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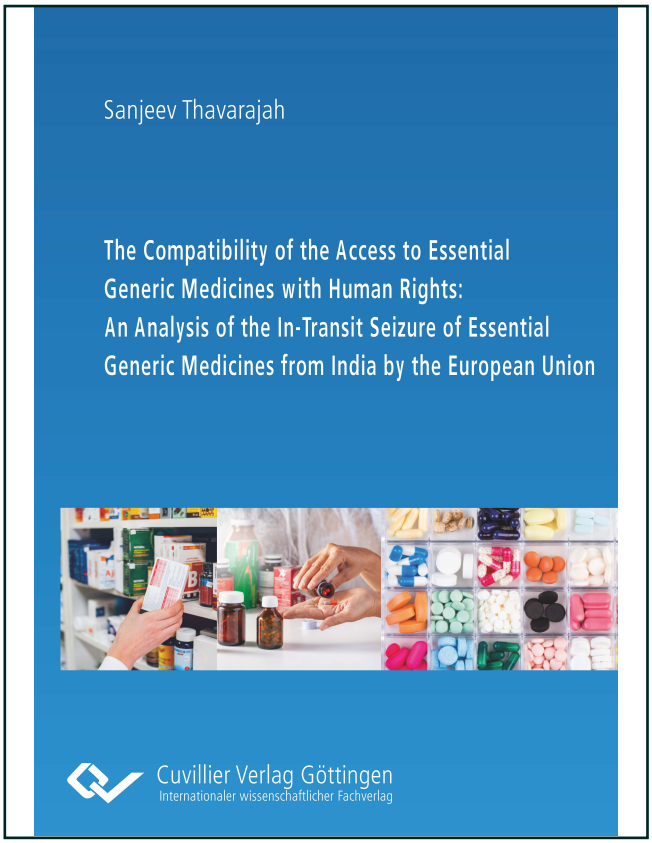
The Compatibility of the Access to Essential Generic Medicines with Human Rights: An Analysis of the In-Transit Seizure of Essential Generic Medicines from India by the European Union



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1. Introduction

"Some 25 to 30 years ago, the world used to think we are a land of snake charmers and black magic. But our youth has surprised the world with its IT skills"[1]

Narendra Modi

The Covid-19 pandemic has sensitised the global community on the importance of the access to essential medicines. The nations of the world have engaged in a fierce battle over the lifesaving Covid-19 vaccines, in which developed nations have come out successfully. The access to essential medicines has long been promoted by the United Nations (UN) and other international human rights organisations. In this context, India seems to have done its bit and has emerged as the pharmacy of the developing world and further has been providing the global poor with the advantage of access to essential as well as generic drugs.[2] Against this background, it would be worth noting that the "Swadeshi" or "Make in India" campaign was launched by the Narendra Modi's government on 25 September 2014 in order to encourage Indian companies to manufacture their products in "Bharat" (India) and provide significant incentives for the same.[3] One of the sectors for which "Make in India" is designated are pharmaceuticals.[4] In this context, it is noteworthy that this research project, *inter alia*, aims to examine the area of the Indian pharmaceutical sector, which seem to have made its mark on the global stage as the world's largest medicine cabinet.

[1] Pandey, Geeta: India: Five unusual messages from Narendra Modi's speech. in: BBC News. Delhi, 2014. - https://www.bbc.com/news/world-asia-india-28799397, DOA: 9.6.2020.
[2] Nonaka, Melissa: Enough is Enough: India's fight against Seizures of Lawful Generic Medicines, in: Journal of Medicine and Law (2011), pp. 37- 57, p. 37.
[3] Firstpost: Make In India, Ayushman Bharat, Swachh Bharat: NDA campaign likely to showcase flagship programmes to attract voters. 2019. - https://www.firstpost.com/india/make-in-india-ayushman-bharat-swachh-bharat-a-look-at-various-schemes-and-polices-of-narendra-modi-government-6237911.html, DOA: 20.02.2021.
[4] Make in India, Sector Highlights: Pharmaceuticals, 2020. https://www.makeinindia.com/sector-highlights-pharmaceuticals, DOA: 15.05.2021.

