

# What is more Important- Intellectual Property Protection or Right to Health Care and Access to Low-cost Life Saving Drugs: A Developing Countries' Perspective

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## ABSTRACT

Globalization of Intellectual Property protection and stronger IP regime has been the hall mark of TRIPs legislation under the WTO framework. TRIPs legislation has been dominated by the interests of the developed and advanced nations and their MNCs. The TRIPs negotiations has been the witness of this dominance and deliberate neglect of the developing and poorer countries' interests related to their right to health care and right to access low-cost life saving drugs. It is no longer hidden about the hidden agenda of the developed countries and their MNCs to capture the developing countries' market through the IP protection rights and thus making the poorer countries vulnerable in terms of access and affordability of crucial life saving drugs. With the pressure from the developing countries only, WTO agreed to recognise the TRIPs flexibilities and developing countries' rights to frame IP legislation keeping in mind the healthcare needs of their larger masses. This became possible in Doha Declaration in WTO Ministerial Conference in 2001 and subsequent compulsory licensing for exports waiver decisions in 2003 and 2005. Now the essence of the WTO regime after two and half decade of TRIPs implementation is that, the developing and poorer parts of the world have a stringent IP protection system especially in their pharmaceutical industries, also they have TRIPs flexibilities to determine better pro right-to-health IP legislation but neither they have been able to realize their right to health needs nor they have access to low-cost cheaper life saving drugs. This paper questions the ineffectiveness of the lopsided TRIPs system and explores the means available with developing countries to deal with it so as to protect their due public health rights.

**Kew Words:** Intellectual Property Protection, WTO-TRIPs Agreement, Right to Health Care, Access to Low-cost Life Saving Drugs; IP Regime; TRIPs Patent Regime.

## Introduction

Its already more than two and half decades since establishment of WTO and adoption of TRIPs Agreement. With an intent of globalization of trade in goods and services GATT and GATS Agreements were finalised with the last round of discussions at Uruguay in 1994. Additionally, globalization and adoption of trade related aspects of intellectual property rights led to framing of TRIPs Agreement under WTO framework. The idea was ensuring level playing field and uniform protection of intellectual property (IP) rights through out the world and promoting technological innovation and rightful returns to the innovators on their research and development (R&D) expenses. The initial aim and negotiations of TRIPs Agreement however led to creation of a stronger IP protection environment by prolonging patent rights protection for twenty years in all fields of technology and disregarding

the healthcare needs of the developing and poorer countries in the process of making IP legislations related to compulsory licensing, generic manufacturing and other essential requirements.

This created a peculiar scenario with the developing countries- they didn't have the choice to choose for their own IP legislation framework, suiting to their socio-economic conditions and trade needs. Immediately after 1995, with establishment of WTO-TRIPs system, they became vulnerable to the dominance of the developed countries' patenting needs whose main aim was to capture the developing countries market especially the most valuable pharmaceutical and drugs market by launching their patented pharma products. But as the developed countries' MNCs patented medicines often come at higher prices due to higher costs of production and costs of R&D, importing, marketing and branding, the developing countries market were suddenly facing the onslaught of high cost drugs from the leading global pharma giants. And at stake was their reliability on generic imports of drugs from global suppliers which was ensuring their survival of the masses as those drugs were coming at a substantially cheaper costs compared to the patented drugs. Thus, there were at stake were the developing countries' right to healthcare and right to access to low-cost life saving drugs. So the global south, the vulnerable developing and poorer parts of the world were facing the intriguing question-, what is more important for them- the stronger global IP protection or their right to healthcare and right to access low-cost life saving drugs of their poor and vulnerable masses? The present paper makes an attempt to examine this issue and throws some light on the challenges faced by the developing countries and explores some plausible solutions to tackle this scenario.

### **TRIPs Legislation and Globalization of Patent Protection**

Globalization of Intellectual Property protection and stronger IP regime has been the hall mark of TRIPs legislation under the WTO framework. TRIPs legislation has been dominated by the interests of the developed and advanced nations and their MNCs. With series of negotiations from mid 1980s till mid 1990s, newer GATT Agreements were finalized and alongwith it were finalized the General Agreements on Trade in Services (GATS) and Trade Related Aspects of Intellectual Property Rights (TRIPs) in 1995. TRIPs Agreement established the process of globalization of patent and other IP protection applicable to all those countries who were signatory in the said regime. India and African developing poorer countries were all on the same boat, who suddenly faced the requirement to recognise developed countries IP rights and provide means to protect them as well as establish robust adjudication mechanism in case of violation of their IP rights. Was it possible in a short and sudden period of time- nay, it wasn't for the poor countries without sufficient resources and infrastructure.

