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The T(i)PP(ing) Point for Pharma: Why having TRIPS+ patenting standards in the TPP is bad news for Developing Countries

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This paper discusses the possible public health implications of TRIPS+ commitments found in the newly born Transpacific Trade Partnership (the "TPP"), with a particular focus on developing countries. It argues that the departure from the normal TRIPS standards with respect to the question of 'what constitutes a patent' is harmful in the long run, not just because it creates an unnecessary burden on the ability of developing countries to produce generic versions of life saving drugs, but because it forces the developmental 'south' to adopt health standards which it cannot in practice uphold, and which, they may not necessarily even want.

Keywords: TPP, TRIPS, Doha Development Round, WTO, UPOV Convention

The TPP is finally alive[1]. One of the two decisive mega-regional trade agreements of the 21st Century,[2] the Trans-Pacific Partnership was concluded on 5 October 2015 in Atlanta, USA. The seemingly endless continuum of adjourned meetings between United States and 11pacific-rim members, a characteristic of such negotiations, was finally broken in an almost unanticipated fashion. After the meetings failed at Maui in August, many had their doubts about the future of the agreement.[3] So when Simon Lester announced that the TPP had finally materialized, at least in theory, it was a defining moment for the international trading community.[4] Already controversial on account of allegations of extreme non-transparency and aggressively *malafide* private sector intervention,[5] the news of the agreement's conclusion sounded the rally call for proponents and critics alike. The toughest step however- getting the deal through the United States Congress - still remains. This is notwithstanding the new "fast-track" authority that President Barack Obama granted to his office last June, which basically reduces the legislature's power over finalizing international trade agreements (like the TPP) to a simple yes or no vote.[6] Regardless of the fate of the TPP in the halls of Washington, it already has the potential to affect several important aspects of international trade, particularly with regard to intellectual property rights.[7]

The problem with the agreement is that its fiction is different from its reality. Initially intended to be a classic tariff-cutting agreement with provisions for lifting of quotas between its members, the TPP has mutated into a completely different creature over time. Only a minority of its chapters, as can be seen from the latest October leaked draft[8] deal with tariffs and quotas. The main body of the agreement seeks to establish new legal baselines for a wide range of issues – from food security to Internet freedom and privacy; freedom of the press to, and most crucially, intellectual property right protection. In this sense, it represents a significant departure from the multilateral model of the WTO, where such issues would be addressed concurrently by the entire 161-strong membership of the organization. This departure is usually defended on the lines of free trade. Though there is an argument to be made about the rather embarrassing failure of the Doha Development Round and the impetus that it has given to WTO-naysayers, the problems that come with regional trade liberalization cannot be ignored. Notwithstanding considerations of trade distortion and diversion, the depth to which political influences of powerful countries can permeate in such regional endeavors is a cause for tremendous worry.

The trouble with the TPP is best contextualized in the public health debate. It has been argued that historically, developing countries have struggled with even the "minimum" TRIPS obligation to grant

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patents in all fields of technology.[9] This is because it hampers the ability of the pharmaceutical industry in these countries to produce generic versions of patented drugs - many of which are essential for fulfillment of public health objectives. These generic drugs are indispensable for reducing medicine prices and increasing global access. India, as the "pharmacy of the world", has taken the biggest hit in this regard.[10] The TPP, spearheaded by the US, intends to make the situation even worse with its ability to restrict access to affordable medicines through stricter IP protection.[11]

Needless to say, the Agreement acquired a massive reputation, with proponents beating the free-trade drum[12] and opponents taking to the streets. [13] To be sure, the debate is fascinating. Conventional trade theory dictates that in an ideal world, tariffs and quotas would be as close to nil as possible. But at what cost? Is it reasonable to undertake ultra-liberalization of already reduced tariffs rates in exchange for obvious harm to international public health? Everyone – from Paul Krugman to Pascal Lamy – seems to agree that the gains from the TPP are little, if at all.[14] And after all, the devil is in the details. If one were to closely read the draft texts that are being released by whistle-blower Wiki Leaks, it becomes evident that the TPP is a blatant strategic move on part of the United States, in furtherance of its 'Pivot to Asia' policy. In its aim of containing China's growing influence in the Eastern Hemisphere,[15] the US seems to be quite content with trading away the legitimate rights of millions of people around the world. In light of all this, it is not surprising that much academic space has been devoted to conduct a cost-benefit analysis of this regional approach to drawing up new trading rules.[16]

