Is there a Need to ‘Substantially Modify’ the Terms of the TRIPS Agreement?

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The TRIPS Agreement is no stranger to controversy and since its inception has been subject to harsh criticism and calls for modification. The task of defending the TRIPS Agreement, particularly from the point of view of an observer from a third world country is, therefore no mean feat. This article focuses on four major fields where a substantial modification of the TRIPS is being debated and suggests that in light of the recent decisions of the TRIPS Council, the special and differential treatment incorporated, the intrinsic flexibilities available, and the initiatives undertaken at Doha, ‘substantial modification’ is avoidable. The first issue of focus is traditional knowledge. It is increasingly felt that traditional knowledge can be protected within the framework of TRIPS, without a substantial overhaul of its provisions, through a ‘Declaration of Traditional Knowledge and Trade’. The second area of focus is ‘seed patents’ and rights of farmers to ‘save seeds’. This area is in line with the larger debate on bringing the TRIPS into conformity with the Convention on Biological Diversity in order to prevent bio-piracy. This segment is concluded with a discussion on how India has incorporated in its local laws the flexibility available inherent in TRIPS. The third area deals with transfer of technology and whether there exists a need for the TRIPS to be reworked to ensure stricter compliance of developed countries to the relevant obligations already listed in the TRIPS. The fourth and final area of focus is the impact of TRIPS on ‘access to medication’ brought to light by campaigns carried out by organizations such as the Third World Network and Health Action International in view of the ongoing struggle for access to HIV medication throughout the world, particularly in South Africa.

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The diplomatic efforts of the United States to crystallize intellectual property as a ‘trade related issue’ under the aegis of the World Trade Organization (WTO) culminated in 1994 in the form of the agreement on Trade Related aspects of Intellectual Property Rights (TRIPS). It was clear that since most US exports relied on some form of intellectual property (potentially reproducible without appropriate permission), a greater protection of these commodities in international markets was essential. It came as no surprise then, that most of the developed world viewed the TRIPS Agreement as an integral part of any new international trade order. Despite the TRIPS being viewed as a Faustian bargain by developing countries, underlying power imbalances ensured that the US position was upheld, with developing countries being given additional time to bring their laws into conformity with TRIPS.

By the year 2000, most countries had signed the TRIPS and were working towards compliance. TRIPS required the domestic legislations of contracting parties to be brought on par with a certain minimum global standard which needless to say mimicked the standards already present in US, Europe, Australia and Japan. As a result, whereas developed countries were required to make only minor changes to their domestic intellectual property (IP) laws for compliance, developing countries found themselves struggling to cope with the substantial legal and enforcement mechanism overhaul that was inevitable, in order to conform to TRIPS. Despite the best efforts of governments around the world, the enforcement or even the widespread acceptance of the underlying justification for intellectual property rights (IPR) remained incomplete. The disputes between the global North and South that plagued the agreement at the time of its conception have escalated with time, with the TRIPS being seen as the ‘central problem’ by forces in resistance to neo liberal globalization.

It is imperative to appreciate that the benefits of free trade though undeniable, are inevitably overshadowed if achieved through a system, which in popular perception is viewed as not beneficial or even illegitimate. Its multi-dimensional impact has ensured that the TRIPS can no longer be termed a

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mere trade agreement. Such an assessment, coupled with voices in resistance to neo liberal globalization\(^8\) have warranted the taking into account of issues of social justice as a prerequisite, if any lasting international trade order based on IP is to be sustained. Knowledge of this background is essential before one can finally proceed to answer the questions as to whether there is a need to ‘substantially modify’ the terms of the TRIPS Agreement.

It is imperative also to qualify at the outset, the meaning and use of the words ‘substantially modify’. It is perhaps best to provide an exclusionary definition so as to elucidate what these words do not entail, namely - stricter enforcement of a provision or alteration in the ideological backdrop of the TRIPS Agreement born out of, (a) a collectively sanctioned declaration to that effect by the members of the WTO or a decision of the TRIPS Council or (b) employment of ‘generic language’ in certain provisions of the Agreement for an interpretation suited to the particularized needs of countries, and differing from western ideology. In other words, ‘substantially modify’ quite simply means a literal change in the text of the TRIPS Agreement as it stands today.

This demand for modification (being championed for the most part by developing countries) is predicated on the charge that the TRIPS Agreement adheres to a ‘one size fits all’ approach, in disregard to the individualized needs of developing countries.\(^9\) Such a demand is fittingly countered by the affirmation of safeguards for the developing world built into the agreement.\(^10\) The existence of special and differential treatment (SDT) towards third world economies in the TRIPS Agreement, only buttresses Professor Samuelson masterful illumination of what can perhaps be called the true mission of the TRIPS Agreement. She states that its intent was not to raise the levels of intellectual property protection to higher planes, as some right holders might wish, but to encourage countries to adopt intellectual property policies that promote their national interests in a way that will support free trade and sustainable innovation on an international scale.\(^11\)

