EasyChair Preprint

№ 6364

The Ethics of Counterfeit Medicine Within the World Trade Organisation – Trade-Related Aspect of Intellectual Property Right.

Ifueko I. Imasuen

August 24, 2021

The Ethics of Counterfeit Medicine Within the World Trade Organisation – Trade-Related Aspect of Intellectual Property right.

Ifueko I. Imasuen, University of East London, United Kingdom

Abstract

Generally, existing studies on the World Trade Organisation WTO- Trade-Related Aspect of Intellectual Property right (TRIPS) revolves around access to medicine debate, exclusive licence, and technology transfer issues in developing countries by placing the protection of intellectual property within the free trade forum of the WTO. The WTO in a bid to link trade and IP within its organisation failed to recognize the ethics of counterfeit Pharmaceuticals. Counterfeit Pharmaceuticals is deliberately and fraudulently mislabelled concerning identity and source and can be said to be a direct consequence of free trade. The WTO failed to identify the moral consequence or amoral effect of counterfeit pharmaceuticals on public health. This paper seeks to examine the ethics of the protection guaranteed by the WTO by demonstrating how what is deemed ethical within the WTO-TRIPS like the protection of property rights is not ethical when counterfeit drugs are involved because a business does not concern itself about the ethics of drugs but on profit and protecting the right.

INTRODUCTION

The term intellectual property is the legal right claimed as a benefit from the creation of human intellect to spur innovation (Firth, 2001) It is a vital part of any society to protect the creative knowledge of Man, so ensuring the legal protection of this 'creativity of man is the '*value of all values'* (Adewopo, 2012) for without law this right cannot be affirmed. The doctrinal episteme of western IP is an introduction by the English law before it evolved to other colonies, without recourse to the fact that knowledge about IP is at variance with the traditional system operating in these colonies (Gana, 1995). However, to consolidate this dilemma on protection, the World Trade Organisation –Trade-Related Aspect of Intellectual Property Right WTO- TRIPS (WTO-TRIPS 1994) Agreement was formed out of the WTO.

The TRIPS Agreement was concluded after negotiations at the Uruguay Round (Uruguay Round, 1994) with a mandate of developing a legal framework to effectively regulate the protection of Intellectual Property Rights (IPR) on a global level, by balancing the views of two opposing groups. The developed countries i.e. the IPR advocates and tariff barriers promoters on one angle and IPR antagonist and free trade promoters (Seuba, 2010). One of the primary requisites of the WTO-TRIPs is to elude the use of unilateral retaliation in trade, consequently prompting the need for a world body that would foster global protection of IPR and technological enhancement in developing countries (Correa, 2000).

The WTO –TRIPS Agreement is regarded as the most important agreement for the regulation of intellectual property right. Its framework created a stronger patent protection regime by restricting legitimate control to an investor, to exclusively enjoy the right of its invention. The implication of this protection with regards to

pharmaceuticals is, it enabled pharmaceutical companies to manipulate the price and supply of medicines because IP rights were owned by these companies. It made drugs unreachable and expensive to the public, especially in developing countries (Osibo, 1998) resulting in the introduction of counterfeit pharmaceuticals into the system.

Counterfeit pharmaceuticals as the name imply connotes ‘a drug which is deliberately and fraudulently mislabelled to identity and source (WHO, 2014) resulting in high morbidity, mortality and damage to public health structure (Cockburn, Newton, White and Akunyili, 2005). Counterfeit stifles economic growth by reducing economic incentives, technological know-how and decreasing product value on Pharmaceuticals (Wilson, 2011). The World Health Organisation (WHO) projected that economic loss to counterfeit drugs as of 2010 would amount to $75 billion resulting in significant loss to pharmaceutical companies (WHO, 2006).

This is a problem of the WTO in its quest to protect intellectual property and to provide access to medicine for developing countries in its free trade arrangement by permitting pharmaceutical patents for both processes and products without considering the ethical implication of this protection to the public. It is a topical issue from legal, economic, industrial and technological perspectives. The difficulties surrounding this problem may steam down from the WTO-TRIPS, based on the fact that it failed to define the scope of what it aims to protect.

Protection of Property Right

To understand the justification for IP in international law, a theoretical evaluation of the concept of IP is essential. In a general context, property connotes physical ownership of landed property; as such property can therefore be defined as a thing that has substantial economic or personal value [1] and it is the fruit of man's labour, whether tangible and intangible[2]. However, some scholars have conceptualized property as a form of right to intangible property, thus the prerogative to exclude others from its use[3]. In a like manner, property qualifies as a natural right that the government ought to recognise and protect[4]. To guarantee this much-needed protection for IP, the government conceptualised IP as a right appertaining to an inventor with strict duties for use by a third party.

