A CASE FOR COMPULSORY LICENSING FOR CANCER DRUGS IN THE LIGHT OF TRIPS AND INDIA'S PATENT LAWS

A Dissertation submitted to the National University of Advanced Legal Studies, Kochi in partial fulfilment of the requirements for the award of L.L.M Degree in International Trade Law

THE NATIONAL UNIVERSITY OF ADVANCED LEGAL STUDIES
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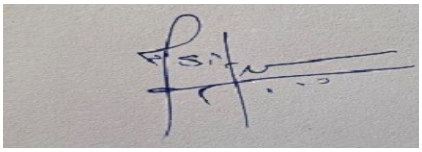
CERTIFICATE

This is to certify that **NIKHIL SURESH**, **REG NO: LM 0220017** has submitted his Dissertation titled "**A CASE FOR COMPULSORY LICENSING FOR CANCER DRUGS IN THE LIGHT OF TRIPS AND INDIA'S PATENT LAWS**" in partial fulfillment of the requirement for the award of Degree of Master of Laws in International Trade Law to the National University of Advanced Legal Studies, Kochi under my guidance and supervision. It is also affirmed that the dissertation submitted by him is original, bona fide and genuine.



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DECLARATION

I declare that this Dissertation titled **"A CASE FOR COMPULSORY LICENSING FOR CANCER DRUGS IN THE LIGHT OF TRIPS AND INDIA'S PATENT LAWS"** is researched and submitted by me to The National University of Advanced Legal Studies, Kochi in partial fulfilment of the requirement for the award of Degree of Master of Laws in International Trade Law, under the guidance and supervision of **Dr. Asif E**, Assistant Professor, NUALS and is an original, bona fide and legitimate work and it has been pursued for an academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University or any other University.

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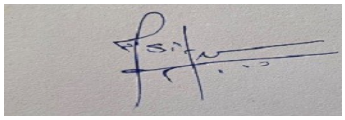

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"Gratitude makes sense of our past, brings peace for today, and creates a vision for tomorrow"

- *Melody Beattie*

Woking on this dissertation have been an immense learning experience. I'm thankful that I had the liberty and resources to work on this project without having to worry about my next meal or about having a roof over my head. Many of our fellow citizens are yet to be privy to what I'm taking for granted.

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- *Natco Pharma Ltd. v. Bayer Corporation*, Compulsory License Application No. 1/2011 (Controller of Patents, Mumbai)
- *Parmanand Katara v Union of India* (1989) 4 SCC 286; AIR 1989 SC 2039
- *Paschim Bangla Khet Mazdoor Samity Vs. State of West Bengal* 1996 (4) SCC 36
- *State of Punjab v. Ram Lubhaya Bagga* (1998) 4 SCC 117
- *Vincent Panikurlangara v. Union of India* 1996 (2) SCC 682
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LIST OF ABBREVIATIONS

- AIDAN — All India Drug Action Network
- AIDS — Acquired Immuno Deficiency Syndrome
- AMA — American Medical Association
- API — Active Pharmaceutical Ingredient
- ARV — Antiretroviral
- CBP — Cost Based Pricing
- DPCO — Drug Prices Control Order
- DSB — Dispute Settlement Body
- EU — European Union
- FDA — Food and Drugs Administration
- FTA — Free Trade Agreement
- GATT — General Agreement on Tariffs and Trade
- GIST — Gastro Intestinal Stromal Tumor
- GSP — Generalized System of Preference
- IIPA — International Intellectual Property Association
- INR — Indian Rupee
- IP — Intellectual Property
- IPAB — Intellectual Property Appellate Board
- M&A — Mergers and Acquisitions
- MBP — Market Based Pricing
- MNC — Multi National Corporation
- NAFTA — North Atlantic Free Trade Agreement
- NHS — National Health Service

❖ NICPR	National Institute of Cancer Prevention and Research
❖ NPPP	National Pharmaceutical Pricing Policy
❖ PBAC	Pharmaceutical Benefits Advisory Committee
❖ PBS	Pharmaceutical Benefits Scheme
❖ PhRMA	Pharmaceutical Research & Manufacturer's Association of America
❖ R&D	Research and Development
❖ SC	Supreme Court of India
❖ TRIPS	Trade Related Aspects of Intellectual Property Rights
❖ UK	United Kingdom
❖ UNHRC	United Nations Human Rights Council
❖ USD	United States Dollar
❖ USTR	United States Trade Representative
❖ UDHR	Universal Declaration of Human Rights

INTRODUCTION

Intellectual Property can be understood as creations derived primarily from the creator's intellect, effort, and mind. When a person makes an Invention that suits the criteria for Patentability, she ought to have rights over it. She ought to be allowed to monetize her Invention as a remuneration for her efforts. She ought to be protected against unauthorized duplication or any other actions by a third party that would jeopardize her rights. Otherwise, the efforts she put can be taken advantage of by another party, which is unfair. However, if the Inventor is given the right to monetize her creation ad infinitum, there is a possibility of monopoly and the dangers related to it. This can be harmful to the society. Hence, Intellectual Property laws allow the Inventor to enjoy monopoly over her Invention for a certain period, usually 20 years, following which the schema of her invention would be made available to the public.

New Inventions can cost anything from a few Rupees to Lakhs. People consume these inventions depending on their purchasing power. People are free to choose the inventions they desire to consume. Non-consumption of an invention does not lead to the death of the potential purchaser. However, particular inventions, such as medicines, can mean the question of life and death for the potential purchaser.

What if the Inventor prices a particular invention to such degree that it is rendered unaffordable to a potential consumer whose life and death depends on the availability of the invention.? Would it be fair to respect the monopoly rights of the Inventor to the exclusion of any other consideration? Because by all means, monopoly rights of the Inventor ought to be respected and accorded legal protection. It is the fundamental precept of Intellectual Property Law. But what about the life of the potential purchaser? What if there are a million potential purchasers for whom consumption of this invention may help them cure their Cancer?

Should we allow these millions to suffer due to the lack of affordability? Should we respect the right of the inventor to enjoy his monopoly and thereby his pricing? Should we negotiate with the Inventor to adjust his price so that it may help society at large? What if the inventor cannot reduce his cost because that would mean he cannot invent other lifesaving inventions?

Or should society determine the price the inventor can levy? How would this affect the Inventor? How would this affect the community? How to arrive at a balance?

These are the cardinal questions one is confronted with when it comes to the aspect of Compulsory licensing.

Compulsory licensing in Patent law legally enables the Government to allow third parties to produce and market intellectual property without the consent of the owner[1].

According to Carlos M. Correa, "Compulsory licensing is a vital instrument to mitigate the restrictive effect of exclusive rights conferred by patent and strike a balance between the title-holder's interests and those of the public in the diffusion of knowledge and the access to, and affordability of the outcomes of, innovation and creativity."[2]

According to Jamie Feldman, "Compulsory licenses are extremely powerful rights granted to governments, which must be used prudently"[3]

Compulsory Licensing is a cardinal provision in the Patent Laws of numerous nations. The TRIPS and Doha Declaration favour Compulsory Licensing as a means to address public health crisis. [4]

The Patent Act of India, 1970 was amended in 1999, 2002 and 2005 to fulfill India's obligations under TRIPS Agreement and the Doha Declaration. These Amendments brought significant changes to the provisions dealing with Compulsory Licensing.

Section 84 to 92 A provides for provisions regarding Compulsory Licensing.

India faces a problem that is common to other emerging and high-income economies: the unsustainable prices of cancer drugs. Medications in oncology are exorbitantly expensive.

[1] Gopalakrishnan N.S., Anand M. (2015) Compulsory Licence Under Indian Patent Law. In: Hilty R., Liu KC. (eds) Compulsory Licensing. MPI Studies on Intellectual Property and Competition Law, vol 22. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-54704-1_2 (Accessed March 10th 2021)

[2] Carlos M. Correa, Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries, 1 SOUTH CENTRE (1999) page 24 http://www.iatp.org/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf (Accessed March 10th 2021)

[3] Jamie Feldman, Compulsory Licenses: The Dangers Behind the Current Practice, J. INTER. BUSS. & L., 137, 137-167 (2009) (Accessed March 10th 2021)

[4] According to Article 31 of TRIPS, Compulsory Licensing may be granted in case of National Emergency or other circumstances of extreme urgency or in case of public-non-commercial use. https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#fntext-7

Cancer Drugs are most costly in The United States of America followed by Canada. Cancer Drugs cost less in India compared to USA and Canada. This might create an impression that Cancer Drugs are more affordable in Developing Nations such as India. However, a study, which took into account Purchasing Power Parity metrics found that Cancer drugs are least affordable in India.[5] This means that even though the price of Cancer drugs is lower in India compared to other Nations, Indians cannot afford Cancer drugs.

The average economic cost of treatment of a typical cancer patient in a government facility in India has been calculated[6] to be INR 22,520 which is unaffordable for a country with average monthly income[7] of estimated INR 9,458.

India has a huge potential to enable drug manufacturers to make use of Compulsory licensing provisions to render Cancer drugs affordable. The originators of the drugs are not at a disadvantage as they shall be entitled to royalties associated with the sale of the drugs. Yet prima facie, it appears that when compared with other low-income countries that has used the provisions for Compulsory licensing, its usage in India seems sparse.[8] My study intends to understand whether there is a case for issue of Compulsory licensing for Cancer drugs in India.

OBJECTIVES OF THE STUDY

The objectives of the Research are as follows:

I. To analyze whether the principle of compulsory licensing is a threat to incentive system of Pharmaceutical Patent.
II. To study the scope of compulsory licensing provisions as adopted in India with regard to cancer drugs.

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[5] Goldstein, Daniel A et al. "A global comparison of the cost of patented cancer drugs in relation to global differences in wealth." Oncotarget vol. 8,42 71548-71555. 9 May. 2017, doi:10.18632/oncotarget.17742

[6] Key Indicators of Social Consumption in India: Health; National Statistical Office. 2018 http://mospi.nic.in/sites/default/files/publication_reports/KI_Health_75th_Final.pdf (Accessed March 10th 2021)

[7] Calculated from India's per capita income (INR 1,13,500) in 2017-2018 https://timesofindia.indiatimes.com/business/india-business/indias-per-capita-income-grows-by-8-6-to-rs-1-13-lakh-in-fy18/articleshow/64403580.cms (Accessed September 3rd th 2021)

[8] Cptech.org. 2021. *Compulsory Licenses*. [online] Available at: http://www.cptech.org/ip/health/cl/recent-examples.html [Accessed 4 April 2021]

III. To determine the challenges to the use of compulsory licensing for cancer drugs and suggestions as to remedy the problem of affordability of Cancer drugs.

HYPOTHESIS OF THE STUDY

- ✓ The Compulsory licensing provisions have not been effectively used by India for Cancer drugs.
- ✓ India is failing in its potential to provide accessible healthcare for its poor and for Impoverished nations by not taking leverage of the compulsory licensing provisions.

OUTLINE OF THE STUDY

Chapter-1: A brief overview of the Patent Regime in India

Chapter-2: The Right to Health and Role of Compulsory Licensing: The Indian Experience

Chapter-3: Compulsory Licensing: Practices in Developing Nations

Chapter-4: Drug Pricing and Affordability

Chapter-5: The scope for Compulsory license for Cancer drugs

Chapter-6: Challenges in implementation of Compulsory Licensing

Chapter -7: Conclusion and Suggestions

METHODOLOGY OF THE STUDY

The method used in the dissertation will be Doctrinal research methodology.

LITERATURE REVIEW

1. *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* by Carolyn Deere, Oxford University Press (2009)

   The book helps in understanding the evolution of TRIPS in the light of its political nuances which have a very definitive and pronounced role in framing of current Intellectual Property Laws. The book provides an evidentiary narrative as to why the developing nations are being pressured to adopt the policies of the Global North and why TRIPS Plus is being pushed forward despite existing debate as to the effectiveness of TRIPS in securing access to medicines to developing and least developed nations. The book analyses the various strategies and carrot and stick approach of the Developed Nations intended at securing the compliance of Developing Nations.

2. *The Truth about Drug Companies: How they deceive us and what to do about it* by Marcia Angell M.D, Random house publications. (2004)

   This book provides a compelling insight into the business model of the Pharmaceuticals. The author establishes the various deceptive practices and lobbying tactics of the pharmaceutical giants intended to bolster its monopoly. The author narrates as to how doctors, politicians and chemists are unwittingly groomed into promoting and defending the interests of pharmaceutical corporations. The book also questions the Research and Development data of these corporations. It also provides effective suggestions as to make drug companies accountable.

3. *The Price of Health: The Modern Pharmaceutical Enterprise and the Betrayal of a History of Care* by Michael Kinch and Lori Weiman, Pegasus Books (2021)

This book provides significant insights about the early history and development of American Pharmaceuticals, starting from the Apothecaries who migrated to US from the Europe to the evolution of early Pharmacopeia, the factors which led to the mass production of chemicals and its aftermath, the history of the Food and Drug Administration and the rationale behind Orphan Drugs Act and the Hatch-Waxman Act. The book then traces the current scenario and identifies the malaises of the American Pharmaceutical Industry.

4. *Drug Wars: How Big Pharma Raises Prices and keeps generics off the market* by Robin Fieldman, Evan Frondorf Cambridge University Press. (2017)

   This book helps to understand the tactics and measures deployed by the Patent Holding Corporations to delay the entry of generics. It helps to understand the nuances of Hatch Waxman Act and how its loopholes are being exploited.

5. *Impact of TRIPS in India: An Access to Medicine Perspective* by Prabodh Malhotra, Palgrave Macmillan (2010)

   The book helps to understand the dismal reality of the healthcare sector of India. It provides insights about the difficulties faced by the common man in securing access to healthcare. It helps to understand the Indian experience with regarding to accessibility, the burden of out-of-pocket expenditures and the impact of TRIPS in drug prices. The author also suggests measures to improve affordability which includes provision for healthcare cards to Indians in the manner similar to Ration cards.

6. *Patent Games in the Global South: Pharmaceutical Patent Law making in Brazil India and Nigeria* by Amaka Vanni, Hart Publishing (2019)

   This book provides information about the development of Patent Laws in India. It takes into account the factor of colonialism and the definitive role that Imperialism played in molding Patent Laws to its favour. It analyses the impact of the Patent Act 1970, the role of generics and the impact of TRIPS. The author was awarded 2018 SIEL-Hart Prize in International Economic Law.

7. *Access to medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to lower drug prices? A review of existing evidence*, Eduardo Urias and Shyama V. Ramani, Journal of International Business Policy (2020)

8. *The 'Compulsory License' Regime in India: Past, Present and Future* by Shamnad Basheer, SSRN Electronic Journal (2005)

9. *How effective has been Government measures to Control Prices of Anti-Cancer Medicine in India*, Sudip Chaudhuri, Centre for Development Studies (2019)

10. *Compulsory License under Indian Patent Law* by N.S Gopalakrishnan and Madhuri Anand, School of Legal Studies, Cochin University of Science and Technology, Kochi (2015).

11. *Compulsory Licensing, MPI Studies on Intellectual Property and Competition Law 22*, edited by Reto M. Hilty, Kung- Chung Liu, Springer (2015)

CHAPTER 1

A BRIEF OVERVIEW OF PATENT REGIME IN INDIA

INTRODUCTION

The idea of commercialization of Intellectual Property was quite alien to the orient. The ancient Indian culture had strong roots in community, harmony, spiritual seeking and the pursuit of self. India's arts, music, poetry, literature can be seen as a celebration of life, an ode to the divine, a treatise on Nature and its elements: a contemplation of the essence and myriads of life.

The most ancient literature in the world is believed to be the Vedas. The Vedic teachings understands the transfer of knowledge, not as a business, but as a soulful exchange, rooted in compassion and respect. It was not a mere commercial transaction but a heart-to-heart communion between the giver and the receiver.

Traditionally, the Guru as the dispeller of darkness (avidya) claimed no monopoly over her wisdom. They attributed their findings to their teachers which may be a person, animals, seasons, and the like. Knowledge was seen as sacred, and a means to contribute to the well-being of all. And exchange of knowledge was rooted in pure intentions.

The Spirit of ancient India has been beautifully invoked in the following Hymn from the Yajur Veda, the translation of which reads:

"May the Supreme Being protect both of us;
(*Aum saha naav avatu)*
May that Supreme Being be pleased with both of us;
(*sah nau bhunaktu*)
May we both work together with vigour;
(*saha veeryam karavaavahai)*
May our study make us both illumined;
(*Tejaswi nav adeetam astu)*
Let there be no misunderstanding between us.
(*maa vidvishaavahai)*

Aum peace! Peace! Peace
(*Aum shantih shantih shantih)*"[9]

The history of India is replete with works of celebrated poets and composers. Kabir, Rahim, Surdas, Mira bhai, Thiagaraja never asserted any rights on their works. This legacy was carried on by innumerable souls like Rabindra Nath Tagore whose beautiful and awe-inspiring Gitanjali begins with the lines- "*where the mind is without fear and head held high, where knowledge is free…"*

The profound wisdom of the ancients and the Vedic knowledge which contemplated in oneness in every being were systemically twisted and misused, resulting in many evils such as patriarchy and casteism. With the advent of colonialism, the European mercantilist influences steered the nation towards the course of ceaseless materialism.

This Chapter seeks to trace India's patent regime from the British Raj to its present position and its effect on pharmaceutical industry.

INDIAN PHARMACEUTICAL INDUSTRY- SCENARIO BEFORE INDEPENDENCE

India is popularly known as the "Pharmacy of the Developing World." India stands as the top provider of generic medicines in the world, and Indian Pharmaceutical Industry is third largest- in terms of volume.

Prior to Independence, the condition of the Indian pharmaceutical industry was deplorable. The British policies were aimed at keeping control of the monopoly of pharmaceuticals to Britain and British importers in India.

The British dominance was secured through several legislations, beginning with Patent Act VI of 1856. The Act provided that an inventor, through the operation of law, could enjoy exclusive privileges over the invention for 14 years. The term "Inventor" was defined to include the actual and genuine inventor as well as an importer of the product into India.

[9] The Upanishads- Katha, Prashna, Mundaka (2017)- Sri M

However, the cost of obtaining exclusive privilege over the product in India, was at that time, INR 100[10], an exorbitant price for an Indian to afford. This prohibitive cost factor meant that only Britishers or extremely wealthy Indians could afford to gain the right to import the product to India.

However, the Patent Act V of 1859 made it impossible for the wealthy Indians to import patented products as well. The Act provided that an importer of an invention within India shall not be deemed to be an "inventor" within the meaning of the Act. Thus, the only means for an importer of an invention to obtain exclusive privilege was to apply for the approval of letters of patent in Britain and subsequently apply for an exclusive privilege in India under Section XX of Act of 1859 as a *British Patentee* claiming priority Rights. The Patent Act V of 1859 was, therefore, an Indian legislation to buttress British monopoly.

Subsequent amendments and modifications of the Patent Act further buttressed British Monopoly. In 1911, the Indian Patent and Designs Act was enacted, which appointed a Controller of Patents to administer the patent system in India. Section 5 of the Act provided that the Controller can reject the patent, if, among other grounds, it is found that the "invention claimed and described is *prima facie*, not a new manufacture or improvement"[11] The section strategically chose not to define those inventions which would be patentable and instead, provided for those inventions which are "not-patentable". This meant that any similarity to the already manufactured patented products, which obviously would be there for pharmaceutical related formulations, could be used to preclude Indian formulas from being granted in the name of not being new manufacture. The foreign Multi-National-Corporations (MNCs) relying on this Act patented all their old and existing products as well as processes. This directly affected Indian Pharmaceutical companies headed by eminent chemists such as T.K Gajjar, Prafulla Chandra Roy, and A.S Kottibhasker, who were producing allopathic medicines as early as 1905[12].

Further, Section 14 of the Act provided that the term of the Patent shall be 14 years. However, subsequent clauses provided that this term could be extended further by the

[10] Vanni, A. (2020). Patent games in the global south: Pharmaceutical patent law-making in Brazil, India and Nigeria; Bloomsbury Publishing Plc Page 109

[11] A COLLECTION OF THE ACTS PASSED BY THE GOVERNOR GENERAL IN THE YEAR 1911 COUNCIL https://legislative.gov.in/sites/default/files/legislative_references/1911.pdf Page 14 (Bare Act 1911)

[12] Chaudhuri, *The WTO And India's Pharmaceuticals Industry* (2006) 21–22.

Controller on application.[13] This meant that the monopoly period could be extended limitlessly.

This provision effectively stunted the growth and development of the Indian Pharmaceuticals sector, strengthened the Monopoly of the Multi-National-Corporations (MNCs), and led to high prices for basic drugs in India. Foreign firms controlled almost 70 percent of the market, and even essential medicines such as insulin and penicillin had to be wholly imported.[14] It is also pertinent to note that these firms never established their manufacturing units in India. Rather, they were keen on importing. All these led to the proliferation of profits for the Multi-National-Corporations (MNCs) and the complete paralysis of the Indian pharmaceutical sector.

