ACCESS TO MEDICINE: RECONCILING THE DEBATE BETWEEN PATENTS AND PATIENTS

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UNDER THE SUPERVISION OF:

PROF. (Dr.) THAMMAIAH RAMAKRISHNA JAISWAL

PROFESSOR OF LAW

National Law School of India University,

Bengaluru

SUBMITTED BY:

ABHISHEEL

LLM/920/2020

Business Laws

CERTIFICATE

This is to certify that, this dissertation on the topic titled **"Access to Medicines:": Reconciling the debate between Patents and Patients"** submitted by **Abhisheel Jaiswal**, I.D. No. 920 in partial fulfilment of the degree of the Master of Laws (LL.M) for the academic year 2020-2021, of the National Law School of the India University, Bangalore is the product of bona fide research carried out by him under my guidance and supervision.

Date: 21.08.2021

Place: Bangalore

Prof. (Dr.) Thammaiah Ramakrishna

Professor of Law

National Law School of the India University

Bangalore

DECLARATION

I, **Abhisheel Jaiswal**, do hereby declare that this dissertation on **"Access to Medicine-Reconciling the debate between Patents vs. Patients**" is the result of the research undertaken by me in the course of my LL.M Programme at the National Law School of the India University, Bangalore, under the guidance and supervision of **Prof. (Dr.) Thammaiah Ramakrishna, MHRD Chair Professor of CIPRA, NLSIU.**

This work is my original work, except for such help taken from such authorities as have been referred to at the respective places for which necessary acknowledgements have been made.

I further declare that this work has not been submitted either in part or in whole, for any degree or diploma at any other University or institution.

Date: 21.08.2021 **Abhisheel Jaiswal**

Place: NLSIU, Bangalore I.D. No. – LLM/920/2020

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Contents

I. INTRODUCTION

'But when India signed the World Trade Organization's agreement on intellectual property in 1994, it was required to institute patents on products by Jan. 1, 2005. These rules have little to do with free trade *and more to do with the lobbying power of the American and European pharmaceutical industries. India's government has issued rules that will effectively end the copycat industry for newer drugs. For the world's poor, this will be a double hit – cutting off the supply of affordable medicines and removing the generic competition that drives down the cost of brand-name drugs.'*

- The New York Times[1]

Samuelson in his *Theory of Public Expenditure* divided goods into two categories viz. ordinary private consumption goods and collective consumption goods.[2] He calls the second category of goods "public goods" and argues that "no decentralizing pricing system can serve to optimally determine these levels of the collective consumption of the public goods" (*emphasis added*).[3] He further argues that without government intervention, it should be presumed that these public goods will always be underproduced as private players have no incentives in investing in such goods.[4] Similarly, essential medicines are also one of the public goods and not adequately provided by the market because of centralized pricing which does not motivate private players to produce enough for the public welfare. Hence, it is the responsibility of the government for the provisioning and supply of essential medicines to meet the demands of the vulnerable section of society.[5]

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[1] *India's Choice*, THE NEW YORK TIMES, (January 18, 2005), available at <https://www.nytimes.com/2005/01/18/opinion/indias-choice.html> (Last visited on 10th August 2021).
[2] Paul A. Samuelson, *The Theory of Public Expenditure*, 36(4), THE REVIEW OF ECONOMICS AND STATISTICS, 387, (1954).
[3] Ibid.
[4] Ibid.
[5] National Human Rights Commission, *Human Rights Advisory on Right to Health in view of the second wave of COVID - 19 pandemic (Advisory 2.0)*, (2021), available at < https://nhrc.nic.in/sites/default/files/Human%20Rights%20Advisory%20on%20Right%20to%20Health_2021_May.pdf> (Last visited on August 19th, 2021)

As per the World Health Organisation, in 2011 about 30% of the world's population were living without access to essential medicine.[6] After 10 years, the COVID-19 pandemic has once again brought the issue of public health concern at the global fora concerning the "access". Like trade, diseases are also now becoming global, and variants of one disease can cross the border within no time.[7] David P. Fidler comments on the globalization of public health that "*Most public health experts agree that the distinction between national and international public health is no longer relevant because globalization has enabled pathogenic microbes to spread illness and death globally, with unprecedented speed. The processes of globalization have undermined the ability of the sovereign state to protect the public from infectious diseases*".[8] However, the cure of such diseases cannot be any kind of trade barriers but only vaccine/medicine which has to be provided across all the countries on an equal basis, and hence the law and policy must be transnational.[9] The COVID-19 vaccine divide between the Global South and Global North has shown the bitter truth of the world trade regime which wanted to abridge the trade across the nations and transfer technology to all. However, TRIPS seems now to be nothing more but a compromised coerced deal which even though provides measures like compulsory license to use in public health emergency and individual countries has discretion over it, still it could not be used because of various repercussions from developed countries lobbied by Multi-National Corporations (hereafter referred to as "MNCs").[10] This divide between Global South and Global North challenges the easy accessibility of life-saving essential medicines across the Global South. Also, India's generic

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[6] Alexandra Cameron et al., *World Medicines Situation 2011- Medicines prices, availability and affordability*, (2011), available at <https://www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch6_wPricing_v6.pdf > (Last visited on 11th August 2021).

[7] David P. Fidler, *The Globalization of Public Health: Emerging Infectious Diseases and International Relations*, 5(1), SYMPOSIUM: THE PUBLIC'S HEALTH IN GLOBAL ERA: CHALLENGES, RESPONSES AND RESPONSIBILITY, INDIANA JOURNAL OF LEGAL STUDIES, 15, (1997).

[8] Ibid.

[9] Benjamin Mason Meier, *Employing Health Rights for Global Justice: The Promise of Public Health in Response to the Insalubrious Ramifications of Globalization*,39(3), CORNELL INTERNATIONAL LAW JOURNAL, 712, (2006).

[10] Aisling McMahon, *Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance*, 47, JOURNAL OF MEDICAL ETHICS, 142, (2021).

pharmaceutical industry which served as the "pharmacy of the world" has suffered a major setback in catering to the need of India and the entire world.[11]

Similarly, commenting upon the Ebola crisis during 2014, the then Deputy Director-General of the World Health Organisation pointed out that the TRIPS regime is not fulfilling its "social function" and absence of effective medicine is 'a market failure because this is typically a disease of poor people in poor countries where there is no market'.[12] Building upon this argument, we can safely presume that even though India is the hub of the generic pharmaceutical industry, access to essential lifesaving medicine is restricted because of the patent monopoly.

Further, as per the NITI Aayog SDG India Index 3.0, the monthly per capita out-of-pocket expenditure on health as a share of the monthly per capita consumption expenditure is at 65% and at very unfortunate and unequal footing which cannot be contrasted with other nations across the world where the monthly out of pocket expenditure is significantly low and this even though we have the biggest pharmaceutical industry in the world.[13] To add to this problem is a continuous decline in expenditure by the government in the healthcare sector as envisaged by the last few years' annual financial statements.[14] However, the most significant player which has devasted the level playing field amongst all stakeholders is patent-holding MNCs. A recent news story about the drug Zolegnsma whose cost is estimated at around Rs. 18 crore/ dose makes us feel numb that whether any medicine could cost such high that thinking about it also become impossible for almost 90% population across the world.[15] Further, remedies like drug price control, Trade Margin Realisation,[16] etc.

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[11] Sakthivel Selvaraj et al., *Economic Barriers to Access to Medicines* ACCESS TO MEDICINE IN INDIA (ed. by Sakthivel Selvaraj, Academic Foundation 2014).

[12] Duncan Matthews, INTELLECTUAL PROPERTY, HUMAN RIGHTS AND DEVELOPMENT-THE ROLE OF NGOS AND SOCIAL MOVEMENTS, (Edward Elgar 2011).

[13] See <https://www.niti.gov.in/writereaddata/files/SDG_3.0_Final_04.03.2021_Web_Spreads.pdf>

[14] See <https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS?locations=IN>

[15] Manoj Dattatreya More, *World's costliest injection not enough as 13-month-old Vedika loses battle to rare genetic disease*, THE INDIAN EXPRESS, (3rd August, 2021), available at <https://indianexpress.com/article/cities/pune/13-month-old-girl-loses-battle-to-spinal-muscular-atrophy-7434562/> (Last visited on 3rd August, 2021)

[16] Statement of Mansukh Mandaviya, Lok Sabha Debates, August 10, 2021.
Press Information Bureau, *NPPA has put a cap on Trade Margin of 42 select non-scheduled anti-cancer medicines under 'Trade Margin Rationalization (TMR)' Approach resulting in reduction up to 90% of Maximum Retail Price (MRP) of 526 brands of these medicines, (*August 10, 2021) available at <https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1744388>

have not been very effective to curb the exorbitant price of medicines and receives a lot of critique from MNCs.[17] Still, it can be safely presumed that there is a common understanding across the access to medicine (A2M) advocates that 90/10 divide exists but the need of the hour is to think that whether a patent should be awarded to promote the innovation or to create a life-threatening monopoly that only caters to a minuscule amount of population.[18]

Recognising the severity of the above-mentioned problem which has various intricacies involved including public international law, international trade law, intellectual property laws (hereafter referred to as "IP laws"), constitutional law, etc. this study analyses the problem faced by public health infrastructure while availing access to medicine across the Indian subcontinent. Further, this study also focused upon how IP laws impact access to medicine and what can be the possible legal framework to avoid TRIPS violation at one end and availing access to cheap and affordable life-saving medicines on the other. Thus, at its broadest framework, this study argues for recognising "access to medicine" as a neo-fundamental right after analysing its importance in a qualitative framework.

1.1 Statement of Problem

The TRIPS Agreement was brought into existence to ensure that IP rights in themselves do not become barriers to legitimate trade. However, 25 years of experience shows that the IP rights have now become a barrier to public health by

[17] Sudip Chaudhuri, *Multinational and Monopolies: Pharmaceutical Industry in India after TRIP*S, 47(12), ECONOMIC AND POLITICAL WEEKLY, 47, (2012).

[18] See Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?* 18 BERKELEY TECH. L. J. 893 (2003). ("[A] 2001 Harvard School of Public Health survey of twenty large pharmaceutical firms found that '[o]f 11 responders, eight had done no research over the past year in tuberculosis, malaria, African sleeping sickness, leishmaniasis, or Chagas disease; seven spent less than 1% of their research and development budget on any of these disorders."). The lack of attention on neglected diseases is also reflect by the efforts of the World Health Assembly to modestly increase the amount of spending on such diseases from the current level of three percent of global research to twelve percent. World Health Organization [WHO], Executive Bd. 124th Session, Public Health, Innovation and Intellectual Property: Global Strategy and Plan of Action: Proposed Time Frames and Estimated Funding Needs, 1, EB124/16 Add.2 (Jan. 21, 2009), available at http://www.who.int/gb/ebwha/pdf files/EBl24/B124 16Add2- en.pdf. This is particularly significant since there has long been a discussion of a 10/90 gap in reference to the fact that only ten percent of research dollars go towards disease that affect 90% of the population. GLOBAL FORUM FOR HEALTH RESEARCH, 10/90 REPORT 2003-2004 35 (2004); see Michael R. Reich, *The Global Drug Gap*, 287 SCIENCE 1979 (2000).

prohibiting access to essential medicines because of the patentability of the product and process both leading to an exorbitant surge in prices of the medicines. Furthermore, generic (off-patent) pharmaceutical industries are left in limbo as they do not have enough infrastructure to compete with MNCs and carry out research and development to create new chemical entities (NCE). This provides an unchallenging monopoly to MNCs to dominate the pharmaceutical market and set the coercive prices of the medicines.