However, the decision to link trade and IP transformed intellectual property discourse in a variety of ways, particularly the inclusion of IP protection into the international trading system of the World Trade Organisation. This inclusion created a unique opportunity to make IP protection an international obligation for member states of the WTO to integrate into its domestic system, failure to implement warrants risk of action under the WTO dispute settlement understanding.

Under the auspices of the WTO, the Trade-Related Aspect on Intellectual Property (TRIPS)[5] agreement provided adequate standards and principles for the regulation of

Trade-Related IP rights and most importantly to this paper, it recognised the need for the creation of a multilateral framework of principles and rules relating to international trade in 'counterfeit good'[6] which includes trade in counterfeit pharmaceuticals. TRIPS agreement integrates the different subjects of IP especially patent protection for pharmaceuticals under the framework of international trade.

WTO-TRIPS agreement did not give a clear definition of Intellectual property rights but generally, it can be defined as those rights imposed by a state upon individuals for a prescribed term, to prevent unauthorized exploitation as a benefit from the creation of human intellect (Blakeney, 1996). The rationale for justifying IPR as a legal right is mostly for economic reasons. As Dutfield and Suthersanen rightly stated that, IPR is an institutional means for firms to be rewarded or it is an incentive for research and development (Dutfield & Suthersanen, 2009).

To Dutfield (2004), the one -size -fits all approach of the TRIPS agreement is intensified by the extension, of the scope of patentable subject matter. To key areas such as pharmaceutical, life form, genetics and plant varieties as seen, in the landmark case of Diamond V. Chakrabarty, where the supreme court held that patentable subject matters include anything under the sun made by man. This meant that TRIPs created stringent conditions especially for developing countries, who do not have IPR to medicine nor hold productive capacity.

With the monopoly conferred by TRIPs, pharmaceutical companies set high prices for patented products. This high price is one of the important factors restricting access to medicine in developing countries. According to Drahos & Braithwaite (2002), the goal of having a global IPR paradigm is not to create a market economy for the developed

countries but for a needy population, also Oguamanam (2013) stated that the adverse health needs of developing countries especially in Africa show the negative impact of strict pharmaceutical IPR protection by multinational corporations without concern for the human right implications.

Balancing Patent Right and Access to Medicine in Developing Countries

The human rights issue under TRIPs is in respect of access to essential medicine, the debate revolves around how to balance the inflated price of drugs and the health needs of the people. Cynthia Ho (2011) argues that the human rights implication of pharmaceutical companies to patent needs to be taken into account because access to medicine affects all citizens of the world. Therefore knowledge about how drugs are protected should not be limited to a few people. Similarly, Sell (2001) examined the access to medicine debate from a political standpoint, sell argued that the overall cost of TRIPs is steeper than dollars, but will be paid with human lives, especially in the face of the HIV/AIDS epidemic. Adding to the access to medicine debate Attaran (2004), researched by collecting data from 65 low-income countries and comparing it with the WHO list of essential medicine, his study proved that patent may not be the direct cause of essential medicine unavailability in developing countries, however, he suggested that poverty poses a far greater limitation to access to medicine than patent.

The article by Article Ho (2011) posits that analysis of different patent perspectives should advance a better understanding of how to balance patent rights and access to medicine. This patent perspective according to Ho will have a significant impact on how the law is perceived and how laws are interpreted. So access to medicine can be deemed a privilege to patent owners to promote innovation. Whereas Lazzarini (2003)

introduced a different approach by stating that the conflict between IP and human rights could be resolved if the trade exceptions under TRIPs can be fully utilized. This exception includes an exception from patentability, parallel import and compulsory licensing; which are powerful tools for countries with serious public health as seen in developing countries. Gana (1996) argues that the real challenge facing developing countries is a developmental issue not the defects of the international proprietary system such as access to medicine under TRIPs. To Ruth developing countries need to embark on comprehensive developmental strategies in the area of education, marketing, economic policy, foreign investments and technological issues instead of blaming TRIPs.

The focus of developing countries health advocates had been getting affordable drugs into its supply system. This introduced the element of counterfeit pharmaceuticals into the system because the need for access to medicine became more important than the protection of IP rights under TRIPs. Counterfeit is a worldwide problem, even if its scope is still unknown but the WTO estimates that over half of the drugs in developing countries are counterfeit. One of the arguments on counterfeit drugs is that counterfeit is primarily an issue of intellectual property. Intellectual Property not only increased the price of innovative drugs but also aggravated the problems of counterfeit drugs (Clift, 2010). Counterfeit is a pervasive problem given the great margin between the market price of drugs, R&D cost and problems of patent infringement all these issues facilitates the growth of counterfeit pharmaceuticals.

