



A Balancing Approach on ‘Right to Patent’ and ‘Right to Health’ during the COVID-19 Pandemic

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Abstract

This paper examines the global COVID-19 Pandemic, and the health sector’s response to it, with challenges to uphold Human Rights in a Crisis. There are difficulties for the people in accessing to medicines due to the restrictive role that is played by the patent system in the process of Intellectual Property Law. Therefore, there is a conflict between the Right to Patent and the Right to Health. With reference to the global Intellectual Property system, this article discusses the problems faced in access to medicines due to the intellectual property rights, and provides suggestions as to how these problems may overcome in the interests of promoting public health while balancing Right to Patent for the best interests of the society. To achieve this aim, qualitative methodology has been used by referring to primary and secondary sources of law.

Keywords; COVID-19, Intellectual Property, Health, Medicine, Patent, Pandemic

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Introduction

“The world needs the vaccine today-not tomorrow-to stop the disease and end the pandemic. We need to embrace the access to medicine-a moment against patent monopoly in life-saving drugs.”¹

In the purview of globalization, everything is on our fingertips. However, microscopic COVID-19 virus was able to control social, economic and political factors of the world. Globally, approximately 550 million confirmed cases reported with more than six million death rate by 2023 June.² This is a highly contagious virus, intensely spreads by way of close contacts with an infected patient without safety precautions. People were not aware about COVID-19 at the beginning and there was no enough access to medicines. Conspicuously, Right to Patent imposed restrictions on the Right to Health. Thus, Right to health and Right to patent collided restraining the interests of people. This necessitated an approach to minimize friction and achieve sustainable development while balancing human rights of the people.

Discussion and Analysis

Health sector was at the front line during the COVID-19 pandemic but there was an inequality in accessing to health all around the world. According to the Census report of the World Health Organization, one third of world population does not have enough access to medicines. The development of the Roadmap for Access to Medicines, Vaccines, and Health Products was done in order to illustrate the work that needs to be done at every stage of the value chain. These steps include the development of clinical and epidemiological research, selection procedures, regulatory

¹ Xiaodong Yuan, Xiaotao Li, Pledging Patent Rights for Fighting Against the COVID-19: From the Ethical and Efficiency Perspective, (Springer Nature, 17 June 2021) <https://www.wright-to-health-and-patent-right-during-covid-19> access on 10th July 2021

² “World Health Organization” 2023 May 11, Weekly epidemiological update on COVID-19 <https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---11-may-2023> access on 16th May 2023

pathways, guidelines for medical treatment, procurement and supply chain, equitable pricing, monitoring availability, and guaranteeing safe and appropriate use among other things.³ In many low-income nations, less than one in 100 people had received a single dosage of the vaccine, yet one and a half years after the virus first appeared, high-income countries had agreements in place to secure enough doses to vaccinate their populations twice again.⁴

There are explicit international, regional and territorial protections to ensure Right to Health. According to the article 25(1) of the Universal Declaration of Human Rights; Everyone has the right to a living standard that is sufficient for their own and their families' health and well-being, including food, clothing, housing, medical care, and essential social services. They also have the right to security in the event that they become unemployed, ill, disabled, become widowed, become old, or experience other uncontrollable circumstances that prevent them from earning a living.⁵ At the same time article 12 (1) of the International Covenant on Economic, Social and Cultural Rights stipulates that, state parties should recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Moreover, all the steps should be taken by the States Parties to the present covenant to achieve the full realization of this right shall include those necessary for the prevention, treatment and control of epidemic, endemic, occupational and other diseases.⁶ 'Health' is a fundamental and indispensable human right and under the General Comment No.14 on the Right to the Highest Attainable

³ World Health Organization. (2019). Roadmap for access to medicines, vaccines and health product 2019-2023: comprehensive support for access to medicines, vaccines and other health products. World Health Organization. <https://iris.who.int/handle/10665/330145>. access on 17th May 2023

⁴ United Nations Development Programme 'Inequality in Access to Essential Health and Medicine: COVID19 Vaccines' 10 February 2023 <https://www.undp.org/publications/in-equality-access-essential-health-and-medicine-covid19-vaccines> access on 17th May 2023

⁵ UN General Assembly, Universal Declaration of Human Rights, 10 December 1948, 217 A (III)

⁶ United Nations General Assembly, 1966, "International covenant on Economic, Social and Cultural Rights" Treaty Series, vol. 993

Standard of Health;⁷ Every person has the right to the best possible level of health that allows them to live a life of dignity. A variety of complementary strategies can be used to achieve the realization of the Right to Health, including the creation of health policies, the execution of World Health Organization (WHO) developed health programs, and the approval of particular legislative measures.⁸

Charter of the UN by articles 55 and 56, discuss the importance of Right to Health and United Nations General Assembly, Political Declaration on HIV and AIDS: Ending Inequalities and Getting on Track to end AIDS by 2030 also explains the importance of reasonable prize for the medicine to enhance availability to everyone globally. Nearly all of these treaties have been adopted since the end of World War and ratified or acceded by states and are binding international law for those states.

