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CROUCHING TIGER, HIDDEN DRAGON: THE TPP'S IPR CHAPTER – ISSUES AND CONCERNS FOR INDIA

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Having begun sometime in 2011, negotiations to draft the Trans Pacific Partnership Agreement (TPP) were concluded in a remarkable span of five years. Given the substantial sectoral coverage and wide membership, the potential market access gains make the TPP an attractive arrangement. It is in this context that many academics and analysts have made a strong pitch for India to join the TPP. However, some of the provisions in the TPP's IPR Chapter which are more protectionist beyond the norms contained in the TRIPS Agreement are a major cause of concern from a public policy perspective. This Article reviews the policy and legal issues and concerns that would arise if India were to conform its patents, trademark and drug regulatory laws to the standards in the TPP's IPR Chapter. Conformity for India, would mean that like other developing countries, it would have to amend many of its laws concerning IPR protection and drug regulation. This would erode the flexibilities available under TRIPS for safeguarding its socio-economic interests such as public health, and setting the platform for further TRIPS plus norms in the world trading system. Even the safeguards proposed in the TPP for interpreting and implementing these IP provisions in a manner conducive to public health do not assuage concerns since the nature of the IP protection standards do not leave any space for such interpretation and implementation. Based on the above analysis, this Article argues that India should very carefully consider seeking membership at the TPP if conforming to the protectionist standards in the TPP's IPR Chapter would jeopardize its socio-economic interests.

I. INTRODUCTION

For more than a decade, success has successfully eluded completion of the Doha Round. A severe blow was dealt in the 10th Ministerial Conference at Nairobi in December 2015 when certain Members went a step ahead and expressed their intent to 'euthanize' the Doha Round. While WTO Members are struggling to complete the marathon, some of the WTO Members have contributed to the growth of Free Trade Agreements (**FTA**) which continue to exponentially rise and fill what Jagdish Bhagwati famously called a "spaghetti bowl". Of the many interesting additions to this spaghetti bowl, there are three particular trade arrangements that are of particular importance and interest. These are the Transatlantic Trade and Investment Partnership (TTIP); the Regional Comprehensive Economic Partnership Agreement (RCEP); and also the Trans-Pacific Partnership (**TPP**).

Of the above mega-FTAs, the TPP created ripples in the world trading system when it was successfully concluded on 04th October 2015. Negotiated by over 12 countries across the Pacific, the TPP covers nearly 40% of the world's GDP. With enhanced market access for TPP member countries being posited as one of the main outcomes of the negotiations, some countries outside the TPP have made no secret their intention to seriously consider joining the TPP. One of the major reasons being advanced for seeking membership at the TPP is the loss on account of trade diversion to TPP Member countries.

At the same time however, several concerns have been raised regarding the normative standards that have been ingrained in the TPP, and the costs that conforming to these standards could present. Besides the WTO plus nature of some of these norms such as competition, environment and labour, the protectionist standards of IP protection that have been contemplated in the TPP are a grave cause of concern. Several interest groups have criticized the

TPPs IPR chapter for its potential to obstruct access to medicines[1]. These concerns particularly hold true for those developing countries that are part of the TPP and whose socio-economic conditions may not be ready for protectionist standards of IP protection.

As far as India is concerned, it is no secret that it is being encouraged to consider joining the TPP.[2] Several trade analysts have copiously written about the gains for India if it joined the TPP, and have thus pitched a strong case for India to seek membership in the TPP. However, any steps in such direction will require serious forethought and careful legal analysis on the implications of conforming to the various normative standards in the TPP. This paper is an attempt in this context.

The purpose of this paper is to review the issues that would arise if India took steps towards conforming the provisions of its IPR regime to that of the TPP's IPR Chapter; something that joining the TPP would definitely entail. The TPP's IPR Chapter covers six categories of intellectual property – geographical indications, patents, undisclosed commercial information, copyrights, trademarks and industrial designs. However, for the purpose of this Article, the possible implications that would arise if India took steps towards conforming its patents, clinical trial data and trademarks laws to the TPP's IPR Chapter are analysed. In the course of my analysis, I take TRIPS as the benchmark for a comparative understanding of India's IP protection obligations under the WTO and the available flexibilities.

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[1] Kajal Bhardwaj and Cecilia Oh, *The Trans-Pacific Partnership Agreement: Implications for Access to Medicines and Public Health*, March 2014, UNITAID, <http://www.unitaid.eu/images/marketdynamics/publications/TPPA-Report_Final.pdf>

[2] See Ashoke Nag, *US Keen on India's inclusion in the Trans Pacific Partnership*, The Economic Times, <http://articles.economictimes.indiatimes.com/2013-08-20/news/41429362_1_indian-ocean-myanmar-asean>

II. INDIA'S PATENT LAWS AND CONFORMITY TO THE TPP'S IPR CHAPTER

India's patent laws are a legacy of British colonial rule. The first statute, granting protection to inventions, was enacted in the year 1856.[3] Subsequently, a revised statute, the Indian Patents & Designs Act, 1911 was enacted.[4] However, it was not until 1970, that independent India enacted its first patent law – the Indian Patent Act, 1970. This Act was modeled on the British Patents Act but included significant flexibilities to suit India's developmental needs; for instance, product patents were not recognized for pharmaceuticals and agro-chemicals for health and food security purposes respectively. The Patents Act, 1970 and patents policy was primarily based on the Report on the Revision of the Patents Law by Justice N. Rajagopala Ayyangar, September 1959 which in no equivocal terms expressed the opinion that the standards of patent protection had to be commensurate with India's stage of development and development requirements.

However, the significant and inherent policy space embedded in India's patents laws did not stay for a very long time. India's tryst with the WTO required it to amend its patent laws in 2005 to conform to higher levels of protection. Notwithstanding, India was still able to embed many flexibilities in its Patent Act flowing from the TRIPS Agreement.

The TPP's IPR Chapter has standards of protection different from that in the TRIPS. Conformity in the Indian context to these provisions will definitely require further amendments if they are more protectionist than the TRIPS standards. This section reviews the provisions in the TPP's IPR Chapter pertaining to patents and assesses the changes that would be required in the Patents Act. This article also discusses the implications arising from conformity in the Indian context.

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[3] M Janodia, et al, *Patents Regime In India: Issues, Challenges And Opportunities In Pharmaceutical Sector*, The Internet Journal of Third World Medicine, 2007 Volume 7 Number 1

[4] *ibid*

A. Expanding the Scope of Patentability of an Invention

As per Article 27.1 of the TRIPS, the criteria for patenting an invention – whether a product or a process – is novelty, industrial applicability, and the presence of an inventive step. TRIPS does not define or stipulate the standard for any of these three criteria. Each WTO Member has been given the flexibility to determine its own standard in its applicable domestic IPR laws. As a result, each Member has been able to establish its own standards of patentability for an invention.

From the Indian perspective, this flexibility has been crucial in allowing patentability only for those inventions that are truly innovative and involve real effort and disallow patents for insignificant inventions. Section 3 of the Patents Act, 1970 establishes criteria as to what does not constitute a patentable invention of a given product. Section 3(d) is by far one of the most important provisions in Indian patent law as it aims to prevent *ever-greening* of pharmaceutical products, such that it would extend the monopoly of a patent holder beyond the term of the patent, viz., 20 years. Section 3(d) fundamentally disqualifies from patentability the *mere discovery* of:

i. a new form of a known substance which does not result in the enhancement of the know efficacy of that substance
ii. any new property or new use for a known substance
iii. mere use of a known process, machine or apparatus, unless such known process results in a new product or employs at least one new reactant

Furthermore, the explanation to section 3(d) clarifies that chemical derivatives of a known substance shall be considered to be the same substance unless there is a significant difference in efficacy of the derivative and the original substance. These standards of patentability in India's Patents Act show that the legislative intent has been to exclude inventions

that are not based on value addition from the scope of patentability.[5] It would seem that legislators intended to ensure a high threshold for an invention to receive patent protection.

