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TRIPS-PLUS PROVISIONS IN FREE TRADE AGREEMENTS (FTAs) VIS-A-VIS PUBIC HEALTH: ISSUES AND CHALLENGES FOR DEVELOPING

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Abstract

This paper is concerned with the issues surrounding the recent trend by developed countries to introduce TRIPS-plus regime in international IPR and trade law and challenges that could be faced by India in this regard. As has been observed recently, developed countries with rich IP portfolios are in the process of advocating and implementing a TRIPs-plus era in the various Free-Trade Agreements (FTAs) concluded between various countries that may have detrimental effects on the public health interests of the developing countries. The paper begins by giving a background of TRIPs; the second part of the paper deals with development of TRIPs-plus era and the related public health concerns and its effects on access to medicines in India. Lastly, the paper concludes with the suggestion that the legislature and the judiciary may play a key role in balancing the conflicting interests of the developing countries and the industrialized nations while implementing TRIPs-Plus IP clauses in FTAs under domestic law.

Keywords: *FTAs, TRIPs, TRIPs-plus, public health, developing countries, developed countries*

Extended Summary: The Trade-Related Aspects of Intellectual Property Rights (TRIPs), signed in 1995, administered by the World Trade Organization (WTO) is to date the most comprehensive treaty for the protection of intellectual property rights across the world. This treaty lays down the minimum standards to be adhered to by the signatory countries in their domestic Intellectual Property Rights (IPR) protection regime. Further, it lays down the minimum enforcement and infringement standards in case of infringement and counterfeiting, including the enforcement of cross-border measures. Keeping in mind the needs of the developing nations with respect to issues such as public health, transfer of technology, socio-economic development, promotion of innovation and access to knowledge, TRIPs' in-built flexibilities allows them to enact provisions that protect the interests of the public at large.

Doha Declaration, on the TRIPs Agreement and Public Health adopted by the WTO Ministerial Conference in 2001, allows developing countries to adopt measures that protect public health, even though it may be detrimental to the individualistic interests of the IP rights owners. It reaffirmed the flexibility of the TRIPs member states in circumventing the patent rights for better access to essential medicines.

India's Section 3(d)[1], of the Patents Act, 1970, inserted by the Patents (Amendment) Act, 2005, permits any improvement over an existing product or an invention, only when "enhanced therapeutic efficacy" may be shown. This provision has been inserted after India acceded to TRIPs, which mandates both product and process patents.

Recently, the IP-rich countries, such as Japan, USA, and the EU wish to push the envelope by enforcing standards that go beyond the TRIPs regime by signing multilateral, bilateral and pluri-lateral Free-Trade Agreements (FTAs)[2] treaties with developing countries that enforce standards more stringent than TRIPs. This is possible because TRIPs itself permits the countries to exceed TRIPs standards. Generally, TRIPs-plus provisions[3] put limitations on parallel imports, data exclusivity, compulsory licensing and provide for

[1]Section 3(d) of the Patents Act, 1970 states: the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the 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. Explanation. -For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;]

[2] For Example: The US–Australia FTA was controversial as it impacted upon Australia's Pharmaceutical Benefits Scheme (PBS) for providing access to affordable medications. For more information, see B. Mercurio, 'The Impact of the AUSFTA on the Provision of Health Services in Australia' (2005) 26 Whittier L Rev, 1051 and P. Drahos et al., 'Pharmaceuticals, Intellectual Property and Free Trade: The Case of the US–Australia Free Trade Agreement' (2004) 22 Prometheus, 243.

[3] For example, US-Australia FTA, in Article 17.9.4., prohibits the adoption of international exhaustion that allows parallel imports from cheaper markets abroad. In addition, Article 19.9.7. allows compulsory licensing only on certain grounds such as public non-commercial use, national emergency or circumstances of extreme urgency.

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patent-term extensions beyond the minimum 20-year period of TRIPs, which could include automatic extensions to compensate for delays in the patent examinations and the calculation of the patent term from the date of the grant of the patent and not from the date of filing of the application of the patent.

The introduction of TRIPs which provides for minimum standards and greater enforcement for intellectual property rights (IPRs) sufficiently placated the demands of the industrialized nations' demands for strong enforcement and protection of IPRs, it now appears that this agreement only served as another step in the pursuit of stronger IPRs.

