IS THE RIGHT TO HEALTH UNDERMINED BY THE AGREEMENT OF TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS?

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Abstract

This article aims to provide a brief overview of the Agreement of Trade-Related Aspects of Intellectual Property Rights (TRIPS). The analysis will be focused on the agreement itself, its flexibilities, and its impacts on the right of access to affordable medicine. Particularly on medicines which are still under patent protection, a standardised protection period of the same, and the inclusion of pharmaceutical products within the ambit of patentable subject matter is arguably affecting one's right to access to affordable medications. Further, the clash of interests i.e between patent holders (mostly, big pharmaceutical companies) and affected people (mainly, patients and their family) is highly likely to happen – especially in poor and developing countries. This paper seeks to assess whether the right to health is undermined by the TRIPS Agreement, and the analysis finds that such right is not adversely affected by the same.

Keywords: *TRIPS, Doha Declaration, Compulsory Licence, Access to Medicine, Parallel Import*

1. Introduction

One's right to property (which includes intellectual property (IP)) is guaranteed and considered as one of human rights. This is enshrined in Article 17 of the Universal Declaration of Human Rights 1948 (UDHR). The Article reads: "Everyone has the right to own property alone as well in association with others". The spirit of the same is further reflected in Article 27 of the UDHR, and Article 1 (First Protocol) of European Convention on Human Rights. Overall, these articles guarantee the protection of IP as 'property' under the purview of human rights and one's right to peaceful enjoyment of his possessions.

On the other hand, the right to health is also guaranteed by the same instrument, as enshrined in Article 25 of Universal Declaration of Human Rights 1948 that reads: "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, and medical care and necessary social services…" In relation to this, Article 12 of International Covenant on Economic, Social & Cultural Rights 1966 requires the states to recognise and realise this right to health at national level. The reading of these articles promote the idea that access to medicine is an important segment of one's right to health (Yamin 2003, p336), and this should be materialised at national level.

The maelstrom of rights and interests begin here. New inventions and discoveries relating to health care and pharmaceutical products (for instance, essential medicines for life-threatening disease) are protectable under patent law. If this situation is carefully scrutinised, one may see the clash between owner's right under patent law and person's right to health – particularly, with the enforcement of the TRIPS Agreement (which will be explained in the following chapter). The question that is to be assessed now: does the TRIPS Agreement undermine the right of access to medicines, especially in developing countries?

2. Methodology

This qualitative research employs analysis of various documents and discussion papers, particularly the TRIPS Agreement, the Doha Declaration, and the 2003 Decision. In addition, this paper has also referred to seminal

contributions from authoritative jurists in this area – such as Carlos Correa, Duncan Matthew, and Graham Dutfield.

3. The Trade-Related Aspects Of Intellectual Property Rights (The Trips Agreement) And Its Impact

Before the advent of the TRIPS Agreement, it is important to note that there was no global uniformity in IP legal framework – as Correa (1999, p 264) had put it, "Historically, countries developed their IPRs regimes in accordance with their own interest and levels of developments". Under the Paris Convention for the Protection of Industrial Property, countries had more flexibilities in structuring their IP national law – they could determine the patent term and exclude pharmaceutical products from the scope of protection (Correa and Mathew, 2011).

As a result, generic drugs i.e copies of original medicines can be produced, and further exported to poor and developing countries. This practice attracts dissatisfaction, especially from the patent owners. Gopalakrishnan (2008,p 396) revealed that big pharmaceutical companies had claimed that cheap generic drugs from developing countries posed a serious threat to their research and development funding. With aggressive lobbying of the US government that sought to eliminate such unwelcome competition from generic drugs producers, the TRIPS Agreement was eventually negotiated and came into force in 1995 (Dutfield, 2008).

With the implementation of the TRIPS Agreement, the state members are now required to harmonise their national law by observing a set of minimum standard of IPRs protection. These include the grant of patents in all fields of technology (by virtue of Article 27 (1) of the TRIPS Agreement), and the grant of 20 years of protection (by virtue of Article 33 of the TRIPS Agreement) if such patent complies with the requirement of patentability. Under this new regime, new life-saving drugs can be patented by the patent owners. That means, the patent owners would have control over pricing and accessibility (the drugs become more expensive). Eventually, one's right to health (particularly access to life-saving medicine) would be problematised by this situation. It is from this view, according to Joseph (2011, p217) that attracts most vocal criticisms, i.e the price of the medicines.

THE DOHA DECLARATION 2001 AND THE 2003 DECISION

In light of the above said problem, most developing countries had insisted the TRIPS Council to reconsider those issues and consequently, the Doha Declaration was adopted in 2001. The most important text that promotes the realisation of right to health (which includes access to medicine) lies in this phrase:

> The TRIPS Agreement can and should be interpreted and implemented in a manner supportive if World Trade Organisation (WTO)'s Member's right to protect public health and, in particular, to promote access to medicines for all.