1.2 Importance of Study

It has been more than 25 years since TRIPS came into existence and 15 years since India moved away from the transition period to overhaul its IP laws following the TRIPS mandate. However, it has many implications and poses a tough challenge to the accessibility of medicine in India. Further, pandemics like COVID-19 have become "new normal" and in such a situation availing TRIPS flexibilities become a must for any nation to address their local concern. Thus, the proper analysis of TRIPS and IP laws dealing with access to medicines becomes imperative on the academia which would help various stakeholders such as the Executive, the Legislature and the Judiciary to take necessary steps to address concerns of the common man whose pocket is not as deep as the person living in the Global North. Further, this study would also become relevant for Indian Patent Office to assess the claim on such a basis that it would maintain the equilibrium between innovation and accessibility. Further, one of the most important stakeholders in this whole game viz. National Pharmaceutical Pricing Authority may frame its policy taking into account suggestions made in this study.

1.3 Aim of the Study

This research aims to analyse the interface between Public Health and Access to Medicine under Intellectual Property Laws in India and to find the existing gaps which can be utilised as an exception to provide rights to the generic pharmaceutical industry based in India so that they can exploit the relevant patent, trademark, etc. within the exceptional clause for catering the demand of the industry. The research

tries to prove that access to medicine is a fundamental right and it has to be realised irrespective of the cost it involves on the government pocket.

1.4 Objectives of the Study

(a) To analyse the existing legal framework of TRIPS with Indian IP laws including Patents Act 1970, Trademark Act 2002, Copyright Act, etc., and to suggest the legal framework which would advance easy access to medicine.

(b) To create an interface between Public Health and access to medicine which can help in recognising access to medicine as a primordial right under the constitutional framework.

(c) To examine the pricing mechanism of pharmaceutical products and to suggest measures necessary to its proper implementation by doing the comparative study.

1.5 Hypothesis

The existing legal framework which intended to balance the innovation and access has failed to achieve its objective and there is imbalance where innovation is incentivised more compared to access by allowing MNCs to exploit citizens by setting up high prices of medicines and violating their fundamental right of access to medicines. Also, the pricing mechanism also fails to readdress the exorbitant amount charged by the pharmaceutical industry.

1.6 Research Questions

Based on the above hypothesis, the author would respond to following research questions in this report:

1. Whether the existing legal (IP) and other legal framework (other laws including DPCO) are adequate to address the imbalance between MNCs monopoly and citizen's access to medicine?

2. Whether citizen can claim access to medicine as a fundamental right under the constitution by reinterpreting it in terms of healthcare?
3. Whether pricing mechanism encapsulated under DPCO readdress easy access to medicine?

1.7 Limitation of the Study

The scope of the study is limited to accessing the availability of access to medicine in light of various IP Laws and does not traverse into other areas of law. However, certain aspects of the constitutional law and trade law have been taken into account to discuss the area of public health but the author does not take into account them as the only viable means to substantiate his claim.

1.8 Sources

The author has referred to both the primary and secondary sources for this study. As a part of primary sources, international and national legislation and case laws have been referred. As a part of secondary sources, the author has referred to books, research articles, websites, databases, etc. mentioned in the bibliography and footnotes. The author has carefully analysed the National Sample Survey-Health (75^{th} Report) published in 2018 by the Ministry of Statistics and Programme Implementation, Government of India to understand the problem of Indian healthcare infrastructure. The author has also referred to various working papers and reports of the national and international authorities. The author has also referred to the manuals governing the patent.

1.9 Citation Style

The Uniform NLS Guide to citation has been followed in this report.

1.10 Chapter Scheme

1. ***Introduction and Research Methodology***: This chapter has introduced in detail that what are the current ongoing debates across the world and within India regarding access to medicine along with necessary facts required to show that India is grappling with poor health infrastructure to provide access to medicine to all. The researcher has further outlined the Research Methodology followed in detail in the present chapter.

2. ***Access to Medicine is a Basic Human Right***: The main argument of the author in this study is to claim access to medicine as a fundamental right after showcasing with relevant data about the current state of affairs in India and how badly the population is affected by paying unnecessary out-of-pocket expenditure in purchasing even essential medicines. Thus, the author argues that the state must provide for the necessary medicines rather than shifting entire burden on citizens.

3. ***The Patient vs. Patent Debates***: The researcher in this chapter has analysed the flexibilities provided under the TRIPS to be utilise by the country to provide access to medicine to all. Along with that, the researcher has suggested five strategies to be adopted to regulate the prices of the medicines by taking a clue from other legal instruments such as GATT also.

4. ***Comparative Study of Drug Pricing Mechanism:*** The researcher has done a comparative study of the Drug Price Mechanism of three countries viz. India, Germany and the USA and found the loopholes in existing Drug Price Control Order, 2013. It has been suggested that India can take the German-based model as inspiration to regulate the prices of medicines effectively as John Hopkins Report (cited) suggests that price and health have a direct correlation.

5. ***Conclusion:*** The researcher concluded with few positive recommendations which the Government can adopt and in failure of which the citizen can approach the Courts to claim access to medicines as Fundamental Right under Art 21. However, the researcher has given due importance to the fact that existing International Economic Order and R&D activities of the pharmaceutical industries should also be appreciated.

1.11 Review of Literature

The *National Sample Survey Report: Health (75th Round)* published by Government of India is one of the primary sources to understand the existing healthcare situation of the India. This study has analysed the Report and based on empirical facts published there has argued for recognising a2m as fundamental right as large amount of Indian population is directly affected by it. However, this report does not answer on what kind of diseases how much expenditure is occurred on medicines individually which would have otherwise helpful to understand the public expenditure on lifesaving medicines.

Sudip Choudhuri in *Multinational and Monopolies: Pharmaceutical Industry in India after TRIP*S has further analysed the practices of MNCs in the pharmaceutical industry and how they claim patent to incentivise their R&D which unfortunately is just to kill the compounds. His other study which is referred in this paper also showcase with evidence that the R&D in Indian Pharmaceutical Industry is just a mere façade and there is hardly any development of New Chemical Entities (NCEs). However, there is need to re-examine the current state of affairs with regard to same by a new study as his study was done more than 10 years ago and since then there has been lot of development in Indian Pharmaceutical industry as pointed out in report of the McKinsey & Co. which suggests that the Indian Pharmaceutical industry has grown with consistent rate of 12-14 % post-2009 and expected to have US $55 billion market by 2020.

Various chapters of the book titled *Research Handbook on Intellectual Property and Human Rights* edited by Christophe Geiger helped in understanding the interface between the IP and HR. Further, the scholars in the field of access to medicines such as Carlos M. Correa, Jayashree Watal, Duncan Matthews, etc. have contributed their

views on various chapters and analysed it from constitutional law viewpoint. However, none of the scholars have made a strong argument for recognising a2m as a fundamental right except by a passing reference which helped in understanding the research gap for this study.

One of the important contributions to understand Indian scenario is done by Sakthivel Selvaraj et al. in a book titled *Access to Medicine in India* which has analysed both the economic as well as trade barriers to a2m and helped in understanding the approach need to be taken to write this paper.

Apart from patent, this study has also looked into trademark law also that how it affects access to medicine. Duncan Matthews in a book titled *Criminal Enforcement of Intellectual Property* has shown that apart from patent there are other forms of IPR which also acts as barrier to access to medicine. However, they also sometimes work as promoting access to right kind of drugs rather than the spurious one. However, even though there are enough evidences that falsified medicines exists which affects the public health, the enforcement agencies in India are failing in its criminal enforcement.

1.12 Research Gap

While there is ample existing literature on the 'access to medicine' and its correlation with TRIPS and IP framework, but there exists a visible gap in the comprehensive analysis of it with the constitutional law and drug pricing mechanism which can help in regulating the prices of pharmaceuticals by recognising the fundamental rights of the citizens. The existing literature on access to medicine is limited to IPR (only Patents) and its anti-competitive issues rather than traversing to other areas of law.

II. ACCESS TO MEDICINE IS A BASIC HUMAN RIGHT

The ongoing pandemic has clearly shown up to the world that even though most of the States are relying on the private players and have given market access to them with a minimal level of regulations to foster the easy accessibility of vaccines, nevertheless the state has a pivotal role when it comes to the welfare of the people. The state does not follow the hands-off approach and still acts as the backbone for the welfare of the masses. Illustrating this example in the context of access to the vaccine, it was witnessed in most of the states across the globe that multiple phenomena took place:

(i) Almost every vaccine for the cure of COVID-19 was either fully developed by the state or it was funded by the state in collaboration with private partners.

(ii) The vaccine-producing company though got the IP rights to manufacture the vaccine but it was the state who took the responsibility of supplying it to the people on a mass scale and in fact WHO coordinated amongst the states for easy accessibility of the same by COVAX program.

(iii) Even though most of the private players across the jurisdiction promised that they will procure and supply n amount of vaccines to people but none of them fulfilled their promises similar in the lines of patent rights where every time they only focused on increasing their profit rather than

fulfilling their duty towards the various stakeholders which provide them market to earn profit.[19]

Further, there exists a wide drug gap/ vaccine divide between people due to various factors. For instance, in India, the distribution of vaccines at their early stages was distributed on a first come-first serve basis to certain age groups. However, slots for vaccination needed to be booked on the government website, and hence only those people who had access to technology along with fast internet and knowledge of booking the slots could avail it.[20] One repercussion of it which often got neglected is that soon after the start of the vaccination drive, the second wave of COVID-19 hit the Indian subcontinent, and unofficially lacks of people died. Now the question arises is whether those people who lost their lives during the second wave belonging to the lower strata of the society would have been alive if the Government was able to inoculate them even though they did not have access to technology? *Charles Beitz* put this arbitrary distribution of resources as, "*The fact that someone happens to be located advantageously with respect to natural resources does not provide a reason why he or she should be entitled to exclude others from the benefits that might be derived from them*."[21] Similarly, though patent gives monopoly to the manufacturers it does not provide them an advantageous position to distribute it unevenly without any formula. Even after getting the patents, the manufacturers must have the onus to distribute the resources in a way that every section of the society should avail as it is the society that has provided them the monopoly rights as an award of their labour.[22]

The Universal Declaration of Human Rights (UDHR) which was adopted by the United National General Assembly (UNGA) in 1948 has been categorically recognised under Art. 25 that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family…".[23] Further realization of these rights is not only the onus of the national government but also of international

[19] See <https://www.mohfw.gov.in/covid_vaccination/vaccination/index.html>
[20] Ibid.
[21] Charles Beitz, THE IDEA OF HUMAN RIGHTS, (Oxford University Press, 2009
[22] Carlos M. Correa, *Mitigating the Impact of IP in developing countries through the implementation of Human Rights*, RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND HUMAN RIGHTS (ed. by Christophe Geiger, Edward Elgar Publishing,1st ed., 2015).
[23] Duncan Matthews, *Right to Health and Patents*, RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND HUMAN RIGHTS (ed. by Christophe Geiger, Edward Elgar Publishing,1st ed., 2015).