The dilemma is clear. Once passed, will the TPP act as a natural subsequent step in the evolution of trade liberalization by opening up previously unchartered and un-negotiated territory or will it turn out to be another thorn in the side of the developing nations; another bone of contention in the larger 'trade versus health' debate? Will it complete the circle of life for trade liberalization? Or will it sign the death certificate for pharmaceutical rights worldwide?

Possibly the best way to answer these questions is through the basic IP concept of patentability. Though the TRIPS Agreement provides a minimum, "floor-level" formulation for what would constitute a patent in the member nations; it provided considerable flexibilities with regard to implementation. This means that in their domestic legislations, members would be free to define patentability in a manner to best suit its regulatory needs. This was possibly one of the reasons for the acceptability of the TRIPS Agreement in the first place. However, agreements like the TPP create difficulties by limiting these TRIPS flexibilities by mandating the adoption of patentability model that are significantly (and often, prejudicially) different from the TRIPS agreement. In this context, *Kilic* and *Brennan* tackle the issue of what is patentable under the TPP in the latest issue of the *Yale Journal of International Law*.[15] The methodology adopted by the authors in the paper is identical to the one that is endorsed in this work: undertaking a comparative analysis between the TRIPS and the TPP draft with respect to the subject matter of patents. Though their piece comprehensively deals with all possible aspects of the problem, the analysis is based on last year's draft of the agreement. This work is a step in furtherance of their efforts.

Like *Kilic* and *Brennan*, the author seeks to highlight the problem of hiking regulation standards in regional trade agreements and then identify the negative effects of such TRIPS+ obligations in FTAs on public health. The fact that the analysis presented here is based on the latest "Consolidated Text" of the Agreement - released after the instrument was finally concluded - gives this work contemporary credit.

How Much is too Much? : Swallowing The TPP's Bitter Pill

The essential argument against the TPP is that it is too much; that it goes much beyond what was agreed during the TRIPS negotiations and that if taken up as a model, it would encroach too far into the regulatory space of sovereign nations. Known in IPR law parlance as TRIPS+ commitments, the provisions of the TPP that derogate from the TRIPS minimum standards[17] deserve close scrutiny.

Article 27 of the TRIPS is the main provision in the agreement that deals with patentable subject matter. Paragraph 1 of the provision, mandates that patents would be available in a non-discriminatory way[18] for inventions that fulfill the criteria of novelty, inventive step and industrial applicability. To determine whether an invention is eligible for a patent, the domestic IP office of a member conducts an inquiry into these criteria in a sequential manner. The

interaction between these criteria in terms of what each of these criteria exactly mean, define the precise scope of patentability. As mentioned earlier, TRIPS provides members with considerable flexibility in determining the breadth that they wish to allot to each of these criteria. In other words, members can establish the standard of proof that a patentee would have to satisfy to the novelty and industrial applicability thresholds.

This definition of patentability is however, limited by the exceptions provided in Paragraphs 2 and 3 of Article 27. The list of inventions which, by the operation of this "legal fiction"[19], are not considered patentable include those that are in opposition to "*order public* or morality" or harmful to "human, animal or plant life or health or…environment".[20] Further, the TRIPS provide that patents can be denied in cases of "diagnostic, therapeutic and surgical methods…" and "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes".[21]

The TPP on the other hand, as can be evidenced from the series of preparatory drafts,[22] has often tried to set entirely new (higher) standards for patentability. At different points of time, in several different drafts, the regional agreement has attempted to condone ever greening of patents, unnecessarily expand the scope of industrial utility and provide for patents on plants and therapeutic methods. All this is not only over and above the minimum standards as provided by the TRIPS Agreement, but the operation of the same can cause obstacles in the achievement of public health objectives – something that the very Agreement seeks to protect.[23] Knowledge Ecology International has undertaken an intensive provision-by-provision comparison of the patentability requirements, as they present themselves in the TRIPS Agreement and the various drafts of the TPP up till the May 2015.[24] Though it seems that latest consolidated text represents a highly watered down version of the agreement, several sticking points still remain. These are discussed below.

