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PATENT RIGHTS & PANDEMICS: A CASE OF PUBLIC INTEREST VIS A VIS MONOPOLY RIGHTS

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ABSTRACT

Unprecedented global health crisis caused by COVID 19 calls for an immediate response from countries to fight the pandemic and provide affordable medical care to its people by invoking provisions under patent laws. We understand patent laws as monopoly rights given to the patent holder for the invention, which makes us contemplate whether public interest holds any place under the patent laws. The paper sheds some light on the never-ending debate between these two opposing views, i.e., public interest and patent rights which has been rekindled and resurfaced due to the pandemic. The paper addresses the problem of access to medicine and how patent laws can be conducive in providing affordable medicine and promoting public health. Furthermore, it also elucidates several legal options available under WTO and domestic legislation under the context of public health, and whether they are adequate to combat the effects of the present pandemic. Finally, we will discuss any other alternative model, apart from compulsory licensing, which needs to be looked into to deal with the current public health crisis.

INTRODUCTION

Pandemic like COVID-19, which has led to mass deaths is not contained merely in a small geographic location[3] but has spread globally at a massive scale with severe international repercussions.[4] The ongoing health crisis, due to this pandemic, in several countries, points out one

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[3] WHO, *Coronavirus disease (COVID 19) Situational Report-102*, who int, https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200501-covid-19-sitrep.pdf?sfvrsn=742f4a18_2 (last visited 20 May, 2020)
[4] *Id.*

stark reality, i.e. how woefully unprepared we are.[5] Not only are the developing countries suffering from this crisis but also the developed countries.[6] The exact quantum of the infections among the population, in various countries like USA, India, China etc.[7] is also shrouded in mystery due to inept state policies, or outright negligence.[8] The race to find a solution to this pandemic is going on all across the globe. Perhaps, there might be a light at the end of this dark tunnel, and humankind will be able to find a cure or a preventive measure.[9] However, merely finding a cure will not be enough to ensure access to health for all people, especially in developing or least developed countries without providing affordable access to the medicine or vaccine.[10] Though there are many hurdles in the way, for the 'Least Developed Countries' (hereinafter as LDC) and developing countries, to provide access to medicine to deal with the pandemic, like lack of infrastructure or resources etc.[11] Furthermore, the biggest hurdle to cross is the exclusive patent rights granted to the patent holder, which looms large on the face of affordable access to the medicine.

The paper aims to assess the role of public interest under the current patent regime. Firstly, it analyses the philosophical underpinnings of patent laws and evaluates whether the underlying objective of patent laws justifies the altruistic framework under utilitarian theory and other related theories. Secondly, it explains the provisions laid down under the TRIPS agreement[12] concerning public health and access to affordable medicine and how developing nations or LDC (least developed nations) can maintain a balance between their obligations under TRIPS and protect the public health of their citizens. Thirdly, this paper highlights the provisions laid down under the Indian patent regime, specifically compulsory licensing and whether they provide a viable solution. Fourthly, it explores an alternative model to combat the present pandemic and face any future pandemics with more

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[5] Wafaa M. El-Sadr & Jessica Justman, *Africa in the Path of Covid-19*, 383 NEW ENGLAND JOURNAL OF MEDICINE ED 11 (2020), David Blumenthal & Shanoor Seervai, *Coronavirus Is Exposing Deficiencies in U.S. Health Care*, HARVARD BUSINESS REVIEW, 2020, https://hbr.org/2020/03/coronavirus-is-exposing-deficiencies- in-u-s-health-care (last visited Jul 19, 2020).

[6] Id.

[7] Gian Volpicelli, *Hidden data is revealing the true scale of the coronavirus outbreak*, WIRED UK, 2020, https://www.wired.co.uk/article/coronavirus-spread-data (last visited Jul 19, 2020).

[8] Philip Bump, *Trump again downplays coronavirus by comparing it to the seasonal flu. It's not a fair comparison.* - The Washington Post, https://www.washingtonpost.com/politics/2020/03/24/trump-again-downplays-coronavirus-by-comparing-it-seasonal-flu-its-not-fair-comparison/ (last visited Jul 19, 2020).

[9] WHO, *DRAFT landscape of COVID-19 candidate vaccines – 9 June 2020,* WHO.INT, https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines (last visited 19 Jul, 2020).

[10] Roxanne Khamsi, *if a coronavirus vaccine arrives, can the world make enough?* 580 NATURE 578–580 (2020).

[11] Christian Franz, Sahil Deo, Sanjana Krishnan and Shardul Manurkar, *COVID19 Vaccine: Development, Access and Distribution in the Indian Context*, ORF , https://www.orfonline.org/research/covid19-vaccine-development-access-and-distribution-in-the-indian-context-69538/ (last visited Jul 19, 2020).

[12] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

preparedness.