Notably, the Doha Declaration recognises the gravity of the health problems faced by the developing countries (such as Malaria, TB, and HIV/AIDS), and it further reaffirms the utilisation of the compulsory licence and parallel import provisions (hereinafter referred to as "TRIPS Flexibilities") under the TRIPS Agreement by all state members.

As regards the TRIPS Flexibilities, it is argued that they are meant to promote right to health and to assist the state members to protect the same at national level. This stance is supported by Dr. Harvey Bale, the Director General of the International Federation of Pharmaceutical Manufacturers and Association, in the WTO symposium in 2007. He strongly asserted that the TRIPS Agreement provides enormous range of flexibilities of which the member states could use in realising the right to health, and the TRIPS Agreement should not solely be held responsible in issues relating to access to medicine.

4. Trips Flexibility: Compulsory Licence And The Doha Declaration

Compulsory licence is specifically mentioned in Article 31 of the TRIPS Agreement. Correa (1999, p274) submitted that this is a useful tool that could drastically improve access to essential medicines. With this alternative, it allows the state members to grant licence to a company, government agency, or any parties the right to produce generic versions of patented drugs, and this could be done without the consent of the patent holder.

Under normal circumstance, the patent owners would provide access of their patented medicines to the market. However, in some extenuating situations, the governments may deem it necessary to grant compulsory licences to allow third parties to produce the medicine in order to ensure that it will be readily available to the general public. The pharmaceutical companies will also be compensated through payment of remuneration. Thus, it can be argued that the TRIPS Agreement (together with the Doha Declaration) do not disregard the right of a state to address issues relating to health effectively, and indeed provide a mechanism to strike a balance of interest between one's right to health and patent holder.

Furthermore, the Doha Declaration has rectified the issue that relates to the manufacturing capacity. Paragraph (f) of Article 31 of the TRIPS Agreement provides that "such use of licence shall be authorised predominantly for the supply of the domestic market of the member authorising such use". This provision is arguably limiting the benefits to countries with good and advanced manufacturing capacities only. As most developing countries do not have sufficient manufacturing capacity or capability, this flexibility is said to have failed in satisfying the needs of those countries. However, by virtue of Paragraph 6 of the Doha Declaration, it recognises such problem and further instructed the TRIPS Council to find a solution. Consequently, in 2003, the WTO announced its decision to implement Paragraph 6, allowing a waiver of "domestic market" restriction on compliance with certain conditions.

With this 2003 Decision, it allows the state members to issue compulsory licence to produce generic drugs for export to least developed countries and other countries which manage to establish that they have insufficient (or no manufacturing capacities) in the pharmaceutical sector. On this note, it could be argued that the TRIPS Agreement (together with the Doha Declaration and the 2003 Decision) appear to assist developing countries with issues relating to access to affordable medicine.

In light of the above, Outterson (as cited in Correa 1999, p274) had stated that many developing countries were not keen to invoke this provision – the countries were sensitive with pressures from developed countries. Plus, this situation was also motivated by political reason i.e to issue compulsory licence for export use was not a viable move as the idea to treat diseased non-citizens (foreigners can't vote) gave no political advantage to the issuing states (Attaran 2003, p748). Be that as it may, the trend had slowly changed. Countries like Zimbabwe, Malaysia, and Indonesia had proven that this flexibility can still be utilised to benefit public health, particularly to reduce the cost of treatment, and provide affordable and free medicine to their citizens;

1. Post-Doha Declaration, Zimbabwe appeared to be the first developing country that had issued such licence (Oh 2006, p25). According to Oh, in May 2002, due to rapid spread of HIV/AIDS, the country had declared a state of emergency, and this was done pursuant to Section 34 and Section 35 of Zimbabwean Patents Act – which effectively gives the power to the Government to allow the use of patented invention during the period of emergency. She further explained that the licence was an 'open' licence (opened to multiple licensees) and that would ensure competition in the pricing of the generic medicines – in other words, more affordable drugs to the patients.

2. Khor (2007, p7) revealed that Malaysia was the first Asian country that harmonised its legislation with the Doha Declaration and the 2003 Decision. Under Section 84 of the Malaysian Patents Act, it allows the grant of compulsory licence in case of national emergency or in public interest. Based on this provision, Malaysia issued the license to import generic Antiretroviral (ARV) medicines from India, and this measure has certainly helped the country in bringing down the cost of treatment (Oh 2006, p28).