The colonial legislation of 1911 was an affront to a fair and equitable Intellectual Property Regime. It was systemically uncivil legislation that was used to stifle and subdue the Industrial growth of India. And it met its purpose.

POST-INDEPENDENCE POLICIES

When India got Independence from Britain in 1947, it was home to a huge population of about 400 million people that represented one-fifth of the world's population. However, our nation was among the poorest in the world. The 1911 Act and the preceding Acts ensured that innovation and local development of technology was undermined. The colonial patent regime prevented India from making its own progress in the pharmaceutical industry.[15] It made the Indian pharmaceutical sector significantly dependent on the monopoly of Multi-National-Corporations (MNCs). This monopoly also led to high drug prices.

Considering these circumstances, the Indian Government, in 1949, appointed a Committee under the Chairmanship of Justice Tek Chand to review the Patent laws in India with the

[13] A COLLECTION OF THE ACTS PASSED BY THE GOVERNOR GENERAL IN THE YEAR 1911 COUNCIL https://legislative.gov.in/sites/default/files/legislative_references/1911.pdf page 18 (Bare Act, 1911)

[14] Planning Commission, 'First Pan (1951–1956)' (Government of India, 1951) ch 32.

[15] SUDIP CHAUDHURI, THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES 128 (2005)

purpose of ensuring that the patent system was more conducive to national interests. The report provided that the existing patent regime offered inequitably strong protection to Multi-National-Corporations (MNCs), which was blocking the Indian manufacturing Industry at its infancy itself.[16] Tek Chand committee report provided for certain changes, including the extension of compulsory licensing in the case of foods and medicines. Further reform was desired, and in 1957 Justice Rajagopala Ayyangar Committee was constituted by the Government, based on which The Patent Act of 1970 was promulgated.

Ayyangar Committee Report provided that the reformed Patent Act must[17]

1. Define those inventions which shall be patentable and render certain inventions that are likely to affect the national interests as unpatentable.

2. Provide remedies against foreign-owned Patents which are not worked in India but which are held to block the industries or to secure monopoly over importation to India.

3. Provide special provisions regarding the licensing of Patents for inventions relating to food and medicine.

One of the cardinal changes proposed by Ayyangar Committee Report was the introduction of patentability to the *processes by which the products are obtained* and to deny patents to products per se.[18] It is pertinent to note that this schema was suggested for products made through chemical processes only, including pharmaceutical products.

This was necessitated for undoing the hurdles that indigenous industry faced at the aegis of the colonial Patent regime. The Patent Act, 1970 was specifically designed to meet the particular requirements of India to encourage rapid indigenous industrial development.

[16] Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry Uday S. Racherla. Springer page 277
https://link.springer.com/content/pdf/10.1007%2F978-981-13-8102-7.pdf

[17] Report on the revision of the patents law by Shri Justice N. Rajagopala Ayyangar: https://spicyip.com/wp-content/uploads/2015/02/Ayyangar_Committee_Report_Trademarks_2015.pdf

[18] ibid

According to Dinesh Abrol, it would have been impossible for the country to develop industrial self-reliance in the chemical industry without the process patents.[19]

The Patent Act 1970, sought to provide for a balance between the protection of patents and the specific needs of the country.

These measures resulted in the phenomenal growth of the Indian generic pharmaceutical industry. Process patent meant that subsequent development and production of patented drugs through reverse engineering would require only a fraction of time and money compared to the original drug discovery process.

One could say that India countered the abusive policies wrought by the monopolistic exploitative practices of product patenting, through process patenting. There seemed no other way to tackle the monopoly stronghold of the MNCs whose policies not only stunted indigenous innovation but also rendered, through its pricing policies, several lifesaving medicines inaccessible to the overwhelming majority of the Indian population. Process patents would not have risen if product patents had not been used to buttress political and colonialist aspirations. Process patents, therefore were not a toast to intellectual property jurisprudence but a survival mechanism against the unfettered abuse of product patent regime by the prominent political powers and its lobbies.

The Patent Act, 1970 helped India transform from having one of the highest drug prices to having the lowest ones[20]. In around 25 years, the capital investment in the Indian pharmaceutical industry increased from INR 225 crores to INR 2,500 crores, and investment in Research and Development (R&D) increased from INR 10.50 crores to INR 320 crores. India became a major player in the pharmaceutical sector. The value of the Indian pharmaceutical industry increased from 100 million rupees in 1947 to 70 billion rupees up to 2000.[21]

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[19] Dinesh Abrol, (1992) " Trade Related Intellectual Property Rights" World Focus Vol. 13 No. 6 June 150, pp 17.

[20] Santanu Mukherjee, (2006) "The new Indian patent law: a challenge for India" Int. J. Intellectual Property Management, Vol. l,Nos. 1/2, ppl3l

[21] S. Banerji, (2000) 'The Indian intellectual property rights regime and the TRIPS agreement', in Clarisa, L. (Ed.): Intellectual Property Rights in Emerging Markets. American Enterprise Institute Press, Washington DC, Vol. 47, p.57. quoted by Santanu Mukherjee, (2006) "The new Indian patent law: a challenge for India" Int. J. Intellectual Property Management, Vol. 1, Nos. 1/2, pp 131

The Indian Government also invested in educational institutions to encourage local technological knowledge as well as in chemistry-based reverse engineering, which formed the core of their processes and product development skills.[22] This encouraged innovation and meant that Indian firms thrived and invested in several kinds of generic activities. An example of Indian drug innovation was the release in 2001 of the HIV drugs which was produced by Cipla. The low price of Triomune prompted Merck to reduce the price of Crixivan, Anti-Retroviral-Therapy (ARV), to roughly the same price, which in turn caused Bristol Myers Squibb and GlaxoSmithKline to follow suit.[23]

IMPACT OF TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

The emergence of India as a strong force in the pharmaceutical field and its price competitiveness posed a challenge to the existing power order, which raised the eyebrows of the Global North and its lobbyists. Through its cheaply priced generics, India was challenging the monopoly of the Pharmaceutical Research and Manufacturers Association of America (PhRMA). PhRMA plays a leading role in contemporary international scenario by influencing Free Trade Agreements (FTA) and suggesting who should be in the Special 301 List. Thus, PhRMA works hand in gloves with the government of USA. TRIPS was a result of lobbying by PhRMA which sought to attack process patenting and strengthen its Monopoly.

The pressure from PhRMA and the USA was persistent from early as 1982 when the USA instituted a ministerial meeting to include “services” within the framework of General Agreement on Tariffs and Trade (GATT). It was opposed by nations such as India, Brazil, and other 22 nations. The pressure and negotiation tactics continued. Out of the 22 countries, 12 countries could be persuaded to change their stance in favour of the North Block, which included the USA, Japan, and European Union. The remaining nations led by India, called the “Block of 10”, stood firm in their stand. In the Uruguay Round (1986), the US succeeded in

[22] Vanni, A. (2020). Patent games in the global south: Pharmaceutical patent law-making in Brazil, India and Nigeria; Bloomsbury Publishing Plc Page 118

[23] Vanni, A. (2020). Patent games in the global south: Pharmaceutical patent law-making in Brazil, India and Nigeria; Bloomsbury Publishing Plc Page 119

inculcating “services” within the framework of GATT,[24] which eventually paved the way for intangible goods such as Intellectual Property to be brought into the ambit of GATT. One key feature of GATT was that it gave nations certain flexibilities and autonomy regarding the inculcation of resolutions, which was exercised by opposing block. The north block was not satisfied with this. In order to further push for Trade-Related Property Rights and reduce the exercises of autonomy by opposing developing nations, vehement pressure tactics were deployed, and the TRIPS was a result of this.

India agreed to the TRIPS Agreement, which prescribes the “minimum standards to be adopted by member countries in respect of Intellectual Property.” India was required to be TRIPS compliant before 2005. Accordingly, India introduced the Patents (Amendment) Bill in 1995. The Bill contained specific provisions which provided for governmental intervention in matters of public interest. It also included certain measures in the interest of national security. This was opposed by the USA, which raised a dispute against India in the World Trade Organization (WTO) Dispute Settlement Body (DSB). The verdict was in favour of the USA, and India was obliged to remove national security provisions and make the Patent Act more TRIPS complaint.[25]

India’s efforts to ensure TRIPS compliance resulted in the progressive undoing of the cardinal principles, such as process patent, which were the foundation for The Patent Act, 1970. The current Act has reinstated the product patent regime and done away with the process patent regime.

Although the global north succeeded in its objective to dismantle India’s process patent regime, the delegation led by India and Brazil could successfully negotiate certain flexibilities, the cardinal among these being Article 31[26]. It is pertinent to note that the TRIPS Agreement does not use the term “Compulsory License” as such. Instead, it uses the words “other use without the authorization of the right holder”. Such use is to be limited to public

[24] S.P. Shukla, “From GATT to WTO and beyond”, (UNU/World Institute for Development Economics Research, Paper no. 195), available at https://www.wider.unu.edu/sites/default/files/wp195.pdf

[25]Socio-economic impact of trips agreement on pharmaceutical patents in developing countries with special reference to India, Surekha Somabalan https://shodhganga.inflibnet.ac.in/bitstream/10603/171625/9/09_chapter%204.pdf page 179

[26]Article 31 of TRIPS https://h2o.law.harvard.edu/text_blocks/6615 (Accessed 12th August 2021)

non-commercial use, in situations of national emergency, and in situations of extreme urgency. Such use is also limited to the supply of the domestic market of the country issuing a compulsory license.

The TRIPS provisions made it difficult for countries to exercise their flexibilities effectively. The term "use without authorization of the right holder" was found to be problematic owing to its vagueness. Further, the provision that the "use" can be made "predominantly for the supply of domestic market" meant that India could not supply medicines to needy nations even in times of national emergency or situations of extreme urgencies. These constraints posed challenges in providing affordable medicines to countries during HIV/AIDS crisis.

DOHA DECLARATION

The TRIPS Agreement succeeded in effectively mitigating the challenges the PhRMA faced in enjoying its monopoly. Post TRIPS regime saw an increase in drug prices. It was alleged that TRIPS posed a substantial impediment for access to medicines[27]. Human rights activists and other stakeholders vehemently criticized the TRIPS regime. Affected by these developments, the Declaration on TRIPS and public health adopted at the fourth ministerial conference in 2001 at Doha openly acknowledged that the public health problems in many countries were connected to the Intellectual property regime under the TRIPS agreement.

The declaration acknowledged the public health problems faced by developing and Least Developed Countries (LDCs). It posited that TRIPS Agreement should be interpreted to protect public health and promote access to medicine for all. The declaration expressly used the term "Compulsory Licenses" and provided that each member has the right to determine the grounds for national emergency.[28] Paragraph 6 recognized the plight of LDCs, and the council of TRIPS was instructed to find an expeditious solution to this problem[29]. Accordingly, in 2017, the WTO rules were amended so that the developing and LDCs facing

[27] Statement by Zimbabwe to WTO TRIPS council, April 5 2001. https://www.who.int/intellectualproperty/topics/ip/tHoen.pdf

[28] Doha WTO Ministerial 2001 Declaration on the TRIPS Agreement and Public Health http://iipi.org/wp-content/uploads/2010/08/Doha_Declaration.pdf

[29] Ibid

health problems and lacking the capacity to produce drugs can seek medicines from the third-party country under compulsory licensing.[30]

CONCLUSION

It is fascinating to witness how politics, business interests, and such factors can dethrone the objectivity of laws, create a legally sound system of abuse and even justify exploitation. While the underlying principle behind Patent Law was to reward the inventor and foster innovation, the colonial legislations were aimed at imposing the monopoly of British Multi-National-Corporations (MNCs). The British Raj stands as an example of how vested interests can affect the course of even an objective and scientific area such as Pharmaceuticals.

While the initial patent legislations by the British were to consolidate their exclusive right to obtain Drugs through importation, the Patent and Designs Act of 1911 equipped the controller to reject patent applications selectively. It simply provided that the Patent Application could be rejected if the subject matter was prima facie, not new manufacture or improvement. Additionally, Section 14 provided that the term of existing patent can be extended well beyond 14 years. This had the result of stifling Indian innovation and bolstering monopoly. Drug prices in British India were among the highest in the world. Indian Pharmaceutical Industry was left incapacitated.

It was only following Indian Independence that India became partially free from the clutches of these exploitative practices. The process patent regime was contemplated as an antidote to the ailing pharmaceutical industry. Our policymakers showed commitment towards securing the availability of drugs at a low price so that the overwhelming majority of our population could have access to medicines. The underlying philosophy was to secure the ideals envisaged in our Constitution. It is again fascinating to observe how the guiding principles and intention of policymakers can have effect on the laws. The Patent Act, 1970 succeeded in reviving the Indian pharmaceutical industry and reducing the cost of medicines. The generic industry played a definitive humanitarian role at the time of the HIV/AIDS crisis. India

[30] WTO Rules amended to ease poor countries access to affordable medicines 23 January 2017 https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm (Accessed on August 14th 2021)

became the leader in showing the world that prices of drugs cannot be allowed to absolve ourselves from serving the needs of the have-nots.

It is not surprising that the process patent regime was perceived as a challenge by the global north. The GATT framework and the Paris Convention were inadequate to persuade developing nations to heed the direction of the Global north. The push for TRIPS and the underlying tactics deployed by the Global north makes one wonder if the Free Trade, which is so vehemently expounded about in academia, is really free. TRIPS effectively succeeded in strengthening the 'IP protection'. But it is pertinent that no effort was made to take cognizance of the problems that arise from the current patent regime -namely, the high prices of drugs. The TRIPS Agreement clearly tips the scale in favour of IP Protection and pays little heed to the accessibility of medicines.

The Doha Declaration was a crucial and much-needed step in addressing the inadequacies of the TRIPS Agreement. It helped to bring the issue of accessibility of medicines to the picture. It affirmed the right of nations to issue compulsory licensing to meet their public health needs.

However, the declaration falls short in certain aspects. It failed to venture into the question of enquiring into the justifiability of pricing practices. It failed to address the practical aftereffects that would follow the abolition of process patents. It mentions nothing about fair and equitable drug pricing to balance the interest of all stakeholders. It fails to address why countries are pushed into issuing compulsory licenses- which is the price of certain medicines renders it inaccessible to millions, thus depriving them of the enjoyment of the highest attainable standard of health as enunciated in the preamble of the World Health Organization.[31]

[31] Constitution of the World Health Organization https://www.who.int/governance/eb/who_constitution_en.pdf

CHAPTER 2

RIGHT TO HEALTH AND THE ROLE OF COMPULSORY LICENSING: THE INDIAN EXPERIENCE

INTRODUCTION

Human Rights are as certain basic and inalienable right a human being has by simply being born. They are understood as the bare minimum standards held to be necessary for humans to live in dignity.[32] The Universal Declaration on Human Rights (UDHR) was contemplated

[32] Tarantola, Daniel. "A Perspective on the History of Health and Human Rights: From the Cold War to the Gold War." *Journal of Public Health Policy*, vol. 29, no. 1, 2008, pp. 42–53. *JSTOR*, www.jstor.org/stable/40207165.

following the ravages and destruction the world witnessed during the two World Wars. The UDHR recognizes certain inalienable rights of all the members of the human family[33].

Article 3 of the UDHR affirms the everyone's right to life and liberty."[34]

Article 25 provides that everyone has the right to certain standards of living which includes access to medical care.[35]

The World Health Organization (WHO) envisions the highest attainable standard of health as a fundamental right of every human being.[36]

The Right to Health finds mention in the International Covenant on Economic Social and Political Rights (ICESR), which was ratified by India. Article 12 recognizes everyone's right to highest attainable standards of physical and mental health. This was envisaged to be achieved through the prevention, treatment, and control of epidemic, endemic, occupational and other diseases. It also envisages to provide medical attention to all in the event of sickness.[37]

PROVISIONS UNDER INDIAN CONSTITUTION ON THE RIGHT TO HEALTH

The Fundamental law of our land is the constitution. It is the foundation upon which the laws of our Nation rests. The Preamble serves as an affirmation of certain core precepts and ideals that are sought to be achieved through the constitution. It gives direction and purpose to the Constitution. The Fundamental Rights and Directive Principles of State Policy are intended to propel the nation to a trajectory in alignment with our Preamble.

[33] The Universal Declaration of Human Rights: History of the Document, UNITED NATIONS, http://www.un.org/en/documents/udhr/history.shtml

[34] Ibid Article 3

[35] Ibid Article 25

[36] CONSTITUTION OF THE WORLD HEALTH ORGANIZATION https://www.who.int/governance/eb/who_constitution_en.pdf

[37] INTERNATIONAL COVENANT ON ECONOMIC SOCIAL AND POLITICAL RIGHTS https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx

The Directive Principles of State Policy under Article 39 requires the State to secure the health and strength of citizens, especially workers and children who are vulnerable. The vulnerable ought to be protected against material abandonment.[38] The State has a duty to improve public health.[39]

Right to Health is not expressly recognized as Fundamental Right in India. Article 21 provides for the protection of life and personal liberty. Indian courts have dared to venture into defining and expanding the terms 'life' and, through repeated pronouncements, affirmed that the term 'life' is not limited to mere animal existence but include the right to certain basic aspects such as adequate nutrition, clothing, and shelter.[40] Health is something which is an integral and crucial part of human life. It is only when a person is healthy can he enjoy and exercise all other rights, including right to movement, right to freedom of speech and expression. In this sense Right to health can be understood as a bedrock of the right to life, the deprivation of which sucks out meaning and purpose away from all other enjoyment of his liberties. The right to health is indelibly linked to access to healthcare, including access to medicines. This is important for a nation like India, where millions are pushed to poverty for want of affordable healthcare.

It is pertinent to note that despite being a crucial aspect to the Right to life and having significance at par with the Right to Education[41], right to healthcare finds no express recognition in the constitution. Right to healthcare is an aspect that is fundamental to humanity and India must commit to the cause of making healthcare accessible to its citizens by including right to healthcare as a part of fundamental right. Nations such as Thailand[42] and

[38] Article 39 (d) and (f) of the Constitution of India

[39] Article 47 of the Constitution of India

[40] *Francis Coralie vs. Delhi* AIR 1981 SC 746, 753

[41] Right to Free and Compulsory Education by virtue of Article 21 (A) of Constitution

[42] https://www.who.int/hhr/news/SEA-HHR_RtH_constitutions.pdf
"A person shall enjoy an equal right to receive public health services which are appropriate and up to the quality, and the indigent shall have the right to receive free medical treatment from public health centres of the State. A person has the right to receive public health services from the State, which shall be provided thoroughly and efficiently. A person has the right to be appropriately protected by the State against harmful contagious diseases, and to have such diseases eradicated, without charge and in a timely manner."

Brazil[43] are few out of the numerous nations that have recognized right to healthcare and accessibility to be fundamental right. India can derive insights from these nations.

RIGHT TO PUBLIC HEALTH AND INDIAN JUDICIARY

Indian judiciary has played a definitive role in the acknowledgment of the Right to health by interpreting it to be an integral part of the fundamental right to life and issuing directions to the State authorities towards securing adequate access to health. On numerous occasions, the judiciary has emphasized the relevance of health to human life.

In *State of Punjab v. Ram Lubhaya Bagga* [44]

The Hon'ble Supreme Court observed that the right to life of a citizen casts an obligation upon the State under Article 21. This obligation is further buttressed by Article 47 and it is the primary duty of the State to secure health to its citizen. The Court opined that opening of Government hospitals and healthcare centres are welcome step but lots of work remains to make these services reachable to people.

In *Kirloskar Brothers Ltd. vs. Employees State Insurance corporation*[45]

The Hon'ble Supreme Court affirmed that the constitution envisages the establishment of a welfare state. providing adequate medical facilities to the people is a primary duty of the Government. The Supreme Court reminded the Government that preservation of life is of paramount importance.

[43] http://www.conselho.saude.gov.br/14cns/docs/constituicaofederal.pdf
"Health is a right to be enjoyed by all and a duty of the State; it shall be guaranteed by economic and social policies that aim to reduce the risk of disease and other maladies and by universal and equal access to all activities and services for its promotion, protection, and recovery."

[44] (1998) 4 SCC 117
[45] 1996 (2) SCC 682 Paragraph 9

In *Paschim Bangla Khet Mazdoor Samity Vs. State of West Bengal*[46]

While acknowledging the challenge posed by lack of financial resources to provide for medical facilities, the Hon'ble Supreme Court observed that the State must take steps to provide medical services to the people citing financial constraints.

In *Vincent Panikurlangara v. Union of India*[47]

The Hon'ble Supreme Court observed that maintenance and improvement of public health are indispensable for the community's very existence and public health must be accorded the highest priority. The Court further observed that State has an obligation to make useful drugs available at a reasonable price so as to be within the common man's reach. The Court affirmed that notwithstanding price, a patient must be in a position to get medicine.

In *Parmanand Katara v Union of India*,[48]

The Hon'ble Supreme Court observed that the preservation of life is of paramount importance because once life is lost, the status quo ante cannot be restored. The court stressed that it is the obligation of those in charge of the community's health to preserve life.

