

Analysing of Free Trade Agreement between India and EU and its impact on the IPR laws in India

Vaibhav Priyadarshi*

In this Article the author makes an attempt to understand that after the FTA between India and EU coming into force, what will be the positive and adverse effects on IPR laws and the condition of common man in India.

1. Introduction

The European Union-India Free Trade agreement is such an FTA (The EU and India launched negotiations for an FTA in 2007. The report was adopted with 326 votes in favour, 226 against and 3 abstentions) but is still in its nascent stage. Efforts are being made to conclude the FTA within the next few months; however, a date cannot be put on when it will come into force as there are certain roadblocks being faced. 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 a comprehensive chapter on Intellectual Property Rights (IPRs).

The need to integrate IPRs into broader development policies has been widely recognised in authoritative reports¹ and in international fora.² The “Objectives” of the IPRs chapter in the proposed FTA³ overlook the differences in the levels of development of India and the EU. The stated objectives are limited to facilitating the production and commercialisation of “innovative and creative products between the Parties” and to achieving “an adequate and effective level of protection and enforcement” of IPRs.

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”.⁴

* Junior Associate, Bodhi Global (an LPO in Pune). E-mail: vaibhavp.hnlu@gmail.com

¹ See: Report of commission on ‘Intellectual Property Rights, Integrating intellectual property rights and development policy’, available at http://www.iprcommission.org/graphic/documents/final_report.htm., last visited (18th October, 2010).

² The World Intellectual property Organization (WIPO) has adopted, in particular, a report on ‘Development Agenda’, available at <http://www.wipo.int/ip-development/en/agenda/>, last visited (19th October. 2010).

³ This analysis refers to the draft IPR chapter of the EU-India FTA in its status before the 6th round of negotiations held from 17 to 19 March 2009 in Delhi, available at http://bilaterals.org/article.php3?id_article=14864, last visited (19th October, 2010).

⁴ Ibid.

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.⁵ Higher 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.

Chapter 1

2. Coverage of the IPRs chapter in the EU-India FTA

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 11th 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 Directive.⁶ Even the United States, which has championed the protection of IPRs, has refused so far to extend protection

⁵ Around 30% (i.e. about 300 million) of the Indian population is below the poverty line. Data available at http://ddpext.worldbank.org/ext/ddpreports/ViewSharedReport?&CF=1&REPORT_ID=9147&REQUEST_TYPE=V IEWADVANCED&HF=N&WSP=N, last visited (21st October, 2010).

⁶ The European Commission has noted that 'The 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, 12th December, 2005, available at http://ec.europa.eu/internal_market/copyright/docs/databases/evaluation_report_en.pdf, last visited (12th Oct. 2010).

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.⁷

2.1 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 parallel imports (under the principle known as "exhaustion of rights"),⁸ 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.

2.2 Copyright and related rights

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 per cent 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 per cent and 4 per cent. In apparently agreed texts, India and EU commit themselves to recognise authors' rights

⁷ 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

⁸ See, in particular, the report of the Doha Declaration on the TRIPS Agreement and Public Health, which explicitly confirmed the right of WTO members to apply such a principle. Available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm, last visited (19th October, 2010).

for 60 years *post mortem auctoris*⁹ (this is also the current term of protection recognised in India).

Fifty years is the minimum term requested by the EU (and apparently accepted by India, except for broadcasts)¹⁰ 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.¹¹ 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)¹² 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 India¹³ (but apparently not agreed upon) is a provision obligating the Parties to recognise a “resale right” for original works of art. Such a right is recognised in India but subject to certain limitations (Section 53A of the Copyright Act, 1957) that the proposed provision would contribute to eliminate.

⁹ The minimum term is 70 years in the case of the EU proposals for Central American and Andean countries.

¹⁰ The TRIPS Agreement established a 50 year minimum term for related rights, but only 20 years for broadcasts (Article 14.5).

¹¹ Interestingly, this proposal has apparently not been made by the EU to the Andean and Central American countries.