Another major attribute highlighted by Bird (2007) is inadequate laws, enforcement mechanisms and the absence of criminal penalties for counterfeiters. Attaran, Bates and Rogers (2011) argued that counterfeit remains legal in international law, mostly due to the definitional scope of counterfeit. The terms counterfeit have different

meanings attributed to it by different countries and up till now, no uniform definition has been proposed globally. To them criminalizing counterfeit medicine on an international scale will offer significant results over the approach adopted by states. They assert that the *actus rea* and *mea rea* of counterfeit medicine should be put into consideration, for by this means the offender can be easily punished.

However the extent of counterfeit drug is largely unknown, but it keeps increasing everyday WHO (2010) estimates that counterfeit drug market could reach $ 75 billion as of 2010 and 25% of counterfeit drugs is consumed in developing countries. WHO presents results from a survey conducted in 20 countries from 1999-2000, the result showed that 60% of drug counterfeit occurred in developing countries. Some of the consequences of the consumption of counterfeit drugs include death as seen in Niger republic in 1995, where 2500 children died from fake meningitis vaccination, 89 deaths in Haiti in 1995 from the consumption of fake paracetamol syrup, 30 deaths in Cambodia after taking fake anti-malaria drugs WHO (2010). Another consequence of counterfeit stated by Nelson, Chang & Vizurraga (2006) is it stifles economic investment and impede the economic growth of states. Counterfeiters have a total disregard for health and safety measures neither are they concerned with product quality nor pay import or export taxes.

However, research by Cockburn, Newton, Agyarko, Akunyili and White (2005) suggested that companies and governments are reluctant to publish the extent of counterfeit in order not to harm sales of a brand–names product. A survey was conducted to check the presence of a reliable database on counterfeit drugs, the report showed that only 48 reports have been received by the WHO from 1999-2002, this estimate is less compared to the death rate, so this report proved the point of non-

disclosure. Similarly Newton & White (2002) conducted a survey in Cambodia, 138 drugs were tested, and the result showed that 38% of the 138 were counterfeit drugs.

A common theme from the literature discussed above is the anomaly around the TRIPs agreement. The primary intention of TRIPs is the creation of a legal and uniform patent administration system for members of the WTO. But instead, it shifted its focus from IP protection to medicine without delimiting its focus. Scholars on TRIPS focused on the human right, developmental and economic aspects of TRIPs, without considering the side effects of unregulated drugs which are counterfeit pharmaceuticals. TRIPs set a viable administrative system, gave patent rights but failed to regulate the technical aspect of the production of drugs. Most research on counterfeit tends to test it consequence, extent and effect but failed to look at the legal aspect of counterfeit.

Ethics of Counterfeit Pharmaceuticals

The pharmaceutical industry produces and develops life-saving drugs used for the treatment of infectious diseases. The WTO estimates the value of the global pharmaceutical industry is worth $300 billion a year. It is also essential to note that 85% of pharmaceutical companies are based in Europe and America, of which these pharmaceutical companies spend one-third of their profit on marketing products instead of research and development. This action the WTO sums up as “an inherent conflict of interest between the legitimate business objectives of producers and the social, medical and economic needs of suppliers and the public to select and use drugs in the most rational way” (WTO, Pharmaceutical industry). Therefore the act is linked to unethical decisions by pharmaceutical companies solely for profit not the provision of public health.

Another issue facing the pharmaceutical industry is the conflict of interests in the area of drug research and development (R&D) predominantly the area of neglected tropical diseases. The pharmaceutical industry spends millions of dollars every year on research and development of drugs needed in developed countries instead of concentrating on prevailing tropical diseases in developing countries. Tropical diseases include diseases such as guinea worm, Yaws, sleeping sickness and leprosy (WHO Third report on Neglected Tropical Diseases, 2015). Which affect over one billion people globally particularly in developing countries. Thus ethically the rightness of the act of pharmaceutical companies can be judged by the outcome of the act; in this case, the outcome is death due to unavailability of necessary medicine for the treatment of disease an act which could have been prevented if adequate research and development is provided for tropical diseases.

Pharmaceutical companies develop new drugs yearly costing millions of dollars for development. In a bid to recoup the monies spent, the drugs chosen for development are drugs that will yield high returns on the company's investment. Drug manufactures take aggressive steps towards hiking up the price of medicines; a famous example is the drug *Daraprim* which *is used for the treatment of toxoplasmosis, a parasitic affliction that affects the immune system of Aids patients* by increasing the price of the drug from $13.50 to $750 (BBC News, 2015). A simple question in this situation will be '*what is the fair and just price for pharmaceuticals'*, a price that can balance the cost of Research and Development and a price that is affordable to the public to prevent patients from resorting to cheaper alternatives such as counterfeit pharmaceuticals. Counterfeit Pharmaceutical as the name connotes is the production and sales of fake and substandard drugs to unsuspecting consumers which is harmful to health. Ethically the trade in counterfeit drugs goes against the moral value of life.