In Sri Lanka, Right to Health is not included in the Fundamental Rights chapter. Nevertheless, indirectly mentioned in Article 27(2)(C) in the Chapter on Directive Principles which is, based on Article 29 which is not justiciable and not protected by any court.⁹ Report on Public Representations on Constitutional Reform (2016)¹⁰ received several submissions regarding health issues which are not covered under the supreme law of Sri Lanka. People complained about difficulties in accessing health care, the quality of health care and medical treatment, the exorbitant cost of private health care as well as the lack of regulation in the sector. Those issues must be considered by the constitutional reform committee to facilitate the Health system.

In India, Right to Health is secured under articles 14, 21 of the Fundamental Rights chapter and articles 39, 41, 42, 43, 51 of

⁷ UN Committee on Economic, Social and Cultural Rights, CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)<https://www.ohchr.org/en/resources/educators/human-rights-education-training/e-general-comment-no-14-right-highest-attainable-standard-health-article-12-2000> access on 17th May 2023

⁸ E/C.12/2000/4

⁹ Constitution of the Democratic Socialist Republic of Sri Lanka, 1978

¹⁰ Report on Public Representations on Constitutional Reform, 2016

Directive Principles of State Policy and Fundamental Duties chapter¹¹. *State of Panjab v Mohinder Singh Chawla*¹² case also identified the importance of Right to Health. Insufficient funding for healthcare systems can cause problems under the pressure of growing populations. Investing in quality health care is the key to enhance fair and easy access to potential health care system.

In the Constitution of South Africa (1996),¹³ Chapter II, Section 27 addresses the importance of Right to Health care in the country.¹⁴ In addition to that *Minister of Health v. Treatment Action Campaign*¹⁵ case discussed the significance of Right to Health for the well-being of the people.¹⁶ Hence, Right to Health is an inevitable right of the people. It is a part of right to life and other social and economic rights depend on the good health and well-being of the people. It is important to prevail a powerful safeguard for Right to Health for the best interest of the people.

According to Albert Einstein, 'Imagination is more important than the knowledge.' Intellectual property system is based on the imagination which covers a range of personal property rights. 'Patent protection' can be considered as one of the main pillars of the Intellectual Property system. In the eyes of law, a patent is a legal title which is able to protect new inventions by giving an incentive to the inventor. The main purpose of a patent system is to stimulate industrial inventions and innovations by granting limited monopoly rights to inventors and by increasing public availability of information on new technology. Patent Rights encourage new inventors by securing commercial advantage.

¹¹ The Constitution of India, 1950

¹² (1997)25C

¹³ Constitution of South Africa, 1996

¹⁴ "(1) Everyone has the right to have access to a. health-care services, including reproductive health care; b. sufficient food and water; [...] (2) The State must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights. (3) No one may be refused emergency medical treatment."

¹⁵ (2002) 5 SA 721 (CC) (South Africa)

¹⁶ see, *Etcheverry, Roberto E. v. Omint Sociedad Anónima y Servicios, General Attorney's 1 December 1999*

Introducing appropriate remedies and medicines is a long process and it is important to appreciate and recognize their contribution towards the process. So, patent is the fuel to the Intellectual Property system which motivates new inventors for creative and progressive thinking for the betterment of the whole world.

Chief Justice Burger explains the sphere of the ‘Patent’ in the case of *Diamond v. Chakrabarty*¹⁷. According to him; ‘anything under the sun that is made by man is eligible for patent protection.’¹⁸ The case of *Attorney General (Cth) v Adelaide Steamship Co*¹⁹ explains monopoly being derogation from the common right of freedom of trade could not be granted without consideration given to the public.²⁰ In the case of new inventions, the consideration was found either in the interest of the public to encourage inventive ingenuity or more probably in the disclosure made to the public of a new and useful article or process.

Section 174 of Paris Convention for the Protection of Industrial Property in 1833, Section 146 of Patent Cooperation Treaty PCT(1970), Section 62 of the Strasbourg Agreement Concerning the International Patent Classification (IPC) (1971), Section 78 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977), Section 32 of the Patent Law Treaty (2000) comprehensively discuss about the importance of Right to Patent to encourage new inventors by recognizing the value of novel knowledge for the advancement of the world.

