TRIPS, MEDICINES AND HUMAN RIGHTS

Written by ***Pavithra Jaidev***

4th Year BBA LLB Student, Jindal Global Law School

20th century had seen the growth of two legal regimes namely Trade and Human rights. These regimes had grown in complete isolation, and therefore had always been in conflict with each other. Over the past decade, popular trade agreements between developed and developing countries have time and again come under the scrutiny of human rights activists, as they proclaimed, that the trade negotiations which took place between these countries led to human rights violations in a huge manner, common examples of the same were inaccessibility to antiretroviral drugs in Africa, and patented drugs used to treat Ebola, malaria, schizophrenia, cancer etc. Based on the same, this paper is an attempt towards bringing to the forefront the most discussed and debated topics of all times which is the relationship between trade and human rights in the purview of how developed countries are using TRIPS to make stringent patent laws, which has made life saving drugs unaffordable for the poor and needy in Africa, and other underdeveloped and developing countries, thereby denying them medical care which is nothing but denial of right to life.

INTRODUCTION

This paper tries to evaluate, the impact of patented medicines upon the right to life and health of human beings. It has been divided into four parts. First part would briefly discuss the relationship between WTO, Human rights and TRIPS. Second part would briefly describe the HIV/AIDS history of Africa. Third part would elaborate upon ARV's and their impact upon the lives of HIV/AIDS inflicted South African natives, and lastly fourth part would describe the current legal remedies available and the way forward.

WTO, HUMAN RIGHTS AND TRIPS

Trade and human rights regimes though are completely different in nature, they are also said to be two sides of the same coin as they both provide benefits to people. On one side there are countries

engaging in trade negotiations with other countries, using corporate sharks to earn profits and further their economic interests, thereby trying to stabilize the economic crisis within their country, but in this bargain they overlook the fact that, during this process they end up hampering the rights of people from other countries. On the other hand human rights advocates believe in the fact that human rights are rights which are inherently available to all human beings, thereby leaving no scope for any kind of discrimination.

Trade agreements entered into by countries are administered by World Trade Organization (WTO) and Human rights are taken care of by United Nations (UN), United Nations General Assembly (UNGA), United Nations Security Council (UNSC) and United Nations Human Rights Council (UNHRC).

In the latter half of the twentieth century in order to encourage invention and innovation, industries invested heavily in research and development, but to their disadvantage they saw their work being copied by other companies, and being sold at a price which was half of what was actually being offered, thereby creating an environment which was more profitable to second movers[1]. Solution to this problem under the WTO framework came in the form of modern-day TRIPS agreement (Trade related aspects of Intellectual Property Rights) adopted in 1994[2]. Purpose of this agreement was to provide adequate standards of protection to all forms of intellectual property.

Since it's adoption it had become an intense subject of discussion, deliberation and debate as it was one of the most controversial international agreement, countries had signed till date. In many countries signing of this agreement posed a major problem because pharmaceutical companies used the protection given via this agreement to wreak havoc upon the lives of people who were already suffering from incurable diseases. These pharmaceutical companies were responsible for deaths of millions in Africa, Latin America, Thailand and many other countries. Therefore though protection of intellectual property has given developed countries a huge advantage, at the same

[1] Second movers advantage, is the advantage companies gain either by copying some other company's business practices or manufacturing processes.
[2] See, Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh, 15 Apr. 1994, 33 I.L.M. 1197 (1994) [hereinafter TRIPS], which, in the 1986-94 Uruguay Round, for the first time negotiated and introduced intellectual property rules into the multilateral trading system.

time it has left developing countries at a disadvantageous position, facing serious challenges with regard to human lives.

Even though all the three regimes recognize the importance of human rights, large scale violations of the same still take place. In order to understand the intricacies of this problem, it is important to go through the case details of one of the worst hit countries in this manner - South Africa, situated in Sub Saharan Africa, it was one of the *most economically strongest African countries, yet two thirds of its population was diagnosed with HIV/AIDS, which comprised of only 11% of the world's population*[3].