It would be important to note that section 3(d) was however not immune from judicial challenge. In *Novartis vs Union of India*, pharmaceutical major Novartis challenged the rejection of patent for the beta crystalline form of *imatinib mesylate* (a drug for treating leukemia and tumors) by the Patent Office and the Intellectual Property Appellate Board. In certain appeals to the Madras High Court, Novartis had also vigorously attacked the provisions of section 3(d) as being ultra vires the Constitution of India and inconsistent with India's TRIPS obligations. These were however dismissed by the Madras High Court.

In appeal (by way of special leave) to the Supreme Court of India, the Supreme Court rejected Novartis' claims to patentability of the salt form of the above drug on the grounds that there was no enhanced efficacy of the drug.[6] In its judgment, the Supreme Court traced the history of patent law in India; discussed the TRIPS Agreement and India's obligations under it; and referred to the concerns raised in Parliament over access to medicines. Commenting on section 3(d), the Supreme Court stated:

> "*103. ....The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on*

[5] N. S. Gopalakrishnan, *TRIPS Flexibilities: The Case of India*, in *Intellectual Property Rights and Access to Medicines*, in *Intellectual Property and Access to Medicines*, World Health Organization, Regional Office for South-East Asia, 2010, Reprint by South Centre 2013, at page 76 [Hereinafter "*Gopalakrishnan – TRIPS Flexibilities*"]

[6] *Novartis AG vs. Union of India*; Civil Appeal Nos. 2706-2716 of 2013, pages 90-94

spurious grounds."[7]

The Supreme Court's jurisprudence reiterates that the scope of patentability under the Patents Act does not extend to an invention which is akin to old wine in a new bottle, unless there is an enhancement of efficacy.

While the standards of patentability laid down in the Patents Act are reasonably strong, the protectionist standards as provided for in the TPP would result in expanding the scope of patentability and concomitantly diluting high standards of patentability. A review of some of the provisions in the TPP's IPR Chapter shows that these countries are also attempting to erode the TRIPS flexibility by expanding the scope patentability under the domestic IPR regime. According to paragraph 2 of Article 18.37 of the IPR Chapter's section on patents:

> *2. Subject to paragraphs 3 and 4 and consistent with paragraph 1,* ***each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product.*** *A Party may limit those new processes to those that do not claim the use of the product as such.*

This provision is in opposition to the sum and substance of section 3(d) of the Patents Act; conformity would mean deleting section 3(d). Sean Flynn, et al in a comprehensive paper on the TPP's IPR chapter, are of the opinion that these provisions are probably targeted against India, and drafted with a purpose to counter the policy embedded in section 3(d) even though India is a not a Party to the TPP.[8] Conformity of section 3 to the above standard in

[7] *id* at page 56

[8] Flynn, et al at page 153. Commenting on Article 8.1 of the February 2011 draft (which is similar in substance and effect to Article QQ.E.1 of the May 2014 draft).

would dilute the fundamental standard of patentability as such which Indian legislators have sought to preserve. The TPP standard aims at granting patents for inventions which are merely variations and not entirely new. However, as per generally accepted patent jurisprudence, patents are to be granted only for inventions that meet the "novelty" criterion. According to renowned TRIPS commentator Carlos Correa, the expansion of the patentability scope by means such as admitting broad claims and diluting patentability requirements would profoundly distort the patents system.[9] Correa also is of the opinion that "as incremental inventions prevail in most sectors, the patent system has increasingly moved away from its objective of stimulating genuine “invention” towards a system for the protection of investment in incremental invention, whether truly incentive or not".[10]

The second concern pertains to the implications for access to medicines in India. The above conformity steps would open the floodgates for evergreening of pharmaceutical patents in India through new forms/new uses of a pharmaceutical drug even if there is no enhanced efficacy of the drug. A country’s patentability standards should be commensurate with its development interests which include the physical health and well-being of its people.[11] A standard which puts generic pharmaceutical products out of reach for a significant proportion of its population on account of monopoly vested with the originator would be inimical to the health interests of its people.

B. Extending Patent Terms

The minimum term of a patent under TRIPS Article 33 is 20 years from the

[9] Carlos M Correa, *Patentability Standards: When is an Invention Patentable*, in *Intellectual Property Rights and Access to Medicines*, in *Intellectual Property and Access to Medicines*, World Health Organization, Regional Office for South-East Asia, 2010, Reprint by South Centre 2013, at page 45

[10] *id* at page 46

[11] *Gopalakrishnan – TRIPS Flexibilities, supra* note 11 at page 78

date of filing. The IPR Chapter does not specify the term of a patent; TRIPS is likely to prevail as the minimum standard of obligation for all Members. However unlike TRIPS, there are provisions in the IPR Chapter which provide for extension of patent term in certain circumstances. While paragraph 3 of Article 18.46 requires Parties to provide for patent term adjustment to compensate for delays in issuance of patents, paragraph 4 permits a Party to exclude from the determination of such delays, periods of time: that do not occur during the processing of, or the examination of, the patent application by the granting authority; that are not directly attributable to the granting authority; that are attributable to the patent applicant.

However, the real pinch concerning patent term adjustment does not arise in the context of delays in issuance of patents but in the context of the delays in granting marketing approval for pharmaceutical products. Paragraph 1 of Article 18.48 requires Parties to make best efforts to process applications for marketing approvals of pharmaceutical products so as to avoid unreasonable or unnecessary delays. Paragraph 2 of Article 18.48 requires each Party to extend the term of a pharmaceutical patent to compensate for delays arising as a result of the marketing approval process. A conspicuous difference is that unlike adjustment of patent term extension for grant of patent where delays not attributable to the patent office and delays attributable to the patent applicant can be factored, there is no flexibility in adjusting patent term extension on account of such delays.

It is important to note that the draft provisions (Article QQ.E.14) when proposed by the United States in the August 2013 draft were opposed by the ten other countries negotiating the TPP. However, in the May 2014 draft, opposition around Article QQ.E.14 seemed to have vanished.

Section 53 of the Patents Act provides that the term of a patent shall be 20 years from the date of filing the application for grant of patent. There are no

provisions in either the Patents Act or the Drugs and Cosmetics Act patent term extension due to unreasonable delay in grant of patent or marketing approval. If India decides to conform either of the above statutes to Article Article 18.48 then the statutes will have to accordingly be amended to allow for patent term extension in case of delays on account of grant of marketing approval.

It is easy to understand where demandeurs of patent term extension on account of delays in marketing approval are coming from: due to delays in granting regulatory approval, the effective period of exploitation of a patent is curtailed. However, the demandeurs for such provisions may be rushing to place the onus on drug regulators for delaying the approval of pharmaceutical drugs without understanding the reason for delays in granting regulatory approval. In the United States, the Food and Drug Authority (FDA), has faced heavy criticism for the delays in granting regulatory approvals for pharmaceutical drugs. However, a study conducted by researchers associated with the FDA on regulatory and scientific reasons for delay in granting regulatory approval by the FDA for New Molecular Entities (NME) for the period 2000-2012 concludes that:

> "*Several potentially preventable deficiencies, including failure to select optimal drug doses and suitable study end points, accounted for significant delays in the approval of new drugs. Understanding the reasons for previous failures is helpful to improve the efficiency of clinical development for new drugs.*"[12]

The study cites that many drugs are not approved by the drug regulator because the information supplied by the applicant is unsatisfactory to make determinations of safety or efficacy. As a result, the applicant has to

[12] Sacks LV, et al, *Scientific and Regulatory Reasons for Delay and Denial of FDA Approval of Initial Applications for New Drugs, 2000-2012.* Journal of American Medical Association, 2014;311(4): 378-384. doi:10.1001/jama.2013.282542

resubmit the information for receiving approval, thereby delaying drug approval process.[13] In such a scenario, it would not be appropriate to push extend a monopoly over a drug on grounds of delay in granting regulatory approval.