This article focuses on four major fields where such modification is being debated and suggests that in light of the recent decisions of the TRIPS Council, the SDTs incorporated, the intrinsic flexibilities available, and the initiatives undertaken at Doha, substantial modification is avoidable. The first area relates to issues of traditional knowledge (TK). As is discussed subsequently, it is increasingly felt that TK can be protected within the framework of TRIPS, without a substantial overhaul of its provisions, through a ‘Declaration of Traditional Knowledge and Trade’.\(^12\) The second area of focus is ‘seed patents’ and rights of farmers to ‘save seeds’. This area integrates into the larger debate on bringing the TRIPS into conformity with the Convention on Biological Diversity (CBD) in order to prevent bio-piracy.\(^13\) The third field deals with transfer of technology and whether there exists a need for the TRIPS to be reworked to ensure stricter compliance of developed countries to obligations already listed in the TRIPS.\(^10\) The fourth and final area of focus is the impact of TRIPS on access to medication highlighted in the campaigns carried by organizations such as the Third World Network and Health Action International in view of the ongoing struggle for access to HIV medication throughout the world, particularly in South Africa.\(^14\)

Nonetheless one must first look upon the TRIPS Agreement in its entirety to decipher the special and differential treatment it affords to developing economies in contrast to its label of ‘one size fits all’.

**Special and Differential Treatment**

Recognizing that developing countries are inherently disadvantaged in their participation in international trade, different rules in addition to differential and more favourable treatment by developed countries was incorporated as a fundamental principle of the General Agreement on Tariff and Trade (GATT) and now the WTO.\(^15\) Notwithstanding its aspiration to establish certain minimum rules for IPR protection, the TRIPS Agreement in consonance with this principle comprises specific provisions calling for SDT. As regards the general implementation of the Agreement, additional time periods to the tune of four years for developing and six years for least developing countries were provided, with an additional five years to countries having to shift from process to product patent protection at the time of coming into force of the Agreement (Articles 65.2 and 65.4).

Aid in terms of specialized training and upgradation of IPR administration, in addition to encouragement of local creativity and innovation resulted from Article 67 requiring developed countries to impart technical and financial assistance to developing nations in order to facilitate
implementation of the Agreement. Such assistance prioritized with the help of Poverty Reduction Strategy Papers\textsuperscript{16}, was forthcoming in a co-ordinated manner both bilaterally and through international organizations such as the United Nations Conference on Trade and Development (UNCTAD), WIPO, WTO and the World Bank.

Moreover, Article 66.2 expects to create a sound and viable technological base in least developing countries by requiring developed countries to promote and encourage technology transfer to them through incentives to enterprises and institutions located in their territories. This is compatible with the Article 7 objective of TRIPS which requires that the protection and enforcement of IPRs ‘should contribute to the promotion of technological innovation and the transfer and dissemination of technology’. Criticisms as regards the effectiveness of this non legally binding provision, and the lack of definite steps for its implementation have been dealt with in greater detail while dealing with transfer of technology.

With the Agreement being indicted with a charge of callous uniformity, developing countries implementing its provisions have sought above all else, to maintain a level of ‘policy flexibility’ in order to pursue their individual development objectives. In fact, flexibility in the interpretation of various articles of the Agreement is what lessens the effect of TRIPS being condemned as an instrument which follows a ‘one size fits all’ approach. The interpretation of Article 31 is one of many such examples where developing countries have successfully obtained consensus on an interpretation that maintains their flexibility to act in public interest through compulsory licensing.

It can therefore be seen that the TRIPS Agreement takes into account the varying needs of developing economies in certain cases, and in certain others, developing economies are free to make use of the flexibility innate in TRIPS, to tailor their domestic implementation to a development agenda that is particularized to their requirements. Nevertheless one must look to areas, where developing countries feel the Agreement has negatively discriminated rather than accounting for their needs, starting with an intellectual resource relatively abundant in developing countries, namely, traditional knowledge.

**TRIPS and Traditional Knowledge**

Global political structures and cultural hierarchies based on colonialism played a significant role in determining who participated in negotiating the emerging global standards for intellectual property, in addition to what kind of knowledge would be protected under this global framework\textsuperscript{17}. Owing to prevailing Western society’s assumptions as to what constituted IP, local or traditional knowledge never found protection in the IP frameworks of the 19\textsuperscript{th} and 20\textsuperscript{th} century.\textsuperscript{18} TRIPS is widely believed to have reiterated this treatment of traditional knowledge.\textsuperscript{19}

Although uncertainty as regards what constitutes TK does not further the cause of its possible protection, WIPO offers a workable definition in stating that TK comprises of tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and, all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields.\textsuperscript{20} In the above definition, ‘tradition-based’ refers to knowledge systems, creations, innovations and cultural expressions which have been transmitted from generation to generation; generally regarded as pertaining to a particular people or its territory; and constantly evolving in response to a changing environment.\textsuperscript{20}