order too as envisaged under Art 28 which reads as "Everyone is entitled to a social and international order in which the rights and freedoms outlined in this Declaration can be fully realized."[24] However, to give teeth to the UDHR, two additional covenants viz. International Covenant on Civil and Political Rights & International Covenant on Economic, Social and Cultural Rights (ICESCR) were also adopted by the UNGA in 1976 which together makes the International Bill of Human Rights and not just a mere declaration.[25] Art 12 of the ISESCR reads as "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." *Hannu Wager and Jayashree Watal* see the IP system as a tool of public policy which is intended to promote economic, social and cultural progress by stimulating creative work and technological innovation and can be used to give effect to and promote values deemed essential from a human rights perspective.[26] However, contrary to their opinion, the IP system seems to look like a blockade in fulfilling of human rights.[27]

Though the developing and underdeveloped countries were provided by the rights under above-mentioned Declaration and Covenants still they were mere declarations on part of the state to fulfil it "on the availability of the resources with the progressive realization".[28] However, the moot question still exists that what is the minimum core of this right that needs to be progressively realized? Whether access to medicine can be the minimum core of the right to health which needs to be progressively realized by the member nation?[29] The WHO Constitution mentions explicitly that the right to health is "enjoyment of highest attainable standard of health" but how to achieve it is not provided. The General Assembly then went on to adopt the 'General Comment 14 on The Right to the Highest Attainable Standard of Health' which gives the content to

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[24] Lanse Minkler (ed.), THE STATE OF ECONOMIC AND SOCIAL HUMAN RIGHTS-A GLOBAL OVERVIEW, (Cambridge University Press, 2012).

[25] Carlos, Supra 23.

[26] Hannu Wager and Jayashree Watal, *Human Rights and International Intellectual Property Law* RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND HUMAN RIGHTS (ed. by Christophe Geiger, Edward Elgar Publishing,1st ed., 2015).

[27] Philippe Cullet, *Human Rights and Intellectual Property Protection in the TRIPS Era*, Human Rights Quarterly (2007) 403-30

[28] Carlos, Supra 23.

[29] Lisa Forman, *What future for the minimum core? Contextualising the implications of South African socioeconomic rights jurisprudence for the international human right to health* GLOBAL HEALTH AND HUMAN RIGHTS: LEGAL AND PHILOSOPHICAL PERSPECTIVES, (John Harrington and Maria Stuttaford (ed.) Routledge 2011)

the right by clarifying that the right to health does not only mean the right to be healthy but beyond that.[30] However, in GC 14 "access to medicine" is still not recognised as part of the right to health by UNGA. Along with this, Art. 28 of the UDHR also imposes the responsibility on the entire global community to 'respect, protect and fulfil' the rights provided in the Declaration.[31]

Joo-Young Lee has categorised the obligation of the State concerning access to medicines in four broad ways:

(a) Access to essential medicines under the right to health;
(b) Access to non-essential medicines under the right to health;
(c) Access to essential medicines under the right to life;
(d) Access to medicines in the context of pandemics as a customary rule.[32]

The United Nation Human Rights Council adopted in its resolution that "access to medicines is one of the fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of mental and physical health".[33] Thus, it recognises the fact that access to medicines is part of the right to health, and right to health further is under the penumbra of the right to life.

To better understand the gravity of the problem, the next section of the chapter would enumerate the cost incurred per person across the country while undergoing hospitalisation and an average share of which is goes for paying high medicine prices.

[30] Ibid.
[31] Ibid.
[32] Joo Youg Lee, A HUMAN RIGHT FRAMEWORK FOR INTELLECTUAL PROPERTY, INNOVATION AND ACCESS TO MEDICINE, (Routledge 2017).
[33] Ibid. See also <https://www.ohchr.org/en/issues/development/pages/accesstomedicines.aspx>

II.I Analysing the National Sample Survey Report: Health (75th Round)

The author has studied the National Sample Survey (NSS) on "Household Social Consumption in India: Health" which was released by the National Statistics Office under the Ministry of Statistics and Programme Implementation, Government of India to understand the current actual scenario of the health sector of India.[34] The survey was conducted by interview method from July 2017 to June 2018 surveying a totally random sample of 1,13,823 households spread over both rural and urban areas across every district of the country.[35] The total sample size of the survey was 5,55,115 people of which 3,25,883 were from a rural areas and 2,29,232 were from urban areas. Considering the vastness of the sample which was conducted over one year through the interview method, this survey may provide a glimpse of the pre-COVID 19 scenarios of the healthcare system in India.

A. Nature of ailment

Based on the severity of the ailment, it can be classified into 11 broad categories:

[34] National Statistical Office, Ministry of Statistics and Programme Implementation, Government of India, *Key Indicators of Social Consumption in India: Health NSS 75th Round* (2018), available at <http://mospi.nic.in/sites/default/files/publication_reports/KI_Health_75th_Final.pdf> (Last visited on 10th August 2021).
[35] Ibid.

(i) Cancer

(ii) Blood diseases: It includes anaemia and bleeding disorders

(iii) Endocrine/ Metabolic: It includes diabetes, undernutrition, obesity, etc.

(iv) Cardiovascular: It includes hypertension, breathlessness, etc.

(v) Infections: It includes HIV AIDS, tuberculosis, malaria, etc.

(vi) Gastrointestinal: It includes gastrointestinal bleeding, lump or fluid in abdomen or scrotum, etc.

(vii) Genito-urinary: It includes pain in the male genital area, reproductive tract infection, etc.

(viii) Musculo skeletal: It includes joint or bone diseases, swelling or pain in any of the joints, etc.

(ix) Respiratory: It includes bronchial asthma, cough with sputum with or without fever and not diagnosed for TB, etc.

(x) Psychiatric and Neurological: It includes hemiplegia, stroke, epilepsy, mental disorder, etc.

(xi) Others: It includes eye, ear, injuries, skin, obstetric ailment.[36]

[36] Ibid.

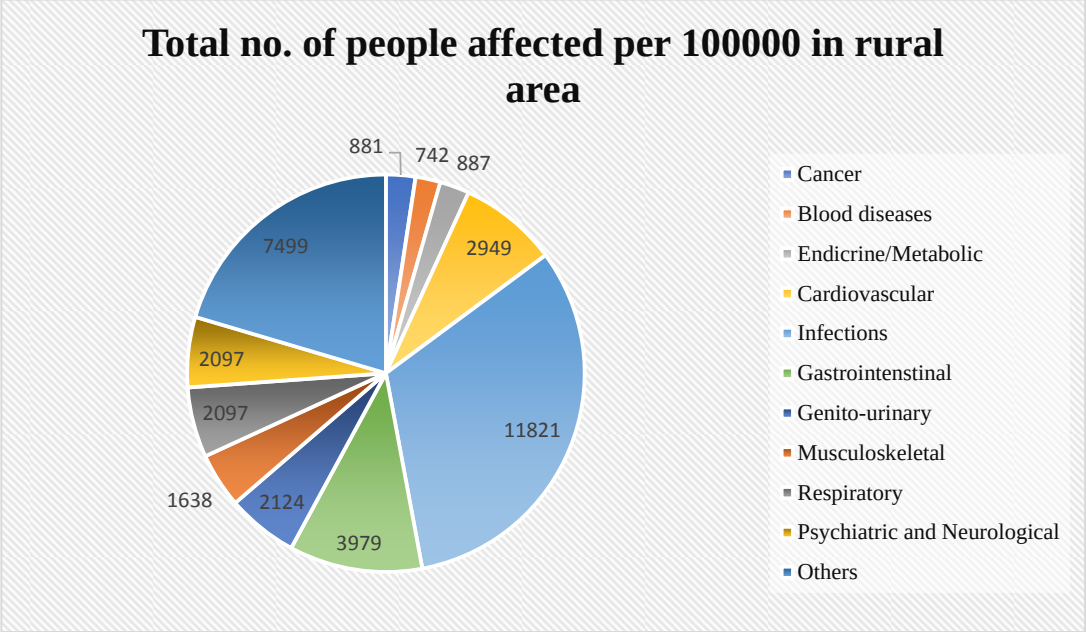
B. Cases of hospitalisation (excluding) childbirth on various ailments per 100000 persons in 365 days

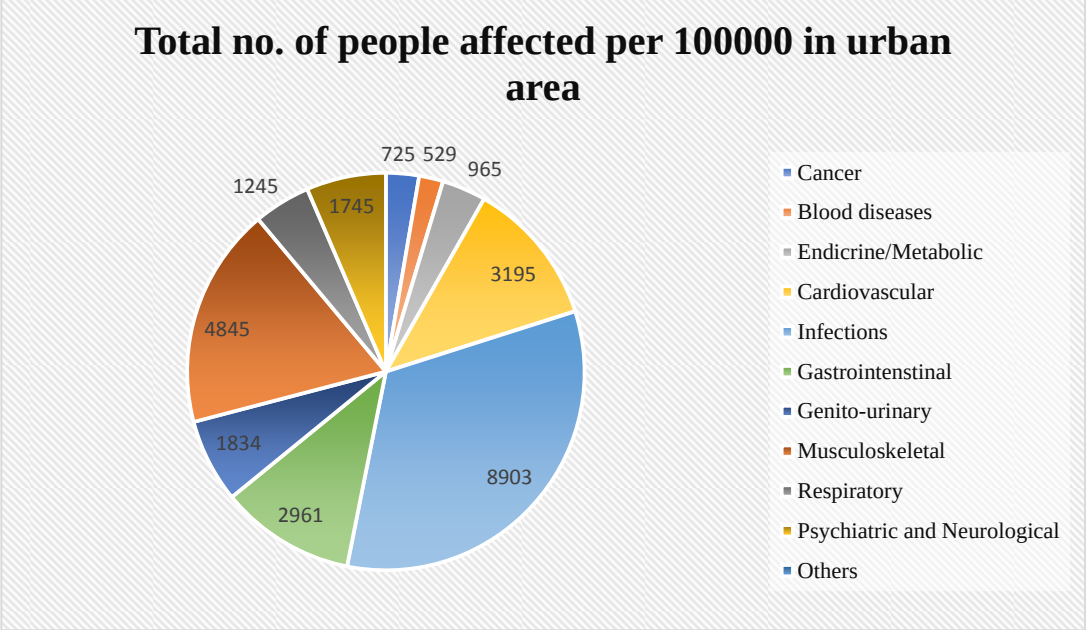
On the above-mentioned 11 broad categories, the NSS has reported the cases of hospitalisation in the last 365 days. The hospitalisation was either on their own will or the advice of the medical practitioner depending upon the severity of the ailment.