On the flip side, extension of patent terms on account of administrative or regulatory delays is a serious issue not just in the context of development of generic medicines but the development of originator drugs. Patent term extension may pressurize drug regulators to expedite the approval of drugs: this may compromise the safety, quality and efficacy of drugs, the assessment of which is the regulator's responsibility. Drug approval is a major legal and moral responsibility; drug regulators need to exercise extreme caution in an objective manner without being pressurized by commercial concerns. As the infamous thalidomide case reminds us, it is better to be safe than sorry.

Besides the above factors, it is important to note that the current term of twenty years for patents itself came to be established on account of administrative and regulatory delays. If one compares the history of patent laws of developed countries such as United States, patents were for a terms of much less than twenty years.[14] Under the Patent Act, 1790 of the United States, patents were granted for a term of 14 years.[15] It was increased in 1836 to 21 years taking into account a 7 year term extension.[16] However, again in 1861, the United States brought it down to 17 years without the possibility of extension.[17] The very purpose of rationalizing patent terms to twenty years under the TRIPS Agreement was to factor administrative and

[13] *Ibid* at page 379

[14] *Patent Term Calculator: History of Changes to Patent Terms*, United States Patent and Trademark Office, <http://www.uspto.gov/patent/laws-and-regulations/patent-term-calculator>

[15] *ibid*

[16] *ibid*

[17] *ibid*

regulatory delays.

Besides the above, there is another patent-related concern. According to IP jurisprudence, the idea of IPR is not to give the holder the exclusive right to use the property to the exclusion of others; instead, the objective of IPR is to prevent others from exploiting the patent without the consent of the owner. This is also the statutory position in most countries including India. According to section 48 of the Patents Act, 1970, on the rights of patentees, a patent granted under the Patents Act confers upon the patentee the exclusive right to prevent third parties from exploiting without consent the product or process under patent.

Drug regulators in both developed and developing countries are burdened due to the increasing number of applications for regulatory approval while being faced with a shortage of resources such as manpower. In the United States for instance, the process of approving generic drugs has slowed to hit a 6-year low.[18] However, efforts are being made in the wrong direction by way of patent term extension to address the issue of regulatory delays. Augmenting the resources of a constrained regulator, and pharmaceutical companies improving upon the quality of clinical trial information they provide, would go a long way in reducing regulatory approvals to vital life saving medicines.

[18] *US generic drug approval delays hit growth plans of Indian Firms*, The Economic Times, 02nd December 2014,
<http://articles.economictimes.indiatimes.com/2014-12-02/news/56649153_1_drug-approval-usfda-drug-applications>

III. INDIA'S DRUG REGULATORY LAWS AND CONFORMITY TO THE TPP'S IPR CHAPTER

A. TPP's Inclusive Approach to Data Exclusivity

In order to be able to market a drug, a drug manufacturer has to receive regulatory marketing approval from the drug regulatory authority. The basis for regulatory approval is the safety and efficacy of the drugs proven by the data generated by clinical trials and submitted to the drug regulatory authority. Clinical trial data forms the key component of applying for and receiving marketing approval for a drug. In case of a generic drug, it would be simple and feasible for the generic drug manufacturer/applicant to rely on the clinical data previously submitted to the drug regulator by the parent drug manufacturer for obtaining marketing approval rather than repeating the rigorous and costly exercise. However, data exclusivity would restrict such a practice for a certain period of time.

This effect of data exclusivity is that it would prevent a generic manufacturer from relying upon clinical trial data previously submitted to show that its drug meets the required safety and efficacy standards. As a result, the generics manufacturer would have to carry out its own test of the generic drugs. This would entail costs and time, and delay the entry of generic drugs into the market. Besides, re-conducting such tests would pose unnecessary costs to the economy and society when viewed from a broader economic perspective. A simple solution would be to *refer* to the clinical trial data already submitted by the originator pharmaceutical company, or evidence of such marketing approval obtained in other countries. This is a flexibility which developing countries have interpreted as permissible under the TRIPS Agreement.

Article 39 of the TRIPS Agreement obliges Members to take steps for the protection of "undisclosed commercial information". According to paragraph 3 of Article 39:

> *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.*

Though Article 39.3 specifies protection of "undisclosed commercial information", developed countries have interpreted the same to include within its scope clinical trial data. Such an interpretation gives rise to the meaning that TRIPS mandates exclusivity of clinical trial data. However, there are two qualifications inherent in Article 39.3. First, Article 39.3 requires data protection only against "unfair commercial use", a term which has not been defined under the TRIPS Agreement. It is difficult to construe the reliance on previously submitted clinical trial data as an "unfair commercial use". Furthermore, it is very important to note that in granting marketing approval based on prior approval or previously submitted clinical trial data, the drug regulators are only making a ***reference***; there is no ***use*** as such by any entity, which is what is proscribed by Article 39.3.

Second, Article 39.3 allows Members the flexibility to refuse data protection for purposes of "protection of the public", yet another term which is undefined under TRIPS. This is a broad phrase which could by all means be interpreted to refuse data exclusivity for public health purposes; such an interpretation is possible in light of the provisions of Article 7 and Article 8 of the TRIPS Agreement, which envisage the protection of public interests, and also the Doha Declaration on TRIPS and Public Health. It would appear that developing countries such as India have refused data exclusivity based on these flexibilities

In the TPP however, it would appear that there in an attempt to entirely circumvent such flexibilities and ensure data exclusivity. Upto the February 2011 draft, proposals on data exclusivity provisions were confined to agricultural chemical products. However, beginning with the August 2013 draft, there have been provisions which seek to extend data exclusivity to pharmaceutical products as well. This was however opposed by most TPP countries.

The proposals regarding data exclusivity later spilt over into the May 2014 draft where the negotiating position almost consolidated leaving very limited opposition. Clause (a) of Article 18.50 requires Parties to prohibit granting marketing approval to third parties (generic producers of a generic pharmaceutical product) on the basis of clinical trial data previously submitted by the originator of the pharmaceutical product, or even the marketing approval granted to the originator, without the consent of the originator. The term of restriction is five years from the date of marketing approval of the pharmaceutical product in the territory of the Party. Clause (b) of Article 18.50 prohibits Parties from permitting generic producers from submitting evidence of prior marketing approval granted in another country except with the consent of the originator producer. This provision as well provides exclusivity for a period of five years from the date of marketing approval of the pharmaceutical product in the other country.

During the negotiations, Malaysia had made a surprising proposal to extent the restriction on reliance on prior marketing approval given in even non-TPP countries. Chile was the only country that developed a proposal that is aimed at facilitating access to medicines: Chile proposed allowing grant Parties to have the autonomy to decide on granting marketing approval for pharmaceutical products based on prior marketing approval.