The fact that UNESCO circulated a preliminary Draft Convention on the Protection of the Diversity of Cultural Contents and Artistic Expressions\textsuperscript{21} has not proved enough effort, and countries such as India have unequivocally stated that because the Doha Round is a development round, it bears the onus to correct the imbalances inherent in TRIPS as regards its failure to protect TK and genetic resources.\textsuperscript{22} With growing conviction concerning the inappropriateness of prevailing international norms, developing countries are calling for a substantial modification of TRIPS by incorporating in it a new *sui generis* right for the protection of TK.\textsuperscript{23}

It is felt however, that instead of modifying the TRIPS Agreement, an instrument in the form of a declaration\textsuperscript{24} such as the ‘The Declaration of Traditional Knowledge and Trade’- affirming that intellectual property rules can and do apply without any modification to certain forms of TK, especially knowledge (e.g., expressions of folklore, arts and crafts) that are exploited commercially\textsuperscript{12}, be adopted in the WTO/Doha Round. It is suggested that before TRIPS is sought to be amended, one must look as to how TK holders can be provided protection within the current framework of TRIPS. Such a suggestion finds
its roots in pragmatism for a number of reasons. Firstly, though one is free to suggest that the TRIPS be amended, such amendments apart from being difficult to predict are likely to require years to negotiate and bring into force. Secondly, even if TRIPS were to be amended it is unlikely that it would be done so in a manner accounting for the needs and concerns of every TK holder. Thirdly, a number of WTO members are of the opinion that a sui generis system of protection for TK is a measure of last resort, as it usually involves establishing a custom made system, without attempting to understand why the existing system is ineffective. Lastly, if TRIPS is reopened to incorporate a sui generis right, demands for higher levels of protection in almost all areas of intellectual property, including the incorporation of TRIPS plus agreements such as the WIPO Internet Treaties are likely to arise. Therefore, a solution having the effect of TK protection within the confines of TRIPS is not ill-conceived.

At the basis of this approach lies the realization that current forms of intellectual property protection are not inherently or structurally incommensurable to the protection of TK of a local community. However, two primary difficulties surface when dealing with the protection of TK through traditional IP based systems. They relate to (a) nature of ownership and (b) nature of object sought to be protected.

As regards ownership, it is generally acknowledged that because the author or inventor of the TK material is not identifiable and there can be no ‘rights holder’ in the usual sense of the term, traditional IP protection cannot be applied. In fact, the author or inventor is often a large and diffuse group of people. In response, it has been suggested that collective ownership of trademarks is well accepted and hence the recognition of a community as the owner of a patent or a copyright should not jeopardize the conceptual underpinnings of intellectual property as it exists today. In fact, the TRIPS does not forbid such attribution and is pliant on this front as it does not directly impose ownership rules. Many countries already have collective works in their national laws and hence a situation where the rights holder is a community, or perhaps, in certain cases, the State, is not an illogical conceptual jump.

As regards the nature of the object that is sought to be protected, the current analysis is limited to the protection offered by patents, copyrights and trademarks under TRIPS. Article 9(2) provides that copyright ‘shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such.’ This does not seem to prevent the protection of folklore or other forms of original literary and artistic expression. In the area of trademarks, extensive use in the form of collective or certification marks by first nation communities demonstrates that there is no significant subject matter incompatibility.

Though it is legitimately asserted that the traditional modes of intellectual property protection have a limited period of protection and hence not ideally suited to safeguard TK, it is asserted that such protection is nonetheless available (as allowed by their conceptual underpinnings) for TK protection, even though they might not be considered as effective as a tailor made sui generis system. Also, considering that a sui generis mechanism at the international level seems improbable at this point of time, protection under TRIPS is in fact the best option. It is stressed that after the particular TK is provided protection under traditional IPR, the holders of the knowledge would gain the benefits of recognition and monetary value and at the same time prevent others from appropriating the same knowledge. Examples of such successful use of IP protection for TK have been highlighted in the Maca plant example and can be applied by traditional communities as well.

Lastly in the area of patents, although the terms ‘patent’ or ‘invention’ have not been defined anywhere in TRIPS, Article 27 does provide that patents ‘shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.’ A footnote to Article 27 interprets the European ‘inventive step’ and ‘industrial applicability’ as functional synonyms of ‘nonobviousness’ and ‘useful.’ In order to meet these requirements, TK holders have in the past entered into partnerships to develop scientific evidence that will convince patent offices of the presence of actual utility. As regards the dichotomy that exists between the patent requirement of novelty and the inherent traditional character of the knowledge sought to be protected the meeting of such a requirement is not as difficult as one would think. For example, even though the Maca plant (Lepidium meyenii) was used by the Inca community to enhance fertility for several centuries, Maca based patent applications were found to be novel and non obvious.
because there existed no documentation in printed format evidencing its use, despite prior knowledge.\textsuperscript{33} Even if documentation were to exist for say the benefits of a particular plant, by combining known knowledge (with known knowledge of another plant) in a unique manner, it may be possible to meet the novelty criteria for a patent, as no prior art would have previously been established documenting the two plants being used in combination.\textsuperscript{33}

According to Gervais, the need of the hour is not the amendment of TRIPS to insert a \textit{sui generis} mechanism but rather the creation of cultural bridges to explain current forms of intellectual property to holders of TK.\textsuperscript{12} Such a move will generate a consciousness of the fact that IPRs are not merely a tool in the hands of foreign powers to victimize TK holders through illegal appropriation of their TK, but can be used by TK holders themselves to protect their interests.

