). None of these provisions, except article 24 on presumption of ownership, seems to have been accepted by India so far. For some provisions, India has proposed alternative texts (in many cases based on facultative clauses or references to applicable existing laws).

The proposed expansion of border measures much beyond what is required under the TRIPS Agreement would make such measures applicable not only to the importation but also to the exportation of goods and to goods in transit. The seizure by European custom authorities of generic medicines in transit through European territory illustrates about the possible implications on legitimate trade of the broad application of border measures.<sup>32</sup> This case not only shows the problems posed by the application of IPRs to goods merely in transit (which may constitute a violation of article V of GATT) but also the inadequateness of applying, as proposed by the EU, border measures to patent infringements. The determination of such an infringement generally requires complex

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<sup>31</sup> See Monika Ermert (2008), ‘Europe May Put ACTA Back On Faster Track’ Intellectual Property Watch, 16 July 2008, available at [www.ip-watch.org/weblog/2008/07/16/anti-counterfeiting-trade-agreement-may-be-back-on-faster-track/](http://www.ip-watch.org/weblog/2008/07/16/anti-counterfeiting-trade-agreement-may-be-back-on-faster-track/).

<sup>32</sup> Particular repercussions had the recent confiscation by Dutch customs authorities of a shipment of the pharmaceutical ‘losartan’ in transit from India to Brazil. See, e.g. Frederick M. Abbott (2009), Worst Fears Realised: The Dutch Confiscation of Medicines Bound from India to Brazil, *Bridges*, March 2009, available at <http://www.frederickabbott.com/uploads/Abbott - Worst Fears Realized - Pages from Bridges-vol13-no1.pdf>.

technical testing and raises difficult legal issues, such as the interpretation of the scope of patent claims (namely in order to establish whether a non-literal violation exists). Custom authorities lack the capacity to properly handle these issues.

### **A noticeable gap**

India has been at the forefront of initiatives aiming at curbing the misappropriation ('bio-piracy') of traditional knowledge and genetic resources. The EU-India draft FTA does not contain, however, any provision on this subject. India may have opted to have these issues out of the FTA discussion to fully preserve its capacity to regulate the matter at the national level. But the FTA might be an opportunity to demand from EU full compliance with the Convention on Biological Diversity and, in particular, the incorporation of an obligation on patent applicants to disclose the origin of biological materials claimed in a patent application. Provisions of this kind were included in the CARIFORUM EPA (article 150),<sup>33</sup> although on terms that do not guarantee the effective implementation by the EU of measures against such a misappropriation.

### **Conclusions**

The proposed chapter on IPRs in the draft FTA between India and EU represents a clear attempt by the EU to increase the level of IPRs protection, without consideration to the development needs of India. The analysis made above suggests that EU may find difficult, however, to obtain the same concessions in the area of IPRs that it extracted in negotiations with other developing countries. Given the role that India has played in resisting the trends towards TRIPS-plus protection in areas of key economic and social relevance for developing countries, the outcome of these negotiations will set a significant precedent for the future of IPRs protection globally. It will also determine, in particular, the role that the Indian pharmaceutical industry may play as a world supplier of low-cost medicines.

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<sup>33</sup> Article 150.4 provides that the Parties 'may require as part of the administrative requirements for a patent application concerning an invention which uses biological material as a necessary aspect of the invention, that the applicant identifies the sources of the biological material used by the applicant and described as part of the invention' (emphasis added).