¹² 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 EPA is less explicit on the subject (“...so that right holders are adequately rewarded for the use of such content” (Article 143.2)).

¹³ A corresponding provision is not included in the CARIFORUM EPA nor in the proposals to the Andean and Central American countries.

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 protection”¹⁴ and, particularly, “anti-circumvention” measures,¹⁵ 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.

2.3 Trade Marks

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 Trade Mark 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 trade mark agents. The amendments proposed by India to Articles 6.3 (“Well-known trade marks”) and Article 6.4 (Exceptions to the rights conferred by a trade mark) illustrate the approach mentioned above, as the alternative texts would refer to what is required under “existing laws”.

¹⁴ “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.

¹⁵ These measures prevent a person from utilising technologies and equipment in order to bypass technical protections, such as encryption methods.

Article 6.4 addresses an issue of particular interest to the EU, as it recognises that a geographical indication may exceptionally coexist, as a “descriptive term” with a trade mark.¹⁶

2.4 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 EPA and in the EU proposal for the Andean countries a softer requirement is established: 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)).¹⁷

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 14th 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

¹⁶ 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, last visited (14th October, 2010).

¹⁷ 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 invalidation 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’.

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 "In 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 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 30th August, 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 6th December, 2005.¹⁸ It further provides that "Nothing 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,¹⁹ 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.²⁰

This provision is modeled on the concept of "supplementary protection certificate" applied in the European context.²¹ 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, which India has refused to grant. This type 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

¹⁸ Both the EU and India have already accepted this amendment and enacted legislation to implement the WTO Decision on the subject of 30th August, 2003.

¹⁹ A similar text is not found in the draft FTAs submitted by the EU to the Andean and the Central American countries.

²⁰ The same position would apply to "plant protection products".

²¹ 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.

disclosure “except where the non-compliance with the formal requirement occurred as a result of a fraudulent intention”.

This 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 10 years in the EU, with a possible additional year (i.e. a total of 11 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.

2.5 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).²² 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 recognised 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.

2.6 Enforcement

²² 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).

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.²³ The European Commission is also a strong supporter of the negotiation of a new Anti-Counterfeiting Trade Agreement (ACTA).²⁴ 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, India has proposed alternative texts (in many cases based on facultative clauses or references to applicable existing laws).²⁵

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

²³ See Carlos Correa, “The Push for Stronger IPRs Enforcement Rules: Implications for Developing Countries” (2009). ICTSD, Geneva, available at <http://ictsd.net/i/publications/42762/>, last visited (19th October, 2010).

²⁴ See Monika Ermert, “Europe May Put ACTA Back On Faster Track” Intellectual Property Watch, 16th July, 2008, available at www.ip-watch.org/weblog/2008/07/16/anti-counterfeiting-trade-agreement-may-be-back-on-faster-track/, last visited (20th October, 2010)

²⁵ *ibid*

transit through European territory illustrates about the possible implications on legitimate trade of the broad application of border measures.²⁶ 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 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.

2.7 A noticeable gap

India has been at the forefront of initiatives aiming at curbing the misappropriation (biopiracy) 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 EPA (Article 150),²⁷ although on terms that do not guarantee the effective implementation by the EU of measures against such a misappropriation.

Chapter 2

3. The pros and cons on IP laws of India after EU-India FTA

3.1 India's obligations and responsibilities

India is a party to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). As per requirements under TRIPS India now grants product patents for drugs and pharmaceuticals. This has already impacted the accessibility and affordability of cheap life saving drugs. However,

²⁶ Particular repercussions had the recent confiscation by Dutch customs authorities of a shipment of the pharmaceutical 'losartan' in transit from India to Brazil. See Frederick M. Abbott, '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_Bridgesvoll13-nol.pdf. last visited (21st Oct. 2010).

²⁷ 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'

provisions like Article 39(3)²⁸ and Article 40²⁹ of the TRIPS agreement have ensured that the door has not been completely shut on India's generic drugs manufacturers and also allowing India to continue to grant compulsory licenses. The dispute is primarily with respect to Article 39(3), where EU opines that India must incorporate the data exclusivity law as India has a responsibility under Article 39(3) to ensure that the data are protected against unfair commercial use.

