

## **TRIPS, patents and public policy: A pot of gold and a tale of woes!**

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That, as we enjoy great advantages from the inventions of others, we should be glad of an opportunity to serve others by any invention of ours; and this we should do freely and generously.

\* Benjamin Franklin

Patents began in a world of machines and chemical processes a substantial, tangible, nuts-and-bolts world -- but now they have spread across a crucial boundary, into the realm of thought and abstraction.

\* James Gleick

The present era has witnessed the metamorphosis of corporations that have been riding the patent wave into global powerhouses controlling both capital and nation-states through the agency of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

Ideas have never been commodified to the extent witnessed in the present era through the medium of patents. The patent is the most potent form of intellectual property rights, through which property rights are exercised over ideas and the results thereof. By empowering the holder of such rights to exclude others from using, selling and making the patented subject matter, it enables control and monopoly over the patented matter. Once confined within borders, these rights and the accompanying control and monopoly now spread their tentacles across the oceans.

Prior to TRIPS, patent laws varied across nation-states, with local laws formulated to suit the needs of each society. Countries like India and Brazil did not provide product patents for drugs as part of a public policy aimed at enabling citizens to access cheaper drugs, while other countries opted to under-enforce patent laws to achieve the same ends. But with the adoption of the TRIPS agreement, all member countries of the World Trade Organisation (WTO) are duty

bound to enforce minimum standards of patent protection and any non-compliance is liable to attract legal action.

Although various provisions of TRIPS[1] apparently allow some flexibility to member countries to promote public policy measures in accordance with their specific needs, these have invariably been interpreted in a manner that promotes the goal of maximising the profits of multinational corporations (MNCs) based in industrially advanced countries.[2] The efforts of governments in industrially developing countries to make effective use of the exceptions provided under the agreement have come under pressure from their counterparts in industrialised countries.[3] This development has led to widespread criticism of TRIPS by the developing world, including governments, NGOs and human rights activists.

This paper attempts to elucidate the minimum standards of patent protection to be enforced by member countries under the agreement. It also explores the provisions within TRIPS that provide scope to promote broader public policy.

1. Patentable subject matter According to Article 27 of the TRIPS agreement, all member countries have to grant patents in all fields of technologies, whether products or processes. Earlier some developing countries granted only process patents, which allowed for reverse engineering to create the product through a different process. In this way they were able to foster indigenous technology that could generate local, low-cost products for domestic markets. In time some countries were able to parlay this advantage into the international sphere as well. For example, Japan and South Korea (in the automobile and electronic industries) and India (in the pharmaceutical industry) became competitors in the global market, mainly by adopting the reverse engineering methodology.

Under the agreement, anything novel, inventive and useful can be patented.[4] The agreement does not define these words, leaving them open to interpretation according to the convenience of patent-holders who are, by and large, based in developed countries. A broad interpretation of the scope of patents would, in effect, block any further progress in that field.

According to the TRIPS agreement, member countries cannot exclude certain inventions from patentability even though the

exploitation of these is prohibited under local law. In other words, they have to grant patents regardless of any prohibition on the commercial exploitation of such a patent. For, example Indian patent laws did not provide for patents in pharmaceutical products but under the TRIPS agreement they will be forced to extend such protection from the year 2005.

The agreement does allow for the exclusion of certain patents if such action is necessary to protect public order or morality or to protect human life and health.[5] This provision provides some flexibility for countries to promote public health policies by claiming their right to protect human life and health, especially in the wake of deadly pandemics like AIDS, which are wreaking havoc in 'developing' and 'least-developed' countries. However, most 'developed' countries do not read this provision as a general exception in favour of public health, thus making it difficult for developing and least developed countries to use it for the benefit of their citizens.

Article 27.3 (b) provides that member countries may exclude certain subject matters

mainly animals, plants and biological processes -- from the patent regime. At the same time it makes a distinction between animals and plants, on the one hand, and micro-organisms, on the other, and provides patent protection to the latter. A number of MNCs have used this distinction to obtain broader patents which enable them to have control over plants and animals even though their exclusive rights are actually restricted to the patented micro-organism which is only a part of the plant or animal as a whole .