One need not go far away to discover that these are the same poor countries who, due to lack of sufficient and efficient infrastructure along with the financial resources, were incapable of developing a robust intellectual property rights creation system in their own country, forget about the protection system of those rights! Rather these countries need all sorts of IP knowledge for their technological base and growth of technical know-how, viz off-patent, generic, expired products, embedded technology and even copied and imitated reverse engineering processes! In this case, creating a one-size fits all approach would not be working well especially for the developing parts of the world.

### **TRIPs and Biasedness Towards Developing Countries**

The TRIPs negotiations has been the witness of this dominance and deliberate neglect of the developing and poorer countries' interests related to their right to health care and right to access low-cost life saving drugs. It is no longer hidden about the hidden agenda of the developed countries and their MNCs to capture the developing countries' market through the IP protection rights and thus making the poorer countries vulnerable in terms of access and affordability of crucial life saving drugs. Major bone of contentions were prolonging life term of a patent for twenty

years which were too long a protection for a poor country and maximum vulnerability in respect to its public health rights. Moreover, issues like allowing both process and product patents in all fields of technology including sensitive areas like- food, pharmaceuticals and agrochemicals. This was creating a one-size fits all approach for all the countries disregarding their unique socio-economic positioning, different stages of economic growth trajectory and different resources availability for technological growth and development.

With hue and cry over these issues from the developing countries, finally TRIPs council adopted measures for taking care of basic necessities of the developing countries for making them IP ready. Thus a ten-year transition period was provided to the developing countries from 1995 to 2005 for adopting changes in their IP legislations for making the developing countries' IP system TRIPs compliant and allow adjustments in their industries for product patent protection especially those industries which didn't recognise product patents. India was also one such country which got this transition period- to frame its IP legislation TRIPs compliant especially to make suitable changes in its IP Act related to food, pharmaceuticals and agrochemicals industry which did not allow product patents earlier.

Likewise, TRIPs Agreement made stricter norms for issuing compulsory licenses (CL) to a third party and importing generic drugs from other countries in case of public health emergency requirements for the country. TRIPs Agreement has already made the process of issuing compulsory licenses cumbersome by including provisions like- issue of compulsory license predominantly for domestic supply [Article 31(f) of TRIPs Agreement], compulsory license also for export purpose to check anti-competitive practices, but existence of anti-competitive practices is to be determined by judicial or administrative process [Article 31(k) of TRIPs Agreement] and so on. In case of semi-conductor industry, TRIPs allows compulsory licensing only for public noncommercial uses [Article 31(c) of TRIPs Agreement]. These conditionalities on compulsory licensing norms has been deliberately made stringent for the developing countries in the name of stronger global IP protection norms. It is clearly visible that CL issuing process has been made difficult and delaying with the restrictive conditions. For genuine public health requirements of a country with no public sector capacity to manufacture the patented drug, a poor country cannot get a commercial CL for importing a cheaper generic drug from a third country. With raising of this issue by the developing countries, however, TRIPs flexibilities were declared in Doha Declaration in 2001, which were further re-emphasized in the subsequent WTO General Council Decisions in 2003 and 2005 on 'compulsory licensing for exports' waiver.

### **Developing Countries' Rights to Public Health and TRIPs Flexibilities**

The hue and cry of the developing countries over their right to public health and access to affordable healthcare and low-cost life saving drugs led to exclusive recognition of the issue and guaranteed adoption of it through Doha Declaration ratified in the WTO Ministerial Conference of 2001 [WTO, Declaration on the TRIPs Agreement and Public Health, Doha, 2001]. The Doha Declaration has clarified that *"each member has the right to grant compulsory licenses and freedom to determine the grounds upon which such licenses are granted"* [Para 5(b) of Doha Declaration]. The issue here is very crucial for the developing and poorer countries as the branded patented drugs launched by MNCs are often very highly costly compared to the generic versions manufactured domestically or imported from elsewhere. Moreover, the MNCs want evergreening of their product patents by extending their patent periods by adding sub-species add-on patents associated with the main patented molecule. To ensure this they want compulsory licensing of the patented drug for generic manufacturing to be cumbersome. Thus this will lead to a costly domestic drugs market for the developing countries dominated by the global pharmaceutical MNCs. Though recent amendments allow countries for generic production of patented drugs, many developing and poorer countries have not been able to enact such IP laws and most of them have not used the TRIPs flexibilities fully. (Nicol and Owoeye, 2013)