At the Doha Declaration³⁰ it was stated that "The TRIPS agreement does not and should not prevent member nations from protecting public health". The controversial Articles 39(3) only protects data from "unfair commercial use" without so much as mentioning the term data exclusivity. There is no question of generic manufactures or compulsory licensing being interpreted as "unfair commercial use". If it weren't for these concepts India and various 3rd world nations would not have access to cheap life saving drugs. A simple example can be seen in the fact that before there was competition form generic drugs antiretroviral drugs cost \$12,000 per person annually but once generic alternatives entered the market the price was reduced to \$350 dollars.³¹ It can thus be seen that in the interest of public health generic manufacturers are very important, essential and permitted under Article 39(3) of TRIPS. Therefore, India has no obligation under the TRIPS to enforce the Data exclusivity law as it is a TRIPS plus provision.

3.2 Impact on other Indian IPR laws

²⁸ Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use, available at http://www.iprcommission.org/graphic/documents/final_report.htm., last visited (18th October, 2010).

²⁹ Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member, available at <http://www.ec.europa.eu/trade/creating-opportunities/bilateral-relations/.../india/>, last visited (19th October. 2010)

³⁰ Doha Declaration on the TRIPS Agreement and Public Health, November 2001, available at www.who.int/medicines/areas/policy/doha_declaration/.../index.html, /, last visited (19th October. 2010)

³¹ See Ermert Monika India-EU Trade Talks Resume under Cloud of Concern for Public Health, available at <http://www.ip-watch.org/weblog/2010/04/27/eu-india-trade-talks-resume-under-cloud-of-concern-for-public-health/>, last visited (21st Oct. 2010).

Article 8(3)³² requires India to provide patent protection to databases. India already provides copyright protection for computer programs. However, India must not be compelled to provide copyright protection to databases as it will be a significant obstacle to the access to knowledge in the public domain, which is very important in an information-based society. Even the U.S.A which is arguably the most pro copyright and patent country in the world has not provided patent protection with respect to databases. Through Article 11.1³³ India are required to comply with various international IPR conventions which India has not ratified so far. This is an effort by the EU to strengthen IPR laws in foreign countries. TRIPS do not obligate India to ratify the Rome Convention which was in existence before the TRIPS itself. Also, the WIPO Treaties have not yet been ratified by India.

In the FTA the European Union wants to extend the rights of the rights of publishers and music/film companies. As per Article 11, India wants to grant protection to the copyright related rights of performers, broadcasting organisations, phonogram and film producers and these shall not expire shall expire not less than 50(or 60 as the case may be) years after the film/phonogram/performance/broadcast is made/performed/broadcasted. The European Union however wants to extend this period and require that if a fixation³⁴ of the performance/broadcast/film/phonogram is lawfully published or lawfully communicated to the public within this period, the rights shall expire not less than 50(or 60) years from the date of the first such publication or the first such communication to the public, whichever is the earlier. The basic difference is the date from which the 50 year period is being calculated. The EU method of calculation from a later date provides longer protection of the related rights. There needs to be careful examination to ensure that we are not giving away public's rights to satisfy big EU copyright holding media companies.

³² For the purpose of this Agreement, intellectual property rights embody copyright, including copyright in computer programs and in databases, and rights related to copyright, rights related to patents, trademarks, trade names in so far as these are protected as exclusive property rights in the domestic law concerned, designs, layout -designs (topographies) of integrated circuits, geographical indications, including designations of origin, indications of source, plant varieties, protection of undisclosed information and the protection against unfair competition as referred to in Article 10bis of the Paris Convention for the Protection of Industrial Property (Stockholm Act 1967).