1. Parallel import Parallel imports take place when a product sold by a patent holder in one country is exported by a buyer to another country where the price for the same patented product is higher. This effectively reduces the profits of the patent holder as the phenomenon of parallel import usually reduces the price of the product in situations where the buyer exports the product at a lower price. For instance, if A, a patent holder, sells his/her product for \$5 in country M and at \$10 in country N, then A is said to be practising price discrimination. If buyer B, who bought the product in country M, exports the same product to country N and sells it at \$7, then A faces a situation where his/her own product, sold in country M, is reducing his/her profits in country N.

Article 28 of TRIPS provides exclusive rights to the patent holder to prevent third parties from making, using, offering for sale, selling, or importing the subject matter of product and process patents. But the footnote to the Article subjects it to the provision of Article 6, which prevents any country from broaching the issue of “exhaustion of intellectual property rights” before the Dispute Settlement Body (DSB). This term refers to the exhaustion of patent rights (ie, once the patent holder has placed the product in the market, he/she loses control over the actions performed on it by the buyer – so the buyer may sell it or import it to other countries without any hindrance from the patent). In effect it means that member countries can import products from other countries only if the exclusive right is exhausted (ie, subsequent to a patent holder relinquishing all rights after the first sale of the patented product in the market, which enables the buyer to use or sell it). For example, A has a patent over a digital pen until he/she places the patented pens in the market; subsequently he/she loses control over the actions performed by the buyer of the digital pen and the buyer may even sell or export the digital pen at a higher price.

This provision ostensibly enables member countries with no manufacturing capacity of their own to import from countries where the product is sold at a lower price, thereby making the product accessible to their people. But the problem arises with the interpretation of the doctrine of exhaustion, including the question of whether to follow domestic or international principles of exhaustion. Developed countries and, especially, MNCs based in these countries, perceive this provision as a major threat that would allow cheaper goods to flood their markets and undercut their profits. Consequently, attempts by developing countries to promote public health through the use of this provision are generally frustrated by constant pressure from MNCs seeking to protect their profits.

For example, 39 multinational pharmaceutical companies challenged Article 15c of the South African Medicines and Medical Devices Regulatory Authority Act (a.k.a. ‘Medicines Act’). This article had empowered the South African Health Minister to import medicines from other countries in case of a national emergency by issuing compulsory license to produce the medicine locally or by permitting parallel import. This provision enraged pharmaceutical

companies and they challenged its legality before the South African Supreme Court. Such intimidatory tactics were employed by these companies mainly in order to discourage other WTO member countries from passing such legislation.

1. Exceptions to the rights conferred Article 30 of TRIPS provides for limited exceptions to the rights conferred on the patent holder. But the difficulty lies in identifying and interpreting these limited exceptions. According to the agreement, "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." This Article ostensibly enables the promotion of public policy and allows for wider access to essential products.

However, the big question about the efficacy of the provision relates to the fact that these limited exceptions are subject to the proviso that they do not unreasonably conflict with the normal exploitation of patent or prejudice the interest of the patent owner. The terms 'unreasonable' and 'prejudice' are so broad and undefined that they can be read in a manner that restricts the scope of the Article, which would suit the interests of developed countries. Narrow interpretations of these exceptions would prevent developing country members from addressing the issue of public policy.[6]

Article 30 represents the best option for developing countries to use in order to promote public health within the patent regime, especially since it is less procedural than other provisions. For instance, it is an easier option than the compulsory license one (mentioned below) because it can be exercised quickly whereas, in granting compulsory license, various procedures – eg, notifying the patent holder of such a grant and fixing appropriate compensation have to be followed. But the exceptions incorporated into the provision have made it vulnerable to misuse by developed countries, which appear to place the rights of patent holders above all, including the larger public interest.

1. Compulsory licensing According to the TRIPS agreement, WTO member countries can use the subject matter of a patent or permit

such use by a third party without the authorisation of the patent holder. However, such use is limited predominantly for the domestic market of the member state authorising such use.[7]

The agreement does not use the term 'compulsory license.' Instead it chooses to employ the term, 'without authorization of the patent holder', which can be understood to refer to a non-voluntary license. Although this provision can be used by member countries to promote public policy through the issue of a compulsory license to a third party, it limits the use of such a license predominantly for the supply of products to the domestic market. This renders it ineffective for member countries that do not have local manufacturing capacity as they cannot issue a compulsory license to import the required product from another member state. Moreover, other member states cannot use the provision to export the patented product as that would be in contravention of the provision. This limitation frustrates the cause of public health policy, for example, since it restricts the ability of developing and least developed countries to provide access to cheap medicines for their citizens.