In order to further this realization the best step at this point in time within the WTO context would be to adopt a Declaration on Traditional Knowledge and Trade. This declaration would reflect the need felt by several WTO Members to protect TK; and express their desire to support technical cooperation, as well as research and development efforts in the application of current IPRs to TK. This declaration would also have the effect of making official certain flexible interpretations of the TRIPS undertaken by developing countries in this regard.

Nevertheless, with the sustainable use of a nation’s biological resources by its local communities being regarded as an essential element of their TK,\textsuperscript{12} any discussion on TK and intellectual property would require a detailed analysis of the relationship between the TRIPS and the CBD which seeks to protect such TK in its own right.

**TRIPS and the Convention on Biological Diversity**

The creation of the Convention on Biological Diversity was in part because of the advancement of genetic sciences and the ensuing debate on the ownership and appropriation of benefits of biological resources under the global intellectual property regime.\textsuperscript{35} Apart from the conservation and sustainable use of biological diversity, the CBD reaffirmed that nations have sovereignty over their biological resources and aimed at establishing equitable sharing of benefits arising out of these genetic resources (Article 1).

Realizing that farmers in developing countries have traditionally relied upon a store of genetic diversity accumulated by hundreds of generations that have observed, selected, multiplied, traded, and kept variants of crop plants\textsuperscript{35} and recognizing that these seeds (which are inadvertently genetically modified by farmers through a process of picking and choosing the best variety) constitute their TK, Article 8(j) of the CBD, requires contracting parties to ‘respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity’. This Article presumably requires countries to prohibit patents on genetic materials such as seeds, where they adversely affect diversity in conventional agricultural practices by replacing traditional varieties with fewer patented ones.\textsuperscript{36} Though it is argued, that it is precisely because of this reason that a \textit{sui generis} system is required, it is worth pointing out that the TRIPS Agreement itself through Article 27.3 calls for a system of protection that may be, if the country in question so desires, \textit{sui generis}. This aspect of TRIPS only furthers the argument that it does not in its present state need to be substantially modified. Also, the above aspect of Article 8(j) appears to be inconsistent with Article 27.3(b) of TRIPS, which specifically allows for the patenting of genetic material. In addition, because such knowledge is yet to be documented, and considering the existence of Article 27.3 (b) of TRIPS, one is faced with a situation ripe for bio-piracy.\textsuperscript{37}

Article 27.3(b) of the TRIPS Agreement states that: ‘parties shall provide for the protection of plant varieties either by patents or by an effective \textit{sui generis} system or by any combination thereof’. The central conflict between the TRIPS and the CBD thus, emerges in relation to their fundamental dogmas - while the CBD looks to intellectual property protection as means of achieving conservation and sustainable use of biodiversity and equitable benefit-sharing, TRIPS appears to consider the strengthening of IPRs as an end in itself.\textsuperscript{38} Countries are faced with the dilemma of having to comply with TRIPS while maintaining a level of sovereignty over IPRs and profits coming from biogenetic resources obtained from within the country.\textsuperscript{39} In a more specific sense the central conflict that exists between the CBD and the TRIPS is that while Article 27.3(b) of the TRIPS provides that members are not to exclude from patentability microbiological processes and plant
varieties, the CBD by way of Article 15.1 takes genetic resources out of the public domain, by allowing nations to determine access to them and by recognizing a source country’s right to benefits and technologies coming from them.\textsuperscript{40}

It is in a bid to reconcile this conflict that developing countries wish for the TRIPS to require patent applications for inventions making use of biological resources and traditional knowledge to disclose the origin of the resources or knowledge, (disclosure proposal)\textsuperscript{41} and to provide evidence that they have been given informed consent and have complied with national legislation regarding benefit sharing.\textsuperscript{42}

Under the TRIPS Agreement as it exists today, countries are under no obligation to ensure or inspect whether there is misappropriation of TK or genetic resources (Article 27). This apparent lack is sought to be remedied through the disclosure proposal\textsuperscript{42} which is an amendment currently being discussed, not only under the agenda of reviewing Article 27.3(b) of the TRIPS but also under the heading of ‘implementation issues’ at the Doha Round. This amendment is thought to be essential to protect that TK which is considered to be most common in developing countries- the knowledge of agricultural resources or seeds.\textsuperscript{11} Its demand plays straight into the larger issue of the ability of TRIPS to cater to the dissimilar needs of developing countries, particularly when they constitute the largest repository of genetic resources.\textsuperscript{43}