³³ Article 11.1 - Protection Granted The Parties shall comply with: Article 1 through 21 of the Berne Convention for the Protection of Literary and Artistic works and appendix thereto (1971); [EU: Articles 1 through 22 of the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations (1961);] [EU: Articles 1 through 14 of the WIPO Copyright Treaty - WCT (Geneva, 1996);] [EU: Articles 1 through 23 of the WIPO Performance and Phonograms Treaty - WPPT (Geneva, 1996)].

³⁴ Fixation in law refers to works entitled to copyright protection.

Article 28³⁵ tries to determine the manner in which Indian Courts must behave on matters relating to interim relief. The courts are to grant “injunctive relief”, a course of action which has been held to be extremely dangerous for all software companies. A good example would be that under the FTA regime if there is a dispute over a piece of software, it would mean that the company using this software could be stopped even before the merits of the case are decided. A recent case in example is the Blackberry case, where RIM, the owner of the Blackberry business was forced to pay \$612 million on a claim which was widely held to be bad in law. Faced with threat of an injunction which would have shut down its entire business and sunk Blackberry, or paying out \$612 million, it chose the lesser of the two evils.³⁶ The main danger of injunctive relief is that money could be exorted from companies on the threat of suing them and closing down their business.

Article 13 talks about protection of Geographical Indications in detail . India is already TRIPS-plus with respect to GIs as it protects GIs under the Indian Geographical Indication of Goods Act, 1999 in a manner similar to that provided under Article 23 of TRIPS. The draft besides protecting GIs in wines, spirits and agricultural products further endeavours to introduce a method for inclusion of new GIs as well as provisions on the application of GIs in internet and other organisational matters. This is a significant achievement for the EU as these nations concentrate the world largest number of GIs. Considering India has a dearth of research based inputs on the impact of GI protection, India should perhaps take a more prudent and far sighted approach and ease into adopting international obligations.³⁷

With respect to trade marks the most interesting impact on Indian law would be that the leaked draft paper in Article 6 says that a geographical indication may exceptionally coexist as a descriptive term in a trade mark. Further the draft requires India to accede to various international conventions like the Madrid Agreement (1989), Singapore Treaty (2006) and the Trademark Law

³⁵ The Parties shall ensure that, where a judicial decision is taken finding an infringement of an intellectual property right, the judicial authorities may issue against the infringer an injunction aimed at prohibiting the continuation of the infringement. Where provided for by domestic law, non-compliance with an injunction shall, where appropriate, be subject to a recurring penalty payment, with a view to ensuring compliance. The Parties shall also ensure that right holders are in a position to apply for an injunction against intermediaries whose services are used by a third party to infringe an intellectual property right.

³⁶ See Prabir Purkayasta and Indranil Mukhopadhyay, EU-India FTA - Free Trade or Reinventing Colonialism, Newsclick, May 24th, 2010, available at <http://www.newsclick.com/articles/index.php?article=1495>, last visited (21st Oct. 2010).

³⁷ Ibid.

Treaty (1994). India however wishes to commit itself to the treaties only to the extent of "endeavouring to encourage accession".³⁸

Chapter 3

4. The positive and negative aspects of the EU-India FTA

4.1 Positive aspects

It is interesting to note that, the Satwant Reddy Committee, an inter-ministerial committee headed by the Secretary of the Ministry of Chemicals and Fertilizers Satwant Reddy, has proposed that multinational pharmaceutical companies be allowed the sole use of their expensive data for a period that's extends anything from 3 to 5 years. Further, the Confederation of Indian Industry (CII) favours data exclusivity for five years. Ranbaxy also supports the CII's view. Biocon Ltd, a Bio-Tech company, also favours it since biotech products need their own data for approval due to their complex nature. The Department of Scientific and Industrial Research (DSIR) has recommended data exclusivity law three years along with sufficient safeguards. Various developed nations around the world have accepted data exclusivity for a period of 5 years on an average. It can thus be safely assumed that India too will eventually join the fold.