Developed country members do not like the idea of compulsory license because they fear that products manufactured through the use of such a provision may flow back to the original patent holder's country and/or to other territories, which may reduce the profits of the patent holder. The United States has used the threat of sanctions, as well as the dispute settlement mechanism, to prevent Brazil, for example, from amending its patent laws to allow compulsory licensing on the basis of lack of local working of the patents (ie, the patent holder does not produce or manufacture the patented product in a country where someone else has obtained a patent for it).

Further, Article 31 stipulates that "member countries can authorise the use of such licenses only on certain reasonable commercial terms and conditions or in a situation of national emergency or other circumstances of extreme urgency." In a case of non-commercial use, the scope and duration of compulsory license is supposed to be only for the limited purpose. The Article also states that the patent holder must be paid adequate compensation, taking into account the economic value of the authorisation.[8]

The main problem with the use of compulsory license is that any such grant of license could be easily challenged and the member countries authorising such use could be compelled to explain and justify the circumstances leading to their action. Terms like national emergency or 'extreme urgency' could be read narrowly by developed countries so as to restrict the use of the provision. As a result, any hope of using the compulsory license to limit the ill-effects of the patent regime is slowly fading.

1. Burden of proof The burden of proving an infringement of patent normally lies with the patentee. However, with the advent of the TRIPS agreement, this burden has shifted to the alleged infringer in the case of a process patent. Under the agreement, the defendant -- ie, the alleged infringer -- has to prove that the process used by him/her is entirely different from the patented process. This provision can be used by large business corporations to threaten smaller competitors with infringement suits, thus effectively preventing them from competing. The prospect of long drawn out court battles, with the onus of proof on them, as well as the possibility of having to pay hefty amounts by way of compensation in the event of losing the case, would naturally discourage them from developing and using alternative manufacturing processes. Thus the provision wipes out the potential of a cheaper alternative to the patented process while giving leeway to the bigger players to monopolise the markets.

2. Pipeline or Mail Box Protection and Exclusive Marketing Rights Under the TRIPS agreement, some developing and least developed countries are allowed a moratorium on product patents in pharmaceuticals and agro-chemical products until 2005 and 2016 respectively. However, during this period, although they do not have to extend protection to product patents, they do have to provide a system for filing patent applications from the date of the entry into force of the agreement itself.

According to some critics of TRIPS, the Mailbox system and the concept and practice of Exclusive Marketing Rights are more powerful than patents; in fact, they have been criticised by many as more severe forms of patent.

Exclusive Marketing Rights refers to a situation in which a patent holder who has been granted a patent as well as a marketing right for a particular product in a member country on or after the date of

entry into force of the agreement, subsequently applies for the same patent in other member countries. According to the agreement, such a person or entity shall be granted Exclusive Marketing Rights in those countries for a period of five years or until a decision is taken on the patent application.

Critics view this provision as more vicious than regular patenting since full protection is provided even before the application for the patent is examined and decided upon. In other words, even though the grant of the patent is not assured, the applicant is granted exclusive marketing rights during the interim period. It stands to reason that if the patent applicant has the exclusive right to market the concerned product within a given country pending the grant of patent by that country, others would be prevented from entering that market.

**Conclusion** The many ambiguities within the TRIPs agreement and the narrow interpretation of its provisions by developed countries and multinational corporations have substantially weakened the efforts of developing countries to promote any sort of public policy. This was evident in Africa, where millions of people suffering from HIV/AIDS could not get access to the medicines they needed as they were too expensive. The example demonstrates that the TRIPS agreement has been used by developed countries to promote the interests of their pharmaceutical companies. The exceptions to exclusive rights to patents within the agreement have been deliberately given a narrow scope, thus frustrating the efforts of developing countries to promote public health via TRIPS.

Endnotes: [1] Articles 6,7,8,27, 28, 30, 31 [2] Ellen 't Hoen: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha, Chicago Journal of International [3] ibid [4] Article 27.1 [5] Article 27.2 [6] Abbott [7] Article 31 (f) [8] Article31