In *Wagar Seva Sansthan Trust vs State (Medical & Health) & Ors*[49]

The High Court of Rajasthan observed that no person, particularly the have-nots, must be made to suffer for the want of money to purchase medicines. The Right to obtain treatment at affordable price is implicit in Article 21 of the Constitution of India. Not prescribing the medicines in generic names may in given facts tantamount to violation of Article 21 of the Constitution of India.

[46] 1996 (4) SCC 36

[47] (1987) 2 SCC 165

[48] (1989) 4 SCC 286; AIR 1989 SC 2039.

[49] *Wagar Seva Sansthan Trust vs State (Medical & Health) & Ors* https://indiankanoon.org/doc/133798147/

These important judgments affirm that the right to healthcare is an integral part of right to life. These cases also throw light on the fact that much is needed to be done to make healthcare accessible for all, especially the weaker sections of the society. The courts also direct the Governments to take steps towards ensuring accessibility to medicines. In one particular case[50], the Court observed that citizens have a Right to obtain treatment at affordable price under Article 21 of our Constitution. These trends throw light on the inadequacies of the Public Healthcare system. The Golden Age of generic medicines could not successfully solve the challenge of access to medicines. In the wake of the demise of process patents, prices of drugs are bound to soar, which is going to be a financial burden to the Governments. Thus, the Government is going to be tasked with the challenge of not only rendering effective healthcare but also coping with the high drug prices, in addition to other challenges.

POVERTY AND ACCESS TO LIFESAVING MEDICINES

Affordability crisis induced due to poverty is a significant impediment to Access to medicines in India. Nearly 80 million Indians lived below poverty line of 1.25 USD in 2018-19. According to WHO, an estimated 649 million people in India do not have regular access to essential medicines.[51]

Further, since in India, most of the spending in healthcare is borne by the individuals and their families, there is an increased risk of these people being pushed to poverty. In fact, studies show that every year, an estimated 32 to 39 million Indians are pushed to below poverty line owing to rising out-of-pocket expenditures on healthcare.[52]

This silent crisis is accentuated by rising drug prices post 1990s. Prior to 1990s, drug prices in India were among the lowest in the World. This could be attributed to two factors- the generics Industry and the Drug Prices Control Order (DPCO). Post-1970 saw the growth of

[50] Ibid

[51] World Health Organisation. The world medicines situation Internet. Chapter 7, Access to essential medicines; p.63. Available from: http://digicollection.org/hss/en/d/Js6160e/ (Accessed on 17th August 2021)

[52] BHARGAVA, Anurag; KALANTRI, SP The crisis in access to essential medicines in India: key issues which call for action. **Indian Journal of Medical Ethics**, [S.l.], v. 10, n. 2, p. 86, nov. 2016. ISSN 0975-5691. Available at: https://ijme.in/articles/the-crisis-in-access-to-essential-medicines-in-india-key-issues-which-call-for-action.

the Generic Industry, which meant a reduced price for medicines. The DPCO fixed a maximum ceiling on Drug Prices and prices could not be increased without Government approval. Post-1990s saw a reduction in drug price control from about 90 % of the markets in 1970 to about 10% of the market in 1995[53]. As a result of this, there was a nearly 40 percent increase in all drug prices between 1996 and 2006. In fact, the Prices of Drugs with no price control[54] grew by a whopping 137 percent between this time period. This predicament is attributable to the decontrol policies of the Government.[55]

The DPCO, by its price decontrol measures, have failed to address the concerns of the poor and the vulnerable. India must take steps to take into account the concerns of the vulnerable and device mechanisms that would ensure accessibility of medicines. The DPCO must be reformed to provide for price control on the basis of formulations rather than on basic drugs. Compulsory Licensing provisions remain a potent tool to bring forth a balance between the interests of the Patent holders.

COMPULSORY LICENSING

Compulsory licensing empowers the appropriate authority to authorize a third party to produce and market an intellectual property without the consent of the owner.[56]

The compulsory licensing provisions are designed to cater to the requirement of the public. Compulsory licensing provides for payment of adequate compensation to the patentholders in the form of royalty. Compulsory licensing may be understood as a tool to prevent the abuse

[53] High Level Expert Group Report on Universal Health Coverage for India, Chapter 3: page 123 http://uhc-india.org/reports/hleg_report_chapter_3.pdf

[54] That is not falling under the price control list or essential drug list

[55] Sengupta A, Joseph RK, Modi S, Syam N. Economic Constraints to Access to Essential Medicines in India. Society for Economic and Social Studies and Centre for Trade and Development in collaboration with the World Health Organisation. http://www. centad.org/download/final_ pdf_12_08.pdf

[56] Gopalakrishnan N.S., Anand M. (2015) Compulsory Licence Under Indian Patent Law. In: Hilty R., Liu KC. (eds) Compulsory Licensing. MPI Studies on Intellectual Property and Competition Law, vol 22. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-54704-1_2 (Accessed March 13th 2021)

of monopoly by the Patent holders. It is a means to balance the public interest with Patent holders.

The provisions regarding compulsory licensing find its place in developed nations, including U.S.A, Germany, Italy and Japan. In fact, USA had proposed to issue compulsory license against Bayer in the wake of 60 people being affected by anthrax. Apprehension of public health crisis caused the US to take steps to reduce the price of anthrax drugs and stock them. But when Developing Nations or Least Developed Countries (LDCs) seek to issue a compulsory license to make available Lifesaving drugs to its millions, it is met with accusations of piracy, foul play, and threat of trade sanctions by the Global North. This was evident in the manner of how the World handled HIV/AIDS crisis. Nations such as Brazil and Thailand were put under enormous pressure by the US to prevent them from taking steps to make ARV drugs available and accessible to the public. The contemplation by the US to take steps to make public health accessible to its own citizens while decrying the efforts taken by other nations to meet the same objective clearly shows the double standards of the US[57].

Nevertheless, the fact that even Developed nations that are vigorous advocates of Free Trade, preserves these provisions and have contemplated and applied these provisions at various junctures add to the relevance of Compulsory licensing.

The provisions related to Compulsory licensing finds place in Chapter XVI of the Patent Act 1970. Section 82 to 94 deals with Compulsory licensing.

Section 84 authorizes the Controller of Patents to grant Compulsory licensing, at any time following three years from the date of grant of Patent, on the grounds of

1. Reasonable requirements of the public not being met; or
2. The invention is not available to the public at reasonable price; or
3. The Patent has not been worked in India.

[57] AIDS, ANTHRAX, AND COMPULSORY LICENSING: HAS THE UNITED STATES LEARNED ANYTHING? A COMMENT ON RECENT DECISIONS ON THE INTERNATIONAL INTELLECTUAL PROPERTY RIGHTS OF PHARMACEUTICAL PATENTS. https://nsuworks.nova.edu/cgi/viewcontent.cgi?article=1414&context=ilsajournal

Among these three grounds, the first and second grounds are of particular significance as valid and justifiable grounds for issuing of Compulsory License.

The question of reasonable 'requirements of the public' and 'reasonable price' is to be determined by the Controller of Patents and for this determination Section 84 (7) provides certain parameters.

The reasonable requirement of the public is said not to have been met,

1) If by the refusal to grant such a license, the existence or development of trade or Industry in India is prejudiced.

2) when the demand for Patented product have not been met to an adequate extent on reasonable terms.

3) When the export market of the product is not being developed or supplied.

4) If by the refusal to grant such license, the establishment or development of commercial activities in India is prejudiced.

Reasonable requirement of the public is also not met when the conditions imposed by the patentee over the licencing of Invention is prejudicial to the establishment of any trade or industry in India. This also applies when the patentee imposes condition on the licensee in a manner promotes exclusive grant back or engages in coercive practise or prevents the licensee from challenging the validity of Patent.

Reasonable requirement of the public is also not being met if the Patent is not being worked in India or the patentee directly or indirectly prevents or hinders such working by means of importation.

Section 90 of the Act provides that the Patentee shall be paid royalty with due regard to the nature of the invention, the expenditure incurred in making, developing the invention, obtaining a patent and keeping it in force. It imposes certain conditions on the licensee to whom compulsory license is granted.

Accordingly, the licensee must:

1. Work commercially on Patent to the fullest extent with reasonable profit.
2. Make the product available to the public at Reasonably affordable price.

It also states that compulsory licensing mainly applies for the supply being made predominantly in the Indian market, but may also be exported, if needed. This may be to ensure compliance with the Doha Declaration Paragraph 6. Section 92 A[58] of the Act provides further clarity regarding exporting of products produced via compulsory licensing and provides that Compulsory licensing can be issued to any nation having insufficient or no manufacturing capacity in the pharmaceutical sector for the particular product. Such compulsory license would be issued to address public health problems but this is possible only if compulsory license has been granted by the country which is in need for Imports from India.

Section 92 provides that Controller of Patent can grant compulsory license for a circumstance of National Emergency or circumstance of Extreme Urgency or for public non-commercial use.

Section 94 provides for the termination of compulsory license if the circumstances that gave rise to the grant cease to exist or of compulsory license. License holder was not able to fulfil the requirements for which the compulsory license was granted.

Section 100 provides that the Government can acquire the Patent for Government use.[59]

Section 102 provides that the Government can acquire Patent for public purpose.[60]

[58] Section 92A: Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided a compulsory license has been granted by such country.

[59] The Patent holder must be notified of the same and adequate compensation must be paid

[60] The Patent holder must be notified of the same and adequate compensation must be paid.

By virtue of section 84, any interested person[61] can apply to the Controller of Patent for Compulsory license and by virtue of section 92 and 102, measures can be taken by the Government in the interest of public.

Compulsory license for pharmaceuticals was granted only once in Natco vs Bayer[62]. This case serves as a parameter to ascertain the consistency of compulsory licensing provisions.

NATCO VS BAYER

On 29-07-2011, Natco, a drug manufacturer based on India, filed an application for compulsory licensing before the Controller of Patent at Mumbai for the compound "Sorafenib tosylate", which was patented by Bayer corporation and sold under the brand name Nexavar. This compound was used for the treatment of advanced-stage of cancer of liver and kidney. Nexavar had to be taken for the lifetime of the patient. The drug was sold at a price of Rs 2,80,428/- per month, which would mean Rs 33,65,135/- per year.[63]

Natco filed for compulsory license under Section 84(1), citing that reasonable requirement of the public were not being met owing to its price. Natco provided that it had attempted to request a voluntary license for the drug which did not materialize and therefore the motion. Natco proposed to sell the drug at the price of Rs 88,001 for one month's treatment.

The question before the Controller was whether Nexavar, with its price, meets the reasonable requirements of the public and whether Natco be granted compulsory license. This question is of particular importance as the determination made by Controller can play a significant role in understanding the working of section 84 and assessing its consistency.

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[61] By virtue of section 84 (6) Controller would take into account the ability of the applicant to work the invention to the public advantage', 'the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted', and 'whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions, and such efforts have not been successful within a reasonable period

[62] *India's first compulsory licence granted to Natco for Bayer's cancer drug*. [online] @businessline. Available at: <https://www.thehindubusinessline.com/companies/Indias-first-compulsory-licence-granted-to-Natco-for-Bayers-cancer-drug/article20408026.ece>.

[63] Natco Pharma Ltd. v. Bayer Corporation, Compulsory License Application No. 1/2011 (Controller of Patents, Mumbai) https://patentdocs.typepad.com/files/compulsory-license-application.pdf

The arguments made by Natco, Bayer, and the decision by the controller of Patent is summarized below:

Natco, relying on various data provided that in the year 2008 alone, more than 20,000 patients having liver and kidney cancer were in need of Nexavar. It provided that the Drug is exorbitantly priced, making it out of reach for a majority of these people. Given the fact that this is a lifesaving drug, even 1% of the public could not derive the benefit of Nexavar.

Bayer challenged the figures provided by Natco and argued that the total number of patients entitled to treatment with Nexavar was INR 8,842 and that alternative treatment options were available to the patients.

The Controller came to the finding that the figures of patients in need of Nexavar are likely to be higher than that which was provided by Bayer.

Relying on the fact that the exorbitant price of the drug makes it inaccessible to the public at large, The Controller issued compulsory license in favour of Natco, envisaging that royalty of 6% be paid to Bayer.

Bayer preferred an appeal to the Appellate Tribunal which, on 4 March 2013 upheld the grant of compulsory license while increasing the royalty payable by Natco from 6 to 7%.

Bayer further appealed before Bombay High Court. The Court, in its judgement dated 15th July 2014, while dismissing the petition, made the following observations:

1. Accessibility of medicines cannot be deprived at the altar of rights of the patent holder.[64]
2. Compulsory licensing is consistent with Doha Declaration [65]

[64] *Bayer v. Union of India*, W.P. Number 1323 of 2013 https://indiankanoon.org/doc/28519340/ (Paragraph 13)

[65] Ibid

Despite the issuance of a compulsory license, Bayer did not make any amends in its prices. In fact, former Bayer CEO made a statement that they did not develop this medicine for Indians; they developed it for Westerners who could afford it.[66] This is unfortunate.

CONCLUSION

In the entirety of India's Patent regime, Compulsory license for an anti-cancer drug has been granted only once, and the first time this was successfully invoked was in the case of Bayer vs Natco. Analysis of the case suggests that the provisions of Compulsory license are equipped to stand the test of judicial scrutiny and constitutional validity.

The term "reasonable requirement of the public," as enunciated in Section 84, provides a wide ambit for the Controller to curb exorbitant pricing of drugs. This can have significant effects on increasing accessibility. The reasonable requirement of the public under Section 84 is consistent with the principles of TRIPS. Article 8 of TRIPS[67] allows members to prevent the abuse of Intellectual Property by right holders, protect public health, and promote public interest in sectors of vital importance to their socio-economic and technological development. This makes India's decision to use Section 84 in granting a compulsory license to Natco fair and justified.

[66] https://www.dailymail.co.uk/news/article-2545360/Pharmaceutical-chief-tries-stop-India-replicating-cancer-treatment.html Former Bayer CEO Marjin Dekkers

[67] Article 8 Principles 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art8_jur.pdf

CHAPTER 3

COMPULSORY LICENSING: PRACTICES IN DEVELOPING NATIONS

INTRODUCTION

The successful grant of compulsory license to Natco for sorafenib compound demonstrated that the provisions in India regarding the grant of compulsory licensing are legally consistent and effective. As a direct result of compulsory licensing, Natco was able to release the generic version of Nexavar, which is named as Sorafenat 200 mg tablets which is sold at the

lowest price globally[68]. This is the right step towards making healthcare accessible and affordable to all, especially the weaker sections of society. The grant of compulsory licensing has been hailed as a welcome measure. However, despite these policy contemplations, compulsory licensing has not been used as a policy option or as a pragmatic means to provide affordable healthcare in India, where annually, 30 to 32 million Indians are put to below poverty line because of the brunt of out-of-pocket expenses to healthcare.[69] The question as to why compulsory license has not been used as an effective policy measure begs attention.

In this context, the use of compulsory license by developing nations are to understand the scope and effects and responses to the grant of compulsory license. Developing nations are taken for study as these Nation have economic challenges similar to that of India

COMPULSORY LICENSING IN BRAZIL

Brazil is one of the nations that posits the right to healthcare as a fundamental right.[70] Article 71 of the Intellectual Property law of Brazil provides that compulsory license can be granted through an act of the Federal Executive Authorities in cases of "National Emergency or Public Interest"[71].

[68] Andrew Hill, et al.TARGET PRICES FOR MASS PRODUCTION OF TYROSINE KINASE INHIBITORS FOR GLOBAL CANCER TREATMENT 6(1) BMJ OPEN 6 (2016)

[69] Impact of TRIPS in India: An Access to Medicine Perspective by Prabodh Malhotra PALGRAVE MACMILLAN DOI 10.1057/9780230290747 page 142-142

[70]

[71] http://www.conselho.saude.gov.br/14cns/docs/constituicaofederal.pdf
"Health is a right to be enjoyed by all and a duty of the State; it shall be guaranteed by economic and social policies that aim to reduce the risk of disease and other maladies and by universal and equal access to all activities and services for its promotion, protection, and recovery."

Despite being the sixth-largest economy in the world, Brazil suffers from poverty and inequality. An estimated 16.2 million people in Brazil live below the poverty line.[72] Access to medicines is a significant matter for Brazil. Brazil has been using compulsory license as a means to persuade corporations to reduce the price of drugs. Between 2001 and 2006, the successful use of compulsory license helped reduce the price of Antiretrovirals (ARVs).[73]

In 2007, in the wake of the Acquired Immune Deficiency Syndrome (AIDS) crisis, Brazil engaged in negotiations with Patent holder Merck, for a price reduction of its ARV drug Efavirenz. Merck offered to discount the price from USD 1.59 to 1.10 per dose, which was deemed unsatisfactory by the Brazilian Government. The Government issued compulsory license on the ground of Public Interest for public non-commercial use for a period of 5 years. The generic version was to be imported from India for a third of the price offered by Merck. Merck filed a preliminary injunction before the Brazilian court, which was rejected, and Brazil successfully obtained the generics from India.[74]

As a result, about 77,000 patients, the equivalent of 42 % of the total number of patients under HIV/AIDS program, were successfully treated with Efavirenz. The grant of compulsory license allowed Brazil to save around USD103.5 million between 2007 and 2012.[75]

The initiative was observed to be consistent with the Doha Declaration and its mandate that TRIPS be in interpreted to be supportive of the member nation's right to protect public health and promote access to medicine for all.[76]

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[72] Poverty in Brazil https://borgenproject.org/poverty-in-brazil/ (Accessed September 13th 2021)

[73] 2001 Efavirenz Merck Discount (77%), 2001 Nelfinavir Roche Discount (69%), 2005 Tenofovir Gilead Discount (5.2%), 2007 Atazanavir BMS Discount (77-78%), 2007 Lopinavir/ ritonavir Abbott Labs Discount (75 %), 2008 Tenofovir Gilead Discount (72%)

[74] Correa C.M. (2015) The Use of Compulsory Licences in Latin America. In: Hilty R., Liu KC. (eds) Compulsory Licensing. MPI Studies on Intellectual Property and Competition Law, vol 22. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-54704-1_3

[75] Correa C.M. (2015) The Use of Compulsory Licences in Latin America. In: Hilty R., Liu KC. (eds) Compulsory Licensing. MPI Studies on Intellectual Property and Competition Law, vol 22. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-54704-1_3

[76] KEI Statement on Brazil Compulsory License on Efavirenz 4th May 2007 https://www.keionline.org/26249 (Accessed on August 13th 2021)

Merck and USA expressed concern over Brazil's action. A spokesperson of Merck said that the move sends a chilling signal to the research-based Industries about the attractiveness of furthering research on diseases affecting the Developing World, and this would harm patients who may require innovative life-saving therapies for potential diseases.[77]

The US Chamber of Commerce opined that Brazil had taken a major step backward by issuing the compulsory license.[78]

It is pertinent to note that Merck and the US Chamber of commerce are particularly silent on whether these innovative drugs are really reaching the ones who are in need of it. While Merck posits that the action of compulsory license is bound to hamper Research, it says nothing about the issue of affordability faced by Brazil. Merck should have reduced the price of the Drug from 30 percent to 60 percent taking into account the plight of the population of Brazil.

Brazil faced further ordeals as USA proceeded to lodge a complaint against Brazil about its compulsory license provisions to the World Trade Organization (WTO). Brazil, however, filed its own complaint challenging USA's Patent Code that had similar undertones.[79] Brazil also made efforts to secure access to AIDS treatment as a human rights issue at the United Nations Human Rights Council (UNHRC).[80] No trade sanctions, therefore, were pursued against Brazil.

The case of Brazil is an example of how political will combined with diplomacy can successfully further the interest of access to medicine by making effective use of Compulsory licensing. In all aspects, the steps taken by Brazil were fair and humanitarian. It is true that the Research and Development (R&D) costs of the manufacturers are important factors, but it is equally patients cannot be left without access to medicines at the altar of monopoly rights of the patent holder. A fair jurisprudence requires that in the event of a humanitarian crisis,

[77] Ibid

[78] Ibid

[79] Bird R, Cahoy D (2008) The impact of compulsory licensing on foreign direct investment: a collective bargaining approach. Am Bus Law J 45:283–330 page 313

[80] Compulsory Licensing- Practical Experiences and ways forward- Springer pp.452

efforts are taken to address the concerns of the weakest of the weak, whereas we see pharmaceutical giants turning a blind eye towards the genuine concerns of the developing and Least Developed Countries (LDCs). In Brazil's case, the refusal by Merck to reduce the price to not less than 1.10 USD was unfortunate. Such a situation justifies the use of Compulsory Licensing provisions.

COMPULSORY LICENSING IN THAILAND

Thailand is another country where the Right to Health is regarded as Fundamental Right.[81]The Thai Patent Act empowers the Director-General for license to issue compulsory license if any product is sold in the domestic market at unreasonably high prices or does not meet the public demand, without any legitimate reason.[82] Further, Section 51 and 52 of the Act provides that State shall issue compulsory license for meeting public needs or for public interest in war or national emergency.