“The issue of access to medicines lies at the crossroads between the systems of international human rights law, intellectual property and trade law.”²¹

¹⁷ 447 U.S. 303 (1980).

¹⁸ *Diamond v. Chakrabarty* 447 U.S. 303 (1980).

¹⁹ [1913] AC 781 at 394 per Lord Parker

²⁰ *Attorney General (Cth) v Adelaide Steamship Co*(1913)18CLR30

²¹ Jennifer Anna Sellin “ Does One Size Fit All? Patents, the Right to Health and Access to Medicines”^Published online: 14 December 2015)

According to Roscoe Pound, Law is a social engineering phenomenon; there should be a balance between the competing interests in the society. There are three types of legal interests namely Private Interests, Public Interests and Social Interests. Right to Health is an essential social interest and it is necessary to uphold the balance with Right to Patent during a pandemic period. As engineers construct new constructions similarly, social engineers are required to reveal the type of methods in the society that provides maximum betterment and minimum friction by balancing Right to Health and Right to Patent.

“Pound thought that the adjustment competing interests with minimum friction and waste had a philosophical value” (1940:80)²²

Small patents, voluntary license, compulsory license, doctrine of exhaustion, business plans, competition of the market and some business strategies play a major role to keep balance between Right to Health and Right to Patent in the modern world for the best interest of the people. It minimizes hindrance to access to medicines. Article 31 of the TRIPS agreement provides some exceptional circumstances which other people are able to use patented products without authorization of the rights holder. COVID-19 was a national emergency; it can be taken as an exceptional opportunity to use patented products without the authorization.²³ Section 17 of the Doha Declaration also recognized the importance of Health.²⁴ To stop the deadly worldwide outbreak, the U.S. Department of Health and Human Services’ Biomedical Advanced Research and Development Authority has partnered with multiple

²² Suri Rathnapala”*Jurisprudence*, Cambridge University press, Third Edition(2017)

²³ Where the law of a Member allows for other use⁷ of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

²⁴ We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate Declaration.

pharmaceutical companies, such as Johnson & Johnson²⁵, Sanofi²⁶, and Regeneron Pharmaceuticals. In addition to that, Auto makers General Motors, Ford and Tesla, Louis Vuitton, L'Oréal, Christian Siriano, Brando and Maxwell companies started to manufacture some health related products to contribute towards the COVID-19 pandemic.²⁷

World Health Organization played a major role during COVID-19 outbreak.²⁸ However, there were some criticisms to the World Health Organization as it acts more like the Chinese Health Organization than the world Health Organization during COVID-19 out-break. Middle-income trap has become a serious issue to the sustainable health system among developing countries. Even though Poland and Taiwan went out of the middle-income trap, many countries are still struggling to achieve this goal.²⁹ Therefore, middle-income trap is a hindrance to the Right to Health. In addition, there should be a proper business plan to execute business ideas regarding Health and Patent. Moreover, there should be an effective prize control system to enhance access to health.³⁰

²⁵ Johnson & Johnson, '*Janssen joins forces with Biomedical Advanced Research and Development Authority (BARDA) to protect communities against threat of a global COVID - 19 pandemic*' (2020) <https://www.jnj.com/media-center/press-releases/johnson-johnson-announces-collaboration-with-u-s-department-of-health-human-services-to-accelerate-development-of-a-potential-novel-coronavirus-vaccine> 8th June 2023

²⁶ Sanofi, '*Sanofi joins forces with U.S. Department of Health and Human Services to advance a novel coronavirus vaccine*' (2020) <https://www.sanofi.com/assets/dotcom/pressreleases/2020/2020-02-18-15-00-00-1986380-en.pdf> accessed on 5th May 2024

²⁷ Roger Strange, *The 2020 Covid19 pandemic and global value chains (2020)*, Journal of Industrial and Business Economics, 455 <https://link.springer.com/article/10.1007/s40812-020-00162-x> accessed on 7th July 2023

²⁸ Gustavo Müller, Melanie Ruelens and Jan Wouters, *THE ROLE OF THE WORLD HEALTH ORGANIZATION IN THE COVID-19 PANDEMIC (2021)* <https://img-cdn.tinkoffjournal.ru/-/final-metaforum-research-report-71221.pdf> accessed on 19th July 2023

²⁹ Felipe, Jesus and Abdon, Arnelyn May and Kumar, Utsav, *Tracking the Middle-Income Trap: What is it, Who is in it, and Why?* (April 1, 2012). Levy Economics Institute, Working Paper No.715 <<https://ssrn.com/abstract=2049330> or <http://dx.doi.org/10.2139/ssrn.2049330> accessed on 15th January 2023