While most Third World countries desire for the TRIPS to be amended in order to prevent patents on life and bio-piracy, the US continues to uphold the patenting of life forms and indigenous knowledge. The US further played a key role in preventing the patenting of life forms and indigenous knowledge, (disclosure proposal) and to provide evidence that they have been given informed consent and have complied with national legislation regarding benefit sharing.\textsuperscript{42}

In light of the prevailing stalemate as regards a solution to the conflict between the CBD and TRIPS, the way forward once again lies not in substantially modifying TRIPS but rather making use of its inherent flexibilities to create avenues for treaty harmonization.\textsuperscript{46}

Scholars such as Bowman are of the view that a broad construal of Articles 7 and 8 of the TRIPS which account for ‘welfare enhancement’ can facilitate the achievement of CBD objectives as well.\textsuperscript{40} She states that harmonization can be achieved through a broad alteration of the exclusive rights provided for in the TRIPS. She bases such alteration not on an amendment to TRIPS but on Article 30 (ref. 47), which she believes may allow for TRIPS-CBD harmonization.\textsuperscript{40}

The market and profit exclusivity conferred by a patent may be subject to exceptions which do not unreasonably interfere with the patent right as provided under this Article. Therefore, where a country would have earlier prohibited a patent in order to protect its biological diversity in accordance with CBD, can now grant such a patent in consonance with TRIPS, albeit with a limit on the exclusive rights. Such limits on exclusive rights may include mandatory joint patentability, benefit-sharing and technology transfers in conformity with Articles 15 and 16 of the CBD. Bowman affirms that though the question as to whether there can be a limited exception to an exclusive patent right would have to be determined on a case by case basis, such an approach definitely falls within the ambit of Article 30 (ref. 40).

**Flexibilities in TRIPS vis-à-vis Local Laws in India**

It can safely be said that India has achieved economic growth through the planning of a meticulous balance of economic needs with social justice.\textsuperscript{48} India, with a view to fulfil its TRIPS obligations, passed the Protection of Plant Varieties and Farmers Rights Act of 2001 (PPVFR Act). The PPVFR Act represents an ingenious attempt on the part of India to make use of the elasticity intrinsic to TRIPS and pass an act to balance the rights of farmers and breeders, considering the huge farming population in the country.\textsuperscript{49} Developing countries have chosen to understand the term *sui generis* as allowing them the discretion of determining the type and design of plant protection regime and hence promote innovative plant breeding while preserving national objectives like protecting biodiversity, traditional farming, and food security.\textsuperscript{50} However, the elasticity offered by Article 27.3 has always been a
subject of debate, fuelled further in no small part because of the mysticism surrounding the standard of ‘effective’ prescribed in that Article. The question then remains whether the PPVFR Act performs the task of fulfilling India’s obligations under the TRIPS Agreement ‘effectively’. In such a scenario one looks to Article 31 of the Vienna Convention on the Law of Treaties, which deals with the interpretation of undefined terms in an international agreement and, requires treaties to be read in the light of their objectives and purposes. Such emphasis on the objective of the treaty is repeated in subsequent clarifications such as the Doha Declaration which states that ‘the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.’ A look at Articles 7 and 8 of the TRIPS (which specify the objectives and principles of the Agreement) leads to the obvious conclusion that an objective interpretation of TRIPS necessitates that the Article 7 requirement of IP mechanisms balancing members’ rights and obligations should be read alongside the Article 8 principles, which vests in members the right to prioritize their national public interests. A plant variety protection mechanism would certainly be considered ‘effective’ under Article 27.3 if it is capable of taking into account national welfare goals and the local needs of farmers. Therefore, a sui generis system (such as the one offered by the PPVFR Act) makes a crucial connection between plant protection and national welfare requirements - which is usually absent is the traditional patent mechanism.

It perhaps for this reason that several developing and least developed nations have chosen to satisfy their TRIPS obligations through a sui generis mechanism. The preamble of the PPVFR Act’s preamble makes it abundantly clear that its central focus rests on addressing India’s national concerns about protecting the rights of traditional farming communities, while at the same time promoting plant breeding by providing IP protection. Thus, the PPVFR Act provides plant protection under three distinct categories: (a) new varieties, (b) extant varieties, and (c) farmers’ varieties, based on community property concepts [Section 15(2)]. It can be seen that accounting for the interest of a farmer and community benefits, have showcased the effectiveness of the PPVFR Act.

The flexibility utilized by PPVFR Act lies in its registration regime, which enables protection for new varieties of plants while at the same time acknowledging the role of local farmers. For instance, every application for registration must include a denomination of the variety and describe (1) the geographical origin of the material, and (2) all information regarding the contribution of the farmer, community, or organization in the development of the variety. In addition, the application must state that all genetic or parental material used to develop the variety has been lawfully acquired. Furthermore, Section 40 requires the breeder to disclose information ‘regarding the use of genetic material conserved by any tribal or rural families in the breeding or development of such [new] variety.’ It is believed that such a system would facilitate benefit sharing with local farmers. The PPVFR Act adds further safeguards by way of rendering a new variety unregistrable if it is likely to deceive the public, hurt the religious sentiments of any class or section of Indians, or cause confusion regarding the variety’s identity, or is not different from every denomination which designates a variety of the same botanical species or of a closely related species registered under the Act. As regards new varieties, the farmer’s contribution is sheltered via a benefit sharing agreement, whereas the breeder’s rights are protected by way of penalties for infringement of their exclusive commercial rights over the registered variety, including licensing, production, sales, marketing, distribution, and import and export.