Thailand was severely affected by the AIDS epidemic. In 2007, around 5,00,000 people Thai people suffered from HIV/AIDS requiring antiretroviral treatment, yet only about 1,00,000 had access to the drugs due high prices as well as budgetary constraints.[83] The high price of

[81] https://www.who.int/hhr/news/SEA-HHR_RtH_constitutions.pdf
"A person shall enjoy an equal right to receive public health services which are appropriate and up to the quality, and the indigent shall have the right to receive free medical treatment from public health centres of the State. A person has the right to receive public health services from the State, which shall be provided thoroughly and efficiently. A person has the right to be appropriately protected by the State against harmful contagious diseases, and to have such diseases eradicated, without charge and in a timely manner."

[82] At any time after the expiration of three years from the grant of a patent or four years from the date of application, whichever is later, any person may apply to the Director-General for a license if it appears, at the time when such application is filed, that the patentee unjustifiably fails to exercise his legitimate rights as follows:(1) that the patented product has not been produced or the patented process has not been applied in the country, without any legitimate reason; or(2) that no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high prices or does not meet the public demand, without any legitimate reason. Section46 of Thai Patent Law
http://thailawforum.com/database1/patent4.html

[83] DR. MONGKOLNASONGKHLA, MINISTER OF PUBLIC HEALTH, cited in MARTIN KHOR, PATENT COMPULSORY LICENSING AND ACCESS TO MEDICINE: SOME RECENT EXAMPLES 12 (Third World Network, Intellectual Property Rights Series 10) https://www.twn.my/title2/IPR/pdf/ipr10.pdf (Accessed July 28th 2021)

Efavirenz meant that the number receiving the drug remained significantly lower. The drug could reach only around 2000 patients when an estimated 12,000 patients in Thailand were in need of Efavirenz. Thailand, therefore, issued a compulsory license for Efavirenz, and a generic version was made available from India. The price was reduced ten times. This meant greater accessibility. In 2010, it was estimated that due to the generic version being made available, the number of patients receiving Efavirenz increased from 4,539 to 29,360.[84]

Cancer, particularly in lungs and breast have been a leading cause of death in Thailand. However, many of the anti-cancer drugs were costly and could not be accessed not only by the poor but also by an overwhelming section of the middle-class. There have been several reports of patients and their families going bankrupt due to the high prices of the drugs.[85] There have also been cases where people stopped taking medicines owing to financial constraints. This prompted the Thai Government to negotiate a reduced drug price. More than 12 rounds of negotiation took place over a period of two months with little progress. Finally, the Thai Government invoked Government use of Patent for four cancer drugs. They included:[86]

1. Docetaxel (trade name Taxotere), which is used for the treatment of lung and breast cancer whose cost was 25,000 Baht for an 80 mg injection while its generic version cost only 4000 Baht signifying a price differential of more than 6 times.

2. Letrozole (trade name Femara), which is used for the treatment of breast cancer whose cost was 230 Baht for 2.5 mg while its generic version cost 6-7 Baht, a price differential of 30 times.

[84] MSF Welcomes Move to Overcome Patent on Aids Drug in Thailand MÉDECINS SANS FRONTIÈRES (Nov.29, 2006) https://www.msf.org/msf-welcomes-move-overcome-patent-aids-drug-thailand (Accessed July 28th 2021)

[85] DR. MONGKOLNASONGKHLA, MINISTER OF APAUBLIC HEALTH, cited in MARTIN KHOR, PATENT COMPULSORY LICENSING AND ACCESS TO MEDICINE: SOME RECENT EXAMPLES 12 (Third World Network, Intellectual Property Rights Series 10) https://www.twn.my/title2/IPR/pdf/ipr10.pdf

[86] ibid

3. Erlotinib (trade name Tarceva) which is used for the treatment of Lung Cancer whose price for one 150 mg tablet was 2750 Baht while its generic version cost 735 Baht signifying a price differential of more than 4 times.

4. Imatinib (trade name Glivec) which is used to combat Chronic Myeloid Leukaemia and Gastrointestinal Stromal Tumor (GIST) whose price for 100 mg tablet was 917 Baht while its generic version cost only 50-70 Baht signifying a price differential of almost 20 times.

Given the economic situation of Thailand, the difficulty that the highly-priced medicine posed to accessibility, and the reluctance of Originator Companies to reduce the prices, the only leeway available was the reliance on Generics. In 2007, Thailand came under the Priority Watch List.

COMPULSORY LICENSING IN ECUADOR

The Constitution of Ecuador, by virtue of Article 363 (7) mandates that the State has a duty to facilitate a good living regime and for the attainment of the same, the State was dutybound to guarantee access to medicines[87]

Compulsory License has been issued on the basis of Presidential Decree No, 118 of November 16, 2009, read with Article 61 of Decision 486 of the Commission of the Andean Community and Article 154 of the Law of Intellectual Property provides that Compulsory

[87] Correa C.M. (2015) The Use of Compulsory Licences in Latin America. In: Hilty R., Liu KC. (eds) Compulsory Licensing. MPI Studies on Intellectual Property and Competition Law, vol 22. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-54704-1_3 page 53

"Guarantee availability and access to medicines of quality that are safe and efficacious, to regulate their commercialization, and to promote the national production and the use of generic medicines that correspond to the epidemiological needs of the population."

License can be granted at any time for the reasons of Public Health, Emergency or National Security.[88]

Between 2009 and 2014, Ecuador has issued 9 compulsory licenses on a total of 7 drugs for the treatment of HIV, Cancer, Rheumatoid Arthritis, and Kidney Transplants.[89]

Government sources report that compulsory license has achieved savings of between 23 % to 99 % in Pharmacy prices of licensed medicines. For example, the drug Etoricoxib costs about USD 0.84 per tablet, but after compulsory license its price was reduced by 99 % to USD 0.0084.[90]

The response of the USA towards Ecuador's policy is significant. Data released by Wikileaks show that US Embassy, MNCs, and three Ministers within the Government tried to sabotage the Ecuadorean President's move to issue Decree 118. The US Ambassador warned officials in the Ecuadorian Ministry that issue of compulsory licensing could jeopardize Ecuador's "IPR eligibility requirements" of Trade benefit programs such as Andean Trade Promotion. The attitude of the US shows a strong bias against compulsory licensing, without seeking to address the public health challenges posed by high prices of medicines. Despite these pressures, Ecuador's policy remains in place.[91]

COMPULSORY LICENSING IN INDONESIA

The Indonesian Constitution recognizes the Right to Health[92] as a Fundamental Right.

[88] Ibid page 54

[89] Ecuadorian Intellectual Property Institute announces savings from compulsory licensing for 9 drugs https://ihsmarkit.com/country-industry-forecasting.html?ID=1065991764

[90] Ibid

[91]Leaked cables show U.S. tried, failed to organize against Ecuador compulsory licensing May 10, 2011 https://www.citizen.org/wp-content/uploads/leaked-cables-show-us-tried-failed-to-organize-against-ecuador-compulsory-licensing.pdf (Accessed August 21st 2021)

[92] Article 28H (1) Every person shall have the right to live in physical and spiritual prosperity, to have a home and to enjoy a good and healthy environment, and shall have the right to obtain medical care.

Article 99 of the Patent Act of Indonesia provides that if the Government is of the opinion that a Patent in Indonesia is very important for the conduct of defence and security of the State or for an urgent need for the sake of public interest, the Government may exploit the relevant Patent.[93]

Indonesia was also hit by the HIV/AIDS crisis. In 1987, the price of ARV treatment was about USD800 to 1000 per person per month. Almost no people living with HIV/AIDS could buy them.[94] In 1999, Indonesia negotiated with several Patent holding drug companies, and the price of ARV was reduced by about 30 %, which helped 79 people get treatment, but still, the cost was unaffordable for many. As India began to produce generic ARV by 2000, generics were obtained from India at USD 84 per person per month. This was about 86% lower than the price of Patented ARVs at that time.[95]

Subsequently, by means of the Government Use provision, Kimia Farma was authorized to produce ARVs whilst the raw materials were imported from India. This led to the reduction of price to USD 38 per person per month.[96]

COMPULSORY LICENSING IN MALAYSIA

The Federal Constitution of Malaysia does not directly include the Right to Health as a Fundamental Right. However, Malaysia has had a Universal Health Coverage system since

[93] The Patent Law of Republic of Indonesia https://www.jpo.go.jp/e/system/laws/gaikoku/document/index/indonesia-e_tokkyo.pdf

[94] Indonesia: Manufacturing generic AIDS medicines under the 'government use' approach *Lutfiyah Hanim & Hira Jhamtani* https://www.twn.my/title2/resurgence/196/cover9.doc

[95] Ibid

[96] Ibid

the 1980s. Section 84 of the Patent Act 1983[97] provides for Government Use of a Patented product for matters of public interest.

Malaysia was another nation that was affected by HIV/AIDS crisis. In 2004, the average cost of treatment per person per month was about USD 315. The exercise of Government Use provision to use Generics offered by Cipla lead to a decrease in the cost of treatment by about 81% which meant that accessibility of treatment increased more than twice from 1500 patients to 4000.[98]

Malaysian Government's decision to issue compulsory license was met with complaints to the Government about" negative implications on Foreign Investment". The USA approached Malaysia and attempted to successfully discourage it from granting compulsory license in the future through FTA.[99]

However, in the wake of the Hepatitis C crisis in Malaysia, where over 5,00,000 patients were in a requirement for treatment, compulsory license was issued in 2017. This was done because the price for the Drug for 12-week treatment was 12,000 USD by Gilead was making it unaffordable to many. By virtue of compulsory license, the price of the Drug for the 12-week course was rendered USD 100- 300 making it accessible to the masses.[100]

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[97] Section 84(1) provides for the "Rights of Government":

"Notwithstanding anything contained in [this] Act –where there is national emergency or where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the Government, so requires; or where a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive, the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or third person designated by the Minister may exploit a patented invention."

https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4-annex1.doc Page 119

[98] Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the "Government Use" option by Chee Yoke Ling Legal Advisor, Third World Network
https://www.twn.my/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/Malaysia'sExperienceInIncreasingAccessToAntiretroviralDrugs-CheeYokeLing[Oct05].doc

[99] ibid

[100] Ibid

The Malaysian experience reaffirmed the need for TRIPS Flexibilities to secure access to medicines. The Malaysian Government took a resolute approach towards eliminating their HIV and Hepatitis C problem.

COMPULSORY LICENSING IN ZIMBABWE

By virtue of Article 76 of the 2013 Constitution of Zimbabwe, Healthcare is a Fundamental Right[101] guaranteed to every citizen and permanent resident of Zimbabwe. Section 31 to 35 of the Zimbabwean Patent Act governs the compulsory license and government use provisions. Section 32 allows for the grant of compulsory license for medicines, and the granting authority is to balance between the Patentholder's rights and the Public.

Zimbabwe also was severely hit by HIV/AIDS crisis. Life expectancy had dropped to less than 41 years, compared to 70 years before the epidemic. More than 2000 people die of various diseases every week.[102] As a response to the crisis and owing to the unaffordability of Patented Drugs, Zimbabwe issued compulsory license for ARV and authorized local manufacturer Varichem Ltd to launch its generic ARV with assistance from India. The compulsory license resulted in a reduction of more than 50 percent of the price, from USD 30-50 per month to less than USD 15 per month.[103]

COMPULSORY LICENSING IN RWANDA

[101] 76. Right to health care 1. Every citizen and permanent resident of Zimbabwe has the right to have access to basic health-care services, including reproductive health-care services. • Requirements for birth right citizenship 2. Every person living with a chronic illness has the right to have access to basic healthcare services for the illness. 3. No person may be refused emergency medical treatment in any health-care institution. 4. The State must take reasonable legislative and other measures, within the limits of the resources available to it, to achieve the progressive realisation of the rights set out in this section.

[102] CAN INCENTIVES TO GENERIC MANUFACTURERS SAVE THE DOHA DECLARATION'S PARAGRAPH 6? STACEY B. LEE https://docplayer.net/36108907-Can-incentives-to-generic-manufacturers-save-the-doha-declaration-s-paragraph-6.html

[103] Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities
https://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_dur_13/wipo_ip_dur_13_ref_t10c.pdf

Rwanda was yet another Nation that was harshly hit by HIV/AIDS crisis. In 2007, there were approximately 1,50,000 people living with HIV in Rwanda. Between the ages of fifteen and forty-nine, 2.8% of the population had AIDS.[104] At the time, the cost of generic ARV treatment ranged from $88 to $261 per year. On July 17, 2007, Rwanda notified the WTO of its intention to import TriAvir for 2 years. Through compulsory license, Rwanda imported tablets of this combination from Canadian generic manufacturer Apotex at the cost of US $0.405 per tablet.[105]

COMPULSORY LICENSING IN MOZAMBIQUE

Mozambique was one of the African Nations worst affected by the AIDS crisis. At the end of 2002, more than a million citizens were infected with HIV, with a death toll of over 2,00,000. The first-line treatment, the triple compound of lamivudine, stavudine, and nevirapine, was procured at USD 140 per person per year.[106] The Government attempted a negotiation with the patent holders, the failure of which resulted in the grant of compulsory license to Pharco Mocambique, which helped increase the accessibility of medicines.[107]

COMPULSORY LICENSING IN GHANA

Ghana is another nation that was severely hit by the AIDS crisis. Ghana issued compulsory license in 2005 on the grounds of Public Interest, which helped reduce the cost of ARVs to more than 50 percent, from USD 495 to USD 235 for one year's treatment.[108]

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[104] CAN INCENTIVES TO GENERIC MANUFACTURERS SAVE THE DOHA DECLARATION'S PARAGRAPH 6? STACEY B. LEE https://docplayer.net/36108907-Can-incentives-to-generic-manufacturers-save-the-doha-declaration-s-paragraph-6.html

[105] Canadian made drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines (December 10, 2007) https://asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and

[106] https://www.who.int/3by5/support/june2005_moz.pdf WHO (June 2005) (Accessed August 21st 2021)

[107] Ibid

[108] https://www.twn.my/title2/IPR/pdf/ipr10.pdf MARTIN KHOR, PATENT COMPULSORY LICENSING AND ACCESS TO MEDICINE: SOME RECENT EXAMPLES 14-15 (Third World Network, Intellectual

CONCLUSION

Practises of several nations points to the inference that compulsory licensing has been used as an effective means of facilitating access to medicines. It is also pertinent to note that almost all cases of issuance of compulsory license, with the exception of compulsory license being issued by Global North, were met with vehement opposition and political pressure from the USA and PhRMA. Nevertheless, successful use of compulsory license has led to accessibility to medicines to fight HIV/AIDS, Hepatitis C, and various forms of cancer in many developing Nations. The framework of Ecuador in issuing compulsory license is noteworthy as the process involved is transparent and systematic. Certain examples, particularly Brazil and Germany, show that compulsory licensing can be used as an effective bargaining mechanism to negotiate a reduction in drug prices. Further, compulsory licensing forms a part of Domestic Legislation in even the USA. The USA was prepared to issue compulsory licensing as a response rise in anthrax cases. This points to the fact that compulsory license is an effective tool in any nation's arsenal to address public health challenges.

India can learn from the practices followed in Brazil. Brazil has incorporated health as a fundamental right. This can serve as a valid justification for compulsory licensing and gives more power to the courts as well as public to raise the public health conditions of the Nation. India must integrate Right to Health as a fundamental Right.

Ecuador stands as another example of a robust compulsory licensing system which is rooted in Transparency. The Government expressly seeks to ensure the affordability of medicines. They engage in a constructive and well-reasoned negotiations with the Pharmaceuticals in such a manner that pubic interest and question of affordability forms a cardinal parameter in price negotiation. Such a process of transparency will keep the nation in good stead.

The examples of Thailand, Indonesia and Malaysia, which are also developing nations, demonstrate the effectiveness and potential of compulsory license to act as a tool to ensure accessibility of drugs. Examples of these nations also demonstrates the reluctance of

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pharmaceuticals to cooperate with negotiations and the pressure tactics of the USA. Despite, these challenges, the commitment of the governments to facilitate access to medicines are admirable.

CHAPTER 4

DRUG PRICING AND AFFORDABILITY

INTRODUCTION

Despite numerous National and International instruments affirming Right to Health as an important human right, the reality of the world is that the majority population faces

significant obstacles in accessing lifesaving medicines such as cancer drugs. In fact, people are being pushed to poverty owing to affordability issues.

Why are drugs priced so high? What options do a patient or his family have when a hefty price tag is put on their lives? Is the current system of pricing consistent with the true cost of its production? How far are we willing to go to protect the monopoly rights of the inventor? Can we go far enough so as to turn a blind eye towards a sick pauper who was unfortunate enough to have contracted a disease, the cure of which would cost a fortune?

The previous Chapters has demonstrated that compulsory licensing is an effective tool for ensuring accessibility. Also, we have seen the successful implementation of compulsory licensing provisions in many Developing Nations.

A core reason why compulsory licensing is contemplated is due to the challenge of affordability of medicines. However, this extremely vital question of affordability, comes to the fore only during public health crisis. The AIDS crisis led to the Global Reduction in price of ARVs because it was a global crisis and a massive activism for the cause of the victims ensued.

What about the situations where a very few percentages of population affected by a particular medical condition cannot obtain drugs due to affordability issues? Why about their Right to access medicines? Can their cause be ignored as they only form a miniscule part of population? Can their predicament be left to continue as it is for the lack of effective collective bargaining power? Is it humane to push them to poverty at the altar of affordability? Who determines the price anyway? Is the rationale behind the pricing well-founded?

This Chapter seeks to examine whether the pricing policy adopted by the Originator Pharmaceuticals are justified.

THE BEGINNINGS OF THE PHARMACEUTICALS AND FOOD AND DRUG ADMINISTRATION (FDA)

Prior to the inception of Pharmaceuticals Industry, Europe and U.S.A had a community of practitioners trained in the science of mixing plant extracts, chemicals and such substances to produce potions that was used for treatment of illnesses. These people were called Apothecary. The United States of America had Apothecaries who migrated from Britain and other European Nations. Through various activities by them in US, a pharmacopeia was compiled in 1820 and a standard of drug prescription was informally established by this practice.[109]

Apothecaries worked by obtaining compounds and potions in a need-based approach. That is, they tended to create their compounds when required and not en masse. This was the traditional approach of Apothecaries which was the unquestioned custom. In 1820s, Emanual Merck, who himself was an Apothecary, after taking over his father's business ventured on to expand his workforce and mass-produce large batches of medicine.[110]

In 1827, Merck and a chemist Serturner, succeeded in developing a pain-relieving compound from Opium, called Morphine. The mass production of this compound and its pain-relieving property led to new era of mass production of Therapeutics. Following the lines of companies that produced pharmaceutical products, Pfizer was established in 1849 in Brooklyn. Eli Lilly was established in 1876 in Indianapolis and Johnson and Johnson was established in 1886. This development in chemical studies and the rise of laboratory manufacturing put the profession of Apothecaries to a decline. During the 1900, Apothecaries were replaced by chemists who sold their cures through Drug Stores. In the 1915, super chains of drug Stores began to arise.[111] Certain companies such as Dow, Merck, through their marketing strategy and attractive pricing eliminated small scale stores and managed to rise as cartels. However, with the boom in Pharmaceutical Industry came the concerns over the quality and trust ability of the drugs. There were incidents of adulteration detected in drugs such as quinine, whose ineffectiveness owing to adulteration led to the loss of lives of US soldiers. The US Congress passed Pure Foods and Drug Act in 1906, which sought to prevent unscrupulous practices such as watering down of milk and adding chalk and plaster to cover up their action and similar adulteration. But nothing existed to check the effectiveness and therapeutic safety and efficiency of medicines.

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[109] Kinch, M. & Weiman, L., 2021. *The price of Health: The Modern Pharmaceutical Enterprise and the betrayal of a history of care*, New York: Pegasus Books.

[110] Ibid

[111] ibid

In 1905, the American Medical Association (AMA) used their lobbying power to compel the Pharmaceutical Companies to demonstrate that their products were effective before they could be advertised in AMA Journals. However, this stringency could not be effectively enforced and there were pervasive allegations of collusion between the Pharmaceutical Corporations and AMA.

In 1937, Bristol, launched Elixir Sulfanilamide[112], which was marketed as a medicine to cure children's ear wax. Their drug was made sweet to accommodate to the palate of children and were to be administered orally. Within days of the product's introduction, several cases of poisoning were reported and more than 100 children died of Ethylene Glycol poisoning of their kidneys.