Ever Greening of Patents: From Now into Forever

The issue of ever greening has plagued the field of patent law from its very inception. It basically involves a patent owner making minor changes to his invention, typically at the end of its patent term, with the aim of obtaining a fresh grant on this, supposedly "new" invention. This cloaks the patented invention in invincibility and entrenches it in perpetuity. Several countries have attempted to contain the issue in different ways, employing a range of impressive legislative and policy maneuvers. One such example is India, which inserted Section 3(d) into its Patents Act to tackle the problem of ever greening by preventing patents on *new forms of existing pharmaceutical substances, unless they demonstrate significantly improved or enhanced efficacy* (Emphasis added). This Section, having "no parallel anywhere else in the world", was the brainchild of a retired justice of the Supreme Court of India, the beloved late Justice V. R. Krishna Iyer.[25] Though it landed India in the middle of a "TRIPS storm" when pharmaceutical giant Novartis was denied a patent on its anticancer drug *Glivec*,[25] it certainly acts as a testimony to the country's policy willpower in the face of external pressure. Though the Section itself has been criticized as being worded too crudely, no one can deny the noble intent behind the same, which is to comprehensively put an end to the problem of evergreening of pharmaceutical patents. [25]

In the latest consolidated version on the IP Chapter of the TPP, Article QQ.E.1 (2) expressly provides that "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.*" This will open the door for flagrant ever greening of patents. This declaration is followed by the line: "*A Party may limit such processes to those that do not claim the use of the product as such*." This is not only ambiguous but also entirely unhelpful. The footnote appended to the provision is a drafter's note, which provides that Article QQ.A.5 is applicable to the entire chapter. Article QQ.A.5 clarifies that members of the TPP may (but are not obliged to) provide for even higher standards than are contained in its IP Chapter, but that at the same time each party would be free to determine the "appropriate method of implementation" of intellectual property protection. This provides absolutely no relief from the problem whatsoever. In fact, it suggests that the members of the TPP can adopt even more stringent IP protection than is required by the agreement. Carlos Carrera clarifies that the "provision [is] aimed at making it mandatory to grant patents on the second use of a known medicine, for instance, in cases where a medicine was administered to treat disease X and it is claimed that it can be applied to disease Y."[26] He explains:

"*This provision would leave TPP parties the option to choose whether to grant patents on 'new uses', 'new methods' or 'new processes' of using a known product. However, unless it is clarified that such methods or processes should be of a technical nature, they may be understood as encompassing patent claims describing how a medicine may be used to address a particular disease. This is the interpretation that will probably be given by the USA, where the new use of a medicine is not patentable as such, but admissible as process-of-use-claims. This means that as long as the claim is on a process for use rather than use, it is admissible as subject matter of a patent. This is precisely what the USA aims at with the proposed text.*"[27]

Article QQ.E.1 (2) seems to be a modification of Article QQ.E.1 of the previous May 2014 draft (as proposed by Australia and the US), which provided:

"*A Party may not deny a patent solely on the basis that the product did not result in enhanced efficacy of the known product when the applicant has set forth distinguishing features establishing that the invention is new, involves an inventive step, and is capable of industrial application.*"

As such, this is to be seen as a direct attack on legislations like Section 3(d).[25] The United States has persistently put India on its "Super 301" list of countries – nations where IP protection is inadequate according to the United States Trade Representative (USTR).[28] The fact that other nations like Philippines and Thailand have recently undertaken legislations similar to Section 3(d)[28] seems to have kicked off the United State's paranoia of a "domino effect". When implemented, the TPP will force countries like Peru, a member of the TPP with a policy against the second use patents, to not only give up the same but also place it in direct conflict with the applicable regional (Andean) law.[29] The United State's affront on beneficial national legislation of other sovereign nations, through the TPP, is noted with concern. In essence, the TPP, in its prior as well as present form, seems to not only allow for ever greening of patents, but its text may actually be read to encourage members to engage in the practice.