This raises the fundamental question- what is more important for the developing and poorer nations: just to be part of discriminating globalized IP order wherein their public health rights are deliberately neglected! The entire developing world has to assert their rights related to ensuring public health protection and access to life saving affordable drugs. This can only be possible when they assert their balancing public health rights within the TRIPs itself- in letter and spirit, not just symbolically. The developing countries must frame their IP legislations as per their domestic needs so as to safeguard their right to health and justifiable access to health care. Already India has included certain norms related to compulsory licensing in its Patent Act (IPA, 1970 as amended in 2005). Under Sec 84(6) of Indian Patents Act (as amended in 2005) India defined the reasonable effort for licensing by a third party to be “not exceeding six months” so as to remove the vagueness on it. Likewise, under Sec 90 (1) of amended IPA, apart from domestic supply requirements, India has added a flexibility of exporting the patented product if reasonable public needs of the product are not satisfied, particularly if the exportable market of the product is not being supplied or developed [under requirement of Sec 84.7(a)(iii) of IPA]. This clearly shows India’s resolve to take care of its domestic generic pharmaceutical industry’s needs. The pressure from the developing countries also resulted into a Decision in 2003 by WTO General Council to temporarily waived the TRIPs conditionalities of Article 31(f) which enabled countries to issue compulsory licenses for exporting to those countries which have no manufacturing capacities to produce the patented product [Decision of August 30, 2003, WTO General Council] which subsequently further made workable in 2005 and permanently waived with two-thirds ratification in 2017. This is helpful especially for countries like India to export its low-cost generic pharmaceutical products to poorer African nations which depend solely on Indian life-saving drugs for fighting against critical diseases like HIV-IDS, TB, Cancer and so on. These measures are thus to be replicated by numerous developing countries and moreover, they must fight unitedly to rectify the discriminating conditionalities of the TRIPs Agreement or threaten to de-globalise the IP regime as a strategic tactic to deal with the developed countries on a truly level playing field alongwith putting their healthcare needs at the front of TRIPs legislation.

### **Challenges of Developing Countries and Potential Solution**

Many studies have found that developing countries and LDCs have not been able to fully utilize the TRIPs flexibilities towards their advantage. Many African countries for example, have not been able to use the compulsory licensing norms for their advantage, rather it has resulted into cumbersome procedures and administrative processes like declaration of emergency before issuing compulsory licensing order, many LDCs of Africa had not taken advantage of LDC exemption on exclusion of patent protection of pharmaceuticals products and process until 2016 or later as agreed with WTO Council (Nkomo, 2010). Moreover, important gaps in incorporating and usage of flexibilities still prevailed, in the developing world (Musungu, Oh, 2006). Further, the practical workability of Doha Declaration 2001 was not addressed in the Declaration itself which was again pressurised by the developing countries to come up with a concrete workable solution. This was addressed in the August 30, 2003 Decision of WTO General Council and December 2005 Amendment of TRIPs Agreement, and subsequently the temporary waiver para 6 of Doha Declaration got permanently waived in January 23, 2017, wherein the compulsory licensing requirement for exporting to developing and poorer countries without manufacturing capacity fully ratified with two-thirds majority. However, the parallel treaties like Substantive Patent Law Treaty (SPLT Treaty) under WIPO and bi-lateral and regional Free Trade Agreements (FTAs) have potential to derail the TRIPs flexibilities declared under Doha Declaration and August 30, 2003 Decision of WTO. (Musungu and Oh, WHO, 2006)

The world is increasingly witnessing de-globalization processes and rise of wave of protectionism in global trade and increase of bi-lateral and regional trade agreements. US and powerful countries like China have time and again led to the forces of unilateral withdrawal from international treaties. If these waves of bilateralism and regionalism keeps on rising then the mechanism of implementing the TRIPs flexibilities will be further difficult. US and Switzerland are eyeing to introduce Non-Violation and Situation Complaints (NVSC) clause into the TRIPs Agreements, which will again be detrimental for the developing countries as patent violation cases can be taken up at WTO against a country even if a de facto patent violation case does not exist. This would examine the TRIPs

non-compliant claims by another country against a country at WTO, which would create further problems and obstacles in framing pro-public health IP legislations among the developing and poorer countries.