The effect of Article 18.50 is that it prevents generic manufacturers of drugs from obtaining marketing approval based on the clinical trial

data/marketing approval of the originator. The above provisions prima facie appear to restrict the objectives of access to medicine and public health since they limit the ability of generic drug manufacturers from using clinical trial data previous submitted to the drug regulator. However, attention is invited to the additional provisions in the TPP. As per paragraph 3 of Article 18.50, *notwithstanding* the provisions of paragraph 1 of Article 18.50, a Party is entitled to take measures to protect public health in accordance with the (a) Declaration on the TRIPS Agreement and Public Health; (b) any waiver of any provision of the TRIPS Agreement granted by WTO Parties in accordance with the WTO Agreement to implement the Declaration and in force between the Parties; or (c) any amendment of the TRIPS Agreement to implement the Declaration that enters into force with respect to the Parties. But these provisions might not provide the saving grace for reasons discussed in Section VI.B of this Article.

The legal framework for regulatory approval of pharmaceuticals is contained in the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 ("**Drug Rules**") framed therein under. Provisions for clinical drug trials/marketing of a drug are contained in Part X-A of the Rules. Rules 122-A and 122-B are the main provisions pertaining to regulatory approval for importing and manufacture of drugs respectively. In order to import a new drug into India, an importer will have to obtain permission from the licensing authority.[19] In order to receive approval from the licensing authority, the importer is required to submit local clinical trial data to demonstrate the safety and efficacy of the imported drug in the Indian context.[20]

However, in case of a drug which is necessary for public interest, the submission of local clinical trial data may not be necessary. The licensing

[19] Sub-rule (1) of Rule 122-A

[20] Sub-rule (2) of Rule 122-A

authority may in such a case decide to grant approval based on clinical trial data available from other countries.[21]

The relevant provisions for manufacture/sale of a new drug are contained in Rule 122-B. The Drug Rules proscribe the manufacture or sale of a drug in India without approval from the drug regulatory authority.[22] Similar to Rule 122-A, a manufacturer of a new drug will have to provide clinical trial data pertaining to the efficacy and safety of the drug,[23] in order to obtain approval. What is important to note here is that Rule 122-B does not require the applicant to submit clinical trial data generated conducted by itself; the Drug Rules only require the submission of clinical trial to prove efficacy and safety of the drug. Since the Drug Rules *do not prohibit* the reliance upon third party data, the drug regulator is not prohibited from considering the already available data on the basis of which it has granted regulatory approval to another manufacturer. Another important provision in Rule 122-B is that the licensing authority is permitted, in public interest, to grant approval based on clinical trial data available from other countries.[24]

From the above provisions, we can understand that consent is not a prerequisite for the use of third party clinical trial data. Data exclusivity provisions are in effect absent from Indian law as far as pharmaceuticals are concerned.[25] On the other hand originator consent is at the heart of the data exclusivity provisions in the TPP's IPR Chapter. If India intends to conform to the TPP's standards, it may require amending the Drugs and Cosmetics Rules. This would definitely curtail India's policy space with regard to access

[21] Proviso to sub-rule 2, Rule 122-A

[22] Sub-rule (2) of Rule 122-B

[23] Sub-rule (2) read with (sub-rule 2A) of Rule 122-B

[24] Proviso to sub-rule (3) of Rule 122-B

[25] In comparison, there is a legislative proposal pending for data exclusivity in agro-chemicals. Sub-clause (6), clause 12 of the Pesticides Management Bill, 2008 pending in the Indian Parliament provides for data exclusivity for a period of three years in respect of pesticides.

to medicines.

It is possible to understand the legal rationale underlying data exclusivity the text of TRIPS Article 39.3 requires the protection of data from "unfair commercial use". Owing to pressure from the pharmaceutical associations in developed countries, demandeurs might cite the proprietary nature of data and the millions of dollars invested into the research and development that goes into producing new drugs. However, as Reichman points out, "*given that originator pharmaceutical companies would have recouped their investments and made their profits by charging high prices in developed countries, it is hard to justify any further protection of investments in R&D beyond territorial patents in the developing countries*".[26]

Correa too addresses this issue from the perspective of legal injury. According to Correa:

> "*The law condemns taking advantage of another's efforts when it is the result of an illegal act, or of an act, which although legal, is dishonest or unfair. In other words, what the law condemns is not the effect of a commercial behaviour (reducing a competitor's market share), but the manner in which such effect is obtained*."[27]

Correa also gives an insightful economic perspective against data exclusivity rules: "*Companies follow attentively what their competitors do and, within the framework of commercial and industrial freedom, attempt to use all the means they can to increase the number of their own customers. If all*

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[26] Jerome H Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case For a Public Goods Approach*, Marquette Intellectual Property Law Review, 13:1, 2009 [Hereinafter "Reichman"] at page 36

[27] Carlos Correa, *Protection of Data Submitted For The Registration of Pharmaceutical Products: TRIPS Requirements and "TRIPS-Plus" Provisions*, *Intellectual Property and Access to Medicines*, World Health Organization, Regional Office for South-East Asia, 2010, Reprint by South Centre 2013, at pages 163-164

use of another's efforts were to be considered as legally prohibited, the market economy, as we know it today, would cease to function. In fact, the dynamics of competition suppose that all economic agents will attempt to take advantage of their competitor's efforts, which would certainly not be illegitimate, unless they were to engage in illegal or morally reprehensible behaviour which could be considered as "unfair"."[28]

In case of seeking abridged approval by referring to previously submitted clinical trial data, it is not the generic manufacturer which relies necessarily has access to or uses the data submitted by the originator company when applying for regulatory approval.[29] It is the drug regulator that, by reference to the first product, relies on the data.[30]

B. Creating a Link That Doesn't Exist: Patent Linkage

The mandate of the drug regulatory authority is to act as a checkpoint for the safety, quality and the efficacy of a pharmaceutical product. However, the TPP's IPR Chapter contains provisions which impose patent-related enforcement obligations on drug regulators. Article 18.51 imposes certain obligations on a TPP Party if it permits third parties to rely on evidence or information concerning safety or efficacy (such as evidence of prior marketing approval) of a pharmaceutical product that has been previously approved by a Party or in another territory (which may not be a TPP Party). If a Party permits such reliance then clause (a) requires a Party to provide a system to provide notice to a patent holder or allow for a patent holder to be notified to the marketing of the pharmaceutical product that the third party is seeking to market the product during the term of the patent. Clause (b) read with clause (c) of Article 18.51 additional requires the Party to give the patent holder adequate time and opportunity to seek administrative and judicial remedies such as injunction prior to the marketing of an allegedly

[28] *ibid*

[29] *ibid*

[30] *ibid*

patent infringing pharmaceutical.

Paragraph 2 of Article 18.51 provides an obligation alternative to the one specified in paragraph 2. According to paragraph 2, a Party is required instead adopt or maintain a (non-judicial) system that precludes the grant of marketing approval to a third party seeking to market a pharmaceutical product which is subject to a patent unless the patent holder consents or acquiesces to the same. The source of information that such system is to be based upon is patent-related information submitted to the marketing approval authority by a patent holder or the applicant for marketing approval, or based on direct coordination between the marketing approval authority and the patent office.

From the above provisions, it is very clear that the drug regulatory authority is being vested with additional obligations which pertain to patent enforcement. There are several issues with this proposition. First, this burdens an already burdened regulator, which is primarily constituted and tasked with the onerous obligation to review pharmaceutical products for quality, safety and efficacy. This goes against the nature of duties and the purpose for which the drug regulator has been constituted. A related issue is that the patent-linkage mechanism can further delay an already a system that is already faced with delays.