After having failed to achieve all they sought in the TRIPs negotiations, the US and the other developed nations have begun negotiating for the inclusion of more protectable subject matter, broader and more extensive coverage, stronger enforcement mechanisms, and weakening of 'flexibilities' and the 'special and differential treatment granted to developing and least developed countries through regional Free Trade Agreements (FTAs). Thus, while many developing countries were still struggling to implement their obligations under TRIPS, developed countries were already raising the level of IPRs through FTAs.

The TRIPS-Plus provisions and resulting standards are designed to best protect domestic interests of developed nations. While some commentators may disagree with this approach, it is in fact no different to any negotiation: the industrialized nation is putting forth its position and the negotiation partner can choose to accept the demand, conditionally accept it in exchange for a concession or outright reject the demand. It is also clear that the TRIPS-Plus provisions appearing in FTAs are identical to aspects of domestic law of the industrialized nation.

In this regard, countries agreeing to such heightened standards must fully recognize they not only are agreeing to amend their IP laws, in most cases without full discussion and input of the IP community and, perhaps more importantly, any economic analysis as to the overall costs of the changes, but that they may be agreeing to standards that are far removed from their own the economic and social needs. Such policies expedite compliance with TRIPS while at the same time force certain developing countries to relinquish their rights granted by the TRIPS[4].

As the industrialized nations have a higher bargaining power in international trade, they impose obligations on developing nations through regional trade agreements to fulfill their own interests through provisions that are similar to their own domestic intellectual property laws, who have to agree to them or face blacklisting or political isolation under international trade. Since no country can today afford to live as a geo-political island, they agree to intellectual property provisions even though they may be detrimental to their own socio-economic interests. Thus, there is a need to reconcile and balance the intellectual property and trade interests of the developing and the industrialized nations, particularly in the arena of public health. It must be also noted that the practice of negotiating TRIPS-Plus provisions is not limited to FTAs with developing countries[5].

TRIPS-plus provisions cover several aspects such as:

1. Patentability of drugs

Several FTAs introduce provisions which prevent national drug regulatory authorities from registering a generic version of a drug that is under patent in the country without the consent of the patent holder. This provision represents a significant shift from traditional operating standards, where the market approval of a drug that is the regulatory approval granted to a product which proves its safety and efficacy, has not been linked to a drug's patent status.

2. Extension of patent term

TRIPs require members to grant patent protection for a period of at least 20 years from the date of filing of an application for a patent. TRIPs do not obligate members to 'compensate' patent holders for 'unreasonable' delays in approving a patent or registering the product by extending the patent term. However, in order to rebalance the effects of the time delay, provisions in certain US FTAs 'compensate' the pharmaceutical companies for any 'unreasonable' delay caused by the national drug regulatory authority in examining an application for registration or from a patent office in assessing the application for a patent by extending the patent term in the same amount of time as the 'unreasonable' delay[6].

[4] To illustrate, Nicaragua agreed to forego its implementation period and immediately comply with its TRIPS obligations in exchange for preferential access to the US market and increased prospects of foreign direct investment.

[5] For instance, the US–Australia FTA imposes a strict IP regime, modelled on the US–Chile and US–Singapore FTAs, requiring Australia to amend several laws.

[6] For example, Article 15(9)(6) of the CAFTA-DR states:
Each party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than five years from the date of filing of the application in the Party, or three years after a request for examination of the application has been made, whichever is later.
Similarly, Article 15(10)(2) of the CAFTA-DR relating to delays in market

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3. Compulsory licensing

Compulsory licensing is a TRIPS-recognized public health safeguard allowing a government to temporarily override a patent and authorize the production of generic versions of a patented product. Since the implementation of TRIPS, the US has sought to restrict the flexibility through FTAs, despite the 2001 Doha Declaration, which affirmed countries' right to use compulsory licensing and to determine the circumstances warranting this action.

4. Parallel Importation

Parallel importation undercuts the ability of a patent holder to engage in price discrimination across national boundaries and can severely reduce profit levels of international companies. Importantly, the Doha Declaration confirmed the existing right available in TRIPS that each WTO Member may establish its own regime of exhaustion_of IPRs. Parallel importing is therefore not in and of itself a violation of TRIPS.