The 21st century has widely been proclaimed to be Asia-centric and in light of this global development this research aims to take an Indo-centric focus. In doing so it hopes to provide a narrative that would give weight to, broadly speaking, a non-Western perspective while highlighting Indian specificities and unique concepts in the area of health. In this respect, this work aims to examine the three main components of the Hindutva (Hindu nationalist) doctrine, namely "Hindi, Hindu and Hindustan" (see chapter 2) which form part of the ideological background of Indian foreign policy at the beginning of the 21st century under the Bharatiya Janata Party (BJP). As part of its Hindu nationalist agenda, the BJP government has engaged in the promotion of traditional Indian medicine in an attempt to seriously challenge the dominance of conventional Western (European) medicine. With regard to the BJP's Hindu nationalist agenda, the second chapter will *inter alia* consider the issue of what the author has termed the "mandarinisation" of India. In other words, the systematic spreading of the linguistic dominance of Hindi, which appears to a long-term objective of the Hindu-nationalists. In this context, International Yoga Day and its symbolics value for the BJP government ambitions to become a yoga guru will be give due consideration. Thus, New Delhi has issued claims about cultural supremacy over the world due to yoga's Indian heritage. Equally, sub-chapter 2.1 will briefly discuss the aspect of civilisational clashes by drawing on Samuel Huntington's theory of the "Clash of Civilisations". This will be followed by sub-chapter 2.2, which will examine the topic of the cow which in Hinduism, and according to Hindu mythology, is sacred and is worshipped by millions. This sub-chapter will pay due regard to the potential medicinal value of Gomutra (cow urine) and other waste products such as cow dung. Gomutra, as per Hinduism, has purifying as well as cleansing characteristics and has been claimed by Hindu nationalist organisations *inter alia* that the Hindu Mahasabha has a viable remedy against the Corona-virus.

This research will also study the case in which a consignment of essential generic medicines from India designated to Brazil was seized, in-transit, by Dutch customs due to a suspected Intellectual Property (IP) infringement (see chapter 3). Following this incident both India and Brazil filed requests with

the World Trade Organization's (WTO) Appellate Body to hold consultations with the European Union on the issue of seizure of in transit generic pharmaceuticals by Dutch custom officials. Against this backdrop, this chapter intends to examine whether the seizure of essential generic medicines from India by the EU is compatible with the standards employed by international human rights law. It will also investigate the impact that European Council Regulation 1383/2003 has on in transit medicine which, by default, was never intended to enter the domestic market of the EU in the first place. In this regard, it is worth noting that both Brussels and New Delhi seems to have much in common, including that they happen to be large democracies with India being the largest in the world. Both adhere to the rule of law, the promotion of human rights and have large economies. New Delhi was also among the first to establish bilateral relations with the European Economic Community in 1963. In recent times, both unions have engaged in negotiations over a bilateral Free Trade Agreement (FTA), which has been put on hold (at the time of writing). On the back of this sub-chapter 3.1 will aim to play devil's advocate and investigate whether there had been quality issues with medicines from India. We shall also turn our attention to the problem of antimicrobial resistance hailing from India which has been detected in the EU. This fact begs the question whether the EU was indeed justified to ban around 700 generics from India in 2015.

Chapter four will examine access to medicines from a human rights point of view. This will be followed by an analysis of the philosophical dimension of the right to health (4.1). It will also investigate whether the access to medicine can be classed as a human right from a legal perspective (4.2). Moreover, this sub-chapter will also investigate the supremacy of legal norms. In other words, it will investigate whether the IP law or international human rights law should prevail in situations where there is a conflict between two competing norms. Sub-chapter 4.3 studies the Maastricht Principles of Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights which *inter alia* places particular obligations upon states, when behaving themselves in a way that has real and predictable effects on human rights beyond their national border. In addition, sub-chapter 4.4 will also explore the

subject matter of evergreen patents, which consists of minor modifications to already existing patents in order to *de facto* prolong essentially the same patent protection. The issue of evergreening will be illustrated in sub-chapter 4.5 via the example of Natco Pharma Ltd v. Bayer Corporation case.

Chapter five will examine the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the access to medicines in the context of human rights. Sub-chapter 5.1 discusses compulsory licenses. In this context, it is worth noting that the Doha Declaration both protects public health and also promotes access to medicines for all. This sub-chapter further examines access to medicines to Least Developed Countries (LDC) and developing countries in the context of the Doha Declaration. Likewise, this chapter will discuss the issue of parallel importation when it comes to safeguard the affordability of essential medicines. This will be followed by the landmark case of Natco Pharma Ltd v. Bayer Corporation (5.1.1). The dispute between the Indian pharmaceutical company Natco Pharma (an Indian company based in Hyderabad) and Bayer on the subject matter of a compulsory licence shall be discussed.