Second, an important point to be made is that the onus of surveillance, which is essentially the duty of the right-holder, is being shifted from a private person to a public authority. This is an unnecessary diversion of public resources, which can instead be used to strengthen the drug regulatory authority. Third, not only is the drug regulatory required to inform the patent-holder of possible infringement, the drug regulator is also required to not grant marketing approval till issues of patent infringement are adjudicated. This is on an absurd assumption that the third party (the generic manufacturer) will launch the pharmaceutical even if the patent is

subsisting. There is thus no reason to associate grant of marketing approval with existence of a patent. The appropriate remedy would be for the right-holder to seek an injunction when the third party has initiated steps to launch the generic pharmaceutical after receipt of marketing approval, which is already available under Indian law. Further, adjudication of patent infringement may take inordinate period of time for settlement. This is bound to further delay the entry of generic pharmaceuticals

India's Drugs and Cosmetics Act are oblivious to the notion of patent for the purposes of granting regulatory approval. Conformity to the TPP provisions would mean introducing, by way of amendment to the Drugs and Cosmetics Act, provisions for patent linkage. However, Indian jurisprudence on the subject of patent linkage gives valid reasons against patent linkage. In the case of *Bristol-Myers Squibb Co vs. Hetero Drugs Ltd*[31], the Delhi High Court had granted an ex-parte injunction in favour of Bristol-Myers staying the approval process of a generic drug which had been submitted by Hetero Drugs to the Drug-Controller General of India.[32] The decision was not uncontroversial to say the least.

However, in the subsequent decision of *Bayer Corporation vs. Cipla and Ors*[33], a single judge bench of the Delhi High Court reversed the jurisprudence and held that no such system could be read into Indian law. The court expressly recognized the difference in objectives of the patent law and the drug regulation law in the country. According to the Delhi High Court, the DCGI, which was established for the purpose of checking drugs for their safety, efficacy and quality could not be expected to discharge obligations under the Patents Act. The decision was first appealed to a Division Bench of the Delhi High Court, which dismissed the appeal and

[31] C.S(OS) No. 2680/2008

[32] Orders passed in *Bristol-Myers Squibb Co vs. Hetero Drugs Ltd*, High Court of Delhi, IA No. 15774/2008 arising out of CS(OS) No. 2680/2008

[33]WP(C) No.7833/2008

upheld the single bench judge's ruling. The decision was further appealed by Bayer Corporation at the Supreme Court of India. The appeal was however dismissed.

The TPP's provisions on patent linkage, which are clearly TRIPS plus, are seem to be solely intended for the purpose of blocking the entry of generic pharmaceuticals into the market. While it is legitimate for a patent holder to expect that his patent not be exploited by another person except with his consent, or in accordance with the patent laws if without his consent, it may be excessive to expect the drug regulator to take on obligations akin to enforcement.

IV. INDIA'S TRADEMARK LAWS AND CONFORMITY TO THE TPP'S IPR CHAPTER

Besides implications for the patents regime and the drug regulatory regime, conformity in the context of the Indian trademark regime as contained in the Trade Marks Act, 1999 could also pose serious implications. These are discussed below.

A. You Shall Not Pass![34] Border Measures Against "Confusingly Similar" Goods

Counterfeiting and trade in counterfeited trademark goods, and piracy and trade in pirated copyright goods are perhaps one of the biggest challenges faced by IP enforcement and customs officials world over. IP-related border measures exercised by customs officials are important in eliminating trade in counterfeited trademark goods and pirated copyrighted goods. The TRIPS Agreement allows Members considerable flexibility in designing the mechanisms for enforcement of IP rights at the borders. However, provisions have been mooted in the TPP's IPR Chapter which distort what is

[34] To those who may not be familiar with this quote, it is taken from the movie *The Lord of the Rings: The Fellowship of the Rings*, in which Gandalf famously utters this line while preventing a fierce and malevolent creature from obstructing him and his motley lot.

intended under the TRIPS Agreement.

Paragraph 1 of Article 18.76 of the TPP's IPR Chapter requires Parties to provide for applications to suspend the release of, or to detain, any suspected counterfeit or confusingly similar trademark or pirated copyright good that is imported into the territory of a Party. The notion of "confusingly similar goods" which was first known to the public in the February 2011 draft, was then carried over to the August 2013 draft and the May 2014 drafts.

The provisions on border measures in the TPP prima facie seem benign and legitimate for the protection of the right holders. It is also *seems* consistent with the TRIPS norms. However, what needs to be understood is the extension of the scope of these measures to "confusingly similar" trademarked goods. Article 51 of the TRIPS Agreement requires, as part of border measures concerning IPR protection, the suspension of release of goods which are *counterfeited trademark goods*. However, the TPP's IPR Chapter goes a step ahead in extending the scope of the measures to "confusingly similar" trademarked goods. The effect of this Article 18.76 is that it would result in juxtaposing goods similar to trademarked goods, but which are not counterfeited, within the definition of counterfeit goods. This is clearly TRIPS inconsistent and is liable to challenge at the WTO's dispute settlement mechanism.

The above provision would have the effect of throwing a huge net around generic medicines as customs officials even from developing countries Party to the TPP would be compelled to seize imported generic drugs for the reason that they are "confusingly similar" to the parent drug. The effect of such provisions is that it would be a deterrence of legitimate trade in generic drugs between countries. The provision also reminds countries of the troubling incidents that took place in May 2009 when German customs authorities seized consignments of the generic drug Amoxicillin

manufactured by India-based Medopharm destined to a Vanuatu on the grounds of alleged trademark infringement. In this instance, German customs authorities seemed ignorant of the fact that the goods in question were not "counterfeited trademark goods" and instead conflated the phrase with "confusingly similar" goods. Though the consignments were ultimately released, it highlights the problems that could arise if "confusingly similar" was the global norm as against the extant TRIPS norm.

Another problem pertains to the destination of the goods in question. Paragraph 5 of Article 18.76 requires that the border enforcement authorities of TPP countries should have the power to initiate border measures *ex officio* for goods that are not only imported or destined for export, but also in transit. This norm is beyond the obligation under Article 51 (read with footnote 13) of the TRIPS Agreement which provides member countries the discretion on whether to extend border measures to in transit goods. During the TPP negotiations, Canada has proposed excluding goods in transit from the scope of border measures. However, clearly, Canada's proposal did not see much support and was not successful.

The threats to legitimate trade in generic drugs as a result of the aforesaid TPP's provisions pertaining to border measures can be understood by the same example of the 2009 seizure by EU customs authorities of Indian-manufactured generic drugs destined to South American countries transiting through Europe. If the scope of destination with respect to "confusingly similar" goods were to extend to in transit goods, this would entail TPP countries across both sides of the Pacific Ocean to seize such drugs, further hindering legitimate trade in generic drugs. Generic drug exporters from countries such as India would have to be wary of transiting through TPP countries.

Border measures pertaining to the protection of IPRs in India have foundation in the Customs Act, 1962. Section 11(2)(n) of the Customs Act

empowers the Central Government to prohibit importation and exportation of any good for the purpose of protecting patents, copyrights and trademarks. Border measures pertaining to imported goods are also contained in the conditions and procedures as specified in the Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007. In respect to section 11(2)(n), the Department of Revenue [under Ministry of Finance, Government of India] has issued Notification No. 51/2010-Customs (N.T.) dated 30th June 2010. This Notification prohibits the import of goods intended for sale in India which have applied a false trade mark; false trade description; violate copyright under the Design Act; violate patent rights; and infringe copyright. Instructions to the customs authorities have been provided by way of Circular No. 41 /2007- Customs dated 29th October 2007 issued by the Central Board of Excise and Customs.