Table: Cases of hospitalisation (excluding childbirth) reported per 100,000 persons during 365 days by broad ailment category

Broad ailment category	Total no. of sample **(Urban +Rural)**	No. of sample surveyed **(Urban)**	No. of people sample **(Rural)**
Cancer	1606	725	881
Blood diseases	1271	529	742
Endocrine/ Metabolic	1852	965	887
Cardiovascular	6144	3195	2949
Infections	20724	8903	11821
Gastrointestinal	6940	2961	3979
Genito-urinary	3958	1834	2124
Musculo skeletal	2919	4845	1638
Respiratory	2691	1245	1446
Psychiatric and Neurological	3842	1745	2097
Others	13493	5994	7499
Total	66239	29377	36862

Source: NSS Report





The above-mentioned data consists of people of all ages distributed across the age of 0-4 years to 40 years of the age and it has been noticed that the diseases spread across persons of all categories of the age. Although the children of 0-4 years and adults of

the age group above 60+ years are the most affected from above diseases, the relative assessment of the data shows that the persons in the rural area under the age group of 30-44 years are having 55.24% of the diseases when compared to the age group of 60-69 years. Similarly, persons under the age group of 45-59 are contributing 75.21% when compared with 60-69 years of the age group. A similar pattern also exists in the urban area. Hence, it can be safely concluded that every age group is getting affected by one or the other 11 kinds of ailments in a significant manner and every age requires the cure from these ailments on an equal basis to save their life.

Further, all the above ailments including category “other” require hospitalisation and are life-threatening. It can be easily witnessed from the data itself that out of 100000 people surveyed in India across the country near about 66239 persons reported across the age group that they required hospitalisation for the cure of such disease in the last 365 days. The next set of data would analyse the cost of expenditure and its source in the process of hospitalisation.

C. Rural and Urban average medical expenditure (Rs.) per hospitalisation cases during last 365 days and its breakup category wise under non-package component

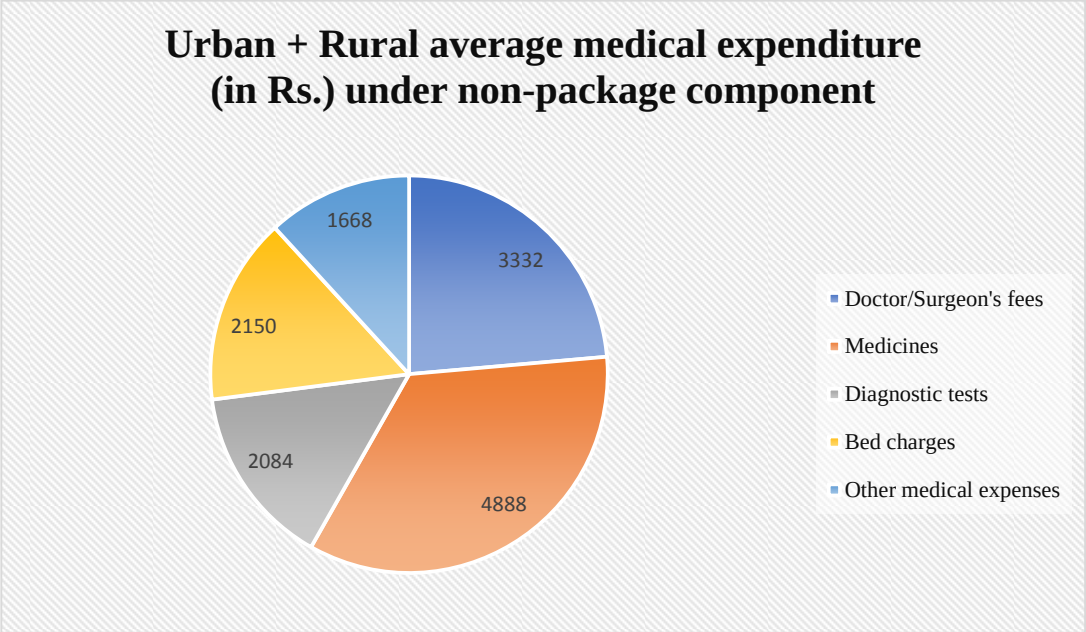
There are two categories of the components viz. package component and non-package component. Under the package component, the patient expense during hospitalisation is covered by various schemes such as Universal Health Coverage, Central Government Health Scheme (CGHS) for Central Government Employees, insurance policyholders, etc. Whereas non-package component includes the vast 85.9% of rural India population and 80.9% of urban India population which are not covered under any schemes and they have to reply on household income/savings (79.5% in rural population and 83.7% in urban population), borrowings (13.4% and 8.5% respectively), etc.[37] Hence this study would only analyse the people who are not covered in any package component as once they undergo the hospitalisation their entire savings gets affected which in turn affects their livelihood and future generations significantly.

Table: Average medical expenditure (in Rs.) for treatment under non-package component per case

	Average medical expenditure under non-package component (in Rs.)						Total hospitalisation cases of ailment
Area	Doctor/Surgeon's fees	Medicines	Diagnostic tests	Bed charges	Other medical expenses	all	
Rural	2946	4687	1889	1853	1546	16676	36862
Urban	4041	5256	2441	2696	1892	26475	29377
Urban+ Rural	3332	4888	2084	2150	1668	20135	66239

Source: NSS Report

[37] Ibid.

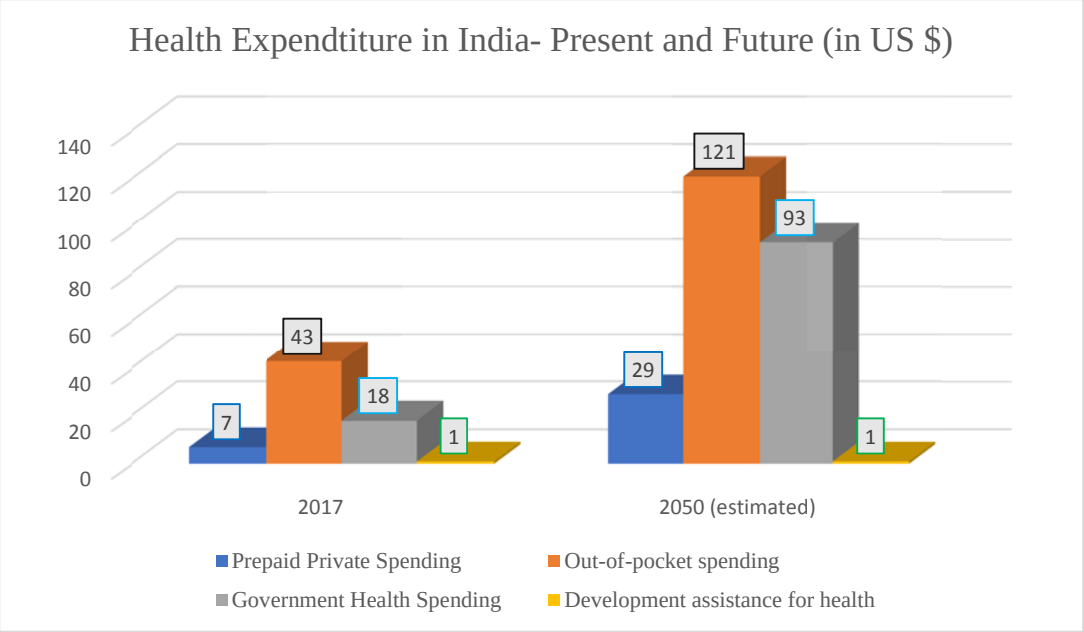


Thus, it can easily be deduced from the above data that near about 1/4th (24.27%) of the total expenses per hospitalisation is spent on the medicines whereas the rest of the other expenses are comparatively lesser than up to 1% to 16% ranging from other medical expenses to surgeon's fees. Medicines being the most important part of the treatment turns out to be most damaging also on the pocket of the persons across the country and even though it may save the life of the person it affects his/her livelihood drastically as most of his/her savings are spent on paying high prices of essential lifesaving medicines. However, if the prices of the medicines would be less then it will surely reduce the 24.27% graph significantly which in turn would leave a positive impact upon the livelihood of people across the country.

A study funded by the Bill & Melinda Gates Foundation has found that in India the out-of-pocket expenditure from 2017 to 2030 would be reduced from currently 64% (approximately) to 50% (approximately).[38] However, it has also been predicted that the total health spending per GDP would not make significant progress i.e., from

[38] GBD 2016 SDG Collaborators, *Measuring progress and projecting attainment on the basis of past trends of the health-related Sustainable Development Goals in 188 countries: an analysis from the Global Burden of Disease Study 2016*, 390, LANCET GLOB HEALTH, 390: 1423–59, (2017).

3.5% in 2017 it may be somewhere around 3.7% in 2030.[39] Thus, this prediction if holds then India may perform poorly in achieving sustainable development goals. To corroborate this point further the Institute of Health Metrics and Evaluation has found the current and estimated expenditure on healthcare and what are the sources for such expenditure.[40]



Source: Financing Global Health Database 2019

[39] Ibid.
[40] Available at <http://www.healthdata.org/india>

II.II Claiming Access to Medicine as Fundamental Right under the Indian Constitution

While the NSS survey was going on, another study simultaneously at the same time frame by the Lancet shows that in 2017, India had 9.7 million deaths and 486 million disability-adjusted life years (DALYs[41]). The DALYs at all ages arose from the YLLs (around 70%), thus, impacting the healthy years of life. The study found that the most common diseases which account for such DALYs are ischaemic heart disease (9·6% of all DALYs), perinatal conditions (8·5%), chronic respiratory diseases (5·7%), diarrhoea (4·7%), respiratory infections (4·5%), cancer (4·0%), stroke (3·6%), etc.[42] To save YLLs suffering from major diseases, the common solution to all such public health problems is one viz. life-saving essential medicines. However, developing countries have their own set of problems such as population burden, budgetary allocations, low level of R&D, etc. which make it difficult for them to avail easy A2M to their citizens. Thus, they have to rely on the MNCs situated at the West to meet their requirement, which, in turn, charges them with a hefty amount for their innovation. However, such a problem could be solved by the generic drugs, if doctors who have taken the Hippocratic Oath[43] can prescribe such drugs in their prescription, along with pharmaceutical giants making them cost-effective.

The Alma-Ata Declaration which was adopted by the WHO in the International Conference of Primary Healthcare was a stepping stone to understand the broader concept of primary healthcare across the world and that health is the fundamental human right that has to be availed to the citizens whatsoever the case may be.[44] The

[41] One DALY represents the loss of the equivalent of one year of full health. DALYs for a disease or health condition are the sum of the years of life lost to due to premature mortality (YLLs) and the years lived with a disability (YLDs) due to prevalent cases of the disease or health condition in a population. See https://www.who.int/data/gho/indicator-metadata-registry/imr-details/158

[42] Geetha R Menon et al., *National Burden Estimates of healthy life lost in India, 2017: an analysis using direct mortality data and indirect disability data*, 7, LANCET GLOB HEALTH, e1675-84, (2019).