Following public outrage, the Congress passed the Federal Food, Drug and Cosmetics Act of 1938. This legislation empowered the Food and Drug Administration to ensure that all medicines are safe to consume. However, the FDA faced several difficulties as they were not empowered to collect information regarding the products. During that time, a German Company Grunenthal, sought to introduce a new drug into US in association with Merell Pharmaceuticals which was housed in US. When Merell applied to FDA to get clean chit, the FDA was skeptical and requested for more information regarding the product. Merell went on to distribute free samples of the new Drug, Thalidomide to US doctors as the law permitted free distribution. Meanwhile, large number of cases came to be reported in Germany of thousands of "thalidomide babies" being born with no arms or legs. The FDA was praised for its stand and US media reported that Thalidomide reached only around 17 consumers due to Merell's free distribution of the drug.[113]

Following the Thalidomide poisoning incident, the US Congress introduced the Kefauver Harris Amendment to the Federal Food Drug and Cosmetics Act of 1962. This empowered the FDA to demand extensive safety and efficacy data before approval of a new drug. In 1969, the National Research Council completed a Retrospective Analysis of 3000 medicines and following the fruition of the study in 1984, more than one third of these medicines were

[112] Kinch, M. & Weiman, L., 2021. *The price of Health: The Modern Pharmaceutical Enterprise and the betrayal of a history of care*, New York: Pegasus Books.

[113] True story of Thalidomide in the US. *US Thalidomide Survivors*. Available at: https://usthalidomide.org/our-story-thalidomide-babies-us/ [Accessed August 30, 2021].

discontinued as they did not meet the standards or because their manufacturers voluntarily stopped the production.[114]

The Regulatory Framework more or less remains the same till date. History evidences that enormous public effort and legislative will was exerted to bring the products made by the Pharmaceutical's under scrutiny for safety and efficacy, but nothing has been done so far to make these corporations accountable for their pricing policies.

THE ISSUE OF RESEARCH AND DEVELOPMENT (R&D)

Pharmaceutical pricing is said to be the natural consequence of the way pharmaceutical products are researched, developed and made available. The reason for the high prices of various Drugs is attributed to huge investment in R&D by most companies. The cost of Developing a single FDA Approved Drug was estimated to be about 2.87 billion USD (2013)[115]

This figure was alleged to be inflated[116]. It is also alleged that these figures do not take into account the fact that most of this research are covered by public funds, such as National Institute of Health. These inconsistencies are due to the fact that clear data regarding various essential parameters for determining the true cost of developing a new drug is unavailable.

We have no option but to take into reckoning the estimate that Research and Development (R&D) for a single drug would cost billions. This would mean that the cost imposed on the product should be justified on the ground that it is essential for the Corporations to recover their R&D costs so that they can continue producing more innovative medicines.

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114 Kinch, M. & Weiman, L., 2021. *The price of Health: The Modern Pharmaceutical Enterprise and the betrayal of a history of care*, New York: Pegasus Books.

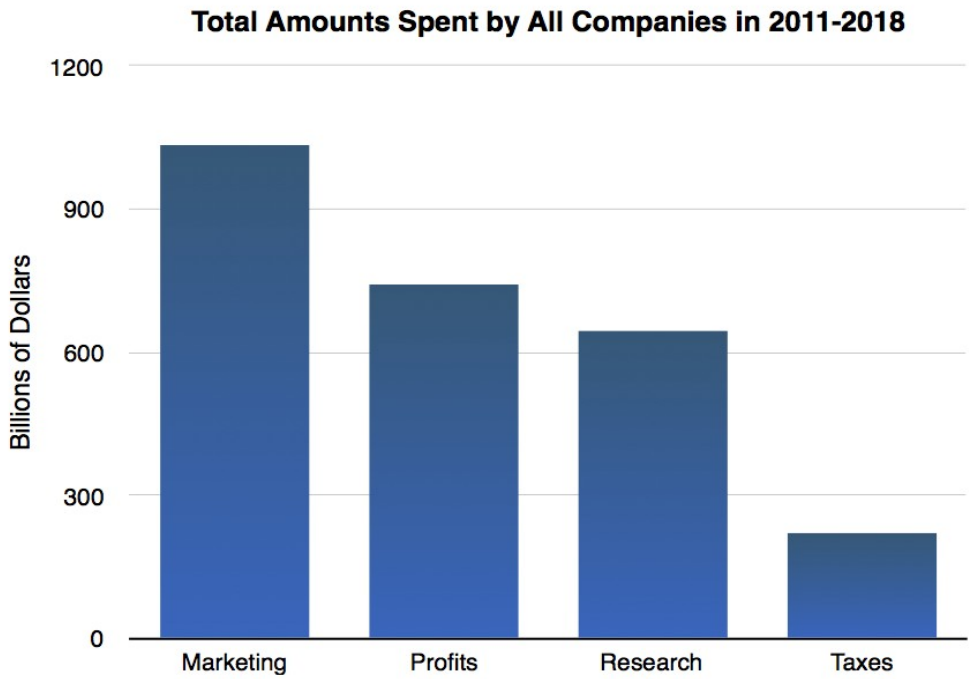
115 DiMasi, J.A., Grabowski, H.G. & Hansen, R.W., 2016. Innovation in the pharmaceutical industry: estimates of R&D costs. *Journal of Health Economics*. Available at: https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub [Accessed August 30, 2021].

116 Anon, 1621 Connecticut Avenue NW - cancerunion.org. Available at: https://cancerunion.org/files/UACT-Tufts-24Nov2014.pdf [Accessed August 30, 2021].

But even assuming this figure to be true, the data collected from major 13 pharmaceutical corporations create dubiousness over the R&D justifications given for price rise.

A study made by David Belk and Paul Belk found that the combined total revenue for these companies from 2010-2018 was about USD3.78 trillion. The total amount they spent on marketing was about 60% more than what they spent on research.

The same information can be represented in the following graphs: [117]



The figure shows the combined profits earned by all 13 major pharmaceutical companies[118] from 2011-2018 compared to amount spent on marketing and research over the same time period.

The proportional allocation of revenue can be understood from the figure below:

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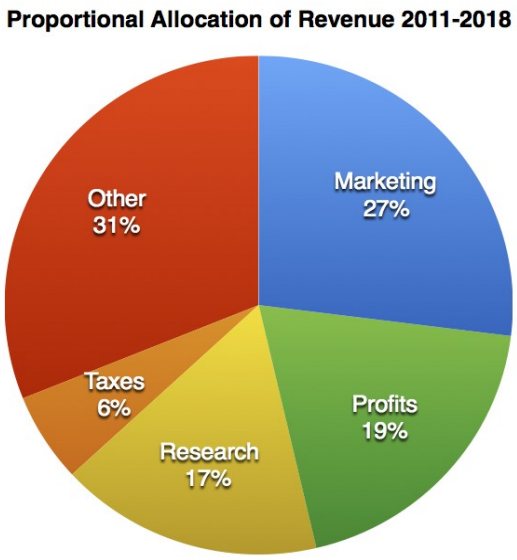
[117] The pharmaceutical industry. *True Cost of Healthcare*. Available at: https://truecostofhealthcare.org/the_pharmaceutical_industry/ [Accessed August 30, 2021].

[118] AbbVie, Abbot, Amgen, AstraZeneca, Bristol Myers Squibb, Eli Lilly, Gliead, Galaxo Smith Kline, Johmson&Johnson, Merck, Novartis, Pfizer, Roche, Sanofi



The study shows that the pharmaceutical companies do spend 17 percent of their Revenue on research but their research budgets are significantly less compared to Marketing Budget. They also made more in profits each year, on average, than they spent on research.[119]

It is inferred that these corporations recover their R&D expenses and much more through their sales.

Further, no amount of R&D argument can account for U.S based Turing Pharmaceuticals raising its price of its drug Darapirm from 13.50 USD a tablet, to 750 USD per tablet on September 2015. An increase of price by 5,500 percent overnight which still remains.[120]

COMPULSORY LICENSING AND RESEARCH AND DEVELOPMENT

Pharmaceuticals lobbies particularly PhRMA vehemently oppose any form of pricing regulations or attempts by State to negotiate prices of Drugs as an affront to innovation. Australia and several European nations have State mechanisms that attempts to Regulate Price and entry of Pharma Products into their market. Through Drug Pricing Control Order

[119]The pharmaceutical industry. *True Cost of Healthcare*. Available at: (Accessed on August 23rd 2021) https://truecostofhealthcare.org/the_pharmaceutical_industry/

[120]Get rich quick with old generic Drugs! The Pyrimethamine Pricing Scandal (Accessed on August 23rd 2021) https://academic.oup.com/ofid/article/2/4/ofv177/2460638

(DPCO) and National Pharmaceutical Pricing Policy (NPPP), India also has mechanisms to regulate Drug Pricing.

All these Regulatory Mechanisms are perceived to be a threat to free trade and innovation attempts are made time and again to deconstruct these frameworks. The Generic Industries and actions such as compulsory licensing are deemed as deplorable practices which needs to be done away with.

According to pharmaceutical corporations, compulsory licensing would substantially lead to the loss of their revenue which in turn would adversely affect the incentive for the company to innovate and find new drugs, therefore ultimately being of detriment to the public.

Research shows that this claim is farfetched.

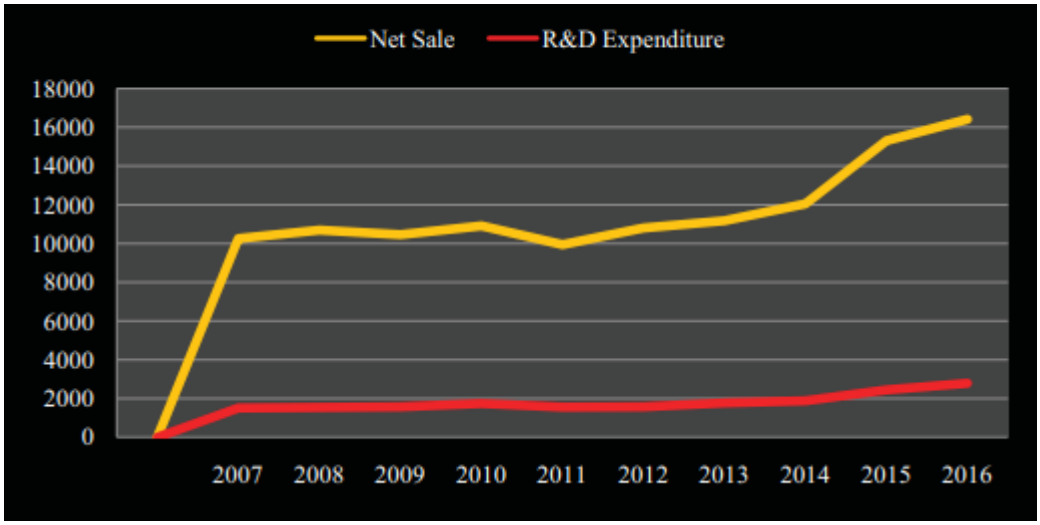
A study by Aswathy Asok, revealed that there is no direct relation between compulsory license and the Research and Development (R&D) expenditure of a company.[121] The data showed that compulsory license had no impact on the R&D allocation. This points to the inference that compulsory licenses do not impact much on the business of the companies, even in the higher income countries.

The issuing of compulsory license can have any impact only if the market where the compulsory license was issued forms a substantial part of market. According to IMS Health (MIDAS), the western part of the globe is the world's largest pharmaceutical market. It constituted 75% of pharmaceutical market in 2016. The other part of the world constitutes only 25% of total pharmaceutical market. Thus, Developing Nations and LDC, by issuing compulsory license have little effect on the Revenue of the Pharmaceuticals.

Compulsory Licenses can threaten the revenue of the Corporations only when they are issued in the Western Markets which makes up to 75 percent market.

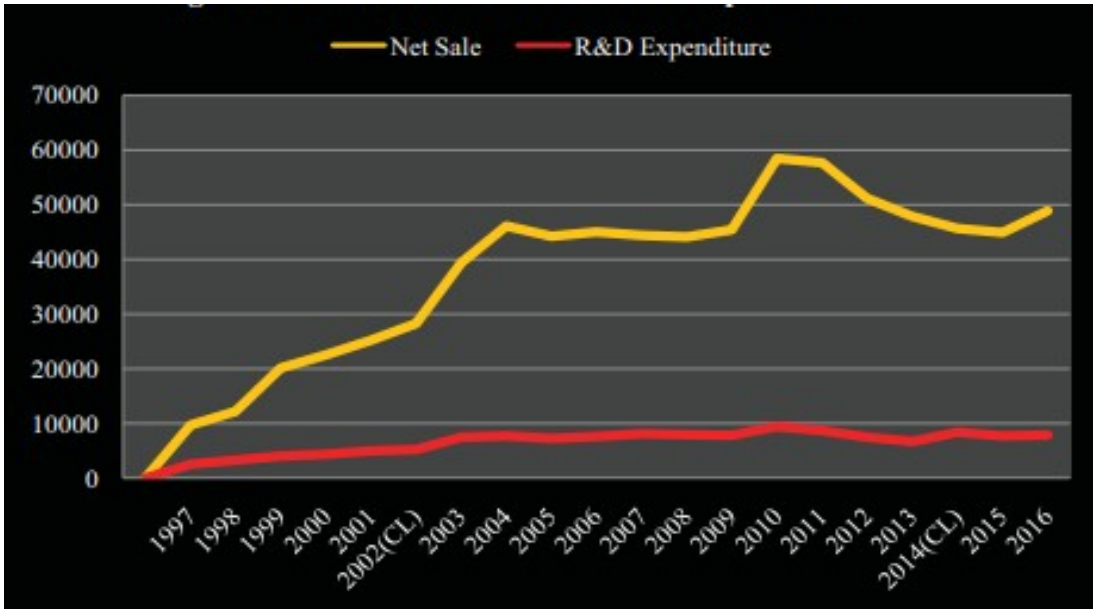
In Bayer's case, where compulsory license was granted to Natco for Nexavar. Data indicate that the net sales of Bayer did not decline after the issuance of compulsory license in India. R&D expenses show an increase after 2012 which testifies the fact that compulsory license issued by India had not affected the company.

[121] Aswathy Asok, Effects of Compulsory Licensing on Public Health https://shodhganga.inflibnet.ac.in/bitstream/10603/331535/8/08_chapter%205.pdf page 249



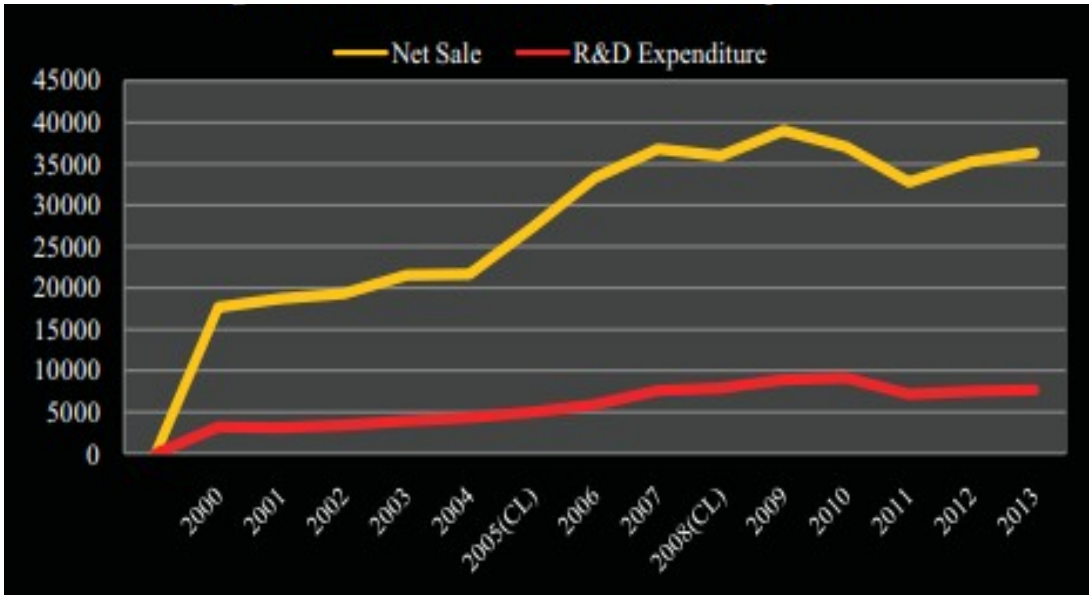
BAYER

The Net Sale and R&D Expenditure of various Pharmaceutical's against whom Compulsory license were issued are shown.[122]



PFIZER

[122] Data obtained from Research by Aswathy Asok, https://shodhganga.inflibnet.ac.in/bitstream/10603/331535/8/08_chapter%205.pdf



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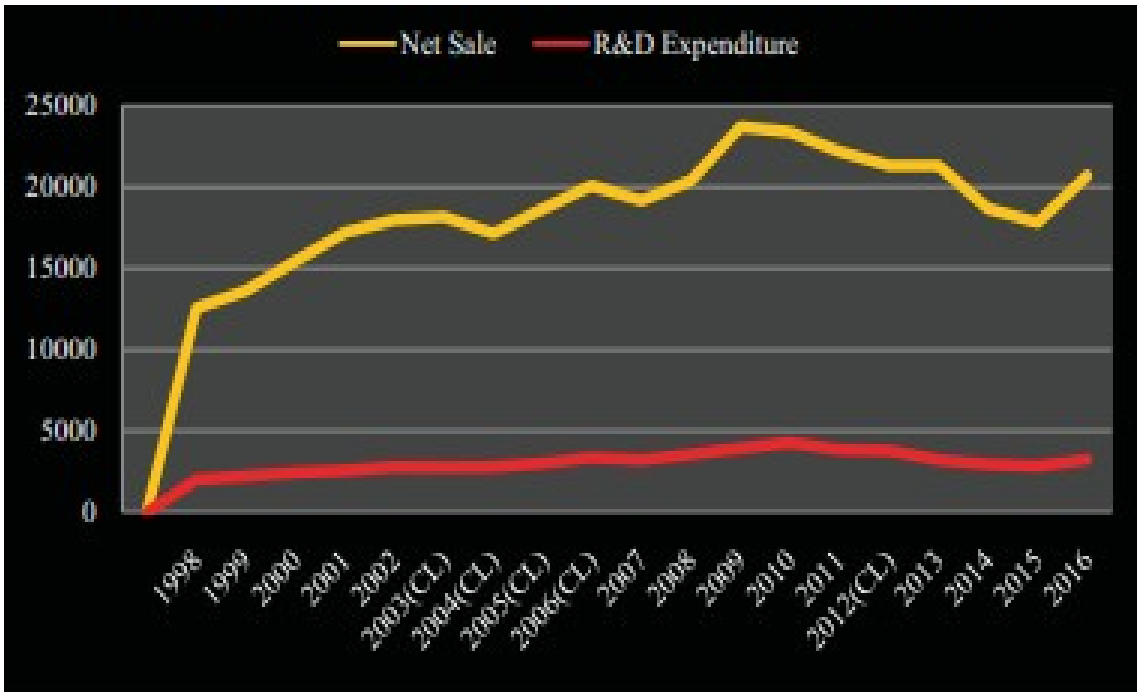