Life is precious thus giving importance to sustaining life should be the number one priority of manufacturers of pharmaceuticals

As far as evaluating the trade-in fake drugs goes, this is an ethical no-brainer: those who produce and knowingly distribute them to unwitting patients are simply immoral and criminal. The real ethical questions concern who is responsible for the enabling conditions of the trade, and who is responsible for doing something about it. Pharmaceutical companies are not just victims here. When the price of legitimate medications essential to health lies outside the financial means of a good percentage of the world's sick, it is hardly surprising that a market exists for cheap substitutes. Pharmaceutical companies also have typically not taken an active, public role in the investigation of counterfeits of their products. Fearing a loss of consumer confidence in their brand, loss of commercial advantage and falling stock prices, they tend to conduct secretive internal inquiries instead of notifying the public about potential dangers. The companies also are reluctant to cooperate with bodies such as the World Health Organization. Unsurprisingly, governments have historically taken the side of pharmaceutical firms on this matter. But the only ones to profit from this atmosphere of secrecy, mutual suspicion and narrow self-interest may be the manufacturers and distributors of counterfeit medications themselves[7].

The meeting of 149 delegates of member states should be seen from two perspectives," Han continued. "On the one hand, the organization has a positive worth, because the will can be discerned to export economic and work laws of western countries to countries where they do not exist. From another viewpoint, however, it is negative, because the magnitude of the meeting does not allow for the discussion of

local problems, more felt by and more urgent for workers. For Han, however, the western industrial world "cannot be blamed for the decision to invest in markets where workers are less protected. This is the nature of business and businessmen. Even Indian industrialists shift their factories to China because the workforce costs less there."[8]

In conclusion, it can be suggested that there existed an anomaly or dichotomy of concepts especially in respect of Pharmaceuticals thus creating a regulatory paradox under the WTO. Hence from a legal viewpoint, some questions need clarifications such as what type of right is protected by TRIPS, what procedural laws can be relied on for the regulation of counterfeit, is patent protection is the problem or access to medicine.

Bibliography

Attaran, A. (2004). How do patents and economic policies affect access to essential medicines in developing countries? Health Affairs, *23*(3), 155-166.

Attaran, A., Bate, R., & Kendall, M. (2011). Why and how to make an international crime of medicine counterfeiting. Journal of International Criminal Justice, mqr005

Bate R. (2008).Making a killing: The deadly implications of the counterfeit drug trade, AEI Press.

Bird, R. C. (2007) Counterfeit drugs: a global consumer perspective. Wake Forest Intellectual Property Law Journal, 8, (3) 387-406.

Blakeney, M. (1996) Trade-related aspects of intellectual property rights: a concise guide to the TRIPs Agreement. Sweet & Maxwell

Clift, C. (2010). Combating counterfeit, falsified and substandard medicines: defining the way forward? London UK: Chatham House.

Cockburn, R. Newton, P. N. Agyarko, E. K., Akunyili, D., & White, N. J. (2005). The global threat of counterfeit drugs: why industry and governments must communicate the dangers. PLoS Medicine, *2*(4), 302

Correa, C. M. (2000) Intellectual property rights, the WTO and developing countries: the TRIPS agreement and policy options. Zed books

Dutfield, G. (2004). Does one size fit all? The International Patent regime, Harvard International Review, 26(2), 50

Dutfield, G. Suthersanen, U. (2008). Global intellectual property law, Edward Elgar Publishing

Firth, A. (2001) Introduction to intellectual property law, Butterworth

Gana, R. L. (1995). Has Creativity Died in the Third World-Some Implications of the Internationalization of Intellectual Property, Denver Journal of International Law & Policy, 24(109)

Ho, C. M. (2011). Global Access to Medicine: The Influence of Competing Patent Perspectives. Fordham International Law journal 35, (1)1-97

Ho, C.M. (2011). Access to medicine in the global economy: international agreements on patents and related rights. Oxford: University Press.

Sell, S. K. (2001) TRIPS and the Access to Medicines Campaign, Wisconsin International Law Journal, 20:481-522

Seuba, X. (2010) Free Trade of Pharmaceutical Products: the limits of Intellectual Property enforcement at the border. *Geneva: ICTSD*.

WHO, Pharmaceutical industry http://www.who.int/trade/glossary/story073/en/ Access (5 February 2016)

WHO Investing to Overcome the Global Impact of Neglected Tropical Diseases, Third WHO Report on Neglected Tropical Disease.

BBC News US Pharmaceutical company defends 5,000% price increase 22 September 2015 Available http://www.bbc.co.uk/news/world-us-canada-34320413 Accessed (05 February 2016)