The distinct head of ‘extant variety’ was created for the specific purpose of protecting traditional or common knowledge, indigenous rights, or a variety in the public domain of which there is common knowledge, thereby encouraging farmers to register varieties they have developed for years, enabling them to pre-empt appropriation by others. Though a breeder, farmer, a community of farmers, a university, or a public sector undertaking could register an extant variety, they are not entitled to exclusive rights over such a variety, which as per Section 28 rests with the government, thereby preventing private acquisition of varieties in the public domain. Lastly a farmers’ variety is one ‘which has been traditionally cultivated and evolved by the farmers in their fields, or is a wild relative or land race of a variety about which the farmers posses the common knowledge.’ These provisions put the government in a position to negotiate the terms of use, particularly as regards farmer’s variety which has been made a sub-set of the extant variety.
The deviation of the PPVFR Act from the traditional concepts of IP is further highlighted by the fact that it permits to retain their traditional right to save and re-use seeds from their harvests.\(^5^4\) It specifically allows farmers to ‘save, use, sow, re-sow, exchange, share or sell his produce’ including non-branded seed, even if it is a protected variety (Section 39).

A significant aspect on which the PPVFR Act differs from the TRIPS and the traditionally western concept of IPR is that it provides for community compensation in the event of their traditional knowledge being used for the development of a new plant variety. Thus a community possesses the right to make a claim for compensation against a breeder if a new variety is derived from information or contributions made by the local community (Section 41). In furtherance of this objective the PPVFR Act mandates that before a new plant variety is registered, the statutory authority should invite claims for benefit sharing. The Act also provides for protection against innocent infringement of protected varieties, upon the establishment of lack of knowledge or awareness of the protected status. Section 42 also dispenses with the requirement of destroying innocently infringing material. Lastly PPVFR Act encourages experimentation and research on protected varieties by allowing anyone to use a registered variety for conducting experiment or research or as an initial source of variety for the purpose of creating other varieties. The statute nevertheless, requires authorization from the owner of the initial variety to derive the second-generation variety (Section 28).

If one is to look upon India’s exercise of the inherent flexibility visible in the provision of the TRIPS Agreement, one need not go further than the Indian Patent Act, 1970. Section 3(p) of the Indian Patent Act, 1970 continues to hold as unpatentable ‘an invention which, in effect, is traditional knowledge or which is an aggregate or duplication of known properties of traditionally known component or components’. In addition the Indian Patent Act, also includes non or wrong disclosure of the geographical origin of biological origin material used in an invention as grounds for opposition and revocation. Undoubtedly, the Indian Patent Act, 1970 has upheld the protection of TK and the promotion of national interest by availing itself of the flexibility inbuilt in TRIPS.

The conflict between the CBD and the TRIPS has been to a great extent normalized as a result of this *sui generis* mechanism designed to protect traditional and community rights, adopted by India and specifically allowed by the TRIPS Agreement itself. This conflict was further addressed with the passing of the Biological Diversity Act, 2002 (BD Act).

The National Biodiversity Authority (NBA) established by the BD Act regulates the practices mentioned in Sections 3, 4 and 6 of the Act, in so far as it grants permits for access to biological resources, and the acquisition of IPR. It is tasked with the responsibility of advising the central and state governments on matters relating to the use and appropriation of biological resources and has the power on behalf of the Central Government, take any measures necessary to oppose the granting of intellectual property rights outside India on Indian biological resources or knowledge associated with such biological resources.

While the NBA makes the decision of whether to grant access or not ‘in accordance with mutually agreed terms and conditions between the persons applying for such approval, local bodies concerned and the benefit claimers’ it has also got the authority to impose other requirements to accomplish the objective of benefit-sharing.\(^5^5\)

The Indian Government has made masterful use of the flexibilities inherent in TRIPS and showcased them exceptionally well in these three legislations. In doing so one can say that at least for now India is insulated from the perceived negative impact of TRIPS and the argument that a country can continue protect its interest within the aegis of TRIPS hold good, further justifying the argument that TRIPS does not need to be substantially modified.

**Technology Transfer**

Though the acceptance of the TRIPS was preceded by a promise of a greater flow of FDI and enhanced transfer of technologies, one is witnessing a growing divide between north and south technology, with doubts being expressed as to the efficacy of IPRs in promoting the development process.\(^5^6\) Such a state of affairs drove Reichman to acknowledge that ‘the benefits of higher intellectual property protection may be very unevenly distributed, at least in the short and medium terms, even though all developing countries
must bear its transactions costs. With respect to this statement the difficulty of India to get access to substitutes of chlorofluorocarbons and the failure of the initiative to establish an International Code of conduct on the Transfer of Technology becomes particularly telling. With a decline in non-equity modes of technology transfer designed to benefit developing countries, a preference for intra-firm technology transfer particularly, when recipients pose as competitors in the future global market, has been witnessed.