³⁰ W.R. Corish, *Intellectual Property; Patents, Copyright, Trade Marks and Allied Rights*, (London Sweet and Maxwell, 1999)

Small patents encourage new inventors while balancing conflict of the rights. Impartial and active contribution of the World Health Organization plays a major role to sequester COVID-19 pandemic. Not only that, Voluntary Licenses also an effective alternative way to address national emergency occasions. Voluntary Licensing has become a key to access to medicines and vaccines during COVID-19 period. Through voluntary licenses which are private contracts, pharmaceutical companies can specify the conditions under which a generic version of a proprietary drug may be made available from other vendors.³¹ It emphasizes how crucial it is to carry out and interpret the Agreement on Trade-Related Aspects of Intellectual Property Rights in order to improve public health by encouraging access to current medications as well as research and development of new medications.

‘Compulsory License’ allows a third party or the government to use a patented invention for a royalty or fee, when the owner is unwilling to work the invented product or to satisfy unmet demand from the public. Compulsory Licenses reduce the unreasonable price of the medicine and health products for the public benefit. The use of forced licensing is permitted by the TRIPS Agreement. A government agency or third party may get a license to utilize a patented invention by compulsory licensing from a competent body without the patent holder’s consent.

The Agreement’s Article 31 lays out certain requirements for the issuance of compulsory licenses.³² Where compulsory licenses are granted to address a national emergency, certain requirements are waived in order to hasten the process, such as prior negotiations with the patent holder to reach reasonable terms. The right to grant compulsory licenses, the

³¹ Baker, Brook K., A Sliver of Hope: *Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines* (February 13, 2018). Northeastern University Law Review, Vol. 10, No. 2, pp. 226-315 (2018), Northeastern University School of Law Research Paper No. 314-2018, Available at SSRN: <https://ssrn.com/abstract=3123108> accessed on 14th May 2024

³² Where the law of a Member allows for other use⁷ of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(h) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization

discretion to choose the conditions under which licenses are granted, the authority to define national emergencies and situations of extreme urgency, and the authority to establish the regime of intellectual property rights exhaustion are just a few of the TRIPS-related rights that are mentioned in the Doha Declaration. The case of *Nacto Pharma Ltd V Bayer Corporation and the Compulsory Licensing Regime in India order*³³ issued compulsory license for the cancer drugs.

If other patent owners adopt a protectionist patent position, such as Gilead, “health or safety needs” could, nevertheless, offer a solid foundation for the exercise of march-in rights and the granting of a forced license during a pandemic.³⁴ However, there may be no need for government action in the form of mandatory patent licenses if more businesses adopt more socially conscious strategy, as AbbVie has done. The availability of this measure, however, might at least provide some solace and encourage businesses to willingly suspend their patent rights during this worldwide public health emergency in order to avoid a government march-in. Alternatively, it might be done as a selfless act of kindness demonstrating that social responsibility has a place in business.³⁵

According to the doctrine of exhaustion, once a patent owner sells a medicine or vaccine product, he cannot sue the purchaser for having an authorized copy of the patented product. Therefore, it assists to improve access to medicines in the health industry. Competition policies contribute to a fair market behavior by controlling patent monopoly and it has the ability to control availability and market price range.

³³ no .45/2013

³⁴ Theodorus Willem Peter van Dijk, *The Limits of Patent Protection* (Universitaire Pers Maastricht.1994)83

³⁵ Nambiar, Kunte and Bhat (2023), «*Protection of intellectual property and human rights during health emergencies: an assessment of the patent waiver proposals*», *International Journal of Human Rights in Healthcare*, Vol. ahead-of-print No. ahead-of-print. <https://doi.org/10.1108/IJHRH-06-2022-0064> accessed on 17th December 2023

Conclusion

Under the human rights umbrella, Right to Health can be considered as a civil right while Right to Patent is fallen under the cultural rights. As discussed above, Right to Health is an inevitable right of the people which strengthens the Right to Life. Even though patent acts as a restriction, it is the best motivation for the new inventors. According to Abraham Lincon, the Patent System added fuel of interest to the fire of genius.

Therefore, setting restrictions and limitation is not practical solution. Utilizing value of both rights by striking balance is the best approach for the best interest of the people during the period of COVID-19 pandemic. Small Patents, voluntary license, compulsory license, doctrine of exhaustion, business plans, competition of the market and some business strategies can be used to minimize hindrance to access to the medicines while encouraging new inventors by protecting patent owners' rights.