3. Indonesia has followed Malaysia's step in overcoming the high cost of medicines. However, unlike Malaysia which imported generic versions of the drugs from India, Indonesia used the compulsory licensing to appoint local manufacturers to produce 7 medicines for treating Hepatitis B and HIV/Aids. (Decree of the President Republic of Indonesia No 76 of 2012). This move has been reported to stimulate local production of the drugs, and eventually drop the price of the same (MSF Responds to issue Compulsory Licences on 7 HIV Drugs, 2012)

From the above examples, it is argued that the TRIPS Agreement (together with the Doha Declaration and the 2003 Decision), have indeed managed to act as a useful tool in improving access to medicine in developing countries where the rights of patent holders are protected i.e the mechanism of "Compulsory Licence" provision. It is perhaps for this reason, Harvey Bale (and other strong supporters of the TRIPS Agreement) argued that the TRIPS Agreement is not an obstacle that hinders the access to medicine in developing countries.

5. Trips Flexibility: Parallel Import – The Trips Agreement and The Doha Declaration

"Parallel Import" is another important TRIPS flexibility that could assist the state members to maximise access to affordable medicines. Parallel import happens when a party purchases a patented product a country (such product is sold there at a low price), and sell the same in another countries where higher price is charged – and there is no concession or licensing arrangement with the patent owner (Salazar, 1998).

Take this situation as an example: suppose a US company had a patented medicine for cancer, which it sells in two markets, Canada (at an expensive price) and Brazil (at a cheaper price). If an India company buys the medicine from Brazil and later sells it in Canada at a price lower than the US Company has offered, such trade is authorised – as it enhances market competition between sources of the same products.

The pivotal legal principle that applies here in this situation is "the exhaustion of IPRs". It refers to instances where a patented product in one market is subsequently exported to a second market and placed on that market without the authorisation of the patent owner (Correa and Mathew, 2011). In other words, from the above stated example, once the US Company has sold a batch of its product in Brazil, its patents rights are exhausted on that batch, and the US company no longer has any rights over what happens to that batch. This international trade activity is allowed by Article 6 of the TRIPS Agreement and Paragraph 5 (d) of the Doha Declaration – whereby, state members are allowed to choose how to deal with exhaustion in a way that best fits their domestic policy objectives. The WTO and influential writers such as Correa and Mathew (2011) argued that this will act as a catalyst that would stimulate competition between pharmaceutical companies.

6. Other Flexibilities

There are also a number of other flexibilities under the TRIPS Agreement which are useful and relevant to the protection of public health (although these are not explicitly mentioned in Paragraph 5 of the Doha Declaration):

1. The state members still have the ability and space to determine what invention that should be granted protection. This, according to Correa (2016) is one of the most important alternative allowed by the WTO. Since the requirements on patentability are not clarified by the TRIPS Agreement, such aspects are then left to the state members' consideration (Gopalakrishnan, 2010) – despite of the strict obligation imposed by Article 27.1 of the TRIPS Agreement i.e to include both products and processes, regardless of the field of technology.

   With this alternative, the policy makers in the state members still have the room to tailor their domestic patent policy in light of their current situation in the country.

2. Apart from compulsory licensing, Article 8 and 30 of the TRIPS Agreement can be used as alternatives to promote and protect public health – by extension, maximising access to medicine (Gupta 2010, p361). He further stated that Article 8 permits the state members to tailor their domestic patent policy so as to protect public health – with this alternative, the state members may reject any patent application if it does not fulfill their national requirements.

7. Conclusion and Future Recommendation

As aforementioned, this paper seeks to analyse whether one's right to health is adversely affected by the TRIPS Agreement. The importance of this brief study is to show that the TRIPS Agreement can act as a mechanism to support the realisation of right to health, particularly the right of access to medicine at national level.

Some quarter may argue that the TRIPS Agreement has worsened the issues relating to access to affordable medicine i.e by standardising the term of protection of new medicines to a longer period i.e 20 years, and by including inventions in all fields of technologies within the ambit of patentable subject matter.

However, a careful analysis of the TRIPS Agreement shows that the TRIPS Agreement does not attempt to suppress the right to health. It might be seen as an attempt to give more monetary gains to the patent holder i.e the pharmaceutical companies. As absurd as it sounds, this premise is rather inaccurate. In fact, it has balanced the rights of the patent holders and the affected people. The TRIPS Flexibilities (particularly, Compulsory Licence and Parallel Import) under the TRIPS Agreement, these are indeed the effective tools in providing and maximising access to medicine. On a separate note, one must not disregard the fact that the problem with access to medicine has existed many years before the advent of the TRIPS Agreement, and it was mainly affected by poverty and the states' poor system of providing the access to the general public – perhaps, a separate analysis on this aspect might be useful in the future.

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