Traditionally, IPRs are 'exhausted' once a product is sold once placed on a market anywhere in the world; in other words, the initial sale ends the IP holders' rights and control over what can be done with that product. Therefore, nothing prevents the importing nation that acquired the pharmaceuticals at reduced prices from exporting the drugs back to the original market or any other market for profit. Attempts at curbing parallel imports, even under the context of a compulsory licence, are fraught with uncertainty. In such a circumstance, the US has sought to impose strict standards on other nations via FTAs providing for the restriction and/or prohibition on parallel importation.

The above demonstrates that the newly granted IPRs pose a threat to the public health and welfare by removing the flexibilities granted in TRIPS and mandating a more restrictive system of healthcare. Thus, there is need to address the question of how to correct for the current cycle of bilateralism that promote TRIPS-Plus provisions.

1. INTRODUCTION

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement settled a minimum standard of regulations for the protection of IPR throughout the world. As an international agreement negotiated by sovereign states, it reflected a mutual consensus among the political parties involved (member states). Developed countries are the major net exporters of knowledge-based products, whereas developing and least developed countries (LDCs) are net importers of such products. As a consequence, the former group generally pursues stringent standards for IPR, while the latter benefits from laxer levels of protection.

Conflicts of interests among groups of countries are critically present in the area of patent protection for pharmaceuticals. Developed countries justify their claim for higher protection of IPR as the appropriate mechanism to provide incentives for innovation (encouraging investment in research and development [R&D]) and developing countries tend to oppose stringent protection in terms of concerns about the access to medicines at affordable prices. Two important issues are therefore comprised in the current debate about IPR and public health: innovation and the capacity to obtain new medicines, on the one hand, and access to medicines at affordable prices, on the other. In the light of public health and development concerns, the final text of the TRIPS Agreement included some scope for flexibility for developing countries and LDCs in terms of implementation time and sensitive issues that were left out of the bargain in order to allow national authorities to adapt their legislation and policies to their particular development and public health concerns. The scope for this flexibility was further clarified in the Doha Declaration
on the TRIPS Agreement and Public Health and in the Decision on Implementation of Paragraph 6.

However, this flexibility, established in the TRIPS Agreement in order to assure that public health concerns are taken into account, represents at the same time a limit to some of the objectives of developed countries and their pharmaceutical industries. To achieve their expectations, developed countries have pursued higher protection of IPR by way of extraterritorial application of their own domestic IPR regulation through different ways.

Bilateral investment treaties or free/regional trade agreements containing investment chapters are one of the tools used in what is described as TRIPS-plus commitments. By incorporating IPR regulations into BITS, the application of rules intended for investment protection could alter the principle and legal standards settled in the TRIPS Agreement.

2. BITS, TRIPS-PLUS AND PUBLIC HEALTH WHAT IS TRIPS-PLUS?

The TRIPS Agreement has settled a minimum playing field for IPR protection. Public health concerns in the TRIPS Agreement were addressed by leaving some issues opened to flexibility and national discretion. By that time, it was also foreseen that agreements such as the Free Trade Area of the Americas (FTAA) could establish more restrictive rules for IPR. TRIPS-plus rules can provide more scope or duration for protection

approval continues:
With respect to any pharmaceutical product that is subject to a patent, each Party shall make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.

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or undermine flexibilities granted by the TRIPS Agreement. This situation was recently re-examined by a recent study that acknowledges lack of implementation of TRIPS' flexibilities along with a spread of new BITS (FTAs) that make that process even more complex. Developing countries and LDCs faced many obstacles with implementation of the TRIPS Agreement, which was considered as too high a standard, at least for some of them.

The reasons why developing countries agree to sign these treaties seem confusing and have been analyzed from different perspectives, although they resemble the reasons why they agreed to sign the TRIPS Agreement. Some authors argue that these agreements provide net gains (gains in some areas like market access that offset costs in other areas like IPR). Some others argue that these treaties are the outcome of pressure from developed countries to withdraw concessions (such as the Generalized System of Preferences [GSP]), or the promise to give special future preferences. The United States, the country that has more intensively pursued this trend, is not likely to change it, even though it faces opposition from nongovernmental organizations (NGOs), public opinion and even internal pressure inside the US Congress (Abbott, 2004a). Some concerns have been expressed that BITS' real benefits are overestimated while their costs might be underestimated.

BITS AND PUBLIC HEALTH ISSUES

The discussion following the TRIPS Agreement centred on the issue of compulsory licensing and parallel importation, and these aspects still remain crucial and unsolved. However, other important issues are moving forward in BITS. Moreover, BITS could limit compulsory licensing mechanisms and the parallel import waiver. The inclusion of IPR protection in BITS also poses a number of new matters. The consequences and future interpretation of most issues still remain speculative.