The border measures in the Indian legal framework described above do not recognize the category of "confusingly similar goods". The legal framework in respect of border measures described above is consistent with the TRIPS norms and will not affect legitimate trade. However, the provisions in Article 18.76 pertaining to "confusingly similar" goods raise serious questions. While conformity to the TPP's standards in respect of border measures will require changes in the applicable Indian laws, the government should be very mindful that such a move is TRIPS inconsistent and would expose itself to litigation at the WTO.

Furthermore, conformity by India to the TPP standards discussed above will sound the death knell for legitimate trade in generic drugs. Hailed as the pharmacy to the developing world, India's exports of generic drugs are crucial to several developing countries which do not have a mature manufacturing base for generic drugs in their countries. Provisions of such a nature also militate against the spirit and text of the Doha Declaration on Public Health.

B. Expanding the Scope of Trademark: More Than Meets the Eye

The very notion of trademark has been understood to be a sign that is visually perceptible. However, the TPP's IPR Chapter seeks to enlarge the scope of trademark by requiring Parties to allow for marks other than those of visual perception such as sound marks and smell marks. According to Article 18.18 of Section C of the IPR Chapter, no Party may deny registration of a trademark for the reason that the sign of which it is composed of is a sound. Additionally, Parties are required to make best efforts to register scent marks. The provisions regarding the types of signs registrable as trademarks have been diluted in the course of negotiations. In the May 2014 draft, Article QQ.C.1 the scope of the obligation was broader as countries were required to allow registration of even scent trademarks. However, probably owing to opposition from countries such as Vietnam, Brunei, Canada and Japan for registrability of trademarks for scents, the provision seems to have been diluted to the nature of a "best endeavour" obligation.

The implication of acceding to the above provisions for India's trademark regime is that definitional changes will be required to the Trade Marks Act, 1999. As per the current definition of a trade mark under clause (zb) of sub section (1) of section 2, "trade mark" means a mark capable of being represented graphically and which is capable of distinguishing the goods or services of one person from choose of others and may include shape of goods, their packaging and combination of colors. Clause (m) of sub section (1) of section 2 defines "mark" to include a device, brand, heading, label, ticket, name, signature, word, letter, numeral, shape of goods, packaging or combination of colors or any combination thereof. The essence of the definition of trademark in Indian trademark law is thus *visual representation*.

If India decides to conform its trademark laws to the TPP's IPR Chapter, India may be required to amend section 2 of the Trade Marks Act to allow for non-traditional trademarks. A serious implication of including scents

within the ambit of trade mark is that a generic drug having a scent similar to a parent drug could be susceptible to IPR enforcement on grounds of trade mark infringement. Such implications for access to medicines are better described by Gopakumar and Smith:

> *"Non-traditional trademarks have direct implications for access to medicines, because the medicine market is highly brand driven. Physicians often prescribe by brand name, leaving consumers little choice. Moreover, consumers may be reluctant to switch to a product with a different taste or smell. Meanwhile, due to the monopoly that results from patent protection, the originator company has ample time to build brand awareness. The pharmaceutical industry may try to use a taste mark or smell mark to block generic competition. This could delay generic competition, and result in prices of medicines remaining high even in the absence of patent monopoly."*[35]

Gopakumar and Smith's concerns are not unfounded. Given how attempts are being made by certain countries to expand the scope of trademark infringement and also the scope of enforcement action in respect of trademark infringement, extending non-traditional trademarks for scents could pose a problem for access to medicines. Though there has been no case yet involving enforcement action in respect of generic medicines for violation of a non-traditional trademark, the same should not be taken lightly; there is need to examine carefully the implications for access to medicines that would follow if registrability of trademarks for scents are allowed. In this context, in its bid to ramp up investor-friendliness and business development, India should not eager to recognize non-traditional trademarks such as scents.

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[35] K M Gopakumar and Sanya R Smith, *IPR Provisions in FTAs: Implications for Access to Medicines*, in *Intellectual Property and Access to Medicines*, World Health Organization, Regional Office for South-East Asia, 2010, Reprint by South Centre 2013, at pages 176-177 [Hereinafter "Gopakumar and Smith"]

V. PUBLIC HEALTH SAFEGUARDS IN THE TPP: NOT SO SAFE; NOT MUCH OF A GUARD

An analysis of the key provisions of the TPP's IPR Chapter, particularly in the context of patents in Section II leads us to extrapolate that access to medicines will be a major area of concern. Interestingly, TPP's IPR Chapter carries provisions that accord recognition to public health concerns. Similar to Article 8 of the TRIPS Agreement, Article 18.3 recognizes the discretion of Parties to adopt measures necessary to protect public health and nutrition, and to promote public interest in sectors of vital importance to its socio-economic and technological development. More specifically undertakings for TPP Parties are provided in Article 18.6, paragraph 1 of which requires Parties to affirm their commitment to the Declaration on TRIPS and Public Health. Clause (a) of paragraph 1 specifically states that:

> *The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all. …*

Clause (b) of Article 18.6 further states that the TPP's IPR Chapter does not and should not prevent the effective utilisation of the four WTO instruments concerning the TRIPS agreement and public health.

Even though the provisions of Article 18.6 expressly recognize public health and access to medicines priorities, concerns arises from the text of clause (c) of Article QQ.A.7. As per this clause, if the TRIPS Agreement is amended or a waiver is received/ granted under the TRIPS Agreement, Parties are required to consult with each other in case of application of a measure, pursuant to an amendment of the TRIPS or a waiver under the TRIPS, being

in conflict with the IPR chapter provisions of the TPP. Undoubtedly the provisions of this clause are vague and lack clarity as to the nature of consultations and what is expected between Parties. This spells uncertainty for any prospective developments in the context of TRIPS and access to medicines.

However, it is very important to note that clauses (a) and (b) of Article 18.6 are not without concern either. Even if they expressly intend that the interpretation and implementation of the IPR provisions should be in a manner conducive to protection of public health, the nature of the provisions in the TPP's IPR Chapter pertaining to patents, border measures and trademarks, makes it difficult to interpret and implement them in such a manner. These safeguards can be effective only if there is some degree of flexibility in the legal provisions. In fact, a major part of the Doha Declaration on TRIPS and Public Health was about clarifying that the inherent flexibilities in the TRIPS Agreement could be interpreted and used for purposes of protection of public health, and not just protection of private intellectual property.

The result of the Doha Declaration is that is allows developing countries such as India to confidently interpret TRIPS as allowing for flexibilities such as not maintaining a data exclusivity regime under Article 39.3; allowing for compulsory license for essential pharmaceuticals; enhanced (therapeutic) efficacy as a criteria for patents in case of known substances, etc. However, as discussed in the previous sections, threshold for patentability; clinical trial data reference; and standards for border enforcements commensurate with TRIPS stand negated upon conformity to the TPP's protectionist standards. In such a context, the public health safeguards envisaged in the TPP may not be of much support, and may merely be desultory in result.

Furthermore, even if it is assumed that the TPP's IPR Chapter contains flexibilities related to protection of public health, past practice by certain

developed countries in the WTO raises uncertainty over whether TPP Parties will be able to exercise these flexibilities. The *EU-Seizure of Generic Medicines*[36] between India and the EU is case in this point. The seizure of a sizeable number of generic drug consignments manufactured in India and destined for developing countries such as Brazil[37] and Vanautu[38] is a grim reminder of how IP protection standards can be used as constructing barriers to legitimate trade in generic drugs inspite of guarantees in the WTO for access to medicines/public health under the Doha Decisions and Declaration.