The Scope Of "Industrial Applicability": The (F)Utility Paradox

After crossing the novelty barrier, a patentee is confronted with the challenge of proving that his invention is capable of "industrial applicability". However, as mentioned, member nations may define what, in their opinion, constitutes the industrial applicability of an invention. In other words, the standard that a patentee must satisfy in order to show that the "workability" of his invention is in order differs from country to country. Depending on the standard adopted by the member country, the patentee faces varying levels of difficulty in demonstrating that his patent "works". If a member were able to make the working requirements so diluted that any and every patentee would be able to successful fulfill them, the entire point of having a criteria for utility would be lost. This is what the TPP, at least in prior drafts, seems to allow for - mainly by preventing members from enacting and maintaining overly strict utility requirement. Commentators have described the controversy surrounding the Canadian case of *Eli Lilly* and Article 10.1 of the previously released drafts of the TPP, which provided that an invention will be "useful" if it has a "specific, substantial and credible utility".[30] It is encouraging that this language has now been phased out.

As You Sow, So Shall You Reap: How the TPP Branched into The UPOV

The chief concern in this regard is Article QQ.A.8.2 (c), which directs each party to accede to and ratify the 1991 International Convention for the Protection of New Varieties of Plants (the "UPOV Convention"). Set up in 1961, the supposed aim of the UPOV was to offer "common rules for the recognition and protection of the ownership of new varieties by plant breeders."[31] Under the revised UPOV Convention, distinct categories of "breeder's rights" have been recognized for plant and seed related innovations. These include exclusive economic rights granted to producers of such plant varieties and the power to curtail usage and sale of their protected fruits or crops varieties by farmers around the globe. This was seen as an attempt to put the UPOV model on the same pedestal as patents.[32] Since the UPOV right is quite powerful, breeders get immense commercial control to the disadvantage of farmers. The loss to genetic diversity and sustainable agriculture as a result of this breeder monopoly is a further reason for concern. The potentially disastrous consequences of this on the international farming community are felt most strongly in the developing world.[33]

From a legal perspective, this approach entails a complete reversion of the explicit exception against patents on plants contained in Article 27.3 of the

TRIPS. Alternatively, one may argue that the problem *is* the TRIPS+ factor itself. Instead of the TRIPS, minimum which allows for an "effective *sui generis*" system, to protect plant varieties, the TPP forces members to adopt the model, provided by the UPOV. As of now only 51 countries are parties to the UPOV Convention; only half of the current TPP membership is a part of the same. Kilic and Brennan point out that the TPP would require 6 members, including Malaysia and New Zealand, to sign onto the UPOV and 3 others (Brunei, Singapore and Canada) to clarify whether patents are available for plants.[34]

Medicine Madness: Patents on Diagnostic, Therapeutic, and Surgical Methods

The only silver lining in this gloomy situation is a small, contained victory for developing countries like India. As Kilic and Brennan point out, the extremely unpopular US proposal to include provisions for medical procedure patents has now been withdrawn.[35] As late as November 2013, the TPP was still in the course of pushing for "patents on diagnostic, therapeutic, and surgical methods for the treatment of humans or animals…"[36] Public health dictates that the monopolization of such treatment be prevented so that access to these are not hindered on account of increased costs. Patenting of diagnostic methods would also affect policies on the use of genetic information in diagnostic testing.[37] The United States could not rally a single supporter for its proposal and it is heartening to note that such language has not resurfaced in the final consolidated text of the agreement. In fact, the office of the Chief Negotiator of the TPP had received impassioned letters from medical universities, pleading them to drop such language from the text.[37] In the opinion of some, the TPP model went even beyond US' own domestic law, which exempts practicing surgeons from patent liability.[38] This positive development can only be attributed to intense lobbying on part of the developing countries inside the TPP circle, which recognized the devastating effects that such a legal provision could have and stood up to US pressure.