As per EU the fears regarding accessibility and affordability of drugs after the enforcement of data exclusivity are baseless. Even when the Patent Act was amended in 2005 in accordance with TRIPS, these fears existed. However, today there is no such evidence of increased inaccessibility or reduced affordability. Big pharmaceutical companies spend 8-10 years and millions on dollars on clinical trials before marketing a drug. If such data are made available to the generic companies, it means that huge investment in Research and Development(R & D) made by the innovator companies to launch new drugs are unprotected. Foreign Direct Investment (FDI) could increase with the inclusion of data exclusivity law currently. Currently bid foreign pharmaceutical companies hesitate to invest in India due to the weak IPR regime that exists.³⁹

India may be excluded from the list of "Priority Watch List" of United States Trade Representative (USTR) under special 301 of the U.S Trade Act of 1974. The Priority Watch List is the list of all those countries that failed to

³⁸ Ibid.

³⁹ See this comparative analysis at The India EU FTA: Depriving The Common Indian Of Life Saving Drugs?, available at <http://www.airwebworld.com/articles/index.php?article=1495>, last visited (21st Oct. 2010).

provide and adequate level of Intellectual Property (IP) protection or market access to U.S manufacturer that failed to provide an adequate level of IP protection. This could lead to a significant expansion of India's trade relation with U.S.A. If such data is protected, big pharmaceutical companies will be encouraged to spend time and money in complex research and development. This will ultimately lead to countries with data exclusivity laws benefiting as they would be providing an incentive for R & D. With increased access to clinical trials in the countries Indian scientists working abroad will be encouraged to return to India and pursue innovation in their own country. India will subsequently gain world class expertise in clinical trials.⁴⁰ Further, according to the Federation of Indian Chambers of Commerce and Industry, the agreement will also ensure that increasing bilateral trade brings benefits to the widest number of people, including Dalits and Adivasis, and contributes to India's achievement of the Millennium Development Goals, including preventing environmental degradation.. Bilateral trade in services is expected to exceed € 246.8 billion by 2015 by the time the FTA in Services is implemented⁴¹.

Negative aspects The Indian Patents (Amendment) Act 2005 does not allow a patent for more than 20 years. Thus, Section 3d of the act does not allow extension or repatenting of any medicines on frivolous ground. Repatenting application by multinational Novartis for anti-cancer Imatinib Mesilate was rejected and Indian companies are now producing the same medicine, bringing the treatment cost down to Rs 8,000 a month from Rs 1,00,000 involving the Novartis medicine. Repatenting of many HIV-AIDS medicines were also refused, and MNCs are now filing court cases for removal of this Section from our patent law.⁴²

4.2 In such a situation, the text of the proposed EU-India FTA says

- (1) The parties recognise that medicinal and plant protection products protected by a patent in their respective territory may be subject to an administrative authorisation procedure before being put on their market. They recognise that the period that elapses between the filing of the application for a patent and the first authorisation to place the product in their respective markets may shorten the period of effective protection under the patent.

⁴⁰ Ibid.

⁴¹ See, EU-India: Free Trade Agreement to be signed by the end of 2010 say MEPs, available at <http://www.europarl.europa.eu/sides/getDoc.do?language=EN&type=IM-PRESS&reference=20090325IPR52628>, last visited (21st October, 2010).

⁴² Available at http://www.bilaterals.org/article.php3?id_article=14864, last visited (21st Oct. 2010).

- (2) The parties shall provide for a further period of protection for a product, which is protected by a patent and which has been subject to an administrative authorisation procedure.
- (3) Notwithstanding paragraph 2 and the extension for a paediatric use for pharmaceutical products, the duration of further period of protection may not exceed five years.⁴³

It is now clear that through an administrative authorisation, medicines patented by any company in any of the 27 EU countries would be extended by at least five years beyond the 20 years limit provided by Indian law. Global export of medicines by UK and German MNCs is next highest to the US's. Thus the proposal upholds the interests of these companies. Free trade is today being manipulated to inflict stringent terms on weaker countries. The stronger countries take full advantage of an FTA to kill certain flexibilities the WTO agreement provides, distorting in particular the clauses on intellectual property rights, data exclusivity and compulsory licenses through a binding agreement. Thus, FTAs are further endangering the access to medicines. The experiences of NAFTA and similar FTAs in Asia Pacific region show that national health systems are facing newer attacks through the FTAs.⁴⁴