Developing nations (and organizations advocating patient's rights) have continuously claimed that the process of strengthening IPR rules is undermining public health. Some of the ways in which Free-Trade Agreements can undermine public health may be stated as below:

TRIPS-PLUS PROVISIONS

1. Linking 'market approval' to the patent status of a drug

Several US FTAs introduce provisions which prevent national drug regulatory authorities from registering a generic version of a drug that is under patent in the country without the consent of the patent holder.

This provision represents a significant shift from traditional operating standards, where the market approval of a drug has not been linked to a drug's patent status. Thus, the patent status of a drug has never had bearing on whether a drug is of sufficient quality, safety and efficacy to be marketed in a particular nation or region. The reason for the separation of patent status and regulatory approval is simple—the authorities granting patents and those granting regulatory and marketing approval offer very different areas of expertise and competency. Simply stated, authorities which assess and grant patents (commonly called patent offices) decide whether the drug at issue is innovative and novel and otherwise meet the criteria for a patent in that country whereas national drug regulatory authorities, on the other hand, simply assess whether the drug at issue is of sufficient quality, safety, and efficacy to be marketed as a potential medical treatment. Thus, national drug regulatory authorities have traditionally not been concerned with the patent status of a drug they are assessing. Therefore, potential infringement of a patented drug by the applicant generic manufacturer has never had a bearing on the decision of a national drug regulatory authority.

As a result, if a patent holder believes a generic manufacturer is infringing its patent, it traditionally has the responsibility to enforce its rights. In practice, this entails the patent holder bringing suit against the alleged infringer in an effort to prevent further sales of the infringing product and recover damages. This process can be lengthy and costly, but ensures the validity of a patent before enforcing the rights asserted by the plaintiff. In addition, IPRs have always been recognized as 'private rights' (TRIPS explicitly supports this position) and it seems logical that the owner of private rights should be responsible for their enforcement. The newly delegated role of the regulatory authority as an 'enforcer' of a private right is therefore a significant benefit to the rights holder.

TRIPS does not specifically address the rights of generic manufacturers to make use of a patented drug prior to its expiration for the purpose of obtaining marketing approval of their generic product. However, Article 30 authorizes limited exceptions to patent rights for such things as research, prior user rights, and pre-expiration testing. The provision has been used to advance science and technology by allowing researchers to use patented inventions to gain a better understanding of the technology. In addition, the provision is also used to allow manufacturers of generic drugs to apply for marketing approval without the patent owner's permission and before the expiration of the patent.

Not only will these provisions delay access to generic drugs, importantly, the linkage between market

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approval to patent status could also be detrimental to countries taking advantage of the TRIPS recognized flexibility of a compulsory license. More specifically, it is unclear whether a compulsory license may be issued to provide entry of generic drugs where the law does not allow registration prior to the expiration of the patent. This potential impediment is caused by the fact that a manufacturer granted authority to produce under compulsory license still must be registered by the national drug regulatory authority. Thus, if the regulatory authority is prohibited from registering generics until the patent expires, the compulsory license will be prevented from coming to fruition.

2. Data exclusivity periods

As discussed above, before marketing or distributing a drug the manufacture must apply for regulatory/marketing approval with a national drug regulatory authority to ensure that the drug is safe, effective, and of sufficient quality. The regulatory authority does not undertake clinical trials or otherwise test the drugs; instead, it relies on the clinical trials and other data conducted and submitted by the applicant. When a later applicant (a generic manufacturer) seeks registration of the same drug, it need not re-conduct the same clinical trials but only must submit and prove that the drug it seeks to distribute is of the same quality and therapeutically equivalent to the previously approved drug. This process facilitates the introduction of generic drugs to the market and, without having to conduct clinical trials, generic manufactures save a significant amount of resources and can introduce their drug on the market at a reduced rate.

TRIPS does not explicitly require members to provide any period of data exclusivity to an original applicant. While the interpretation of TRIPS on this point is contentious, the wording of Article 39.3 merely states the need to protect 'undisclosed test or other data' from 'unfair commercial use' and 'disclosure', provided that the data required 'considerable effort' to generate, that it is undisclosed and that the product involves a 'new chemical entity'. TRIPS does not dictate how protection should occur or the limits of such protection. On the contrary, the text indicates that it is up to the individual member to determine what constitutes 'unfair'. In addition, the provision does not define what is meant by a 'new chemical entity'.