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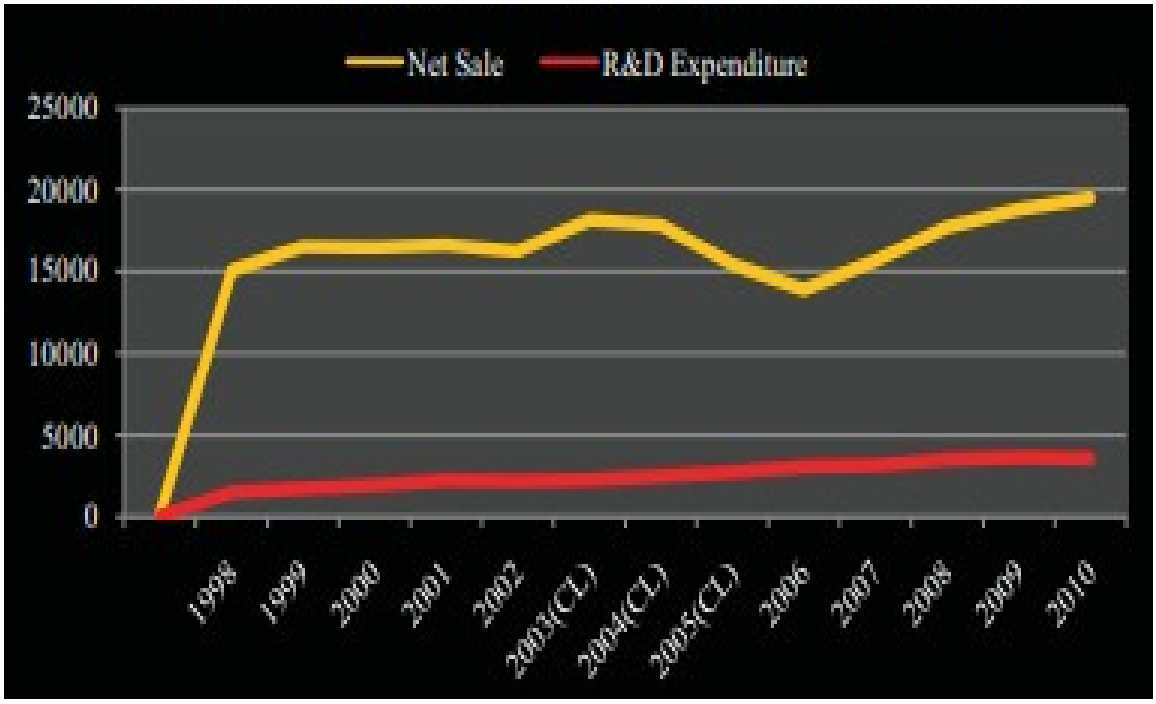
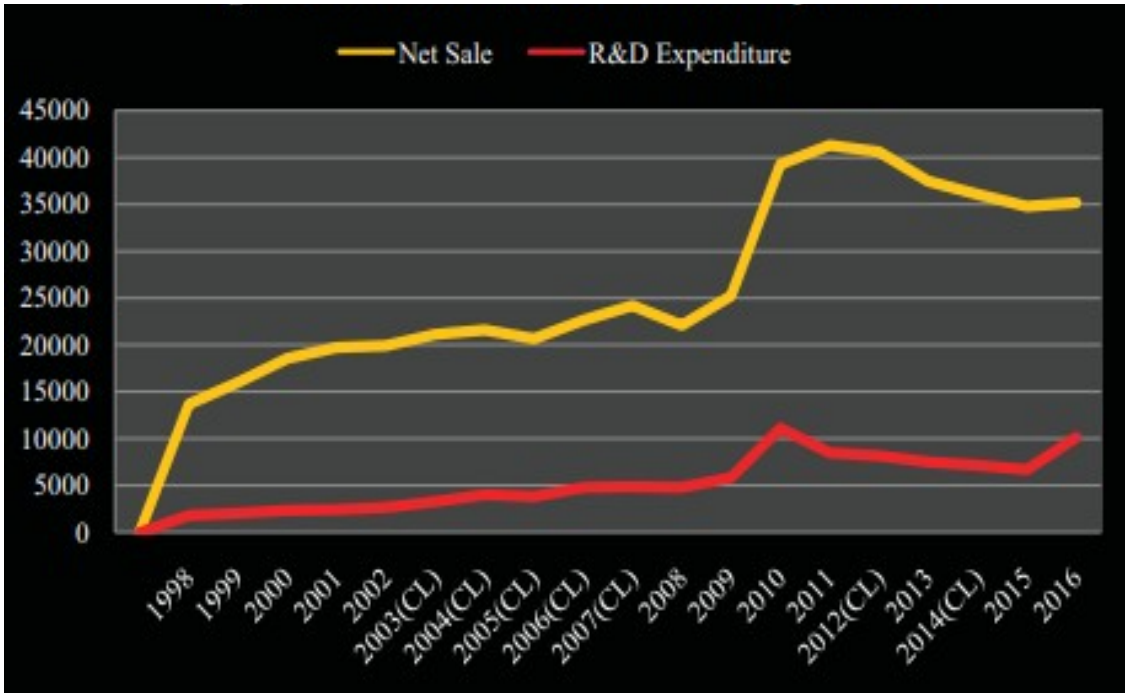


BRISTOL-MYERS SQUIBB



MERCK

As a summary, the data collected reveals absence of any direct relation between compulsory license and R&D expenditure of the company.[123]

CONCLUSION

The Pricing model adopted by the pharmaceutical giants are unscrupulous. The brunt of these pricing is borne not only by Governments and Public of Developing Nations and Least Developed Countries LDCs, but citizens of nations such as USA itself.

Faced with surging pharmaceutical costs, patients are often forced to choose between their medication and their mortgage. In U.S.A where there is no regulation on Drug Pricing, Manufacturers elevate prices of life-saving drugs used to treat cancer, diabetes, and multiple sclerosis by more than ten percent annually.[124] This is putting a lot of strain on US medical care system and currently policies are being devised to address the growing concerns of unfettered drug prices[125]. Senators in USA, such as Bernie Sanders are pushing for legislation to enable government to negotiate drug prices covered under Medicare.

Even in United Kingdom (UK), which stands as a remarkable example of proving access to healthcare, the rise in price of medicines, including cancer drugs have been compelling the National Health Service (NHS) to reform cancer drugs fund and take other policy actions.[126]

Understandably, Intellectual Property law seeks to balance the monopoly to the inventor vis-à-vis rights of the public. When it comes to access to healthcare, the enjoyment of monopoly of the inventor cannot allowed be at the cost of access to medicines for lifesaving drugs. If the invention was regarding a material which has little to do with sustaining life -for example,

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[123] Aswathy Asok, Effects of Compulsory Licensing on Public Health https://shodhganga.inflibnet.ac.in/bitstream/10603/331535/8/08_chapter%205.pdf

[124] Ibid

[125] Allowing Medicare to Negotiate Drug Prices , Cristi Martin, May 05, 2021 https://www.commonwealthfund.org/publications/explainer/2021/may/allowing-medicare-negotiate-drug-prices (Accessed on August 23rd 2021)

[126]Rising Spend on NHS Medicines could Jeopardize patient's access to Drugs, Warns the Kings Fund 26 April 2018 https://www.kingsfund.org.uk/press/press-releases/rising-spend-nhs-medicines-patients-access (Accessed on August 24th 2021)

gadgets, then a high pricing and relative unaffordability is understandable. But when it comes to lifesaving drugs, the rationale behind the current pricing schema, which effectively takes accessibility away from poor and puts huge financial burden on the economies of the developing Nations and LDC are something which requires urgent redressal.

With the Post TRIPS Regime and the curbing of Process Patent, India, unlike many European Nations, do not have an effective healthcare system and Government cover for treatment. Treatment costs are out-of-pocket expense for most Indians. With the demise of process patents, India is vulnerable to the menace of monopoly and high drug prices which the USA is facing. With the current Patent regime, India is susceptible to bearing the brunt of the power of the Pharmaceutical Corporations. Problems in access to medicine is bound to be a reality in the coming years not only for the poor in India but the middle class as well.

CHAPTER 5

THE SCOPE OF COMPULSORY LICENSING FOR CANCER DRUGS

INTRODUCTION

Cancer, as a disease, was written and documented for from earlier ages. Hippocrates, The Father of Medicine is said to have used the term “Karakinos” (which means Crab) as the lumps resulting from cancer seemed to bear resemblances to the limbs of a crab. Modern medicine identifies Cancer as a non-communicable disease marked by the presence of cancerous lumps in any part of body. The study of Cancer is called Oncology and the term is derived from the root “Oncos” which in Greek meant “Swelling”[127].

[127] Understanding what cancer is: Ancient Times to present by American Cancer Society https://www.cancer.org/cancer/cancer-basics/history-of-cancer/what-is-cancer.html [Accessed August 24th 2021]

There are several forms of Cancer, the most common of them includes lung, stomach, liver, colorectal, prostrate, breast. There are about 14 million new cases each year and cancer accounts for about 8.7 million deaths per year.[128]

Conventionally, the Developed Nations witnessed the prevalence of Cancer but occurrences have increased significantly in Developing and Least Developed Countries during recent years. More than 60 % of Cancer cases are reported from Asia, Africa and Latin America and about more than 70 % of Cancer deaths occurs in these regions.[129]

Cancer treatment is performed primarily by means of surgery, chemotherapy, radiation Therapy or a combination of any of these. Chemotherapy involves ingestion of a single drug or a combination of drugs. The term for treatment lasts for about 4 to 6 months or more, depending on the type and stage of cancer.[130]

Cancer is accounted for as the second leading cause of death worldwide, treatment for cancer is regarded as expensive and the price of Cancer drugs are exorbitant which renders it unaffordable for many in Developing and LDCs. The average price of Cancer therapy has increased from 5000 USD per month in 2003 to 10000 USD per month in 2013.[131] In the coming years, Cancer related deaths in Developing and LDCs are likely to be greater than that of Developed Nations.[132]

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[128] GBD 2015 Mortality and Causes of Death Collaborators. Global, regional, and national life expectancy, all-cause mortality, and cause-specific mortality for 249 causes of death, 1980–2015: a systematic analysis for the Global Burden of Disease Study 2015. The Lancet. 2016; 7; 388:1459–1544.

[129] Bernard W. Stewart, Freddie Bray, David Forman, Hiroko Ohgaki, Kurt Straif, Andreas Ullrich, Christopher P. Wild, Cancer prevention as part of precision medicine: 'plenty to be done', *Carcinogenesis*, Volume 37, Issue 1, January 2016, Pages 2–9, https://doi.org/10.1093/carcin/bgv166

[130]How long Chemotherapy is given: Chemocare https://chemocare.com/chemotherapy/what-is-chemotherapy/how-long-is-chemotherapy-given.aspx [Accessed on August 25th 2021]

131 Compulsory Licenses for Cancer Drugs: Does Circumventing Patent Rights Improve Access to Oncology Medications? https://ascopubs.org/doi/full/10.1200/JGO.2016.005363 [Accessed on August 28th 2021]

132 Cancer is on the rise in developing countries: by Julio Frenk, MD, MPH, PhD Dean, Harvard School of Public Health

https://www.hsph.harvard.edu/news/magazine/shadow-epidemic/ [Accessed on August 28th 2021]

INDIA- CANCER DRUGS AND AFFORDABILITY

The World Health Organization (WHO) estimates that India has a Cancer mortality rate of 79 per 1,00,000 deaths. In the year 2018 alone, more than 7 lakh Indians died of Cancer.[133] The treatment for Cancer is among the highest among Non-Communicable Diseases. Lack of proper financing mechanisms and heavy out-of- the pocket expenditures put households to financial constraints and pushes them to resort to risky means for bearing the expenses.[134]

The Government of India, controls drug prices primarily through the Drug Price Control Order. The Government, through the Drug Prices Control Order 1970 ventured to fix the maximum ceiling limit for selling the price of drugs. The Prices of 18 Active Pharmaceutical Ingredients (APIs) known as Bulk Drugs were fixed. For the rest of the Drugs, prices could not be increased sans approval of the Government.

Later on, with DPCO were revised in 1979, 1987 and 1995. These orders varied from each other only with respect to the number of drugs that came within the price control. Over the course of years, the scale of control has been diluted.

Significant changes were introduced through National Pharmaceuticals Pricing Policy, 2012 and the enactment of Drug Prices Control Order 2013. A significant change introduced was regarding the mechanism of price control While the earlier principle of regulating prices were through Cost Based Pricing (CBP), the current basis for regulation is through Market Based Pricing (MBP).

Under the Cost Based Pricing method, manufacturers were required to make available their pricing data covering all aspects of production. The pre-determined profit also had to be revealed. Under CBP, the retail price of a product was fixed taking into account the material cost, conversion cost, packaging cost, maximum allowable post manufacturing expenses which included the profits sought to be made.[135]

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[133]Cancer Statistics India by India against Cancer: An initiative by National Institute of Cancer Prevention and Research (NICPR) http://cancerindia.org.in/cancer-statistics/ [Accessed on August 28th 2021]

[134] Joe W. Distressed financing of out-of-pocket healthcare payments in India: incidence and correlates. Health Policy and Planning. 2015;30: 728–741. https://pubmed.ncbi.nlm.nih.gov/24966294/ [Accessed on August 28th 2021]

[135] DRUGS (PRICE CONTROL) ORDER, 1995 The Gazette of India - Extraordinary http://dca.ap.nic.in/sites/default/files/2017-11/Drugs_PriceControl_Order%2C1995.pdf

The reason for doing away with CBP, according to National Pharmaceutical Pricing Policy (NPPP) 2012, is that CBP are required to provide their pricing in an "extremely" detailed which can be "intrusive" and highly resisted by individual manufacturers which may result in "possible manipulation" in providing the base costing data.[136]

The Market Based Pricing Model seeks to put a ceiling price which would be fixed and this would provide manufacturers to fix their price below the ceiling price. For fixing the ceiling price, the simple average of prices of all brands of a product with market share of more than one percent or more is taken. Manufacturers would be able to fix any price for their products equal to or below the ceiling price.[137] This is done to provide for a more business friendly market condition.

Through this, the Government seeks to balance the requirements of the market economy with that of a reasonable price control. However, it is pertinent to note that through MBP, nothing is done to address the pricing practices of the manufacturers. There is no schema to probe into any "possible manipulation" in cost data. The conclusion is that the manufacturer can price the product at the ceiling limit under MBP even the cost of production is far time lesser than the price.

PRICE STRUCTURE OF CANCER MEDICINES

For understanding the price structure of anti-cancer medicine, the [138]research by Sudip Choudary is relevant.

The database for study indicated 131 molecules which were identified as anti-cancer molecules. Out of these 131 molecules, 40 were included under DPCO for price control, 32 were not under DPCO, 2013 but trade margin has been capped and 59 were neither under DPCO nor under trade margin control.

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[136] NATIONAL PHARMACEUTICALS PRICING POLICY, 2012 (NPPP-2012) https://jetro.go.jp/ext_images/world/asia/in/ip/pdf/nppp_2012_en.pdf

[137] NATIONAL PHARMACEUTICALS PRICING POLICY, 2012 (NPPP-2012) https://jetro.go.jp/ext_images/world/asia/in/ip/pdf/nppp_2012_en.pdf page 9-10

[138] Refers to study by Sudip Chaudary ; (2019)How Effective Has Been Government Measures to Control Prices of Anti-Cancer Medicines in India?. SSRN Electronic Journal. 10.2139/ssrn.3767833 https://www.researchgate.net/publication/338828463_How_Effective_Has_Been_Government_Measures_to_Control_Prices_of_Anti-Cancer_Medicines_in_India [Accessed on August 29th 2021]

Prices of Anti-Cancer Medicines under DPCO, 2013

The study showed that prices are exorbitant for many anti-cancer medicines despite price being fixed under DPCO.

The costliest medicine under the DPCO price-controlled group was Trastuzumab– a medicine used for breast cancer which is sold under brand name Kadcylaby Roche and the medicine costs Rs 210440.47 for one 160 Mg injection.

There were 14 medicines which were priced more than Rs 50,000 which accounted for 15 % of the sales. Examples include Rituximab, a medicine for treating leukaemia which was sold by Dr Reddys at Rs 79732.50 for one 500 mg infusion, Bortezomib which was sold by Janssen Rs 60360 for one 3.5 mg injection.

65 medicines, which account for one-fourth of the sales were priced greater than Rs 15,000 per dose. 122 medicines which accounts for more than one-third of sales is priced more than Rs 10,000. Since Cancer medicines need to be taken for multiple times over a period of time, the combined cost of the medicines is bound to be several times the price indicated.[139]

Another noteworthy aspect is that the lower-priced SKUs are not necessarily sold more. In fact, the *SKUs with prices more than the median price account for about 88.6% of the sales for Trastuzumab.*[140]

[139] *ibid*

[140] Chaudhuri, Sudip. (2019). How Effective Has Been Government Measures to Control Prices of Anti-Cancer Medicines in India?. SSRN Electronic Journal. 10.2139/ssrn.3767833. https://www.researchgate.net/publication/338828463_How_Effective_Has_Been_Government_Measures_to_Control_Prices_of_Anti-Cancer_Medicines_in_India [Accessed on August 29th 2021]

Molecule	No of SKUs	Price of highest priced SKU,Rs	Unit of highest priced SKU	Price of lowest priced SKU, Rs	Unit of lowest priced SKU	Median Price, Rs	Sales share of SKUs with prices > median price
Trastuzumab	20	210440.47	160 mg injection	1950.00	150 mg injection	58160	88.6
Rituximab	35	79732.50	500 mg infusion 50ml	4337.21	100 mg injection 1 ml	34123.31	48
Bortezomib	20	60360.00	3.5 mg injection	2625.00	2 mg injection 1 ml	12003.835	57.7
Paclitaxel	76	37000.00	300 mg injection	639.50	100 mg injection 16.67 ml	4642.61	58.2
Docetaxel	57	21111.00	80 mg injection 2 ml	765.00	20 mg injection	7500.00	77.9
Doxorubicin (liposomal)	16	20056.00	50 mg injection 25 ml	4013.62	10 mg injection 5 ml	7924	64.9
Temozolomide	46	17857.15	250 mg capsule	89.42	20 mg capsule	1731.00	69.24
Filgrastim	24	10990.00	6 Mg Prefilled Syringe 0.6 Ml	400.00	300 Mg Injection 1 ml	1428.25	47.2
Oxaliplatin	36	10419.40	100 mg infusion 50 ml	1137.89	50 mg injection	2726.91	67.1
Gemcitabine	46	10216.35	1400 mg injection 20 ml	442.00	200 mg injection	3015.39	72.2
Cyclosporin	36	9375.00	100 mg tablet	19.53	25 mg capsule	57.89	57.6

Molecule	No of SKUs	Price of highest priced SKU,Rs	Unit of highest priced SKU	Price of lowest priced SKU, Rs	Unit of lowest priced SKU	Median Price, Rs	Sales share of SKUs with prices > median price
Pegylated interferon alpha 2a	1	8040.00	180 mg injection 0.5 ml	8040.00	180 mg injection 0.5 ml	8040.00	
Doxorubicin (plain) l	29	7514.28	20 mg injection	93.00	10 mg injection	654.76	75.8
Carboplatin	26	3601.19	600 mg injection	740.00	150 mg injection	1931.93	68.9
Melphalan	6	2416.00	50 mg injection	87.00	2 mg tablet	161.93	46.1

Source: Chaudhuri, Sudip. (2019). How Effective Has Been Government Measures to Control Prices of Anti-Cancer Medicines in India?

Prices of Anti-Cancer Medicines not under DPCO, 2013 but under Trade Margin Cap

Among the prices of Anti-Cancer medicine falling under the Trade Margin Cap, three of these drugs were priced at Rs 1,00,000 per dose including the Cabazitaxel which were sold at Rs 3,30,000 for 60 mg injection.

About eight products were priced at more than Rs 50,000 which accounted for 5.5 % of Sales. The Medicines which were priced at Rs 15,000 or more per dose accounted for 29% percent of sales.

In this case also, a huge price difference can be observed. For example, the medicine Bevacizumab is sold in 20 different SKUs with prices varying between Rs 116000 (400 mg injection 16 ml) and Rs 24000 (100 mg injection 4 ml). The median price of it was Rs 31225. Data shows that more than 90 percent of sales share of the medicine was greater than the median price[141]

[141] Chaudhuri, Sudip. (2019). How Effective Has Been Government Measures to Control Prices of Anti-Cancer Medicines in India? SSRN Electronic Journal. 10.2139/ssrn.3767833. https://www.researchgate.net/publication/338828463_How_Effective_Has_Been_Government_Measures_to_Control_Prices_of_Anti-Cancer_Medicines_in_India Page 14 [Accessed on August 29th 2021]

Prices of Anti-Cancer Medicines with no Price or Trade Margin Control

There are 59 drugs in this category which account for one fifth of the total sales of cancer medicines. 40 products cost more than Rs 25,000 per dose among which 5 medicines costs Rs 1,00,000 per dose[142]

The study shows that despite DPCO interventions, the price of Cancer Drugs remains out of the reach of general public.

NEED FOR STRONGER GOVERNMENT POLICIES

Serious illness can put an average Indian's economic situation in jeopardy and can pose significant distress to households. Out-of-pocket expenses to medical treatment have been a silent crisis for Indian citizens. A lack of Organized Lobbying on the part of citizens to demand Right to Life guaranteed under Article 21, through adequate healthcare measures has been prolonging the crisis. In this regard, many Developing and Developed Nations suggests of means through which policies can be facilitated to supplement accessibility of healthcare within the means of the Government.

The Australian Model adopts a system of Pharmaceutical Benefit Scheme (PBS) whereby prescription medicines are subsidized. The Pharmaceutical Benefits Advisory Committee (PBAC) plays a crucial role in determining the pricing policy. The Body consists of nominees representing each stakeholder, including the consumer, the industry nominees, health department nominee and recommends price after comparing prices in similar nations, analyzing the dosage of medicine and making a cost-based analysis. Similar cost-based analysis is followed in South Africa. In Nations such as Britain and Japan, comprehensive health coverage is provided by the Government. The UK, while setting prices of the medicines holds consultations and cost-benefit analysis before permitting the drug to enter the market.

The Report of the Committee on Price Negotiations for Patented Drugs acknowledges that even following negotiations, Prices of Patented Drugs will remain largely unaffordable to the

[142] Ibid

majority of Indian population. Apart from suggesting policy measures to improve the Health Care Systems, and provide for Insurance Coverage in respect of Medical Treatment, the Committee suggested an evidence-based cost-based pricing schema.

However, the DPCO being modified in 2013 to replace Cost Based Pricing model with Market Based Pricing Model raises concerns. MBP does not provide empirical justification for replacing CBP model as a viable alternative. MBP fails to address the concern of Price setting by the Pharmaceuticals. While many nations are keen to involve the element of cost involved in the making of drug to set a reasonable price through negotiations, the Indian Government's stance to retract from enquiring into the costing of drugs is a step backwards when seen from a public policy perspective.