The method adopted in FTA formulation is to extend the period of a patent beyond the WTO stipulated 20 years. This allows continuation of monopoly and a rise in medicine prices as a country is not able to produce or procure once-patented medicines even after international patent period expires. To bind it further, data exclusivity is also enforced, even though it is not an obligation under the WTO agreement. While asking for patent on a medicine, its inventor has to submit all test data to establish its novelty, superiority and safety. A company conducts such a test over a long period of 5 to 10 years, and such data are enormous as clinical trials are carried out on several thousands of people. Generic drug manufacturers wait for expiry of the patent period to start production of the earlier patented medicine; this ends monopoly and brings down prices. These generic drug producers do not need to perform any clinical trials or submit any test data; such trials are not only repetitive but involve huge cost too. But the simple precondition of submission of test data would block the production of generic drugs. One of

⁴³ Ibid.

⁴⁴ See Guha Amitaya, EU-India Free Trade Agreement: Threatening our people's health a new(May 2, 2010), available at <http://indiacurrentaffairs.org/eu-india-free-trade-agreement-threatening-our-people%E2%80%99s-health-anew-amitava-guha/>, last visited (21st Oct. 2010).

the numerous post-TRIPS mischiefs of the drug MNCs is therefore to push the countries into FTAs.⁴⁵

4.3 Blocking generic medicine production

So far, our laws do not ask for submission of test data for licensing of any medicine whose patent period is expired. A generic medicine can be registered if the manufacturer shows that it is therapeutically equivalent to an existing medicine. There is no requirement for a generic company to perform lengthy clinical trials to establish that it is safe and effective; reliance on the original product's data is sufficient for the drug authority to approve its marketing. Generic medicine producers thus produce medicines immediately after expiry of its patent and sell them cheaper all over the world. India is the fourth largest producer of medicines in the world. Many poor countries having no medicine production capacity immensely benefit from cheaper Indian medicines. But the EU wants data exclusivity introduced in India. If companies are required to generate their own test data to register a generic medicine, this will impose huge costs on them. Given that generic manufacturing relies on low profit margins, this may even have the effect of killing competition altogether. Article 10 of the proposed agreement says:

The parties will enact and implement legislation ensuring that any information submitted to obtain marketing approval, i.e. registration of pharmaceutical products will remain undisclosed to third parties and, that during this period of protection, no person or entity (public or private), other than the person or entity who submitted such undisclosed data, rely directly or indirectly on such data in support of an application for medical product approved/registration.

It further says during this period, "any subsequent application for marketing approval or registration would not be granted, unless the subsequent applicant submitted his/her own data (or data used with authorisation of the right holder) meeting the same requirements as the first applicant. Product registered without submission of such data would be removed from the market until the requirements were met."⁴⁶

⁴⁵ Such is the objective of the rich countries, and multinational medicine companies spend large sums of money to lobby that their governments to impose FTAs on the weaker countries. Despite the economic slump, the US pharmaceutical and health products industry spent a whopping 267 million dollars in 2009 on lobbying more in one year than any other single industry ever spent. Ibid.

⁴⁶ Ibid.

It is obvious that the purpose is not only to block the production opportunity for Indian companies but also force many countries to buy medicines from the MNCs at much higher prices. Further, data exclusivity could effectively block compulsory licenses, which are a legal means to overcome a monopoly. Even if a company is given authority to produce the generic version of a drug under compulsory license, it still needs to register the drug with the DCGI in order to market it in or export it from India. Data exclusivity would prevent such registration for the period of exclusivity, thereby preventing the use of a compulsory license in that period. This is another method to allow the pharma multinationals' monopoly to continue.⁴⁷