BRIEF HISTORY OF AIDS IN AFRICA

HIV/AIDS, a rare disease without an identifiable cause was recognized by the world in the year 1981[4]. *In the year 1990, the number of people living with HIV/AIDS worldwide, was approximately 10 million*[5]. *In the following years, by around 1995, a range of new drugs were introduced in the market which were known as the antiretroviral (ARV) drugs, these drugs though did not cure HIV completely, they did slow down the reproduction of HIV causing virus in the body*[6]. *By the year 1997, due to the introduction of these drugs, the number of AIDS related deaths had significantly declined in the U.S*[7]. *These drugs were marketed by pharmaceutical companies which strongly patented their medicines, as a result of which less than 7%*[8] *of people living in developing countries, in immediate need of ARV treatment had access to these drugs, resulting in deaths of more than 20 million people and another 40 million people suffering from HIV/AIDS worldwide*

[3] See, WHO, World Health Report 1 (2004); UNAIDS, 2004 Report on the global AIDS epidemic 13, 23, 30 (2004).
[4] See, *History of HIV and AIDS overview*, available at, http://www.avert.org/professionals/history-hiv-aids/overview (Page last reviewed: 26 January, 2016), (Next review date: 26 July, 2017).
[5] See, Prof. William W. Fisher III and Dr. Cyrill P. Rigamonti, *The South Africa AIDS Controversy: A Case Study in Patent Law and Policy*, The Law and Business of Patents, Pg. 2, available at, http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf (Last updated: February 10, 2005).

[6] Id.
[7] Id.
[8] Id.

by the end of the year 2003[9]. *In the year 2012*, 9.7 million people worldwide were recorded to be on ARV treatment, with 7.5 million of those people living in Africa[10].

Everyone acknowledges and appreciates the progress that has been made in recent years with regard to preventing the spread of HIV/AIDS and getting people to use ARVs, but one question which remains unanswered is as to why did the deaths in Africa start to decline since 2007[11], when in US the decline in the number of deaths had started way back in 1995 when ARVs were actually newly introduced in the markets[12]. Why a gap of 12 years? Millions of people in Africa had died during the time in which ARVs came to the market and people in Africa could access them[13]. Many of those deaths could have been prevented if only people had access to ARVs. What stopped them from having access to ARVs? Why couldn't they afford it?

ARV's AND HIV/AIDS INFLICTED SOUTH AFRICAN NATIVES

The answers to the above raised questions are quite obvious, which is that the drugs were quite expensive. ARVs at the time were sold at a price of $10,000 USD per person per year[14]. This price was completely out of bounds for most people in Africa, where the market for ARVs comprised of only 1% of the pharmaceutical industry's total revenues[15].

Most people believed that pharmaceutical companies, sold newly invented drugs at high prices in order to recoup the costs made towards R&D, thereby giving exclusive rights to drug producing

[9] Id.
[10] See, Dr Gundo Weiler, *Global Update on HIV Treatment 2013: Results, Impact and Opportunities*, IAS 2013, WHO Satellite 30 June 2013, 12.30 - 14.30, Pg. 4, 5 (Source: 2013 Global AIDS Response Progress Reporting (WHO/UNICEF/UNAIDS)) available at, http://www.who.int/hiv/events/2013/1_weiler_report_ias_v5.pdf

[11] See, *Update Africa*, UNAIDS special report, Pg.13, UNAIDS / JC2507 E (English original, May 2013) available at,http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/unaidspublication/2013/20130521_Update_Africa.pdf
[12] See, Hannah Keppler, *The Untold AIDS Story: How access to antiretroviral drugs was obstructed in Africa*, available at, https://theejbm.wordpress.com/2013/10/01/the-untold-aids-story-how-access-to-antiretroviral-drugs-was-obstructed-in-africa/ (Posted on: October 1, 2013).
[13] Id.
[14] See, Rochelle P. Walensky, Paul E. Sax, Yoriko M. Nakamura, Milton C. Weinstein, Pamela P. Pei, Kenneth A. Freedberg, A. David Paltiel, and Bruce R. Schackman, *Economic Savings Versus Health Losses: The Cost-Effectiveness of Generic Antiretroviral Therapy in the United States*, available at, http://annals.org/article.aspx?articleid=1556848 (Published on: 15 January, 2013)
[15] Supra note 12.

companies to sell their drugs at any price they wish to for 20 years, in order to incentivize the existing costs they incurred as well as to cover the expenses related to creation of a new drug. For people in the US, this was acceptable because their health insurance could cover the expenses of the drug, whereas in Africa, most people had to pay for their medicines out of their hard earned money, so they simply could not afford ARVs[16].