It is also pertinent to note that DPCO covers for less than 10 percent of the Indian Pharmaceuticals Market.[143]

In 2019, NPPA put a cap on prices of 42 cancer drugs at 30 percent which reduced the medicine's price by almost 90 percent in some cases[144]. This is a welcome step. However, this step is perceived to be a half-digested respite owing to the flawed MBP policy. All India Drug Action Network (AIDAN) posits that Price of the Cancer Drugs shows exorbitant trade markups[145], some even to the scale of 1500%. Trade markups for 388 out of 526 brands are greater than 100%.[146]. In effect, according to AIDAN, the Government's action had the effect of legitimizing the exorbitant pricing by the brands. Further, the selection of 42 Cancer Drugs have not been made adhering to any particular schema and there have not been any

[143] All India Drug Action Network – Anti Cancer Drugs- Caps on trade margins will still leave most patients poorer- September 2019 https://aidanindia.wordpress.com/2019/09/13/anti-cancer-drugs-caps-on-trade-margins-will-still-leave-most-patients-poorer/ [Accessed on August 29th 2021]

[144] Press Information Bureau Government of India Ministry of Chemicals and Fertilizers: (November 2020) (https://pib.gov.in/Pressreleaseshare.aspx?PRID=1670707)

Erlotinib 150 mg tab under Brand Birlotib was revised from Rs.9999/- to Rs.891.79/-, showing a decrease of 91.08%. Similarly, the MRP of Pemetrexed 500 mg injection sold as Pemestar 500 was revised from Rs.25,400/- to Rs.2509/- which was 90% less than pre-revised price. Of the 124 medicines which used to cost more than Rs.20,000/- pre-regulation, only 62 did so subsequently.

[145] A markup is the difference between an investment's lowest current offering price among broker-dealers and the price charged to the customer for said investment

[146] All India Drug Action Network – Anti Cancer Drugs- Caps on trade margins will still leave most patients poorer- September 2019 https://aidanindia.wordpress.com/2019/09/13/anti-cancer-drugs-caps-on-trade-margins-will-still-leave-most-patients-poorer/ [Accessed on August 29th 2021]

consultation with stakeholders representing Cancer Patients. Further, apart from the named 42 drugs, most other Drugs remain expensive[147]. The root cause of the problem is perceived as the unwillingness to address the Pricing Policy by Manufacturers.[148]

The NPPA invoked Section 19 of the Drug Prices Control Order 2013[149] to regulate the ceiling limit. The powers vested to the Government by virtue of this section can be used as an effective means to regulate retail prices of Cancer Drugs in the interest of Public Health. In fact, this provision has been invoked to regulate the price of Coronary stents, Oximeter and several similar measures during the Pandemic[150]. It is also pertinent to note that the U.S.A voiced it opposition to NPPA's decision to regulate the price of Coronary Stents.[151]

CONCLUSION

Given the crucial question of affordability and inaccessibility of access to cancer medicines for the masses, the Government is failing in its Constitutional Obligation to secure Right to Life which includes Right to health

While the policy measures by NPPA is welcome, the foundation of MBP is flawed. India must stake steps to correct the irregularities in the Pharma market. India should constitute or empower existing bodies to Negotiate and bring down the prices of Cancer Drugs, use a cost-based approach and fair pricing model and invoke compulsory license, if necessary, to make Cancer medicines accessible to all.

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[147] For example, Cetximab, used to treat head, colon, rectum and neck cancer costs Rs 94,544 per dose

[148] Chaudhuri, Sudip. (2019). How Effective Has Been Government Measures to Control Prices of Anti-Cancer Medicines in India? SSRN Electronic Journal. 10.2139/ssrn.3767833. https://www.researchgate.net/publication/338828463_How_Effective_Has_Been_Government_Measures_to_Control_Prices_of_Anti-Cancer_Medicines_in_India page 28

[149] Section 19. Fixation of ceiling price of a drug under certain circumstances.- Notwithstanding anything contained in this order, the Government may, in case of extra-ordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any Drug for such period, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year.

[150] NPPA caps trade margin of pulse oximeter, digital thermometer and 3 other medical device at 70 percent. (July 14 2021) https://www.livemint.com/companies/news/nppa-caps-trade-margins-of-pulse-oximeter-digital-thermometer-at-70-11626280616601.html [Accessed on August 29th 2021]

[151]

CHAPTER 6

CHALLENGES IN IMPLEMENTATION OF COMPULSORY LICENSING

INTRODUCTION

In today's Globalized World, it would seem that Trade is Free and countries are Sovereign in their true sense. The fact is that the Nations are interdependent in the Global village. Moreover, while the Sovereignty of each member Nation is acknowledged, some nations are more Sovereign than others. Despite several International Conventions and Institutions, it is a tacitly present and silently accepted practice that Developed Nations influence and shape the policies of Developing Nations and Least Developed Countries (LDCs) by adopting a strategy of political pressures, trade sanctions, and other means.

Contemporary political history shows that the USA goes to the extent of funding coups and dismantling governments, to forward its business and defense interests. Political pressure, lobbying, sanctions, and in extreme cases, coups have been instituted to protect vested interests of the USA. There is a strong collusion between politics and trade. The Global north tends to nurture a political atmosphere that suits their trade narratives and covertly and overtly try to challenge alternative models of Intellectual Property laws from coming up. Anything that is perceived to be against the interests of the USA is attacked and decried.

Such maneuverings pose a significant challenge for Nations to implement compulsory licensing. This Chapter seeks to understand the external and internal challenges that directly or indirectly influences nations from exercising its Flexibilities. The primary challenge towards the issue of compulsory licensing is external pressures backed by lobbies such as Pharmaceutical Research and Manufacturers Association of America (PhRMA).

UNFREE TRADE AND UNFAIR PATENT REGIME

The very conception of the Trade-Related Intellectual Property Rights Agreement TRIPS and how it was imposed by Developed nations such as USA and European Union is wrought with elements of threats and coercion.

Following decolonization, the Latin American nations and Asian nations, including India envisaged a Patent policy suited to protect domestic industries. These included policies which favored local manufacturing over foreign manufacturing.[152]

This was owing to the fact that these Nation's economy was severely affected by Monopolistic policy of the Imperialistic Global North which also rendered domestic industries in shambles.

In the 1970s, Patents from decolonized nations accounted for only one percent of the then-existing 3.5 million patents.[153] Corporations of the Global North owned 80 percent of Patents. This situation made technologies Inaccessible for domestic Markets of decolonized nations. Nations took steps to revive their infant industries by various means, including amending their Patent protection of laws in a manner to suit the needs of their economy.

The 1980s saw the rise of nations such as India and Brazil in the production of generics. It is also pertinent to note that these periods witnessed significant developments in the pharmaceutical scenario of the USA. The Kefauver Harris Amendment of 1962 empowered the Food and Drug Administration (FDA) to approve a drug on the basis of its Safety and Efficacy. This move was opposed by the Pharma giants. Further, the Drug Price Competition and Patent Restoration Act (Hatch-Waxman Act 1984) which sought to encourage the entry of Generics into markets by simplifying New Drug Application procedures raised concerns for the Originator Companies whose revenue is heavily linked to Monopoly Rights.

They must have been wary of the rising proclivities of the public and State towards generic drugs and the potential impact on their monopoly rights. Although in US, a Patent holder of Drug enjoyed monopoly rights for a period of 20 years, other nations provided for much less term protection for Drug Patent. The adoption of these policies by US could pose a severe threat to the interests of the pharma lobby.

The Pharmaceutical lobby responded to this development by making use of the loopholes in the Hatch-Waxman Act to delay the entry of generics in the market, indulging in

[152] Deere Birkbeck, Carolyn, The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries (2008). Oxford University Press: Page 40

[153] ibid

evergreening of Patent and such practices within the US. In the International Intellectual Property scenario, the PhRMA advocated for IP Protection which favored extended product patent regime for patent holders of drugs. Their lobbying prompted the USA to amend its Trade Act in 1984 which introduced the Section 301 Report to impose Trade Sanctions for those countries that do not have IP Policy that is favorable to the interest of PhRMA.

Further, in the same year, the Generalized System of Preferences (GSP) Policies of US were fine-tuned through the GSP Renewal Act to include Intellectual Property Protection as a criterion for entailing the benefits of GSP. It is pertinent to note that prior to this move, 140 Nations including Brazil, India were beneficiaries of GSP. The inclusion of Intellectual Property as criterion were aimed at pushing the US Agenda.[154]

In 1985, Global North led by US tried to introduce the aspect of 'Trade Related IP' into the auspices of GATT Negotiations which was opposed by Developing Nations led by Brazil and India, who argued that GATT's purview should be limited to Trade in goods, and IP negotiation be carried out through (World Intellectual Property Organization) WIPO.

The following years witnessed vigorous attempts by US and European Union to generate a consensus for their IP Demand by offering rewards for complaints through GSP and imposing Sanctions for Non-Compliance through withdrawal of GSP benefits and section 301 actions. These measures, along with Bilateral and Regional Trade Agreements, were intended to silence oppositions.

The Global North tried once more to introduce their Intellectual Property demand into the GATT Negotiating Table at Punta de Este which was opposed by a "block" of 10 Nations which included India, Brazil. The Group of 77 Nations went on to issue a collective statement that IP Protection is being used as a means to promote Trade Interests of the Developed Nations and that these pursuals would lead to concentration of Economic and Technological powers to the Developed Nations.[155] This did not result in any change. The US and EU continued its pursuit to isolate and separate defiant Nations through its policies. The US

[154] Deere Birkbeck, Carolyn, The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries (2008). Oxford University Press: Page 49

[155] Deere Birkbeck, Carolyn, The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries (2008). Oxford University Press: Page 54

succeeded in imposing its IP Demand upon Mexico through (The North Atlantic Free Trade Agreement) NAFTA. Nations such as South Korea and Singapore were provided favorable GSP Packages in exchange for their commitment towards US Intellectual Property Demand.

As for Brazil and India, which were labelled "Hard-line" countries, Trade threats were pursued. U.S Pressurized Brazil by using Section 301, which compelled the Brazilian President in 1990 to announce that it would comply with the Intellectual Property demands stipulated by US. India was also listed in the 301 Report. Along with the TRIPS Negotiations, the creation of WTO was envisaged, and India was offered Trade benefits with respect to textiles and agriculture in exchange for compliance with TRIPS. India decided to agree. The presence of flexibilities offered a respite. These flexibilities were to be used by developing nations to help their citizens gain access to lifesaving medicines. However, various impediments were placed upon developing nations when they tried to exercise these flexibilities.

The Doha Declaration was a result of frustration of developing nations, public outrage, Activism and demands to address the problem of accessibility to medicines, particularly in the light of HIV/AIDS crisis. sections of society within the US and Europe began calling out the "unconscionable"[156] practices adopted by the Global North regarding Intellectual Property protection.

Despite Doha Declaration, US has been actively lobbying to minimize the scope of compulsory license and negate Flexibilities of TRIPS. The major Challenges to compulsory license come in the form of Free-Trade Agreements and TRIPS Plus, Special 301 Reports.

TRIPS PLUS AND FREE TRADE AGREEMENTS (FTA)

[156] In 2008, the chief economics commentator for the *Financial Times* described constraints upon developing countries in the area of IP as 'unconscionable' -- Deere Birkbeck, Carolyn, The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries (2008). Oxford University Press: Page 2

The Free Trade Agreement, also called TRIPS Plus Agreement can be understood as Agreements that are sought to include Intellectual Property protection levels at a deeper level compared to the minimum standards of IP Protection mandated by TRIPS. The TRIPS Plus has no formal relationship with the TRIPS Agreement TRIPS Plus is meant to signify that these terms go beyond the standards mandated by TRIPS. TRIPS Plus compliance is sought through means of Free Trade Agreements.

TRIPS Plus contains terms which are meant to restrict the flexibilities under TRIPS. They are deliberate attempts by US to reduce the power of Flexibilities accorded to Member Nations involves significantly limiting the scope of exercise of Flexibilities by Member Nations.

FTA have been entered into by US with Nations including Jordan, Singapore and Australia. The agreements tend to reduce or limit the option of exercising the TRIPS Flexibilities by various means which includes:

1. Data Exclusivity

The Generic Manufacturers rely on the safety and efficacy test data of the Originator Companies in order to submit the safety and efficacy for its bioequivalent. The reason for this is that Bioequivalent compound is having similar chemical properties to that of the original compound and hence the tests with respect to original compounds would suffice to prove the efficacy of bioequivalent compounds. Data Exclusivity can be understood as a practice whereby Drug Regulatory Authorities are precluded from allowing generic manufacturers from relying on the safety and efficacy data of the originator for a certain period of time[157] which is subject to the terms of the Agreement. In other words, Data exclusivity gives the Originators Exclusive Right over the test data for a certain period of time. Data Exclusivity would effectively curtail grant of authorization for compulsory license.[158] If a generic manufacturer is granted a compulsory license, he will not be able to make effective use of license if he has to wait for the expiry of Data Exclusivity before he can gain the

[157] Data Exclusivity in International Trade Agreements: What consequences for access to medicines (Médecins Sans Frontiers) 26th May 2004 https://msfaccess.org/data-exclusivity-international-trade-agreements-what-consequences-access-medicines [Accessed on August 29th 2021]
[158] Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals: Charles Clift http://www.iphandbook.org/handbook/ch04/p09/ [Accessed on August 29th 2021]

approval of the Regulatory Authority. Thus, data exclusivity puts constraints upon compulsory licensing by potentially delaying the entry of Generics.[159]

In 2011, EU- India Trade Agreement was negotiated with provisions of Data Exclusivity. India rejected the Agreement.[160]

2. Patent Linkage

Patent linkage refers to the requirement of linking regulatory approval of pharmaceutical products to the patent status of the product.[161]. Enforcement of Patent linkage would mean that when a company files for a Patent application, it has to declare that there is no prior Patent granted to the product. The Regulatory Authority would operate under a duty to scrutinize and verify if there is a prior patent existing with regard to the product in question. This would result in overburdening of the Regulatory Authority and would delay the process of grant of Patent to generic manufacturers.[162]. Patent linkage can be harsher than data exclusivity in the sense that where data exclusivity will end with the term of protection of data, the patent linkage extends till the expiry of the patent and in cases where the patent term is extended due to delay in market approval, then patent linkage will also be extended. This would also limit the scope of compulsory licensing.

Patent Linkage was also an element in EU-India Free Trade Negotiation of 2011[163].

3. Patent term extensions

[159] Impact Assessment of TRIPS Plus Provisions on Health Expenditure and Access to Medicines https://apps.who.int/iris/bitstream/handle/10665/205326/B2072.pdf [Accessed on August 29th 2021]

[160] Open Letter to European Commissioner on EU India Free Trade Agreement and its impact on Access to Medicines https://msfaccess.org/open-letter-european-commissioner-eu-india-free-trade-agreement-and-its-impact-access-medicines (10th April 2018) [Accessed on August 29th 2021]

[161] Eugenia Costanza Laurenza, The Scope of 'Patent Linkage' in the US-South Korea Free Trade Agreement and the Potential Effects on International Trade Agreements 6(3) EUR. J. RISK REG. 439-442, 439 (2015).

[162] Patent Linkage -An overview (February 3, 2019) https://www.bananaip.com/ip-news-center/patent-linkage-overview/ [Accessed on August 29th 2021]

[163] Open Letter to European Commissioner on EU India Free Trade Agreement and its impact on Access to Medicines https://msfaccess.org/open-letter-european-commissioner-eu-india-free-trade-agreement-and-its-impact-access-medicines (10th April 2018) [Accessed on August 29th 2021]

Under the TRIPS, Product Patent is provided for a period of 20 years. Patent Term Extension envisages on extending this term of protection further extension of term would mean extended monopoly for the Patent holder and delayed possibility of entry of generics. Extended monopoly can have effect on the drug's affordability. For example, a study revealed that if a 10-year Patent Extension was granted under the proposed Free Trade Agreement between, USA and Thailand, there would be a 32 percent increase in the Price Index of the medicines over the following 20 years, and the Domestic Thai Industry would lose 3,370 million USD.[164]

In 2015, A study on the potential Impact on Affordability of Medicines in Australia following the Trans-Pacific Partnership Agreement found that extended Data Protection for biologic drugs placed a cost of 205 million Dollars of Public money in the year 2013-14 alone.[165]

A study by Oxfam on the Impact of USA-Jordan Free Trade Agreement found that medicine prices have increased up to 20 percent since 2001, owing to Monopoly. Anti-diabetic medicine Metformin in Jordan was 800 percent higher than in Egypt. Anti-hypersensitive drug Atenolol in Jordan was priced 367 percent higher than in Egypt.[166]

As a result of the Central American Free Trade Agreement, prices of some medicines in Guatemala rose by as much as 846 percent.[167]

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[164] Damaging impact of two proposed TRIPS-plus measures in RCEP trade deal (12th June 2016) https://msfaccess.org/damaging-impact-two-proposed-trips-plus-measures-rcep-trade-deal [Accessed on August 29th 2021]

[165] THE TRANS PACIFIC PARTNERSHIP AGREEMENT, INTELLECTUAL PROPERTY AND ACCESS TO AFFORDABLE MEDICINES Submission to the Productivity Commission Inquiry into Australia's Intellectual Property Arrangements Dr Deborah Gleeson School of Psychology and Public Health La Trobe University 24 December 2015 https://www.pc.gov.au/__data/assets/pdf_file/0003/195258/sub128-intellectual-property.pdf [Accessed on August 29th 2021]

[166]Oxfam: All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines (21st March 2007) https://oxfamilibrary.openrepository.com/bitstream/handle/10546/114080/bp102-all-costs-no-benefits-trips-210307-en.pdf;jsessionid=EE481301EDD6020895E8234503579514?sequence=1 [Accessed on August 29th 2021]

[167] Shaffer E, Brenner J. A trade agreement's impact on access to generic drugs. [Online] Health Affairs 2009; 28(5):w957-w968. Available from: http://content.healthaffairs.org/content/28/5/w957.full.pdf+html. [Accessed on August 29th 2021]

Currently, Free Trade Agreements and TRIPS Plus compliance are actively sought by Global North. While these agreements would fulfil the Intellectual Property demands of the Global North, it comes at the cost of making medicines inaccessible and unaffordable to millions. The effects of TRIPS Plus provisions on Nations provide that they are well against Public interest.

THE SPECIAL 301 REPORT

The Special 301 Report is a yearly report made by the United States Trade Representative (USTR) on the status of various Nations vis-à-vis the IP Requirements of the US. The USTR was empowered to prepare Special 301 Report through an Amendment of the US Trade Act in 1988.[168] According to the USTR, the purpose of the Amendment is to secure 'adequate and effective' protection of IP Rights for US and to seek 'fair and equitable' market access to US persons. Section 301 of the US Trade Act empowers the President of the United State to take retaliatory measures against Foreign Government in the form of Trade Sanctions to remove any impediment that burdens and restricts US commerce upon the intimation from USTR.[169]

The USTR, in its preparation of Annual Special 301 Report seeks input from various stakeholders primarily the PhRMA and the International Intellectual Property Alliance (IIPA). Simply put, USTR is an agency that listens to the demands from PhRMA and IIPA to take action against any policy taken by any Foreign Government that seeks to jeopardize their trade interest. According to James Love, the Special 301 is a secretive, intensively managed process within the Government.[170]

USTR designates as Priority Foreign Countries those countries that have the most onerous or egregious acts, policies, or practices that can have an adverse impact on US products[171]. This is targeted at Nations at which US plans to take stringent retaliatory measures. Further It

[168] 2020 Special 301 Report https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf

[169] Section 301 of the Trade Act of 1974: Origin, Evolution, and Use (December 2020) https://sgp.fas.org/crs/misc/R46604.pdf

[170] James Love, USTR's New Hearings on 301 List KNOWLEDGE ECOLOGY INTERNATIONAL (January 13th 2010) https://www.keionline.org/21171 [Accessed on August 29th 2021]

[171] 2020 Special Report https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf

classifies its Trading Partners into Priority Watch List and Watch List based on extend of IP Demand of US. Priority Watch List nations are those Trading Partners whose IP Regime have been of particular concern to US and against whom Trade Sanctions are likely to be pursued. Watch List Nations are perceived as having deficient IP regime but are not of particular priority.

The USTR develops action plans for each of these countries giving its recommendations and guidelines. It sees actions of Foreign Trading Members as 'problematic' 'inadequate' 'outdated' deficient'.[172]These terms appear to be of unilateral indictments against Member Nations. The USA, through its Report sits upon as an arbiter and enforcer of its version of IP Rights Regime upon other Nations while the fact remains that US Citizens are themselves victims to their skewed IP Regime which has made US Drug Prices the highest and the world and continues to push US citizens into debt on account of affordability of medicines.