[43] It is an oath of ethics taken by medical professionals. See <https://en.wikipedia.org/wiki/Hippocratic_Oath>

[44] See <https://www.who.int/teams/social-determinants-of-health/declaration-of-alma-ata>

Declaration specifically mentions that provision of essential drugs is one of the most important components of primary healthcare.[45] The Declaration has explicitly referred to the International Economic Order and mandated that "Economic and social development, based on a New International Economic Order, is of basic importance to the fullest attainment of health for all and the reduction of the gap between the health status of the developing and developed countries."[46] Similarly, the new International Economic Order post-1955 i.e., the TRIPS regime is also under the same mandate that reduction of gap in health status has to be reduced among all the countries, and access to essential drugs is one of the most important tools in achieving it. *Laurence Helfer* and *Graeme Austin* argue that striking the appropriate balance between recognising and rewarding human creativity and innovation on the one side and ensuring public access to these fruits of the human intellect on the other side poses the 'central challenge' when reconciling both.[47]

On similar lines, various international instruments such as UDHR, ICESCR, etc. explicitly recognises the fact that protection of IPRs has been recognised as basic human rights. Human rights advocates have also made concerted effort in securing such rights particularly concerning access to medicines.[48] However, UN Committee on Economic, Social and Cultural Rights has pointed out in 2001 itself that the promotion of IPRs over other economic, social and cultural rights "has significant economic, social and cultural consequences that can affect the enjoyment of human rights." *Carlos M. Correa* and *Matthews D*. have also raised the concern in the UNDP report that "the realization of access to medicines as a human right is heavily dependent on the legal framework applicable to the production and distribution of medicines, including intellectual property rights" as TRIPS Agreement has significantly increased the global drug gap.[49]

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[45] Ibid.

[46] Graeme W. Austin and Laurence Helfer, HUMAN RIGHTS AND INTELLECTUAL PROPERTY: MAPPING THE GLOBAL INTERFACE, 100, (Cambridge University Press 1st ed. 2011).

[47] Ibid.

[48] Giovanetti T and Matthews M., *Intellectual Property Rights and Human Rights*, Inst. for Policy Innovation, IDEAS (Inst. for Policy Innovation, Dallas, Tex.) available at <https://www.ipi.org/docLib/IPandHumanRights.pdf-OpenElement.pdf>

[49] United Nations Development Programme, *The Doha Declaration 10 Years on and its impact on Access to Medicine and Right to Health*, (2011), <https://www.undp.org/publications/doha-declaration-10-years-and-its-impact-access-medicines-and-right-health> (Last visited on 1 August 2021).

Srividya Ragavan points out that Ayyangar Committee constituted by the Govt. of India well understood the fact that the right to health and essential medicines is a part of the right to life and the high prices of patented products at that time denied Indian citizens access to resources such as medicines as drugs price in 1961 in India was said to be the amongst the highest in the world.[50] Hence the original intent of the enactment of patent laws in India was not to grant product patents for drugs as it would have a major impact on access. However, to conform with the TRIPS regime, the country has harmonised its patents law accordingly though the price India paying for it is very high. Art 196 of the Brazilian Constitution, on the other hand, explicitly guarantees that "Health is a right of all and a duty of the state…". Arguing on similar lines, the Indian Judiciary also declared in *Bandhua Mukti Morcha*[51] that Art 21 of the Indian Constitution includes the right to health. Further, in the case of *Mohinder Singh Chawla*, the court also clarified that the government has a constitutional obligation to provide health facilities.[52]

However, unlike Brazil's National Health System which provides universal healthcare to all Brazilian citizens, Indian Ayushman Bharat Jan Arogya Yojana is means based system where only a certain set of people can "claim" their fundamental right. Further, the eligibility criteria are itself manifestly arbitrary which envisages that if any member of the family earning more than Rs. 10000 per month or if a family owns a pucca house of 3 or more rooms, etc. would be excluded from the policy. [53]Whereas, on the other hand, the Govt. has provided a house to the poor under Pradhan Mantri Awas Yojana where many people got 3 or more rooms house. Thus, by providing one benefit from one hand the state is snatching the other right from other hands. Also, there would be a conflict between the two fundamental rights viz. right to health and right to livelihood if both of them would not be provided. Hence, the role of the Judiciary would become pertinent to balance both the rights.

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[50] Srividhya Ragavan, *Of the Inequals of the Uruguay Round*, 10 (2), MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW, 281, (2006).
[51] Bandhua Mukti Morcha v. Union of India (1984) 3 Supreme Court Cases 161.
[52] State of Punjab v. Mohinder Singh Chawla, (1997) 2 SCC 83
[53] Dipa Sinha, *Why the Poor Will Not Be the True Beneficiaries of the 'World's Largest Health Programme*, THE WIRE, (February 1, 2018).

Further, the Indian Supreme Court while expanding the horizon of the term "dignity" under the right to life in *Puttaswamy* has taken a clue from various international instruments to fill up the gap.[54] The right to health which is the core of dignity also encompasses the right to essential medicines which is further accentuated by the various international legal orders at place including Sustainable Development Goals which India is bound to achieve by 2030.[55] The author has pointed out elsewhere that the 28th World Health Assembly for the first time in 1975 at Geneva took the resolution that nation-members may compile the list of essential drugs[56] as per the needs of the country for health services taking into account the structure and development of the rural and urban areas. The resolution also said that where the country already has a local pharmaceutical production and a large segment of people have a low income, the country may introduce a generic medicine scheme to complement the commercial drug market.[57] Thus, this was the inception of recognising the need for essential medicines to cure public health care needs. However, 40 years down the line from 1975 the problem to provide essential medicine persisted and among other earlier resolutions, this time the global community recognised the need for "sustainable development" and adopted Sustainable Development Goals (SDGs) to be achieved by 2030.[58] Goal 3 of the SDGs, i.e., "Good health and well-being" has well recognised that to ensure good health there is a need for A2M at all levels of the age. Target 3.8 has been set to "achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all". This shows that to achieve good public health and sustainable development there would always be a pressing demand for access to safe, quality, and affordable essential medicine to all which could only be met when the generic pharmaceutical industry would be in a situation to

[54] KS Puttaswamy and Another v. Union of India and Others, 2017 SCC OnLine SC 996, decided on 24-08-2017.

[55] See <https://www.undp.org/content/undp/en/home/sustainable-development-goals/goal-3-good-health-and-well-being/targets.html>

[56] India at present has 376 medicines in National List of Essential Medicines, 2015. See <https://www.nhp.gov.in/NHPfiles/NLEM%2C%202015.pdf>

[57] World Health Assembly, 28. (1975). Twenty-Eighth World Health Assembly, Geneva, 13-30 May 1975: resolutions and decisions, annexes. World Health Organization.

[58] See <https://www.undp.org/content/undp/en/home/sustainable-development-goals/goal-3-good-health-and-well-being/targets.html>

manufacture the bioequivalence[59] of active pharmaceutical ingredients (API)[60] in a mass scale. Further, along with individuals, it is also necessary that generic pharmaceutical industries should also be provided with the same fundamental right viz. right to produce essential drugs under Art. 19 (1) (g) or the state may use its eminent domain (if the compulsory license does not work) to acquire the property of any pharmaceutical industry to fulfil its obligation towards its citizens. The Delhi High Court also noted in *F. Hoffmann-L Roche Ltd. And Anr. v. Cipla Ltd.* [61]Also found that producing generic pharmaceuticals accentuates the right to access to life-saving drugs. The court noted that:

> *"Undoubtedly, India entered into the TRIPS Regime, and amended her laws to fulfil her international obligations, yet the Court has to proceed and apply the laws of this country, which oblige it to weigh all relevant factors. In this background the Court cannot be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted. Such injuries to third parties are uncompensatable [sic]. Another way of viewing it is that if the injunction in the case of a life saving drug were to be granted, the Court would in effect be stifling Article 21 so far as those would have or could have access to Erloticip are concerned."*

Further, Art XX(b) and Art XX (d) of the GATT empowers members to promote the domestic public interest even if it is contrary to their general obligations under WTO.[62] Thus, such interpretation by the court would not conflict with the TRIPS.[63] Thus, if the petition comes before the Supreme Court, then it must also follow the same approach which Justice Ravindra Bhat followed when he was in the Delhi High Court of balancing all relevant factors.

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[59] Sandeep K. Rathod, *The curious case of India's Bolar provision*, 0(0), JOURNAL OF GENERIC MEDICINES, 1, (2017).
[60] Ibid.
[61] F. Hoffmann-L Roche Ltd. And Anr. v. Cipla Ltd 2008 SCC OnLine DLT 148
[62] Carlos, *supra* note 75, 14. See also Daya Shanker, *Access to Medicines, Paragraph 6 of the Doha Declaration on Health and Developing Countries in International Treaty Organisations*, 2, INDIAN JOURNAL OF LAW AND TECHNOLOGY, 17, (2006).
[63] Stephen P. Marks, *Access to Essential Medicines as a Component of the Right to Health* REALIZING THE RIGHT TO HEALTH, 87, (Mary Robinson and Andrew Clapham (ed.), 2009).

III. THE PATENTS VS. PATIENTS DEBATE- RECONCILING IT UNDER THE TRIPS

A. Interface between Trademarks and Public Health

The WHO Report on the Global Tobacco Epidemic 2021 conforms that tobacco attributable diseases include heart and lung disease, cancer, diabetes, and chronic respiratory diseases are one of the major causes of non-communicable diseases which further increases the severity of the COVID-19 on any person.[64] The author has shown in Chapter II that the Indian health infrastructure is mostly overloaded by the above diseases and hence causing severe expenditure from public funds in curing the above diseases caused by use of the tobacco products. The WHO Report also predicts that reducing tobacco use would also reduce the burden of non-communicable diseases, which accounts for 71% of the global diseases and the same corollary can apply to India as well.[65] Hence, India to reduce tobacco use adopted the WHO Framework Convention on Tobacco Control (FCTC) and implemented National Tobacco Control Programme.[66]

Art 11 of the FCTC which deals with Packaging and Labelling of Tobacco Products mentions that:

> *Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that: (a) tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, **trademark**, figurative or*

[64] World Health Organisation, *WHO Report on the Global Tobacco Epidemic 2021*, available at <https://www.who.int/publications/i/item/9789240032095 (Last visited on 17th August 2021)>

[65] Ibid.

[66] Centre for Law and Policy Research, Litigating Tobacco and Public Health, (2018), available at <https://clpr.org.in/wp-content/uploads/2018/10/Booklet_PublicHealth.pdf> (Last visited on August 21, 2021). See also< https://fctc.who.int/who-fctc/overview>.

any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as "low tar", "light", "ultra-light", or "mild";[67]

The Convention has specifically mentioned that public health concerns would overrule the trademark protection as tobacco advertisement also attracts a bountiful of individuals towards it.[68] However, none of the countries filed any "Intellectual Property objection" concerning the curtailment of trademark rights. This conforms to the *Charan Devereaux et al.* conclusion that the TRIPS was a coerced deal that was entered to fulfil the agenda of pharmaceutical MNC's protection of technology viz. patented medicine only and not of global justice.[69] The Karnataka High Court in the case of *Tobacco Institute of India*[70] also found that COTPA (Packaging and Labelling) Amendment Rules, 2014 does not affect the trade interest of the industry under Art. 19(1) (g).[71] Concerning patent, the similar argument under Art. 19 (1) (g) was supported by the Single Judge Bench of Delhi High Court in the *Bayer Corporation* case where it was opined that the generic pharmaceutical industry can claim Bolar Exception as a right and not a defence.[72] If this would have been upheld by the Division Bench it would have further accentuated the access to medicine to be claimed as a fundamental right by the generic pharmaceutical industry and expedite the process of manufacturing generic drugs.