Potential solution and strategies for developing countries would thus be clearly understand the global processes undergoing in matters of trade and intellectual property rights. Basic infrastructure for IP protection should be created and sufficient manpower for IP management and administration should be developed. Developing countries must know how to co-operate among themselves keeping their collective interests at the fore front at the Ministerial Conferences. Learning from other countries experiences gives a leverage for advanced framing of their priorities in intellectual property matters. Some poorer countries may fall prey to bi-lateral and regional trade negotiations imposed by advanced nations. More often this has vested interests from that of the developed trade partner. Keeping singular interests in mind, the developing country may join such trade partnerships, but it must be without sacrificing its collective stand in TRIPs matters declared jointly with the developing countries group. The developing countries thus must clearly puts their quid-pro-quo strategies with a long term perspectives.

## Conclusion

The agenda of the developed countries and their MNCs continues to capture the developing countries' market through the IP protection rights and thus making the poorer countries vulnerable in terms of access and affordability of crucial life saving drugs. With the pressure from the developing countries only, WTO agreed to recognise the TRIPs flexibilities and developing countries' rights to frame IP legislation keeping in mind their healthcare needs of their larger masses. This became possible in Doha Declaration in WTO Ministerial Conference in 2001 and subsequent Decisions and TRIPs Amendment Protocol of 2005. Now the essence of the WTO regime after two and half decade of TRIPs implementation, is that the developing and poorer parts of the world have a stringent IP protection system especially in their pharmaceutical industries, also they have TRIPs flexibilities to determine better pro right-to-health IP legislation but neither they have been able to realize their right to health needs nor they have access to low-cost cheaper life saving drugs. With rise of parallel forces of patent treaties and free trade agreements (FTAs) questions arise how biasedness of TRIPs system towards the developing countries would be dealt with and their due public health rights would be protected. Potential solution and strategies for developing countries would be to clearly understand the global processes undergoing in matters of trade and intellectual property rights. Along with creation of basic infrastructure for IP protection and manpower for IP management, developing countries must know how to learn from others and co-operate among themselves keeping their long term collective interests at the fore front of negotiations.

## References

1. Correa C., 2000, Integrating public health concerns into patent legislation in developing countries, South Centre, Geneva
2. Decision of 30 August 2003, WTO General Council, Implementation of Paragraph 6 of The Doha Declaration on the Trips Agreement and Public Health (WTO Document WT/L/540)
3. Garrison, C. 2005, Patent Exceptions in Developing Countries, UNCTAD
4. Kumar N., 2003, 'Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries', *Economic and Political Weekly*, January 18, p 218.
5. Lalitha, N., 2002, 'Indian Pharmaceutical Industry in WTO Regime: A SWOT Analysis' *Economic and Political Weekly*, August 24, pp 3542-3555.
6. Mirandah, Gladys, 2005, 'India: Bolar provisions in India's patent law', *Managing Intellectual Property*, November, at <http://www.managingip.com/Article/1254871/Bolar-provisions-in-Indias-patent-law.html>
7. Musungu, S.F; Oh, C., (2006). The use of flexibilities in TRIPS by Developing Countries : Can they promote Access to Medicines? WHO; <https://apps.who.int/iris/handle/10665/43503>

8. Nicol D., Owoeye O.; 2013; Using TRIPS flexibilities to facilitate access to medicines; Bull World Health Organ. Jul 1; 91(7): 533–539
9. Nkomo, M; (2010), The Under-utilization of TRIPS Flexibilities by Developing Countries: The Case of Africa, WTO Colloquium Papers; [https://www.wto.org/english/tratop\\_e/trips\\_e/colloquium\\_papers\\_e/2010/chapter\\_11\\_2010\\_e.pdf](https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2010/chapter_11_2010_e.pdf)
10. Nogués, J.J., 1993, 'Social Costs and Benefits of Introducing Patent Protection in Pharmaceutical Drugs in Developing Countries', *Developing Economies*, XXXI (1), March, 24-53.
11. The Patents Act, 1970, Gazette of India, at [www.ipindia.gov.in](http://www.ipindia.gov.in).
12. The Patents (Amendment) Act, 2005, Gazette of India, at [www.ipindia.gov.in](http://www.ipindia.gov.in).
13. WTO, Agreement on Trade-Related Aspects of Intellectual Property Rights, WTO at [www.wto.org](http://www.wto.org).
14. WTO, Declaration on the TRIPs Agreement and Public Health, Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, at [www.wto.org](http://www.wto.org).
15. WTO, 23 January 2017, Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), [https://www.wto.org/english/tratop\\_e/trips\\_e/tripsfacsheet\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm)
16. WTO, Decision of 6 December 2005, Amendment to the TRIPs Agreement, General Council, WT/L/641, 8 Dec 2005, [https://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm)