Recent US FTAs, however, seek to bring its FTA partners into line with American domestic law by preventing the later applicant and the national authority from relying on the clinical studies and data provided by the original applicant when seeking to register the generic version of the drug for a given period of time following the first registration. Thus, a generic manufacturer wishing to market and distribute a generic whilst the period of data exclusivity is in force must conduct its own clinical trials and other data and submit its findings to the national authority.

From a public health perspective, this requirement is difficult to justify and the generic industry will find it difficult to implement such onerous requirements. Even if generic manufacturers were able to generate this data, the cost of the resulting drugs produced would rise considerably as well as delay the generics introduction into the marketplace. Moreover, such duplication of testing is arguably unethical, as it simply is repetition in testing and clinical trials where the safety and efficacy of a product has already been determined.

Several FTAs also effectively prohibit generic manufacturers from using evidence of registration of the originator drug in another country to prove the safety and efficacy of their version. The only condition that can be imposed on the originator is to require marketing approval be sought within five years of registering the product in a country other than a member of that particular FTA. This TRIPS-Plus provision is difficult to justify as, depending on how the originator times entry into the market, the effect of the provision could result in ten years of test data protection. For example, a pharmaceutical company could register the original drug in one of the FTA-member countries but wait five years before submitting the market approval application in another FTA-member country. It would then be entitled to a further five years of exclusivity from that date.

In addition, certain FTAs eliminate the Article 39.3 requirement in TRIPS which protects data only in cases where the pharmaceutical in question utilizes 'new chemical entities' and where the generation of data involves considerable effort. The effect of this provision is to allow a first registrant of a new pharmaceutical product to obtain protection even in the case of old and well known products and such protection may be sought irrespective of whether any effort was spent in the generating the data.

Finally, as noted above, FTAs link test data protection to the patent term, generic manufacturers may not obtain marketing approval at any time during the patent period, even when a compulsory license is issued, and even in preparation to enter the market upon patent expiry, both of which are allowed under TRIPS.

Data exclusivity can also act as a *de facto* patent, ensuring a minimum period of monopoly for pharmaceutical companies, preventing competition, and in some instances, it may even prohibit a generic manufacturer from seeking registration in a country. Furthermore, a period of exclusivity relying upon the registration in another country potentially deprives a country of the drug for the entirety of that period.

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It is also important to note that the period data exclusivity negotiated in FTAs is independent from the patent process and applies regardless of whether the drug is patented in the country. Thus, the effect of a period of data exclusivity where a patent does not exist serves to maintain an artificial barrier to entry into the marketplace and higher prices to consumers.

3. Patent term extensions

TRIPs requires members to grant patent protection for a period of at least 20 years from the date of filing of an application for a patent. However, as medical products require lengthy testing periods and regulatory approval, pharmaceutical companies wishing to apply for patent protection must do so at a very early stage of basic research, many years before filing an application for regulatory approval. In total, the patent and regulatory approval process often lasts between eight and twelve years, meaning a company which has gained a patent for a drug will have its monopoly period significantly shortened.

However, in order to rebalance the effects of the time delay, provisions in certain US FTAs 'compensate' the pharmaceutical companies for any 'unreasonable' delay caused by the national drug regulatory authority in examining an application for registration or from a patent office in assessing the application for a patent by extending the patent term in the same amount of time as the 'unreasonable' delay.[7]

It is common international practice to grant extensions for delays caused by registration and examination, especially in developed countries. However, there is concern for developing countries from a public health perspective over what is considered 'reasonable'. Given the resource constraints on national drug regulation authorities and patent offices in developing countries, an arguably 'reasonable' delay could possibly exceed six years. The extra years added to a patent may not have serious implications in developed nations or even industrialized developing countries, but may have serious consequences for public health in poorer developing countries due to the fact that the provisions extend the time period drug companies are free from generic competition, thereby delaying significant reductions in price which follow the introduction of generic competition. Such delays could prevent large portions of the population from accessing needed drugs and further deepen the public health crises currently engulfing much of the developing world.

4. Limits on compulsory licences

Compulsory licensing is a TRIPS-recognized public health safeguard allowing a government to temporarily override a patent and authorize the production of generic versions of a patented product. Since the implementation of TRIPS, the US has sought to restrict the flexibility through FTAs, despite the 2001 Doha Declaration, which affirmed countries' right to use compulsory licensing and to determine the circumstances warranting this action.