The other major issue with access to medicine from a trademark point of view is substandard and counterfeit drugs.[73] Due to the high cost of essential lifesaving drugs, the downtrodden section of the society prefers and purchase counterfeit drugs rather than their generic and patent version as for many of them accessing generic versions

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[67] Ibid.

[68] Jeffrey M. Samuels, *Public Health and Trademarks: Plain Packaging Laws and the TRIPS Agreement* RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND HUMAN RIGHTS (ed. by Christophe Geiger, Edward Elgar Publishing,1st ed., 2015).

[69] Charan Devereaux et al., CASE STUDIES IN US TRADE NEGOTIATION Vol.1: MAKING THE RULES, 55, (1st,2006).

[70] Tobacco Institute of India v. Union of India 2016 SCC OnLine Kar 2209

[71] Roger Bate, *Fatal Pharmaceuticals- The Indian Counterfeit Drug Market*, 11(1), GEORGETOWN JOURNAL OF INTERNATIONAL AFFAIRS, 125, (2010).

[72] Bayer Corporation v. Union of India 2017 SCC OnLine Del 8209.

[73] Roseann B. Tarmini, *Copyright and Trademark Issues in Pharmaceutical Industry- Generic Compliance or Brand Drug Imitating- "Copycat or compliance"*, PENNSYLVANIA BAR ASSOCIATION QUARTERLY, 34, (2013).

is also a far-fledged dream.[74] However, the use of such drugs leads to failure of medication or development of antimicrobial resistance which further poses a problem to public health.[75] A recent report of the Pharmaceuticals and Medical Devices Bureau of India has found in its study that even major pharmaceutical companies in India are manufacturing substandard drugs and banned them from the market.[76]

B. TRIPS Flexibilities, Indian Patents Act and Advent of MNCs

The author has found in his earlier studies about the Advents of MNCs and steps taken by the Indian Government to counteract it which is a premise for rebuilding the same argument here as nothing has substantially changed over the past year. It was found that the 2001 Doha Declaration on the TRIPS Agreement and Public Health which affirmed the member countries right "to protect public health and, in particular, to promote A2M for all" and "to use, to the full, the provisions in the TRIPS Agreement which provide flexibility for this purpose," including compulsory licenses issued in response to national health emergencies was one stepping stone in the Transnational Legal Order (TLO) where access to medicine TLO negotiated their terms well despite facing stiff challenges from IP TLO.[77]

Flexibilities under the TRIPS and Doha once again gave us the chance to amend our Patents Act by incorporating the 2005 Amendment Act which substituted S.3(d) of the Act which is the unique provision in the whole world to prevent the practice of the evergreening of the patents by pharmaceutical MNCs.[78] Art.27 of the TRIPS provides

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[74] Duncan Matthews, *Counterfeiting and Public Health* CRIMINAL ENFORCEMNT OF INTELLECTUAL PROPERTY: A HANDBOOK OF CONTEMPORARY RESEARCH (ed.by Christophe Geiger, Edward Elgar Publishing,1st ed., 2011)

[75] Ibid.

[76] Kiran Somvanshi, Substandard drugs are a bigger problem for India than fakes, THE ECONOMIC TIMES (May 2, 2019) available at <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/substandard-drugs-are-a-bigger-problem-for-india-than-fakes/articleshow/69137983.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst>

[77] Laurence H. Helfer, *Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines*, TRANSNATIONAL LEGAL ORDERS, 311-316, (Terence C. Halliday ed(s)., 2015).

[78] Sec. 3 (d) Patents Act, 1970 - the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new

flexibility to the countries to decide upon "any criteria for novelty".[79] The Indian Parliament making use of this flexibility incorporated words in Indian Patents Act viz. "does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process". The Indian Supreme Court in *Novartis vs. Union of India*[80] faced the problem of interpreting S.3(d) of the Patents Act. The Court held that efficacy means "therapeutic efficacy" and any secondary patent would only be granted if it is new. The interpretation given by the Supreme Court accelerated the process of curbing anti-competitive practices undertaken by the MNCs by filing "Markush claims" claiming that new drug is more efficient, less toxic and cheaper than original ones.[81] This has made it mandatory that from 2005 onwards only a new chemical entity (NCE) would be granted patent.[82] Sudip Choudhuri found in his study that amongst all industrial sectors, most of the R&D takes place in the pharmaceutical sector in India.[83] Recent data also shows that the drugs and pharmaceutical industries spent the largest amount i.e., approximately 8000 crores per annum in NCE R&D with the highest 313 R&D units situated in the country. The government has also increased the FDI to 100% in the greenfield pharma sector whereas 74% in the brownfield pharma sector which may further increase the R&D and would promote the manufacturing of essential lifesaving medicine at low cost.[84]

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property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

[79] Carlos M. Correa, *Integrating Public Health Concerns into Patent Legislation*, 12, (Working Paper, South Centre, 2000).

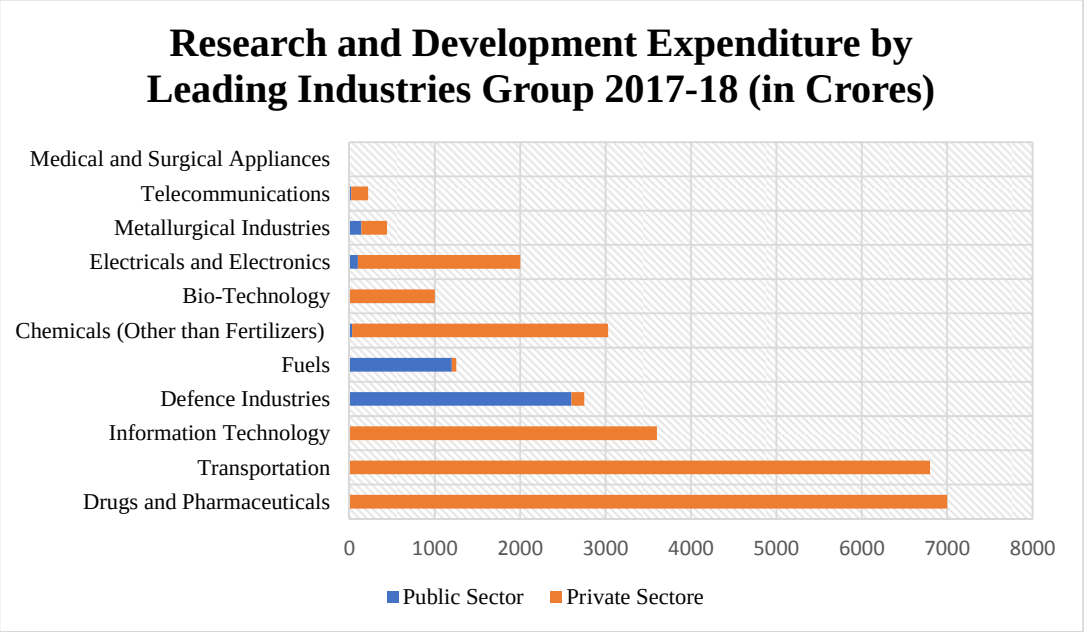
[80] Novartis AG v. Union of India, 2013 SCC OnLine SC 271.

[81] Manish Kumar, *India: Markush Claim*, (May 13, 2020), MONDAQ, *available at* <https://www.mondaq.com/india/patent/930570/markush-claim> (Last visited on 01 January, 2021).

[82] Sudip Chaudhuri, *Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS, 4, (*Working Paper No. 614, Indian Institute of Management, Calcutta, 2007).

[83] Ibid.

[84] See <https://www.fdi.finance/sectors/pharmaceuticals#:~:text=100%25%20Fdi%20In%20Drugs%20And,thereafter%20through%20government%20approval%20route>.



Source: NSTMIS, Department of Science and Technology, Government of India

S.83(a) of the Patents Act lays down the objective of the Act as "that patents are granted to encourage inventions and to secure the inventions are worked in India on a commercial scale to the fullest extent". However, the study undertaken by *Shalini* and *Rekha* found that MNCs used tactics like patent thickets or patent clusters to get patents for their incremental innovation.[85] *Tahir Amin* also found in his study that there is not much invention of NCEs as of now taking place, but in contrast, the MNCs are filing a greater number of patent applications as that of development of new NCE.[86] *Sudip* also found in his study that most of the major MNC make a contract with the Indian pharmaceutical industry to fund their R&D. However, these MNCs play a foul tactic with the Indian pharmaceutical industry by stalling their funds which makes it difficult for them to carry on their research forward or if any way any compound is developed to any extent and MNCs feel that such NCEs has a potential in future but are not developed because of financial crunch then MNCs ask

[85] Shalini Arora and Rekha Chaturvedi, *Impact of TRIPS on Providing Easy Access to Affordable Medicines in India*, 22, JOURNAL OF INTELLECTUAL PROPERTY RIGHTS, 261, (2017).

[86] Tahir Amin, *Re-visiting the patents and access to medicines dichotomy: an evaluation of TRIPs implementation and public health safeguards in developing countries*, GLOBAL GOVERNANCE OF HIV/AIDS: INTELLECTUAL PROPERTY AND ACCESS TO ESSENTIAL MEDICINES, 25, (John Harrington ed(s). 2013).

them to license them after paying a hefty amount for their work to actually "kill" their compound to enter into the market.[87]

Art.8 which governs the principles of TRIPS provides flexibility to the member-nations as it says "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition". Utilising flexibilities provided under the TRIPS, the Indian Patents Act was subsequently amended to make it more citizen-friendly which would help the Indian Government and IP Office to involve every section of the society into Patent allocation by substituting S.25 of the Act which empowers any person to file pre-and post-grant opposition against the patent.[88] Thus, S.25 was amended in a manner that public health should be given priority even after the TRIPS adventure. Many authors have argued that most of the IP laws do not take into account the public who is the ultimate authority for granting patents as a reward to the patent owners and provides them a limited monopoly.[89] However, the Indian Patents Act has done well theoretically to overrule such objection. Still, there are still practical constraints when it comes to filing the opposition as most of the citizenry is not well aware of their rights. However, such pro citizen provision helps in the protection of public health and monitoring the affordability of prices to the public by the public itself. Recently, countries like Brazil have proposed to amend their Patents Act in line with the Indian Patents Act.[90]

Parliament has used other flexibilities also to make the Patents Act pro-consumer and the Indian Judiciary also played a pivotal role in interpreting it accordingly. They are as follows:

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[87] Sudip, *supra* note 77, 8.

[88] Tahir, *supra* note 81, 26.

[89] For instance, See Thomas Pogge et al., *Introduction: Access to essential medicines: public health and international law*, INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES, 10, (Thomas Pogge ed (s)., 2010).

[90] Roberto Romandini, *Flexibilities under TRIPS: An Analysis of the proposal for reforming Brazilian Patent Law*, 15, THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW, 150, (2016).