While the drugs continued to be out of reach for people living in Africa, the same wasn't the case for those who were living in countries such as Thailand, the medicines produced in Thailand were more affordable because generic companies in Thailand were able to produce the drugs at a lesser price, this was because of the rights to exclusivity[17] on ARVs. South Africa was restricted from importing cheaper generic drugs from India or Thailand. But as mentioned earlier Africa consisted of only about 1% of the pharmaceutical industry's profits, therefore even if they allowed Africa to import generics, drug companies wouldn't have lost out on profits anyways. So then what was the problem?

The problem was that pharmaceutical companies were worried about the fact that allowing countries like South Africa, to import generic drugs would set a precedent, for encouraging governments of other countries, such as US, UK and China, the profit making hubs to try and do the same, thereby ultimately diminishing their profits. Nevertheless, thankfully WTO recognized all of these concerns in 2001 Doha round and solved these major issues upto a very large extent.

CURRENT LEGAL REMEDIES AND THE WAY FORWARD

Today, application of certain procedures introduced via TRIPS have largely reduced the deaths caused by HIV/AIDS. Two popular mechanisms in the same context are: Compulsory licensing and parallel/grey imports.

Compulsory licensing is a process whereby government allows third parties to use an invention without the patent holder's permission[18]. Though the term compulsory licensing does not appear

[16] *Supra* note 12
[17] Id.

[18] See, *Access to AIDS medicines stumbles on trade rules,* Volume 84, Number 5, Bulletin of the World Health Organization, 337- 424, available at, http://www.who.int/bulletin/volumes/84/5/news10506/en/, (May, 2006).

anywhere in the literature of the TRIPS agreement, the phrase "*Other use without Authorization of the Right Holder"*[19] *under Article 31 establishes that it is a part of the same. Compulsory licensing is provided in situations where the proposed user had tried to seek voluntary license from the patent holder upon reasonable terms of remuneration but the same was refused. Circumstances where there is no need to try for a voluntary license, in order to get a compulsory license is in the case of: "national emergency", "other circumstances of extreme urgency", "public non-commercial use" (or "government use") or anti-competitive practices*[20].

Compulsory licensing is an attempt towards: one, providing scope for research into development of new medicines and two, promoting access to existing medicines[21]. It is mainly a process which allows generic drug companies (companies which manufacture patented drugs) to sell medicines for half the price quoted by the patent holders, because only the costs of producing the medicine would be charged and not the costs of research and development[22].

Second is *Parallel imports or grey imports,* this process allows a developing or under developed country to make use of the *principle of exhaustion*[23], which means once a company has sold a batch of it's drugs, it's patent rights gets exhausted whereby the patent holder has no right over what happens afterwards with that batch. For example, if a package of paracetamol, supposedly a patented drug, is being sold at $50.00 in America and at $150.00 in South Africa, a South African company (or the government itself) can import the drug from America and sell it at a lower price without the authorization of the South African patent holder[24].

Though these provisions were present in the TRIPS agreement from the very beginning, countries never understood the meaning of these provisions in keeping with the principle of promotion of public health. Further under the influence of pharmaceutical lobby, developed nations would threaten to impose trade sanctions on countries which would try to make use of these flexibilities.

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[19] See, *Under TRIPS, what are member governments' obligations on pharmaceutical patents?* **FACT SHEET:** TRIPS AND PHARMACEUTICAL PATENTS, **Obligations and exceptions,** available at, https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#bolar, (September, 2006).
[20] Id.
[21] Id.
[22] See, Junaid Subhan, *Scrutinized: the TRIPS agreement and public health*, available at, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2323529/#b17-mjm0902p152 (Published on: 9 July, 2006).
[23] *Supra* note 19.
[24] *Supra* note 22.