The restrictions placed on compulsory licensing through FTAs exist at two levels. First, FTAs indirectly restrict compulsory licensing as a result of the data exclusivity provisions discussed above. Second, direct restrictions limit the grounds on which compulsory licences can be issued. For instance, and unlike TRIPS, these provisions are drawn in the negative and confine the use of compulsory licences to specified cases, such as remedying an anti-competitive practice, public non-commercial contexts, national emergencies and other cases of extreme urgency, and the failure to meet working requirements.

5. Limits on parallel importing

Parallel importation undercuts the ability of a patent holder to engage in price discrimination across national boundaries and can severely reduce profit levels of international companies. Importantly, the Doha Declaration confirmed the existing right available in TRIPS that each WTO Member may establish its own regime of exhaustion of IPRs. Parallel importing is therefore not in and of itself a violation of TRIPS.

International price discrimination (i.e. tiered pricing) benefits developing countries and other countries with elastic demand for the product. It also allows companies to charge a high price in countries able and willing to meet the higher price (most often developed nations) in order to recoup the costs of offering a lower price to those markets unable or unwilling to meet the higher price. Manufacturers often engage in price discrimination between national boundaries, as the elasticity of demand differs widely between markets; thus, when there is a low elasticity of demand in one country (low rate of exit) and a high elasticity of demand in another (high rate of exit), manufacturers will price products accordingly. Attempts at curbing parallel imports, even under the context of a compulsory licence, are fraught with uncertainty.[8]

[7] For example, Article 15(9)(6) of the CAFTA-DR states: Each party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than five years from the date of filing of the application in the Party, or three years after a request for examination of the application has been made, whichever is later.

[8] For example, US FTAs with Morocco (Article 15(9)(4)) and Australia (Article 17(9)(4)) prohibit parallel importation; however,

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CONCLUSION

The above demonstrates that the newly granted IPRs pose a threat to the public health and welfare by removing the flexibilities granted in TRIPS and mandating a more restrictive system of healthcare. These currently reduce the flexibilities of TRIPS and possibly negatively impacting the public health choices of FTA partners. There is a need for careful public policy balancing the interests of the rights holder with that of the public. Developing countries must resist being coerced into granting IPRs to the detriment of the welfare of its people. These governments must commit to improving the health and welfare of their nations by, *inter alia*, allocating more funds to health, stemming corruption, improving infrastructure, and encouraging doctors to train and remain in the country.

REFERENCES

Abbott, Frederick M. and Reichman, Jerome H., The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions. Journal of International Economic Law, Vol. 10, pp. 921-87, 2007; FSU College of Law, Law and Economics Paper No. 07-25; FSU College of Law, Public Law Research Paper No. 287.

Abbott, Frederick M., The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO (March 31, 2002). Journal of International Economic Law, Vol. 5, p. 469, 2002.

Abbott, Frederick M., The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health. American Journal of International Law, Vol. 99, pp. 317-58, 2005; FSU College of Law, Public Law Research Paper No. 164; FSU College of Law, Law and Economics Paper No. 05-19.

All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines, Oxfam International (2007).

Arcuri, Alessandra and Castro, Rosa, How Innovative is Innovative Enough? Reflections on the Interpretation of Article 27 TRIPS from Novartis v. Union of India (July 14, 2008). Society of International Economic Law (SIEL) Inaugural Conference 2008 Paper.

Attaran, Amir and Champ, Paul, Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute. Yale Journal of International Law, Vol. 27, p. 365.

Basheer, Shamnad and Kochupillai, Mrinalini, TRIPS, Patents and Parallel Imports: A Proposal for Amendment (October 19, 2008). Indian Journal of Intellectual Property Law , Vol. 2, pp. 63-86, 2009.

both agreements provide the prohibition may be limited to cases where the patent owner has placed restrictions by contract or other means. Notwithstanding this footnote, the provision may effectively prohibit parallel importation and essentially allow patent holders, through contract law, to segment markets and maintain price discrimination. Furthermore, the US–Singapore FTA (Article 16(7)(2)) also restricts parallel importation by allowing patent holders to block paral-lel importation into either country when the same is done in violation of a distribution agreement anywhere in the world.