The ambiguity as regards the preferential and developmental rights of developing countries has played a substantial role in fostering these unfavourable circumstances. This becomes evident with Article 67 of TRIPS which required developed countries to provide technical and financial corporation, but afforded no specific obligations or operative mechanism to do so. Later, Article 66.2 created a mechanism to counter this by requiring contracting parties to provide incentives under their domestic legislation to corporations in order to promote transfer of technology to least developing countries. To this effect, developing countries have demanded greater lucidity with regards the implementation of Article 66.2, particularly with respect to environmentally sensible and other horizontal technologies so as to help them create a sound and viable technological base.

Taking a significant stride forward to alleviate this concern, the TRIPS Council adopted a decision to help realize the objectives of Article 66.2. It called for developed countries to provide for annual reports which would provide information on their technology transfer initiatives. Such a step was perfectly suited to counter the apprehensions of developing countries, keeping in mind the limitations inherent with the concept of technology transfer. Technology transfer to developing countries is a difficult concept to define as it takes place in diverse and non obvious ways. Technology transfers are often embodied in imports, or in general or specific training, it can also result from foreign direct investment or specific assistance programmes. Thus, it is often very difficult to assess the actual fact that technology has been transferred or the effectiveness of various incentive instruments that have been used for this purpose. Hence the Council’s decision necessitating annual reporting is perhaps the most effective first step in assessing and ensuring the implementation of the provision.

**TRIPS and Public Health and Access to Medication**

The failure of the its third Ministerial meeting in Seattle in 1999, and a similar less than satisfactory result in Cancun in 2003, resulted in the WTO facing a severe legitimacy crisis, with its members questioning the organization’s ability to meet the needs of its 148 members poised at strikingly dissimilar levels of development. Predictably the TRIPS Agreement once again, found itself at the vanguard of this criticism, being charged with the failure to fully comprehend the concept of varying levels of intellectual property protection customized to the differential developmental needs of third world economies, particularly in relation to public health.

With fewer than 5 per cent of people in the developing world in need of anti-retroviral treatment actually receiving it, and with this figure falling to only 1 per cent in Sub-Saharan Africa, the UN Sub Commission on Human Rights adopted Resolution 2000/7 on ‘Intellectual Property Rights and Human Rights’ which recognized the fact that the implementation of TRIPS could adversely affect human rights, principally with respect to right to health.

The Doha Ministerial Conference in a bid to placate the growing concerns on access to medication made every effort for a breakthrough which would significantly reduce the tension with respect to access to life saving drugs between the developing and developed world, in the fourth session of the Ministerial conference in Doha. This session witnessed the adoption of the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) whose objective was to make obvious the flexibilities inherent in TRIPS, which could be employed to ensure easier access to medication in the light of public health crisis.

The primary flexibility as regards public health provided for in TRIPS, relates to Article 31, namely, compulsory licensing that permits governments to authorize the use of the subject matter of a patent granted to another, without the authorization of the right holder, on the condition that an effort has been made to obtain authorization from the patent holder on reasonable commercial terms and within a reasonable period of time. The condition is waived in cases of national emergency, extreme urgency or public non-commercial use.
The true essence Article 31 of the TRIPS was rendered ambiguous by the influence of pharmaceutical giants and was once again expounded by the Doha Declaration.46 Paragraph 5(b) clearly states that ‘each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted’ to enable the State concerned to have access to generic and therefore affordable versions of essential drugs.76 Therefore even though Article 31 appears to be saddled by procedural conditions for granting compulsory licences, in no way does it limit the grounds on which compulsory licences can be granted. Furthermore, the Doha Declaration explicitly gives each Member ‘the right to determine what constitutes a national emergency or other circumstances of extreme urgency’ in addition to specifying that ‘public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency’.

Nevertheless it is important to note that compulsory licensing is the only procedure explicitly accepted for making available generic versions of patented drugs to patients under the declaration. Parallel importation71 was excluded from the declaration keeping in mind the bar instituted by Article 31 (f) of TRIPS which requires compulsory licensing to be invoked predominantly for the supply in the domestic market of the Member authorizing such use.72 In limiting itself to compulsory licensing with no scope for parallel importation, the Declaration had in effect excluded most African Nations, who do not possess the local infrastructural and technological capacity to manufacture drugs. This problem was recognized and a waiver providing this flexibility was agreed upon, according to which the obligations of an exporting Member under Article 31(f) of the TRIPS Agreement were to be waived for producing and exporting a pharmaceutical product under a compulsory licence for the benefit of an eligible importing member. This waiver enabled countries unable to produce pharmaceuticals domestically to import patented drugs made under compulsory licensing elsewhere.73

Lastly, least developed countries, under the Doha Declaration have been provided with the opportunity to increase their own capacity to manufacture generic drugs or obtain low-priced drug imports from other Members, by granting them an exemption from providing patent protection to pharmaceutical products and enforcing such rights until 2016 (ref. 70).