In 1997, US had threatened South Africa that it will impose trade sanctions against it, if it did not repeal a section of the Medicines and Related Substances Control Amendment Act which allowed compulsory licensing and parallel importing[25].

It was these events that drew the wrath of public health advocates worldwide, as a result of which on November 14, 2001 in Doha, WTO made a historic declaration clarifying the importance of certain provisions which were in favour of the underdeveloped and developing countries. In paragraph 5 (d)[26], it was clarified in particular that member nations had the right to engage in parallel importing without any sort of interference from external actors. Further the difficulty with compulsory licensing was resolved. The difficulty was that supply of imported drugs to a developing nation was allowed only if the proposed licensed product was manufactured in its jurisdiction[27], but the problem lay in the fact that developing nations rarely had the infrastructure required to support a stable pharmaceutical industry, therefore it was recommended that under the agreement, all least developed countries (LCD's) which were WTO members would be exempted from the requirement of producing patented drugs under compulsory license[28]. Furthermore, countries which fell outside the LCD definition could issue a compulsory license (if the drug is patented in it's jurisdiction) for the supply of a developing country if that country's public health situation fell under any of the criteria specified in Article 31 (b)[29], thereby solving the problems associated with both the mechanisms.

Though the deaths caused by HIV/AIDS have comparatively reduced, there are three recommendations which are an attempt towards improving the public health situation within the existing framework of the TRIPS agreement:

[25]See, *PATENT PROTECTION AND ACCESS TO HIV/AIDS PHARMACEUTICALS IN SUB-SAHARAN AFRICA,* THE WORLD INTELLECTUAL PROPERTY ORGANIZATION, Pg. 19 and 20 available at, http://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/iipi_hiv.pdf
[26] *Supra* note 22.
[27] TRIPS Art. 31(f) requires production under compulsory licensing to be "predominantly for the supply of the domestic market."
[28] *Supra* note 22.
[29] *Supra* note 19.

1. Define the term essential medication and create a distinction between essential medication (medicines for diseases such as HIV/AIDS, Ebola etc) and non – essential medication (medicines for health concerns such as high cholesterol, BP etc)[30].
2. Provide process patents (patent for manufacturing process) for essential medication, but ensure certain restrictions are imposed upon the second developer with regard to commercializing its product, and product patent (patent for the product itself) for non – essential medication[31].
3. Make compulsory licensing an obligation and not an option for essential medication[32].

Also pharmaceutical companies and their future business leaders must try to draw inspiration from Jonas Salk[33] an avant-garde, who had developed the first effective patent free polio vaccine. Until Jonas had discovered the vaccine, polio was considered to be a nightmare for the people living in the post-war era. His humanitarian legacy was brought to light by Michael Moore in *Capitalism: A Love Story*[34]. *Salk's intellectual gift is the best example of the fact that companies must go beyond their interests of profit maximization and instead be the saviors of our civilization.*

CONCLUSION

It may be concluded by saying that there is ample evidence in support of the fact that conflict of interest between trade, intellectual property and human rights does exist. Developed countries use intellectual property in a manner whereby goals and obligations of underdeveloped and developing economies get seriously affected. But recognition of this problem alone is not the solution, instead encouraging member countries to make full use of TRIPS flexibilities, compulsory licensing procedure, and parallel imports is the need of the hour and compliance with the same needs to be looked into by the WTO by reading TRIPS provisions in the light of its aims, objectives and principles. Lastly, the touch stone which all underdeveloped and developing countries must aim at

[30] *Supra* note 22.
[31] *Supra* note 22.
[32] Id.
[33] *See, Wasima Khan,* Profits, Medicine, and the Human Right to Health in the Pharmaceutical Industry: Educating (Future) Business Leaders, *available at,* http://www.aaas.org/news/profits-medicine-and-human-right-health-pharmaceutical-industry-educating-future-business-2 (Published on: 16 September, 2015).

[34] Id.

achieving is that, the Guidelines for pharmaceutical companies – in relation to access to medicines submitted in 2008 by UN Special Rapporteur Paul Hunt to the UNGA, is brought to light and put to use, as it is one of those documents which has been neatly chalked out in order to solve the major problems associated with the controversial debate of pharmaceutical companies *v*. right to health and life.