(i) **Compulsory Licensing:**

The phrase "other use" under Art 31 of the TRIPS provides flexibility to the states to incorporate compulsory licensing procedure of the subject matter of the patent without the authorization of the patent holder in domestic legislation relating to patents. The member nations have been provided flexibility to determine grounds according to their situation for granting a compulsory license. "Non-working" under S.84(1)(c) has been one of the grounds which has been incorporated by many developing economies to prevent MNCs from getting patents and then preventing new entrants from the market.[91] TRIPS specifically do not provide for this ground but Art.5-A of the Paris Convention[92] makes this as a ground for granting of compulsory license and it is part of the TRIPS as per Art.2[93]. Thus, even if Art.27 TRIPS does not provide the requirement of "locally produced or imported", Art.27 being a general rule and Art.5-A being the special rule will prevail.

Further, the original Art.31 (f) of the TRIPS made it mandatory that supply of such products after the grant of a compulsory license shall be made predominantly for working in the domestic market. However, to avail easy access to medicine Para 6 was incorporated into the TRIPS by Doha Declaration which provides that "countries which do not have manufacturing units, they can import such patented medicines and country at which compulsory license is granted they can export".[94] This was declared as a "historic moment" as it was perceived that this will facilitate

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[91] BN Pandey and Prabhat Kumar Saha, *Natco–Bayer Verdict Decoding Local Working Requirement*,1(20), *ECONOMIC AND POLITICAL WEEKLY, 62, (2016).*

[92] Art.5-A (2) Paris Convention for the Protection of Industrial Property: Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

[93] Art.2(2) TRIPS: Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

[94] WHO, Implementation of the Paragraph 6 of the Doha declaration on the TRIPS Agreement and Public Health, WT/L/540 (2003).

for import of cheap drugs to poor countries. On the contrary, Gopakumar argues that developing countries have been defrauded once again by the West as this has been now been made TRIPS+ requirement as this requirement for the grant of compulsory license was not there in Art.31 itself.[95] In India, to date, only one compulsory license has been granted in the case of *Bayer Corporation v. Union of India*[96] where the Supreme Court favoured generic drug manufacturer Natco against Bayer's interest to easy access to sorafenib tosylate in India to fight against liver and kidney cancer. However, the continuous surveillance by USTR and fear of trade sanction has made even granting of compulsory licences even in an emergency situation almost impossible and hence this flexibility is a toothless tiger.

(ii) <u>Bolar Exception:</u>

The leading and controversial US Supreme Court judgment of *Roche vs. Bolar*[97] and its aftermath led to allowing any person to work upon the patented products for the regulatory approval from the drug controller authorities so that they can be ready with the bioequivalence of the pioneer drug available with them for introducing it to the market immediately after the expiry of patent term. This in turn prohibits the *de facto* monopoly of the MNCs to charge higher prices even after the expiry of the patent in the absence of any generic drug.[98] Art.30 gives flexibility[99] to member nations to incorporate such exceptions to the rights conferred in their patents act and India incorporated S.107-A(a)[100] into its Patents Act. Recently in

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[95] K. M. Gopakumar, *The WTO Deal on Cheap Drugs: a Critique*, 7(1), JOURNAL OF WORLD INTELLECTUAL PROPERTY, 108, (2004).

[96] Bayer Corporation v. Union of India 2014 SCC OnLine SC 1709.

[97] Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc. (733 F.2d 858, 1984).

[98] Shamnad Basheer and Prashant Reddy, *The "Experimental Use Exception" through the Development Lens*, 50(4), IDEA-INTELLECTUAL PROPERTY LAW REVIEW, 834 (2010).

[99] Art.30 Exception to Rights Conferred- Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

[100] S. 107A Certain acts not to be considered as infringement. -For the purposes of this Act, -(a) any act of making, constructing, [using, selling or importing] a patented invention solely for uses

Bayer Corporation vs. Union of India[101], the Delhi High Court has decided that in S.107-A (a) the term 'sale' also includes 'export'. This interpretation would now provide the generic pharmaceutical industry of India to export their drugs which in turn will further increase their revenue which they can utilise in their R&D budget for producing NCEs.

(iii) <u>Parallel import:</u>

Ricardo's theory of comparative advantage has ruled international trade from time immemorial where he argues that any country it does not have the manufacturing capacity to produce any product, they must import it from another country where it would become cost-effective for them.[102] Art.6 of the TRIPS gives enough flexibility to the member nations to decide on their exhaustion rights i.e., whether they want to exhaust their products in national or international markets.[103] S.107 (b) of the Act permits the importation of any patented products by any person authorised by the drug controller authority to produce and sell them.[104] Thus, if any product is available at a higher rate in India then the other manufacturer can import it from the international market where the price of such product would be effectively low. This, in turn, prevents the MNCs from keeping the prices high of their patented medicines in Indian territory. However, one of the significant threats to parallel import provision is entry of counterfeit drugs into the market through foreign channels. This in turn while solving problem of access makes another issue in the area of public health.

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reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, [use, sale or import] of any product; shall not be considered as an infringement of patent rights.

[101] Bayer Corporation v. Union of India 2019 SCC OnLine Del 8209.

[102] Mitsuo Matsushita et al., THE WORLD TRADE ORGANINATION, 1, (3rd edn. 2015).

[103] Meenakshi Rao Kurpad, *The Crack in the Wall: Parallel importation as a "flexibility" within the Indian patent system to ensure access to medicine*, 7, THE INDIAN JOURNAL OF INTELLECTUAL PROPERTY LAW, 30, (2014-15).

[104] S.107-A (b) Patents Act,1970: importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as a infringement of patent rights.

(iv) Drug Price Control Order,2013:

Bhaskarbhatala argues that effective control on the price of drugs may make it easily accessible which has been taken due care of by the DPCO,2013.[105] DPCO 2013 has also empowered NPPA to ask for cost data of imported drugs. However, DPCO (Amendment), 2019 has drastically impacted A2M as it has excluded "orphan drugs" and imported patented drugs from the purview of it. The comparative study taken under the next section of this paper provides an approach that Indian Pharmaceutical authorities such as NPPA may take to control the prices of drugs.

Thus, all the above flexibilities lead to the "rule of five" which was prevalent before TRIPS, which says that the entry of 5 pharmaceutical companies in the market reduces the cost of the medicines effectively by restricting anti-competitive practices.

[105] Ajay Bhaskarabhatla, REGULATING PHARMACEUTICAL PRICES IN INDIA: POLICY DESIGN, IMPLEMENTATION, AND COMPLIANCE, 120, (1st ed., 2018).

IV. COMPARATIVE STUDY OF PRICING MECHANISM- BALANCING ACCESS TO MEDICINE AND PATENTS MONOPOLY

The National Health Policy 2017 of India has explicitly mentioned its aim as:

> "*The primary aim of the National Health Policy, 2017, is to inform, clarify, strengthen and prioritize the role of the Government in shaping health systems in all its dimensions- investments in health, organization of healthcare services, prevention of diseases and promotion of good health through cross sectoral actions, access to technologies, developing human resources, encouraging medical pluralism, building knowledge base, developing better financial protection strategies, strengthening regulation and health assurance.*"[106]

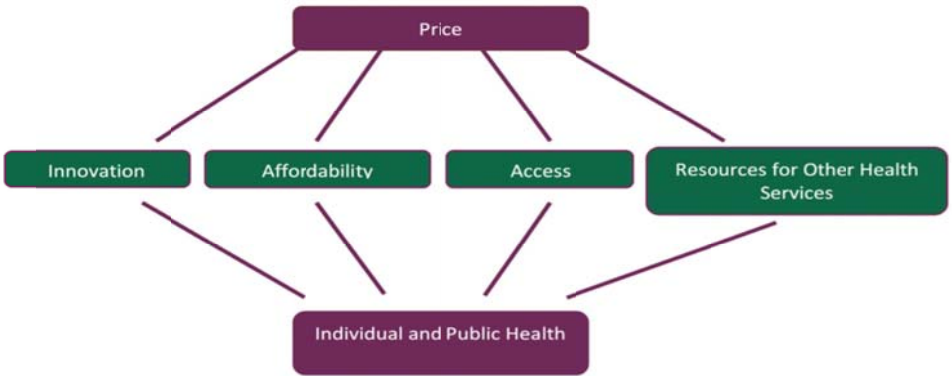
One of the important aims to achieve health for all is by providing access to technologies as mentioned in the aim itself. Thus, it is beyond any doubt by reading it in context with the Art.27 of the TRIPS that technology here includes "medicines" also and hence it is mandated on part of the government also to provide access to medicine. This chapter would comparatively analyse three other healthcare systems to make a demand for access to medicine as a priority under National Health Policy similar to that of other countries. One of the important tools which are seen in all National Health Policies is that government only acts as a regulator to ensure easy access to medicine by setting the price cap on the pharmaceutical products. In India also the NPPA regularly monitors the price of pharmaceutical products under the

[106] National Health Policy 2017, Ministry of Health and Family Welfare, Government of India, available at https://www.nhp.gov.in/nhpfiles/national_health_policy_2017.pdf

Drug Price Control Order.[107] However, whether it is effective or not is a matter of quantitative study.

A Report from John Hopkins Drug Access and Affordability Initiative have graphically shown the relationship between Price and Health which is the reason that this chapter has been put at the place.[108] The graph depicts that the price has a direct impact on health on four basis viz. innovation, affordability, access, and resource for other health services.[109]

Relationship Between Price and Health



Source: Pharmaceuticals-Innovation, Access and Affordability Chartbook

A. United States of America

The pricing mechanism in the USA can be traced back to 1962 when the monopolist drugs companies were ruining the health of the market and people which attracted the attention of the US Congress and led to the passage of the Kefauver-Harris Drug Act

[107] See https://www.nppaindia.nic.in/wp-content/uploads/2020/07/Functions-of-NPPA.pdf
[108] John Hopkins Bloomberg School of Public Health, *Pharmaceuticals: Innovation, Access and Affordability Chartbook*, (2019) available at https://www.jhsph.edu/research/affiliated-programs/johns-hopkins-drug-access-and-affordability-initiative/includes/jhdaai_chartbook_2019.pdf (Last visited on August 21st, 2021).
[109] Ibid.

1962 after a prolonged Congress Committee hearing. [110] The passage of this Act effectively broadened the FDA's regulation on prescription drugs and mandate that drugs not only should be safe but has to be effective before coming into the market. Thus, it gave an upper hand to FDA to check any spurious goods into the market and also to regulate all drugs before entering the market.[111]

Since its inception, the US industries are the most innovative and costly in the entire world as the cost of R&D affects the price of medicine to the great extent.[112] Adding to this, the drug price regime is also the most complex system in the US as it has a multi-player model and a unique overlay of market access requirements. The largest government-funded programs in the US are Medicaid and Medicare and this insurance covers even drugs expenditure but is subject to laws and regulations. Now under this insurance, whether the drug product is covered and at what price differs from person to person after checking each payer's coverage, coding, and payment criteria. [113]

Medicare covers people who are aged 65 and above whereas Medicaid covers people with low income. Both affect the significant population and are helping to a greater extent too. However, concerning drug products coverage, there is a bit of difference between the two. Medicare requires that only that drug product can be covered which is "necessary and reasonable for the treatment or diagnosis of an illness or injury or to improve the functioning of the malformed body member". Whereas in the case of Medicaid states are given free hand to make policies according to their needs. Hence almost all of the states have provided coverage to prescription drugs even if not mandatory under Medicaid. Further, drugs can be purchased by state and manufacturers through the Medicaid Drug Rebate Programme where states are mandated to maintain an "open formulary" and manufacturers would provide a rebate if the "best price" of drugs would be paid.[114]

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[110] Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84(4), THE MILIBANK QUATERLY, 670, (2006).
[111] Ernst R. Berndt and Joseph P. Newhouse, *Pricing and Reimbursement in US Pharmaceutical Markets*, 10, (Working Paper 16297, National of Economic Research, 2010).
[112] Ibid.
[113] Ibid.
[114] So-Yeon Kang et al., *Comparative Approaches to Drug Pricing*, 41, ANNUAL REVIEW OF PUBLIC HEALTH, 500, (2020).