Regardless of the breakthroughs, it can be understood that access to public health is much more than mere availability of cheap drugs. Special measures are necessary to encourage foreign direct investment and technology transfer targeted at the development of the pharmaceutical manufacturing capacity of developing countries. There still exists a need for appropriate guidelines for access to the global fund for HIV/AIDS, and for global bulk drug procurement mechanisms that could further lower prices while maintaining quality control.74 Nevertheless, it can be safely said that the global community has taken considerable efforts to achieve a more balanced approach between access to medicines and protection of IP rights and as such there exists no need to substantially modify, the terms of the TRIPS agreement in this regard.

Conclusion

After examining the various consultations around the world centred on the provisions of TRIPS, it is concluded that there exists no need to substantially modify its provisions. This is so because none of the issues discussed require a change that needs to be achieved through a substantial modification of TRIPS. It is an accepted fact that that the TRIPS Agreement has always provided member countries with a certain flexibility in terms of how they interpret their obligations.75 This ‘wiggle room’ exists precisely because consensus building on all issues at the international level is not always a possibility and countries are given the option to draw upon the broad language available in the instrument to customize domestic implementation in a manner best suited to their individual needs.75 It is felt that there already exists in TRIPS, the flexibility required to address the various concerns surrounding it and hence it is simply a matter of deviating from a US centric interpretation of the Agreement towards one with a more objective world view.14

The objectives of the TRIPS Agreement highlighted in its Article 7 states that, enforcement of IP mechanisms should ‘contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge’. Furthermore, Article 7 also requires technology to be promoted in a manner conducive to social and
economic welfare. Hence it can be safely asserted that the core objective of TRIPS is the balancing of IP protection obligations with the promotion of social and economic welfare. Article 8 lays down the principles according to which the obligations under TRIPS are to be fulfilled and recognizes each member’s right to adopt public health and public interest measures. The provisions of TRIPS are amorphous enough to imbibe specific changes through a mere interpretation of its terms without the requirement of a substantial modification in most cases.

Having established that the TRIPS is in no need of substantial modification, one may conclude by stating that its continued future in the same form requires merely an understanding by the developed countries that developing countries who seek to implement the TRIPS while accounting for its flexibility, do not seek to dismantle its ideology, but rather to promote its evolution in order to harmonize the interests of the global North and South.7

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16 Poverty Reduction Strategy Papers (PRSPs) are prepared in consultation with the International Monetary Fund and the World Bank describing the country’s macroeconomic, structural and social policies and programs over a three year or longer horizon to promote broad-based growth and reduce poverty and are the basis on which a country can be considered for debt relief; http://www.imf.org/external/np/prsp/2001/sen/01/ (5 November 2010).
23 WIPO Intergovernmental Commission on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Revised version of traditional knowledge: Policy and legal options, WIPO/GRTKF/IC/6/4; Carvalho E D, Protection of traditional biodiversity-related knowledge:
A declaration serves as a guiding factor in the interpretation of existing agreements thereby allowing for a degree of flexibility because it does not culminate in a hard WTO law. It may also include a political undertaking not to resort to dispute-settlement. There is no example of a clear conflict between a WTO text and a declaration being brought to the attention of a dispute-settlement panel.


For example, the Costa Rica bio-prospecting contracts involve partnering with companies or institutions who receive property rights for purchased material in exchange for payments. In the case of successful developments, research, and commercialization, inventors receive protection through IPRs and in return provider communities are rewarded with royalties and milestone payments and other non-monetary transfers, thus allowing for the access to biogenetic resources while providing for the fair and equitable sharing of benefits; Richerzhagen C and Holm-Mueller K, The effectiveness of access and benefit-sharing in Costa Rica: Implications for national and international regimes, *Ecological Economics*, 53 (4) (2005) 445-49.


Bio-piracy refers to the appropriation of biological resources held by a local community through patents in the absence of prior art by persons outside the local community and subsequently excluding them from use of their benefits; Nijar G and Ling C, Implications of GATT on biodiversity: From common to private ownership, http://forests.org/archive/general/gattbiod.htm (8 November 2010).


Unlike European patent law, US law provides for the granting of a patent to anyone who has invented or discovered and then asexually reproduced any distinct and new variety of plant. This includes cultivated spores, mutants, hybrids, and newly found seedlings; Hansen S A, Traditional knowledge and intellectual property: A handbook on issues and options for traditional knowledge holders in protecting their intellectual property and maintaining biological diversity (AAAS, Washington, DC), 2003, p. 11, http://shr.aaas.org/tek/handbook/handbook.pdf (9 November 2010).


Article 30 of TRIPS states that, Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