Basheer, Shamnad and Reddy, Prashant, 'Ducking' TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d) (January 17, 2009). National Law School of India Review, Vol. 20, No. 2, pp. 131-155, 2008.

Basheer, Shamnad and Reddy, Prashant, The 'Efficacy' of Indian Patent Law: Ironing out the Creases in Section 3(d) (January 2, 2008). Scripted, Vol. 5, No. 2, August 2008

Basheer, Shamnad, India's Tryst with TRIPS: The Patents (Amendment) Act 2005. Indian Journal of Law and Technology, Vol. 1, 2005.

Bonadio, Enrico, Compulsory Licensing of Patents: The Bayer/Natco Case (2012). (2012) European Intellectual Property Review (Issue 10), pp. 719-728.

C. Correa, 'Negotiation of a Free Trade Agreement European Union-India: Will India Accept Trips-Plus Protection?', (2009) Oxfam Deutschland and Evangelischer Entwicklungsdienst Analysis,

Castro, Rosa, Intellectual Property Rights in Bilateral Investment Treaties and Access to Medicines: The Case of Latin America. Journal of World Intellectual Property, Vol. 9, No. 5, pp. 548-572, 2006.

Chatterjee, Dr. S., Flexibilities Under Trips [Compulsory Licensing]: The Pharmaceutical Industry in India and Canada (June 14, 2007).

Cotropia, Christopher Anthony, Compulsory Licensing Under TRIPS and the Supreme Court of the United States' Decision in eBay v. MercExchange, PATENT LAW: A HANDBOOK OF CONTEMPORARY RESEARCH, Toshiko Takenaka & Rainer Moufang, eds., Edward Elgar Publishing Co., 2008.

D. Chakraborty and A. Kumar, 'EU-India Bilateral Trade and Investment Agreement: Opportunities and Challenges', in L. Peral and V. Sakhuja (eds.), The EU-India Partnership: Time to Go Strategic? (EUISS and ICWA, 2012), 57-74.

Fink, Carsten, How Stronger Patent Protection in India Might Affect the Behavior of Transnational Pharmaceutical Industries (May 2000). World Bank Policy Research Working Paper No. 2352.

Gathii, James Thuo, The Doha Declaration on Trips and Public Health Under the Vienna Convention of the Law of Treaties. Harvard Journal of Law and Technology, Vol. 15, No. 2, 2002.

Grosse Ruse-Khan, Henning, A Trade Agreement Creating Barriers to International Trade? ACTA Border Measures and Goods in Transit (June 16, 2011). American University International Law Review, Spring 2011; Society of International Economic Law (SIEL), Second Biennial Global Conference University of Barcelona, July 8-10, 2010; Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper No. 10-10.

Grosse Ruse-Khan, Henning, From TRIPS to ACTA: Towards a New 'Gold Standard' in Criminal IP Enforcement? (April 19, 2010). Criminal Enforcement of Intellectual Property: A Blessing or a Curse?, C. Geiger, ed., Edward Elgar, 2010; Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper No. 10-06.

Grosse Ruse-Khan, Henning, The International Law Relation between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities? (May 19, 2011). Journal of Intellectual Property Law, Vol. 18, No. 2, p. 1, 2011.

Helfer, Laurence R., Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking. Yale Journal of International Law, Vol. 29, p. 1, 2004; Loyola-LA Legal Studies Paper No. 2003-28; Princeton Law and Public Affairs Working Paper No. 04-004.

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

Kapczynski, Amy, Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector (2009). California Law Review, Vol. 97, p. 1571, 2009; UC Berkeley Public Law Research Paper No. 1557832.

Lidgard, Hans Henrik and Atik, Jeffery, Facilitating Compulsory Licensing under TRIPS in Response to the AIDS Crisis in Developing Countries (August 2005). Loyola-LA Legal Studies Paper No. 2005-18.

Médecins Sans Frontières, 'EU India Free Trade Agreement: Investment and Intellectual Property Chapters Threaten Access to Medicines', (2011) Médecins Sans Frontières Briefing Note,

Médecins Sans Frontières, 'EU India Free Trade Agreement: Investment and Intellectual Property Chapters Threaten Access to Medicines', (2011) Médecins Sans Frontières Briefing Note,

Mercurio, Bryan Christopher, TRIPs, Patents and Access to Life-Saving Drugs in the Developing World. Marquette Intellectual Property Law Review, Vol. 8, 2004.

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