Further, there are multiple other negotiators also involved in the drug supply chain to set the prices of medicines such as wholesalers, pharmacies, providers, payers, and pharmacy benefit managers (PBMs). Hence it makes the whole process very complex.[115]

B. Germany

In Germany, health insurance is a mandate for all. *Gemeinsamer Bundesausschuss* - G-BA provides and maintains a list of the drugs which will be covered under statutory health insurance (SHI).[116] If any medicine wants to enter into the market which has added therapeutic effect, then the national association of statutory health insurance funds (GKV-SV) and the pharmaceutical company have to negotiate the price of that pharmaceutical products, unlike the US where the market forces determine the prices. This negotiation keeps the price significantly low as it will be the Government who ultimately as the insurer has to pay the prices of the medicines as 90% of the population have to take SHI. [117]

Otherwise, if any drugs do not have added therapeutic effect, then the price is negotiated with the goal that the added price of the therapy should not exceed the annual cost of therapy with other appropriate comparator and if in any case, this

[115] Rujul Desai et al., *Pricing & Reimbursement Laws and Regulations 2021|USA*, GLOBAL LEGAL INSIGHTS, <https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/usa> (Last visited on August 3, 2021).
[116] OECD, *Pharmaceutical Reimbursement and Pricing in Germany*, (2018), available at <https://www.oecd.org/els/health-systems/Pharmaceutical-Reimbursement-and-Pricing-in-Germany.pdf> (Last visited on August 10, 2021).
[117] Ibid.

negotiation fails or agreement does not reach to its conclusion within 6 months then it would lead to the arbitration proceedings to judicially decide the prices.[118]

This internal reference pricing mechanism is purely confidential and the public is not allowed to participate in it. Since the government has the burden to reimburse the amount to the insured, this mechanism helps in setting up the limits of the drugs which will be provided under SHI rather than directly regulating pharmaceutical prices by setting up maximum prices.[119]

C. India

The 28th World Health Assembly for the first time in 1975 at Geneva took the resolution that nation-members may compile the list of essential drugs[120] as per the needs of the country for health services taking into account the structure and development of the rural and urban areas. The resolution also said that where the country already has a local pharmaceutical production and a large segment of people have a low income, the country may introduce a generic medicine scheme to complement the commercial drug market.[121] However, 45 years down the line situation has been changed a lot. In India, the NPPA maintains the list of essential medicines and also maintains the rate of that medicines by Drug Price Control Order 2013.

At present, we have the National Pharmaceutical Pricing Policy 2012 in force which regulates the pricing of various essential drugs mentioned in the National Essential

[118] Ulrich Reese and Carolin Kemmner, *Pricing & Reimbursement Laws and Regulations 2021|Germany*, GLOBAL LEGAL INSIGHTS, available at <https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/germany> (Last visited on August 3, 2021).

[119] Ibid.

[120] India at present has 376 medicines in National List of Essential Medicines, 2015. See <https://www.nhp.gov.in/NHPfiles/NLEM%2C%202015.pdf>

[121] World Health Assembly, 28. (1975). Twenty-Eighth World Health Assembly, Geneva, 13-30 May 1975: resolutions and decisions, annexes. World Health Organization.

Medicine List. One of the stated objectives of NPPP- 2012 is to "put in place a regulatory framework for pricing of drugs to ensure availability of required medicines - "essential medicines" - at reasonable prices."[122] DPCO 2013 has also empowered NPPA to ask for cost data of imported drugs. However, DPCO (Amendment), 2019 has drastically impacted access to medicine as it has excluded “orphan drugs” and imported patented drugs from the purview of it. The pricing mechanism before 2012 was based on maximum allowable post-manufacturing expenses (MAPE).[123] But, NPPP-2012 sought to restrict the price regulation to certain essential formulations only.[124] Although the prices of all drugs were required to be monitored, the ceiling price could be fixed only in respect of specified formulations that were considered essential medicines. To escape this liability of price fixation, pharmaceutical companies change the essential ingredient of the drug with similar therapeutic another active pharmaceutical ingredient which will not be in the list of “essential”. Hence this is one of the tactics applied by the manufactures to escape their liability and DPCO becomes ineffective in one or other ways to achieve its objective.

[122] See National Pharmaceutical Pricing Policy 2012 at <https://pharmaceuticals.gov.in/sites/default/files/National%20Pharmaceutical%20Pricing%20Policy%202012_1.pdf>
See also Sanofi India Ltd. and Anr. v. Union of India 2019 SCC OnLine Del 7669

[123] Piyush Kunnapallil, *Drudgery of Drug Price Controls: Who Benefits?* 1 (unpublished manuscript, on file with the Ctr. for Civil Soc’y), *available at* <http://www.ccsindia.org/Intern2002_11_drug_controls.pdf> (last visited on June 2021). See also <http://hsrii.org/wp-content/uploads/2014/06/NPPP-EPW-2012.pdf>

[124] Sakthivel Selvaraj et. al., *Pharmaceutical Pricing Policy: A Critique*, 47(4), ECONOMIC AND POLITICAL WEEKLY, 20, (2012).

V. CONCLUSION

The Government of India through its flagship programme of Ayushman Bharat has opened Jan Ausadhi Kendra to provide access to medicine to every corner of the country. As per the latest data available, there are around 6511 Jan Ausadhi Kendra operating across the country where every section of the society is provided with a generic drug at a minimal price. As of now, the Jan Ausadhi Kendras are providing 8146 types of drugs and medical devices at the most minimal prices compared to the market.[125] E.g., a vial named "Gemcitabine" 0f 1000 mg dose is available at Rs. 836 in the Jan Ausadhi Kendra whereas the same medicine of the same dose is available at the market with the cost of Rs. 6100 to 6300 with the alternative brand name "Gemitrate" or "Gemibine".[126] Thus, such a stark difference between the generic drugs themselves makes accessibility very difficult for most of the citizens for the entire treatment. The situation gets worse when it comes to the price of patented medicines which are life-saving but are not provided by Jan Ausadhi Kendra. Further, there is a list of essentials to be met to be eligible for purchasing medicines from Jan Ausadhi Kendra and a significant population misses it.

Further, COVID-19 has put millions of families from the lower middle class to the poverty level as most of them have lost their livelihoods. However, they are still not covered under any of the schemes and eligibility criteria making it difficult for them to purchase medicines from pharmacies, whereas not covered under Jan Ausadhi Kendra till now also does not provide them its benefits. To solve the above problem, it should be imposed as an obligation on the part of the state to provide access to healthcare facilities to all including access to essential lifesaving medicines similar to the German Model. Thus, the researcher suggests the following recommendations for easy access to medicines for all:

1. Making health insurance mandatory for all irrespective of their income. However, the government should make a differential pricing policy of insurance where the minimum amount should not be equal but be based on the income of the citizens.

[125] See <https://pmjay.gov.in/sites/default/files/2020-08/JAK-center-list.pdf>

[126] See <https://www.1mg.com/search/all?filter=true&name=Gemcitabine and https://pmjay.gov.in/sites/default/files/2020-08/Janaushadhi-generic-list.pdf>

2. Providing benefits of Ayushman Bharat to all citizens irrespective of their backgrounds and also accessibility to Jan Ausadhi Kendra.
3. The Price Control Mechanism for other pharmacies should be enforced by NPPA where prices of all the medicines should be fixed after negotiation with comparing the prices of same medicines with other low-middle income countries (LMICs) and there should also be capping off the prices on medicines which are not in essential medicine list. However, this process should take into consideration NLEM, and only then it can be enforced for the reason that the pharmaceutical industry plays foul by replacing the APIs of essential with non-essential.[127]

To provide the above remedies, the judiciary can declare access to medicine as a fundamental right under the "appropriate proceedings" as Chapter III has factually shown the problems faced by Indian citizens.[128] The author does not support providing all medicines as freebies otherwise it would surely affect the morals of the R&D industry but curbing the unexceptional high prices provided by patent monopoly makes stiff challenges for access to medicines for all. Once it would be declared as a fundamental right, the public would have the right to approach the court at least to make recommendations 1-3 in force which is also one of the directive principles. Further, this approach has also been taken by various other countries as Hans V Hogerzeil et al. in their studies found that in 59 out of 71 countries, access to essential medicines as part of the fulfilment of the right to health could indeed be enforced through the courts, with most coming from Central and Latin America. Success was mainly linked to constitutional provisions on the right to health, supported by the human rights treaties. In 49 (83%) of 59 successful cases and all countries, the right to health was specifically quoted as being related to the right to life.[129] Logically, this argument was usually linked to cases of life-threatening diseases in which treatment was potentially life-saving. Thus, the courts in these countries provided access to

[127] Owain David Williams and Hans Löfgren, *The New Political Economy of Pharmaceuticals: Conformity and Resistance in the Global South* THE NEW POLITICAL ECONOMY OF PHARMACEUTICALS PRODUCTION, INNOVATION AND TRIPS IN THE GLOBAL SOUTH (ed.by Hans Löfgren and Owain David Williams, 2013).
[128] See Art 32 of the Indian Constitution.
[129] H V Hogerzeil et al., *Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts*, 368, LANCET, 305-11 (2006).

medicines to its citizen by reading it under the right to health and India cannot make any excuse for not fulfilling its obligations towards its citizens for whatsoever reasons. There are two models of IP viz. rule based and principle based.[130] The principle-based model argues that the core value of world trading system i.e., prosperity of the people must be given primacy over the incentives to the industries. The principle-model argues that there is "something" to be interpreted beyond the black letters rules which are fundamental for any system.[131] Thus, it is the duty of the courts to balance the "corporate innovation" in one hand and "human rights" on other.

The most important factor is a careful examination of the patent which may to a great extent curb the unwanted monopoly provided to the MNCs where claims filed by the attorneys are highly technical and hence making it difficult for the Patents Office to comprehend. India can take the route of Brazil to evaluate the pharmaceutical patents where they follow two tier-structure i.e., the patent claim must be first evaluated by the health experts, and then only it should be forwarded to Patents Office after examining whether a patent should be provided or not.[132]

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[130] Yogesh Pai, *Promoting Diversity in Pharmaceutical Innovation and Access: India's Experience in the Post-TRIPS World* DIVERSITY IN INTELLECTUAL PROPERTY: IDENTITIES, INTERESTS AND INTERSECTIONS, 16 , (Irene Calbolian and Srividhya Ragavan (ed.), 2015).

[131] Ibid.

[132] Nishid A Gangwal, *Impact of Patent Law on Regulations facilitating Access to Medicines: A Comparative Study*, 304, (D. Phil Thesis, National Law School of India University, 2017) [unpublished].

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