Chapter six will examine the subject matter of traditional knowledge, an emerging area in the field of Intellectual Property Right (IPR), specifically, the exploitation of India by Western multinational corporations. The reason for choosing the aspect of traditional knowledge, in the Indian context, is twofold. Firstly, traditional knowledge is a rather newly emerging area in the field of IP law and does indeed create a crossroad between the illegitimate exploitation of traditional knowledge and international human rights law. Secondly, the subjects that have been exploited represent something that is quintessential Indian, and illustrates the detrimental consequences of biopiracy and IP theft by Western multinationals for the original IPRs owners. This chapter will also look into the subject matter of traditional knowledge exploitation. This chapter will examine bioprospecting of the following items: neem, turmeric, basmati, Trichopus zeylanicus and Yoga (exhibit A-E). Most of the items discussed in the chapter are plants, except for yoga. The majority of these plants have medicinal value, which have been

developed for centuries by utilising Indian traditional medicine. As for yoga, it is both ancient and would technically fall into the category of Indian traditional medicine due to its health benefits. The Basmati exhibit displays the dilemma of misappropriation of traditional agricultural knowledge by an American multinational for the Indian staple Basmati rice. In all this, this chapter aims to investigate the EU's involvement in this area. Finally, exhibit F will consider whether traditional knowledge could be classed as a property right. In doing so, this part will focus on Morris Cohen's work on "Property and Sovereignty".

Chapter seven will consider Brussels' position as a major economic player on the world stage. In particular, this section will examine whether the self-image proclaimed image of the EU as both a norm- based and responsible international actor is indeed able to stand the test of time. In this regard, this chapter endeavours to reflect on the aspect of international trade agreements of the EU. More precisely, it will address the higher IPRs ("TRIPS plus") standards that seem to be part and parcel of both bilateral and multilateral trade agreements of the EU. It shall also consider both FTA's and Economic Partnership Agreements (EPA) of the EU with LDC and developing nations. In addition, it will examine whether the IPRs that are applied by the Brussels could potentially obstruct the full enjoyment of human rights. Sub-chapter 7.1 aims to briefly examine the opportunities for the signing of a FTA between Brussels and New Delhi against the backdrop of the seizure of essential generics from India.

Chapter eight considers the other relevant impact factors with regard to relations between the EU and India. Sub-chapter 8.1 will investigate the 2015 dispute between India and the EU over ban of 700 generic medicines from India. Moreover, this section will also consider the EU's unwillingness to waiver the IPRs protection of the Covid-19 vaccines and India's "vaccine maitri" initiative. Sub-chapter 8.2 aims to examine Brexit and its consequences for the UK's relations with the EU and India. The dispute between the Brussels and London over Covid-19 vaccine distribution shall also be discussed in sub-chapter 8.3, which covers aspects of both

unilateralism and multilateralism. It will examine whether the EU and India are taking a unilateral or multilateral approach when engaging in international relations.

To conclude, chapter nine aims to provide an answer to the research question on whether the seizure of essential generic medicines from India by the European Union, designated to developing countries, is compatible with international human rights law. In doing so, the final segment intends to provide tangible recommendations for safeguarding the access to essential generic medicines. Equally, it will provide an outlook with regard to future areas of research in this context.

1.1. Research Question

The Covid-19 pandemic has increasingly highlighted the dependency of the global community on Covid vaccines and other related pharmaceutical drugs. In this context, unlike the rich developed world, vaccines against Covid-19 remains out of reach for most populations living in both the LDC and developing countries. The rich nations in the West, *prima facie*, appear to be protective of IPRs and more precisely when it comes to sharing their IP knowledge to the Covid vaccines with the developing nations and LDC. In particular, the EU bars its pharmaceutical companies from exporting Covid vaccines to nations lacking production capabilities. Brussels' protectionism of its pharmaceutical industry seems to be hardly new. Already as early as in December 2008, EU customs authorities seized hypertension drugs suspected of patent infringement.