Trips+ Provisions V *Affordable Medicines*

It would seem that wanting more could actually get you less. In the pursuit of standards higher than those enshrined in the TRIPS, agreements like the TPP take the liberty of trading away the public's right to access medicines at affordable prices. It has been noted that one-third of the global population survives without access to essential medicines.[39] The problem in developing countries is even more acute where the figure is closer to 50%.[40] By permitting menacing IP problems like ever greening of patents, the TPP will increase the cost of the drugs and impede the entry of generic drugs into the global marketplace. A very strong case has now been gathered against such TRIPS+ provisions in free trade agreements and several detailed policy briefs document the growing literature denouncing these provisions for their conflict with the public health promoting spirit of the Doha Declaration.[41] Other briefs bring to light disturbing realities: if in place a decade ago, the TPP would be a major obstacle in the development of the same HIV treatment that cures millions today.[42] Some commentators have also provided detailed proposals to make pharmaceutical patent provisions in the TPP more palatable.[43]

To be sure, the negative impact of FTA provisions on public health and TRIPS flexibilities is nothing new; [44] but the scale at which the TPP is committing this crime is preposterous, even by US standards. Krista Cox argues that even the promises of increased FDI opportunities in the US market should not be incentive enough for members to undertake obligations which are going to be so harmful to public welfare in the long run.[45] In this regard, the US policy has been clear. It will exploit FTAs as a tool for its TRIPS+ propaganda with almost zero regard to public health interests of developing countries. The only beneficiaries in this would be the US based pharmaceutical companies.[46]Surprisingly, the US negotiates these FTAs from the bargaining position of a supposed losing party. In its opinion, such FTAs are a way to reach the objectives of TRIPS, which the agreement could not supposedly realize. The usual defense for all this is the intention to promote and incentivize technical innovation. Though the massive R&D costs incurred by the pharmaceutical industry are well documented,[47]the importance of generic medicines is undeniable, and in this debate, paramount.[48]In any case, the agreement when enforced will entail several restrictions on some forms of governmental action and has the potential to affect countries even outside the TPP fold. This point is addressed in the conclusion.

Conclusion

What makes the field of IPR law fascinating is the sheer number of considerations that it must take into consideration while formulating policy objectives,

including the promotion of technical innovation and the protection of legitimate rights of IP holders. While IPRs should ideally operate in a way to promote international trade, the TRIPS agreement provides that a balance of rights must be maintained between right-holders and the public.[33] In the same breadth however, Article 8 provides that public health measures must be TRIPS compliant – which leads to a problematic conundrum. What is the point of heralding public heath when ultimately it is going to be subservient to the force of IP protection and international trade? To remedy this, Paragraph 6 of the Doha Declaration on Public Health clearly lays down that public health is the priority and must be given precedence over individual patentee rights.

In light of this, the public debate surrounding the TPP becomes extremely relevant. In this paper, I have discussed the possible consequences that TRIPS+ obligations in the TPP will have on public health, particularly in the pharmaceutical sector and with respect to access to affordable medicines. In its final form, the agreement fairs poorly in at least two out of the four considerations adopted in this study. It is guilty of providing for ever greening of patents and requiring compliance with the controversial UPOV Convention. In the past the TPP has also borne the allegation of distorting the regulatory autonomy of member countries by providing for different means of determining industrial utility. The only positive development is the dropping of the proposal on surgical and therapeutic patents.

The biggest problem with the TPP is the precedent it will set. At one point of time, TRIPS+ commitments were viewed with skepticism even when they were located in smaller, bilateral FTAs. And now, the same are being tolerated on a broader, regional level with the TPP. The US strategy seems to be working and it would be naïve to assume that it would not parade its success loudly. Despite resistance from the South, the message from industrialized nations to developing countries like India seems to be clear – do what you can, but you cannot run away from the difficulties of TRIPS+ commitments. As is the plight of the TPP nations, so shall it be for you. So goes the line - *tuyoserá, Y tuyoserá* – it will be yours.

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