The issue has been adequately highlighted by India in the WTO TRIPS Council. According to India:

> "*It is ironical that while on one hand WTO has taken steps to promote access to affordable medicines and remove obstacles to proper use of TRIPS flexibilities, on the other hand some Members seek to negate the same by seizing drug consignments in transit and creating barriers to legitimate trade*."[39]

India further added:

> *In addition to going against the spirit of a rules based trading system and impeding free trade, such acts represent a distorted use of the TRIPS Agreement and the international IP system and*

[36]*European Union and a Member State Seizure of Generic Drugs in Transit*, WT/DS408 and WT/DS/409. See Request for Consultations by India here and by Brazil here.

[37]The active pharmaceutical ingredient (API) of the drugs destined to Brazil from India which were seized by Dutch customs authorities was Losartan Potassium. Losartan Potassium is vital to treating aterial hypertension.

[38]In Vanautu's case, the API of the drugs in question headed from India but seized by German customs authorities was Amoxicillin, which is critical to treatment of bacterial infections.

[39]Intervention by India, Agenda item 'M' - OTHER BUSINESS Public Health dimension of TRIPS Agreement, TRIPS Council, available at <http://www.ip-watch.org/weblog/wp-content/uploads/2009/03//intervention-by-india.doc>

circumscribe-flexibilities enshrined in TRIPS."[40]

Drawing the attention of other WTO Members to the issue, India further stated: "*This is the effort to implement the protection and enforcement of IPRs in a maximalist manner and thereby upset the delicate balance between rights of IPR holders and the public policy objectives under the TRIPS Agreement.*"[41]

Brazil had also highlighted the detrimental nature of the seizure of the generic medicine consignments in a separate statement to the TRIPS Council.[42] Brazil importantly highlighted the systemic importance that the seizure of generic drugs in transit posed. The important legal issue which Brazil highlighted:

> "*14. Such excessive and inappropriate interpretation of IP rights granting extraterritorial effects runs counter (to) the objectives and purposes of the TRIPS Agreement. Such interpretation effectively guts the provisions granting TRIPS flexibilities to developing countries.* ***It offends Articles 7 and 8 of the Agreement***.[43]

VI. THE "DIFFERENTIAL" APPROACH IN THE TPP'S IPR CHAPTER: NOT SO DIFFERENT

During the negotiations leading to the TPPs final texts, concerns were raised by certain developing countries regarding the protectionist standards of IP protection envisaged in the TPP's IPR Chapter, especially in the context of access to medicines. To assuage these concerns, the United States, in November 2013, proposed the incorporation of differential treatment provisions. According to the United States' Trade Representative, the United

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[40] *ibid*

[41] *ibid*

[42] Intervention by Brazil, <http://www.ip-watch.org/weblog/wp-content/uploads/2009/03//intervention-by-brazil.pdf>

[43] *ibid*

States is in favour of a differential approach to "tailor potential flexibilities based on countries' existing laws and international obligations".[44] The United States intended to base this flexible approach on the provisions in bilateral free trade agreements entered into with its partner countries such as Chile, Peru, etc.[45]

The impression that was purported to be conveyed when the "differential approach" was proposed was that protectionist IP standards envisaged in the TPP's IPR Chapter would be less onerous for developing country Parties. The United States even cited the presence of these "differential approach" provisions in the FTAs that the United States has entered into with various developing countries. For the purpose of understanding the nature of these differential provisions, some of these FTAs – the one ones with Peru, Chile and Colombia –were analysed.

An analysis of these differential provisions shows certain shortcomings. First, the differential approach provisions are limited to only a handful of provisions. By being limited in scope, the differential approach fails in its objective of not being as comprehensive as required in the interests of the developing country parties to these FTAs. They do not cover crucial aspects such as data exclusivity; ever-greening; patent linkage, et al (Not that accepting these provisions are acceptable otherwise). Second, the nature of the leeway that these differential approach provisions provide for developing country partners seems very constricted. These provisions are narrow and temporal since they accord nothing more than transitional periods/grace periods for these developing country Parties to abide to the higher standards of IP protection. Furthermore, not only are the transitional

[44] *Stakeholder Input Sharpens, Focuses U.S. Work on Pharmaceutical Intellectual Property Rights in the Trans-Pacific Partnership*, Office of the United States Trade Representative, Blog, <http://www.ustr.gov/about-us/press-office/blog/2013/November/stakeholder-input-sharpens-focuses-us-work-on-pharmaceutical-IP-in-TPP>

[45] *ibid*

periods of a short duration, but they provide no further flexibilities which may be required by the developing country partner in certain circumstances.

Unsurprisingly, a similar approach has been adopted in the TPP's IPR Chapter. An analysis of the TPP's IPR Chapter shows that these differential provisions are indifferent to the development status of these TPP developing countries. Like in the FTAs, they are merely in the nature of transition periods for developing countries, which again, are of a short duration. A key difference is that these differential provisions in the TPP's IPR Chapter are broader in scope as they extend to data exclusivity, patent term adjustment, and enforcement.

The special and differential treatment (S&DT) provisions of the WTO have often been criticized for being hortatory and lacking the teeth to compel developed countries to accord more consideration to developing countries in the WTO.[46] There are however certain exemptions for developing and LDC countries in terms of complying with certain obligations under the covered agreements.[47] Even so, preferential trade agreements have generally given a miss to providing the type of S&DT that has developed at the WTO.[48] The TPP is no exception to this assessment.[49] The United States' proposed differential approach is loaded with crucial shortcomings that undermine the interests of developing countries. As analysed above, it would suffice to say that this differential approach is significantly weaker than the S&DT concept in the WTO. While FTAs may possibly improve access to the

[46] *See* Sonia E. Rolland, *Considering Development in the Implementation of Panel and Appellate Body Reports*, 4(1) TRADE L.& DEV.150 (2012), at page 193

[47] For instance, Article 27 of the SCM Agreement has differential rules with regard to export subsidies for certain groups of developing countries. LDC Members are altogether exempt from the requirement of abolishing export subsidies under the SCM Agreement

[48] Joel P. Trachtman, *Development Aspects of a Trans-Pacific Partnership* (November 3, 2011). Available at SSRN: http://ssrn.com/abstract=1953943 at page 3

[49] *ibid*

developed country's markets, the disadvantage is that such FTAs undermine the right of S&DT explicitly recognized under the WTO framework.[50]

VII. #TRIPS PLUS: RINGING IN TRIPS PLUS OBLIGATIONS THROUGH THE TPP

The TRIPS Agreement was a significant addition amongst the various trade disciplines introduced through the Uruguay Round. Though the TRIPS committed members to promise protection for IPR at various levels in the domestic regime, a salient aspect of the TRIPS is that Members are not obliged to provide IPR protection in their domestic laws beyond the minimum standards prescribed in the TRIPS.[51] However, this has not prevented the rise of efforts to introduce TRIPS plus norms in the world trading system outside the WTO. In fact, it could be said that in many ways, the TRIPS Agreement was the first step towards a maximalist regime of IPR protection.[52]

The world trading system is no stranger to efforts aimed at introducing TRIPS plus norms in the various legal treaties. The traditional route for pushing TRIPS plus norms has been through TRIPS plus obligations embedded into many bilateral/free trade agreements. FTAs signed between certain developed and developing countries in the name of market access and trade integration reflect the situation more accurately.