4.3.1 Peripheral measures

But our government is not bothered about adverse impacts on Indian pharmaceutical exports. New barriers are being created through peripheral measures to curb export of Indian generic medicines. All of a sudden, EU customs officials are seizing Indian medicines exported to Latin American countries for suspected infringement of intellectual property rights under the European Commission's Customs Regulation No. 1383/2003. Though the destination were the Latin American countries, EU countries are halting our exports' movement en route though their regulations go beyond the TRIPS obligations. While India has challenged this intrusion, the proposed FTA has a clause of a similar nature. Article 27 says:

The parties shall, unless otherwise provided for in this Section, adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of goods infringing an intellectual property right may take place, to lodge an application in writing with competent authorities, administrative and judicial, for the suspension by the customs authorities of the release into free circulation or the retain of such goods." Here the term "importation" would mean, for the EC, exportation or re-exportation. Agreeing to such a clause would be detrimental to the export of Indian medicines.

4.3.2 Abrogation of commitments

In its haste to finalise an FTA with EU, our government has forgotten its commitments to international agreements. Mention worthy here is the Doha declaration of WTO, clearly stating that all care should be taken to safeguard public health before entering an agreement:

⁴⁷ Ibid.

We agree that the TRIPS agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS agreement, we affirm 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.⁴⁸

The WHO assembly on Global Strategy and Plan of Action (GSPA) on intellectual property, held in May 2008, made a similar statement:

to “take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection that is required by the agreement on trade related aspects of intellectual property rights.

The United Nation Special Rapporteur on the Right to Health has cautioned the nations about the problems emerging out of such FTAs:

These agreements are usually negotiated with little transparency or participation from the public, and often establish TRIPS-plus provisions. These provisions undermine the safeguards and flexibilities that developing countries sought to preserve under TRIPS. Studies indicate that TRIPS-plus standards increase medicine prices as they delay or restrict the introduction of generic competition. As FTAs can directly affect access to medicines, there is a need for countries to assess multilateral and bilateral trade agreements for potential health violations and that all stages of negotiation remain open and transparent.

It seems that the FTA will keep everything open for EU multinationals and impose a stronger patent regime than what the WTO agreement requires. Without considering the Indian people’s interest and ignoring the international commitments on the people’s health, the government is hurrying to finalise it.

5. 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

⁴⁸ See ministerial conference, fourth session, Doha on 14th November, 2001, available at www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.pdf, last visited (21st Oct. 2010).

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.

The gist of this ongoing controversy is that the European Union wants India to strengthen its IPR regime while India is hesitant to do so. Both sides have very valid reasons for sticking to their views. The only method of resolving this stand off is through both parties compromise on their stand to some extent. From a common Indian's point of view it would seem very reasonable to agree with India government who are not willing to give in to the EU demands in their current form. However, it is noteworthy that there are various quarters within India itself which are in favour of strengthening the IPR laws, specifically in favour of the data exclusivity law. The crux of the issue with respect to data exclusivity law is that test data which are products of long and intensive research, involves considerable amount of expenditure and so the innovator must have a right to reap the benefits of his efforts. This argument seems fairly reasonable, if only the consequences were not so far reaching, as is evident from the Indian side's view in a previous Section of this paper. A profit sharing arrangement must be developed by which generic manufacturers are allowed to reverse engineer patented drugs and market them in India; however a percentage of the profits should go to the patent holder. The question of what percentage of the profits amounts to reasonable compensation is a matter that will have to be negotiated by both parties, i.e. India and the EU.

Further, it is imperative that the Appellate body of the World Trade Organisation clarify the real purpose behind enacting Article 39(3) of the TRIPS agreement. There is no real defect in the law because intention of the framer of Article 39.3 was to allow sufficient flexibility to member states to apply and interpret law according to their local conditions and peculiar situations. Therefore, when India opines that it is not obliged to enforce the data exclusivity law, and the EU takes an opposing stand neither of them can be said to be wrong as developed countries can bear the cost of public health while the lesser developed nations cannot. We can thus conclude by saying that the Indo-EU FTA could eventually benefit both parties; however, we must be careful not to jump the gun.