The 2020 Special 301 Report mentions nothing about the exorbitant pricing of medicines that is hampering accessibility of medicines. It is pertinent to note that the term 'affordable' finds mention only once and that was pertaining to providing affordable medicines to its own market and the way it sought to make medicines affordable to U.S citizens is by allowing US Intellectual Property owners to use and profit by removing all trade barriers of other nations. The US blames protectionist policies of member nations for the exorbitant price that the US citizens have to pay for their medicines while no concern is cast over the arbitrary and outrageous pricing policy of US Pharmaceutical companies such as Turing and Mylan. The presumption of US that its Pharmaceutical Industry is beyond suspicion is fundamentally flawed. The Report puts IP Rights over access to medicines. While it posits for a balance, clearly it seemed to be concerned more about IP Protection. This is observable from the fact that US has been pushing for limiting the grounds of Compulsory Licensing and imposing sanctions upon Nations for their compulsory license. Further, the FTA Policy of the USA with its Patent Exclusivity provisions and similar aspects is clearly meant to defeat the TRIPS Flexibilities Balance, if any is sought in favor of IP Protection.

Since its inception in 1988 the USTR's Special 301 report has been expressing its discontent against the compulsory licensing provisions, particularly against Developing and LDCs. It is pertinent to note that US is silent on the Compulsory license being issued by Developed

[172] 2020 Special Report https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf

Nations such as Germany, Italy, Hungary and Israel (compulsory license issued for Remdesivir)[173] whose name do not find mention in Special 301 report.

Special 301- Indian Experience

India was included in priority foreign country list in 1991 because of its compulsory licensing provisions.[174]

USA imposed trade sanction on India in April 1992 by suspending duty-free privileges on pharmaceuticals, chemicals and related products under Generalized System of Preferences (GSP) which cost approximately $80 million for India[175].

India issued its first ever compulsory license in 2012, which was one of the main reasons for its designation as a Priority Watch List in the 2012 report.[176]. The Report stated that the United States will be closely monitoring the developments concerning compulsory licensing of patents in India following the broad interpretation of compulsory licensing by the Controller General of Patents[177]. For the same reason, India remained on the Priority Watch List in 2013. When the Indian Intellectual Property Appellate Board (IPAB) upheld the Controller's Decision in 2013, the USTR made the same observation.

In its 2014 submission, the PhRMA had urged the elevation of India into the Priority Foreign Country List, citing the reason of compulsory license and the likelihood of Indian Government to issue more compulsory licenses. Though not labelled as a Priority Foreign

[173] Hungarian compulsory license for remdesivir raises a stir with BIO, PhRMA and the US Chamber of Commerce (March 8th 2021) https://www.keionline.org/35558 [Accessed on August 30th 2021]

[174] United States Trade Representative, 1994 National Trade Estimate Report on Foreign Trade Barriers Page 123 https://babel.hathitrust.org/cgi/pt?id=uc1.31822017491531&view=1up&seq=133&skin=2021&q1=india%20compulsory%20licensing

[175] Ibid page 122-123

[176] USTR National Trade Estimate Report on Foreign Trade Barriers 182 (2013). https://ustr.gov/sites/default/files/2013%20NTE.pdf

[177] USTR 2012 SPECIAL 301 REPORT 35. https://ustr.gov/sites/default/files/2012%20Special%20301%20Report_0.pdf

Country, in the 2014 Special 301 report, India remained on the Priority Watch List which continued till 2020.

As per the latest Special 301 Report, taking into account the Pandemic, USA have affirmed the use of Compulsory License as a means to address Public Health Crisis.[178]

INTERNAL CHALLENGES

Post TRIPS Indian Pharmaceutical regime poses serious challenges to Compulsory Licensing. Patent holding corporations does this primarily through Pre-emptive Injunctions, Voluntary Licensing and Mergers and Acquisitions.

Pre-emptive Injunctions

In India, the law governing the grant of injunctions is set down in the Civil Procedure Code, Foreign MNCs are accused of pre-emptively using Injunctions to delay the entry of generic medicines[179].

There has also been reported instances of Injunctions being granted ex-parte. The Economic Times, for example, reported that the number of ex parte injunctions has grown from six in 2012, to 10 in 2013 and over 15 in 2014. [180]

Several scholars and health activists have expressed concerns regarding the negative impact of such interim restraining orders to the public and patent law in India. In their extensive analysis of ex parte injunctions in Indian courts, Basheer et al note that these injunctions have

[178] 2021 Special 310 Report https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20(final).pdf

[179] Aparajita Lath, 'Analyzing The Pitfalls Of Indian Patent Injunctions Based On Fear Of Infringement' (2014) 19 Journal of Intellectual Property Rights 255. See also Times of India- Economic Times, 'Pharma MNCs Use RTI Law to Protect Market for Patented Drugs & Delay Entry of Generics' (2013), available at http://articles.economictimes.indiatimes.com/2013-01-24/news/36526946_1_generic-firms-generic-version-bayer-spokesperson

[180] Ibid

a ‘draconian’ effect on competitors, who are forced to desist from manufacturing and selling the allegedly infringing good, as well as on consumers, who are denied access to cheaper goods.[181]

Leena Meenghaney, describes these injunctions as ‘tactics employed by foreign MNCs in post-TRIPS India to not only limit market access of competitor but also to control the access of cheaper generic versions.[182]

Voluntary License

A voluntary license is where an ‘innovator pharmaceutical company of a patented product offers, on his own accord, a license to a third party (usually a generic producer to produce, vend and distribute the patented product’. In exchange, the generic producers ‘pays royalty to the innovator company on the net sales made by the licensee’.[183]

In 2014, Gilead also issued another set of voluntary licenses to 11 Indian companies to manufacture and sell Sovaldi, a patented Hepatitis C drug in several low- and middle-income countries. The deals entitle the licensees to full technology transfer of the Gilead manufacturing process to enable them to boost production, and the licensees are free to fix their own prices for their versions against a seven per cent royalty payment on low generic sales to Gilead. In addition, the geographical scope of the agreements excludes certain middle-income countries with high rates of Hepatitis C, such as Brazil and Ukraine. The deals have generated a lot of division among health activists within and outside India as many see it as a move by Gilead to tightly control competition.[184]

Voluntary licensing, in the manner being pursued by Gilead and others, limits the option of full use of flexibilities such as compulsory licenses and patent oppositions.[185]

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[181] Vanni, A. (2020). Patent games in the global south: Pharmaceutical patent law-making in Brazil, India and Nigeria; Bloomsbury Publishing Plc Page 147

[182] Ibid

[183] Tahir Amin, ‘Voluntary Licensing Practices in the pharmaceutical sector: An acceptable solution to improving access to Affordable medicines? (February 2007) https://www.i-mak.org/wp-content/uploads/2017/10/Oxfam-VoluntaryLicensingResearchIMAKWebsite.pdf [Accessed on August 29th 2021]

[184] Vanni, A. (2020). Patent games in the global south: Pharmaceutical patent law-making in Brazil, India and Nigeria; Bloomsbury Publishing Plc Page 152

Mergers and Acquisitions

Mergers and Acquisitions (M&As) within the Indian pharmaceutical industry is not a new phenomenon.

Notable takeovers include the takeover of Ranbaxy by Daiichi Sankyo in June 2008, Orchid by Hospira USA, Piramal by Abbott (US), Shantha by Sanofi Aventis, Matrix by Mylan (US) and Para by Reckitt Benkiser, to mention a few.[186]

These trends have a significant role in reducing the activism role which was played by Generics, especially in the wake of AIDS crisis. This effectively curtails the ability of generics to stand for matter of principles.

Also, most of these acquisitions are brown field in nature. This delays technology transfer. This also challenges India's ability to cater to public health concerns. This trend raises a question as to ability of India to independently use the flexibilities under the Doha Declaration.

CONCLUSION

India has a strong legal framework and constitutional justification for issuing of compulsory license. The Flexibilities of TRIPS undoubtedly provides that member nations can take necessary measures to protect public health of the citizens. Apart from the Natco case, there have only been two other instances of compulsory license application in India. BDR Pharmaceutical filed a Compulsory license application for an anticancer drug Dasatinib, which is sold under the trade name Sprycel and patented by Bristol-Myers Squibb. The

[185] Voluntary Licenses and Access to Medicines https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf

[186] Vanni, A. (2020). Patent games in the global south: Pharmaceutical patent law-making in Brazil, India and Nigeria; Bloomsbury Publishing Plc Page 152

application was rejected[187] Lee Pharmaceutical Company also filed a compulsory license application for AstraZeneca's diabetes management drug Saxagliptin. The decision was rejected in January 2016[188] It is pertinent to note that there have been very few cases of compulsory license application in India. The reluctance of India to issue compulsory license may be linked to the pressure exerted by the USTR and the US International Trade Commission on the Government.

Developing countries and LDCs face problems when they try to meet these objectives as evidenced from the situation of Brazil, Thailand, Indonesia and the like. It is important to note that even in this time of AIDS/HIV epidemic, where medicines were inaccessible for a vast stratum of the population, little concrete effort was put by the Global North or the Pharmaceutical giants. It was only due to the Generic Manufacturing and effective intervention by Governments, coupled with agitation by citizen groups and activists, that major Corporations considered looking into their own pricing policies. Needless to say, had it not been for price competitiveness displayed by generic industries, the price of these essential lifesaving medicines would not have changed much.

It is also pertinent to note that in their unequivocal solidarity with the Rights of the Patentholders, little effort is taken by the Global North and PhRMA to consider the accessibility factor or take a humanitarian approach. The Free Trade Agreements stand as a testimony for the propensity of these bodies to secure Patent Monopoly at the expense of affordable healthcare to all. The TRIPS- Plus Policy and Free Trade agreement seem to be moving in a trajectory that seeks to undermine the flexibilities secured under TRIPS Doha Declaration. The sanctions approach by the USA by penalizing Nations such as Brazil, India, Thailand, Indonesia, and similar nations for its policies regarding compulsory licensing is a violation of international principles.

[187] Dilasha Seth and Soma Das, 'DIPP Defers Decision on Issuance of Compulsory Licence for Cancer Drug Dasatinib' (2014), available at http://articles.economictimes.indiatimes.com/ 2014-10-16/news/55106950_1_cancer-drug-dasatinib-health-ministry-compulsory-licence

[188] Compulsory Licence Application Filed Over Astrazeneca's Saxagliptin' (2015), available at http://spicyip.com/2015/07/compulsory-licence-application-filed-over-astrazenecas-saxagliptin.html

CHAPTER 7

CONCLUSION AND SUGGESTIONS

The objectives of the Research were as follows:

I. To analyze whether the principle of Compulsory Licensing is a threat to incentive system of Pharmaceutical Patent.
II. To study the scope of Compulsory Licensing provisions as adopted in India with regard to cancer drugs.
III. To determine the challenges to the use of compulsory licensing for cancer drugs and suggestions as to remedy the problem of affordability of cancer drugs.

Whether the principle of Compulsory Licensing is a threat to incentive system of Pharmaceutical Patent.

It is inferred that grant of compulsory license by developing nations such as India has no effect upon the revenues of the pharmaceutical corporations. Therefore, compulsory licensing cannot threaten incentivization of innovation. There are no studies or literatures which identifies compulsory licensing as a reason for jeopardizing the Research and Development (R&D) costs of the corporations against whose products, compulsory licensing has been issued.

Western nations form 75 percent of the total market of major pharmaceutical corporations. India and many developing and least developed nations falls within the remaining 25 percent of market. The grant of compulsory license is rare and invoked only with reasoned justifications in the interest of public. Given these twin premises, compulsory licensing cannot jeopardize the R&D allocation of the pharmaceutical corporations.

The scope of Compulsory Licensing provisions as adopted in India with regard to cancer drugs.

Cancer drugs are a luxury in India. For the common man, Cancer drugs are obtained by incurring financial burdens such as borrowings. Needless to say, Cancer puts a patient's family under enormous financial stress in addition to mental stress.

Understanding of the subject matter leads to the inference that compulsory licensing provisions are consistent with the Constitution of India as well as international instruments, including Doha Declaration.

The *Natco vs Bayer* case clearly demonstrated the scope of compulsory licensing.

In India, compulsory licensing is of vital significance because there are numerous cancer drugs which are far from the reach of public. Compulsory licensing is not an end or a solution in itself. It is rather a definitive step towards addressing the problem of accessibility. We need a robust healthcare system similar to that of the National Healthcare System of Britain.

If we are to become a Welfare State, a vigorous public health body that negotiates and regulates the prices of drugs is of paramount importance.

compulsory licensing is quite a drastic measure, and the needs for its invocation becomes unnecessary once Government takes proactive measures to effectively negotiate and bring down drug prices.

Generally, the talks of compulsory licensing come to forefront only in cases of a global crisis such as HIV/AIDS or COVID Pandemic which more contagious. Much of the woes and pains of Cancer patients are ignored by the society despite the fact that cancer is the second most leading cause of death worldwide. The plights of cancer patients deserve much more attention and concern. Further, there is little awareness about the financial ordeals that a cancer patient has to go through. We might be under the impression that the Regional Cancer Centre and Jan Aushadi outlets have led to affordable Cancer Treatment. But this is far from truth. Although the Indian Medical Association mandates that generic drugs should be prescribed to patients, it is seldom followed. Further, the patients are led to believe that generics are of low quality. Few people would venture to take risk when it comes to Cancer drugs and they would go with the expensive branded ones. Afterall, it is a matter of grave importance to the life of the patient and their loved ones would seek for the best of treatment regardless of costs. The very practice of bargaining on the life of a patient and the helplessness, pain and indignation a family goes through, merits concern and empathy.

These challenges cannot be addressed through Compulsory licensing alone. Compulsory licensing is only one among many remedies to address the exorbitant pricing for Drugs.

The Pharmaceutical giants under the PhRMA have made stellar contributions towards medicine. If it was not for their innovation and hard work, much of today's cures for Cancer would not have materialized. However, it is important to recognize that these corporations were not an independent entity in itself that made strides towards medicine singlehandedly. These institutions were supported by publicly funded Research Institutions such as National Health Institute. The corporations must take a humane approach towards drug pricing. Their attacks at South Africa, Thailand and Brazil for taking pro-public measures to cater to their sick, is unfortunate.

It is also unfortunate that India was subjected to criticisms by the global north for the grant of compulsory license on Nexavar when nothing could be shown to prove that Natco or the Indian administrative system engaged in any acts of foul play.

While the grant of compulsory License for Nexavar brought down the price of the drugs to INR 8,800 per month, still this price is unaffordable for a vast section of our population.

This demonstrates that compulsory licensing is not an all-in -all remedy to accessibility. It is just one among many means to facilitate accessibility.

To determine the challenges to the use of Compulsory Licensing for cancer drugs and suggestions as to remedy the problem of affordability of Cancer Drugs

Rendering affordable healthcare is a daunting challenge for Governments all over the world. This is particularly true for developing nation such as India.

As discussed earlier, compulsory licensing is one among many means to facilitate affordability of Cancer Drugs.

Study of the subject matter leads to the inference that there are numerous challenges to the use of compulsory license.

Firstly, only an 'Interested party' having the capacity to manufacture the subject matter can apply for compulsory licensing. Incapacity to manufacture the said compound can lead to the rejection of application. This means that an application for compulsory license would sustain only if the applicant has the capacity to manufacture and sell drugs. There would be very few companies that would be willing to apply for Compulsory license. The ethics and ethos of Indian Generics have changed. In the 1970s we had Cipla and similar generic companies which were founded on certain principles which aimed to place service over profit. Such ethos appears to have been be eroded. This can be inferred from the divergence of generics coalition from healthcare activism post-liberalization. Few Indian generics are really 'Indian'. Mergers & Acquisitions have resulted in Internationalization of generics (For example, Ranbaxy was taken over by Daichi Sankyo, a Japanese MNC in 2008). With these agreements being mostly brownfield in nature, the independence of indigenous companies is compromised. Further, with the expansion of markets for Indian generics overseas and lot of interests at stake, few generic companies are willing to engage into a direct challenge with originator MNCs which characteristically respond to compulsory licensing applications with

a slew of legal hurdles such as pre-emptive Injunctions, among other tactics. This can be financially draining for a potential generic challenger.

Therefore, the possibility of an "Interested party" to seek for a grant of compulsory license is rendered cumbersome and if at all it happens, the generic companies must be prepared to handle intense pressure tactics and legal hurdles from MNCs. In today's market environment, such a move would be considered imprudent and risky. (But nevertheless, it is a humane thing to do).

Second, there is a dearth of data and statistics to measure the accessibility of medicines. The determination of number of patients who are eligible for a particular cancer drug proves to be difficult and this is bound to pose a significant challenge for the applicant to establish whether "reasonable requirements of the public" are being met or not.

Third, compulsory license shall be sought by the applicant only after efforts to obtain voluntary licenses have failed. This have been cited as the reason for rejection of compulsory licensing application filed by BDR pharmaceuticals for Dastanib[189]. The process of negotiating a Voluntary License can be used by originator corporations to delay and cause impediment in the process. Further, assuming that a negotiation succeeds, a mere issue of Voluntary License may not necessarily mean that public health requirements are being met. There is a possibility of collusion between the generic company and originator corporations which may defeat the purpose of lowering the price to the maximum extent possible.

However, by virtue of Section 92 of the Patent Act, the Government can issue compulsory license for 'public non-commercial use'. This has not been used so far in India. Application was filed recently by Natco invoking section 92 for Barcitinib, a drug used for treatment of Covid[190].

Apart from the technical and legal aspects, perhaps a more deceptive means of challenge comes in the form of TRIPS Plus provisions. These provisions are meant to render compulsory licensing practically ineffective. The Free Trade Agreements (FTA) invokes measures such as Patent term Extension, Data Protection and Patent Exclusivity which is

[189] https://www.khuranaandkhurana.com/2013/11/13/indian-patent-office-rejects-compulsory-licensing-application-bdr-pharmaceuticals-pvt-ltd-vs-bristol-myers-squibb/ BDR Pharma submitted that it would sell dastanib for INR 135 per tablet as opposed to INR 2761/- which was priced by BristolMyersSquibb

[190] Patent Application can be found on https://spicyip.com/wp-content/uploads/2021/05/Natco-Baricitinib-CL-Application.pdf. (Application filed on May 3, 2021)

clearly meant to bolster the position of the Intellectual Property Holders and anaesthetize the flexibilities affirmed in the Doha Declaration. Numerous FTAs (e.g. Jordan's FTA with USA) have resulted in the increase in drug prices. It is unfortunate that such negotiations, which clearly undermine the public health aspect of the TRIPS and Doha Declaration, are ongoing on unabated. One might argue that it is well within the discretion of Independent Nations to enter into FTAs and it has been entered freely and willingly. But more often than not, these agreements are a part of the carrot and stick policy of the global north which seeks to drive nations to accede to their terms, upon promise of trade benefits and preferences- much like the TRIPS Agreement.

In addition to these challenges, the Special 301 report which is issued by one sovereign nation to police the rest of the sovereign nations to accede to its trade demands, and deploy sanctions when its own 'IP requirements' are not being met, is unfortunate. The Report clearly serves as the mouthpiece of the PhRMA lobbies. Rather than striving to seek for a healthy balance between public health and IP Protection, the Global North shows greater leanings towards IP Protection. Political and diplomatic pressures are exerted upon developing and least developed nations to prevent the Governments from issuing compulsory license. The case of Brazil is a telling example.

At this juncture, it is pertinent to observe that IP Policies of the global north cannot be accepted as an ideal schema of jurisprudence which balances the interest of the public with the patent holders. It is inferred from the study that the IP systems of the global north is heavily leaning towards IP Protection. It almost excludes public interest. The dubious and arbitrary pricing by the corporations have been vexing the public and the governments alike. In USA, instances where drug prices have been increased to more than five-fold overnight have been reported. Further, there have been numerous instances where citizens of US cross borders and purchase drugs from Canada or Mexico because of the exorbitant cost of prescription drugs back home. All these facts prove that US IP Protection regime does very little to tackle the problem of high prices of prescription drugs. Citizens of US themselves are the victims of the Patent Regime of their Nation. Nations such as Britain, Australia have been struggling to make their public health system function effectively due to the exorbitant prices of the drugs.

This brings to the crucial and the most cardinal question which is the root of the problem of affordability: Who determines the prices of the drugs? Are the prices of Drugs justified? Can

we trust the prices that the pharmaceuticals are pushing forth? Works by Angell M, Goldstein et all points to the inference that there is a total lack of transparency regarding the pricing process of the drugs. This is a significant global concern. It is unfortunate that the IP Regime of the global north, especially that of US, does very little to curb the abuse of monopoly by its pharmaceutical giants.

Further, another cardinal question we have to ask is this- why 20 years of monopoly? Research by Angell M et all points to the inference that pharma corporations get back the costs they invest in R&D in less than 10 years. A serious study must be conducted to determine the time period of grant of monopoly rights for pharmaceutical patent, especially given its public health ramifications.

A policy of health insurance, robust health care systems, collectivization and compulsory licensing are welcome and necessary steps. But without ensuring transparency in pricing of the drugs, there cannot be a sustainable solution for the problem of accessibility of drugs.

In this regard, it is suggested that India must take steps to bring down the prices of cancer drugs by invoking compulsory licensing provisions.

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