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[50] Gopakumar and Smith, at page 174

[51] Article 1.1, TRIPS Agreement

[52] Bryan Mercurio, *TRIPS-Plus Provisions in FTAs: Recent Trends*, in REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM, Lorand Bartels, Federico Ortino, eds., pp. 215-237, Oxford University Press, 2006 at pages 215-216. According to Mercurio, "*TRIPS should never have been viewed as the final statement on international IPRs, but rather as merely a stage (albeit an important one) in a larger cycle alternating between bilateral, regional, and multilateral forums; and second, that the world has moved beyond the multilateral phase and into a bilateral phase; a phase which is seeing the negotiation increased IPRs and placing increased obligations on signatories*".

The Jordan-United States FTA of 2000 was one of the very first FTAs to contain TRIPS plus provisions. Since then there have been many such FTAs between the demandeurs of protectionist IP standards (namely the United States and the European Union) and other developing countries.[53] As a result of the MFN clause of the TRIPS Agreement, these FTAs have created a de facto regime for certain TRIPS plus norms such as data exclusivity.[54]

Negotiating an FTA on a one-to-one basis may be tiresome. Also, while it may be not so difficult to convince smaller developing countries to accept TRIPS plus norms through FTAs, it may not be possible to do so with major developing countries such as India, China and Brazil. Civil society groups and academics in many of these countries would stymie any move by their governments to consider signing TRIPS plus FTAs. It would be perhaps be simpler from a negotiating point of view to draw an arrangement that would be broad in coverage and tempt countries with market access benefits to attract membership. Such an arrangement could also double up as a gold standard incorporating TRIPS plus standards. It would be clear that TPP is an attempt in this direction to give shape to a new trade regime of TRIPS plus norms.

By multilaterally entrenching TPP Parties to commit to protectionist IP standards, the demandeurs are attempting to reset the minimum international standards. Facilitated by the TRIPS' MFN clause, the TPP's standards may quite possibly become the new minimum standard for future negotiations in international IP obligations.[55]

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[53] Mohammed El Said, *The Morning After: TRIPS-Plus, FTAs and Wikileaks - Fresh Insights on the Implementation and Enforcement of IP Protection in Developing Countries*, PIJIP Research Paper No. 2012-03, American University Washington College of Law at page 14

[54] *ibid*

[55] Bryan Mercurio, *supra* note 66, at page 223. He explains this in the context of FTAs in general. The same can be understood in the context of the TPP.

The obvious risk posed by these TRIPS plus FTAs is that they erode flexibilities guaranteed to developing countries in the TRIPS Agreement to safeguard their public interests. The bigger danger is that there is no ceiling for this erosion. That is, given what has been eroded today, an international legal obligation even more detrimental may be sought to be imposed tomorrow. The absence of ceilings in the TRIPS Agreement is what underlines this threat. In the context of the TPP, if the demandeurs of higher IP protection standards have their way, they might be able to set the agenda for even higher standards for protection of IPR in the future. The effect of conformity to TPP standards given the number of countries involved and the high protectionist IP standards would be mean ratcheting of global IP protection standards.

Prominent IPR scholars such as Henning Grosse Ruse-Khan have rightly advocated for a ceiling on TRIPS-plus obligations. They highlight that ceilings may be instrumental in protecting individual rights such as the protection of public health.[56] Like other scholars in the field, he has argued that extending TRIPS-plus standards in international trade and investment treaties can reduce access to medicines.[57]

VIII. CONCLUSION

The TPP is undoubtedly a new chapter in the history of efforts to introduce TRIPS plus norms through non-WTO Agreements: most of the standards of IP protection in the TPP are more protective than those required by the TRIPS Agreement. Given the general opposition to a maximalist TRIPS agenda at multilateral fora such as the WTO, these demandeur's have responded by pursuing such an agenda earlier through bilateral trade agreements and now by way of mega-FTAs such as the TPP.[58]

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[56] Henning Grosse Ruse-Khan, *Time for a Paradigm Shift? Exploring Maximum Standards in International Intellectual Property Protection*, 1(1) Trade. L. Dev. 56 (2009) at page 87

[57] *Id* at page88

[58] *See* footnote 7 to Flynn, et al

This paper has analysed and discussed the implications that would arise if India joined the TPP and subsequently revised its IPR laws to conform to the protectionist standards contained in TPP's IPR Chapter. Given the Indian government's impetus to boost exports, this *could* be the temptation for India to take steps towards conforming to the TPP's IPR chapter. However, based on the analysis in this Article and for reasons discussed below, the Indian government should exercise great caution.

The standards of IP protection in the TPP's IPR Chapter are undoubtedly more protectionist than those provided for in the TRIPS and in India's IPR regime. In the case of border enforcement measures, it is clearly TRIPS-inconsistent and fall afoul of WTO Member nations commitments at the WTO. Conforming to these protectionist standards could present varied implications for the trademarks, copyrights and most importantly, the patents regime. Some of the major changes that would have to be carried out include deleting section 3(d) of the Patents Act and thereby allowing for evergreening of pharmaceutical patents. It is important at this juncture to highlight that such norms are actually TRIPS minus rather than TRIPS plus as they lower the threshold for patentability rather than maintain a strong standard which is what IP jurisprudence advocates.

Given the strong resistance by the developing world in general against more protectionist standards of patents for pharmaceutical products, it would now seem that different channels for maintaining protectionist grip on pharmaceuticals are being made. Some of these are attempts to extend such protection through the regulatory front. In the TPP context, these include data exclusivity; patent linkage; and expansive border measures. Data exclusivity is especially becoming an increasingly acceptable alternative to patent protection for pharmaceutical products.[59] These could spell negative effects to India's generic drugs industry by slowing and halting the

[59]Reichman at page 36

production of generic medicines.

The TPP also has major implications for legitimate international trade in generic medicines given that the TPP's IPR Chapter intends to expand the scope of trademark protection-related border measures to confusingly similar goods. Like how blocking rivers would dry up the oceans, similarly, blocking export, import and even transit of generic drugs on the grounds of being "confusingly similar" goods could halt legitimate international trade and thereby access to generic pharmaceuticals. An important aspect of the provisions concerning border measures is that India will not face problems only on account of conforming to these provisions, but if other countries conformed their border measures to the TPP's protectionist standards.

The presence of public health safeguards which apparently guarantee the rights of TPP Parties to access medicines may seem to assuage concerns. However, as was emphasized in Section V, the absence of many flexibilities in the IPR Chapter as compared to the TRIPS Agreement makes these safeguards moot. The differential provisions for developing countries fall well short their development concerns.

In light of the concerns raised in this Article, it is also time to seriously reconsider binding ceilings in the TRIPS Agreement in the WTO with the objective of limiting attempts to export TRIPS plus norms through the non-WTO routes. One example of such an effort could be a moratorium agreed to by the WTO Membership, atleast on certain aspects such as more protectionist standards for patent protection, though arriving at a consensus on such a moratorium could be politically and pragmatically difficult to achieve.

While India is not a member of the TPP, it would be in India's best interests to resist any pressure towards conforming to the IPR provisions of the TPP in its current form. The costs of conforming to the strong protectionist

standards in the TPP's IPR Chapter do not justify any benefits that may be derived from joining the TPP.[60] Furthermore, like how Ha Joon Chang described the First World's attempts in "kicking away the ladder" for the developing world, conforming to the TPP's protectionist standards would mean that India itself would be "kicking away the ladder" without even having reached the top.

[60] For an excellent analysis of the issues on the costs that would entail if India joined the TPP, *See* Abhijit Das, *India and the Shadow of the TPP*, Economic and Political Weekly, November 7, 2015, Vol. 1 No. 45