To begin with, the EU has implemented Council Regulation 1383/2003 which has placed the supply of essential generic medicine under considerable scrutiny. This has meant that Indian companies have been on the receiving end of the sanction directed at IP violators. Thus, the overarching research question of this PhD project is whether the seizure of essential generic medicines from India by the European Union, designated to developing countries, is compatible with the right to health. More precisely, it will further examine whether the access to essential generic medicines could be classified as falling under the category of the right to health (human right) and consequently whether the seizure and subsequent detention of the in transit cargo of these medicines would qualify as a violation of international human rights law. In this context, it would be relevant to examine whether international human rights law should supersede intellectual property law in cases in which a norm conflict arises. More importantly, this work will assess whether the right to health, in the form of access to medicines, should take precedence over IP law in case of a conflict between both norms.
Another issue that will be investigated is whether Brussels' utilisation of IPRs protection, and the subsequent seizure as well as detention of generic

medicines from India, could, potentially, have created a barrier to international trade in the field of generic medicines.

The final aspect that is worth examining is whether the seizure of Indian generics, due to suspected IPRs violations, has been applied in a protectionist fashion to protect the EU's domestic pharmaceutical industry against cheaper competition from India. A reason for this presumption could be drawn from German Chancellor Angela Merkel's statement that the EU had "permitted" India to become a major pharmaceutical producer in the world, while the EU's industry had deteriorated at the same time. On another note, it is worth noting that the term medicines shall be used as a holistic term throughout this work and shall include all pharmaceutical and medical products. Similarly, the subject matter of international human rights law will be analysed from a holistic point of view covering *inter alia* the aspects of politics, law, human rights, medicine, IPRs and trade. Finally, the timeframe for this research will be limited to the beginning of the 21st century.

1.2. Methodology

This dissertation is undertaken in the form of classical desk-based research. Both secondary and primary literature (case law) are discussed as part of this research project. This research utilises the online library catalogue of Philipps-University Marburg. Equally, monographies, anthologies, periodicals, online journals, newspapers article, legal and other databases are consulted. With regard to the legal databases, this work consults Westlaw, Nexis Uni and JSTOR. Equally, extensive case law in the areas of national, region (EU) and international intellectual property law will be considered. Likewise, the websites and databases of different national and European patent offices is given due consideration. Similarly, the website of the WTO also serves as a vital source for this research. More particularly, the TRIPS Agreement is covered in a substantial manner. Multiple international human rights conventions and national as well as regional human right instruments are also covered in detail.

1.3. Literature Review

This chapter will provide an overview of the literature that has been employed as part of this research. To begin with, we shall contemplate on the notion of natural law and human rights. According to Malcolm Shaw, natural law predates the establishment of the nation state, it is recognised by the states rather than being created by them. The subject matter of natural law and, more precisely, natural rights was developed in the wake of the 17th century and is closely linked to John Locke. These natural rights are covered, *inter alia*, the following: the right to life and liberty.[5] For Gabriele Ali, national and supranational governments on the other hand bestow IPRs. They are subject to rigorous statutory limitations, are alienable and limited in time. They can both be revoked and owned by multinational pharmaceutical and other corporations.[6] To put it in another terms, IPRs are artificial in nature and not inherent. Human rights lawyers have also argued that IPRs have been a considerable obstacle when it comes to the full realisation of the access to essential medicines globally. In this context, patents have served as a reason for impeding the capillary distribution of affordable drugs.[7]

Today the political universality of human rights can hardly be refuted. The experience of World War II has further strengthened acceptance of the idea of human rights. Most of the international community of states have accepted the universality in one shape or form.[8] According to Louis Henkin the concept of human right has virtually been incorporated into almost every nation's constitution in the world.[9] In the religious context all major religious have, *prima facie*, downplayed doctrines that happened to conflict with human rights, for instance, subordination of women or intolerance towards other religions. Human rights are commonly regarded by a multitude of religions as the bare minimum requisite for the good society, particularly,

[5] Shaw, Malcolm: International law. 6th ed. Cambridge: Cambridge University Press, 2008, p. 266.
[6] Alì, Gabriele: Intellectual Property and Human Rights: A Taxonomy of Their Interactions, in: International Review of Intellectual Property and Competition Law (2020), No. 51, p. 411-445, p. 416.
[7] Ibid.
[8] Henkin, Louis: The Universality of the Concept of Human Rights, in: The Annals of the American Academy of Political and Social Science (1989), Vol. 506, No. 1, pp.10-16, p.13.
[9] Ibid.