PHILOSOPHICAL UNDERPINNINGS OF PATENT LAWS

A popular understating of Patent rights is that it confers exclusive monopoly rights on the patent holder for his invention. Such an assertion leads us to question whether the patent regime is solely made to support the commercial exploitation of invention or does it also serve any public interest. In order to decipher the underlying objective of patent rights, it is pertinent to delve deep in the patent jurisprudence.[13] There are several theories which explain the fundamental principles of patent laws. Interestingly, Utilitarian theory posits that creators are rewarded for fulfilling a larger goal of public utility.[14] It advocates that monopoly right is bestowed upon the creators so that they can benefit the public at large and maximize overall public utility.[15] William C. Robinson highlighted the point that the patent protection is justified only when it fulfils three objectives; it rewards the inventor for his skill, effort and labour; incentivise him to further his technological advances, and most importantly it provides immediate knowledge of the scope and nature of the invention to the public, which serves the public interest.[16]

Further, it is pivotal to throw light on the foundation of patent rights. One argument is that Patent rights are statutory rights which means it is granted by the State. A State by a statute confers certain exclusive rights (like monopoly rights) to the patent holder to exclude others from using his work. Since the authority to grant the monopoly rights flows from the State, it can be argued that the State also has the authority to prevent absolute monopoly or retract some of the rights over the granted for a patented invention, to protect the public interest.[17] This argument gains credence, based on the Social Contract Theory, which posits that rights are enforced by the State, and the State itself is a creation of contract entered between the State and the public with an underlying objective of benefit to the public.[18] Further, one may also point out that exclusionary rights in a patent is for a limited period and is granted to the innovators so that the public can be benefitted from the diffusion of knowledge about the

[13] Klitzke, Ramon A, *Historical Background of the English Patent Law*, 41 J. PAT. OFF. SOC'Y 615 (1959).
[14] FISHER, WILLIAM, THEORIES OF INTELLECTUAL PROPERTY," IN NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY 168 (2001).
[15] Katz, Larissa, *Ownership and Social Solidarity: A Kantian Alternative*, 17 LEGAL THEORY 119 (2011).
[16] WILLIAM C ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS (1890).
[17] Matt Schrage, *Rousseau and Locke on Property and the State*, HARVARD.EDU, (2018), https://blogs.harvard.edu/mattschrage/2018/04/26/rousseau-and-locke-on-property-and-the-state/ (last visited Jul 26, 2020).
[18] Id.

invention.[19] This shows that under a normative framework, the property rights are not absolute.

Another pertinent theory which emphasises the philosophical justification of the patent rights is the Bargaining theory, which posits that the inventor is granted the exclusive monopoly rights for a limited period in exchange that disclosure of the invention can serve public interest and society can be benefitted from this invention. In *Tubes, Ld. v. Perfecta Seamless Steel Tube Company,*[20] Lord Halsbury said that it is a bargain between the State and the inventor: The State says, "If you will tell what your invention is and if you will publish that invention in such a form and in such a way as to enable the public to get the benefit of it, you shall have a monopoly of that invention."[21]

The patent regime in India is formulated with an objective of promoting innovation and at the same time with an intention to make the invention accessible to the public at large.[22] The patent legislation in India is being drafted in a manner to provide an equilibrium between the rights of the innovators to encourage scientific and technological advancements and meeting the needs of the general public.[23] Theory of moral justification also emphasised on the public interest aspect. It states that the State is bestowed with the duty to protect the public interest under patent laws. Trade-Related Aspects of Intellectual Property Rights (Hereinafter TRIPS) also play a pivotal role in providing an optimal balance between public interest and rights of the patent holders. It allows the member states to refuse patentability of such invention which does not serve the larger public interest.[24]

TRIPS, PUBLIC HEALTH AND PHARMACEUTICAL PATENTS

The WTO was established in the year 1994, as a result of the Marrakesh Agreement. The TRIPS agreement was also signed by various counties during the same time.[25] The objective of TRIPS is to create an international Intellectual Property (IP) protection regime and

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[19] Denicolò, V., Franzoni L.A, *The contract theory of patents,* INTERNATIONAL REVIEW OF LAW AND ECONOMICS 23, 365–380 (2003).

[20] (1902), 20 R.P.C. 77, at pp. 95-96

[21] Id.

[22] Public Health and Patents, WIPO, https://www.wipo.int/patent-law/en/developments/publichealth.html

[23] Devika Agarwal, *Intellectual property rights: Locating public interest in the law,* FIRSTPORT, https://www.firstpost.com/long-reads/intellectual-property-rights-locating-public-interest-in-the-law-3388388.html

[24] Ashwani Kumar Bansal, *Public Interest in Intellectual Property Laws*, 55 JOURNAL OF THE INDIAN LAW INSTITUTE 4 473-503 (2013).

[25] Gustavo Bravo, *From Paris Convention to TRIPs: A Brief History*, 12 J. Contemp. Legal Issues 445 (2001).

amicably resolve any IP related issues.[26] Further, Article VII, titled *objectives*, provides that the objective of TRIPS should be to provide IP protection which not only supports innovation and dissemination of technology but also it should be done in such a way as to create a balance between the social or economic obligations and IP rights obligation.[27] To ensure that the objectives are met, TRIPS agreement puts an obligation on the member states to abide by the provisions contained under TRIPS and amend/create municipal laws which conform with the provisions.[28] While discussing the issue of 'access to medicine' the most appropriate IP to be discussed is the Product-Patent. Patents rights are usually granted on any new inventions. Article XXVIII of TRIPS provides for the rights to be conferred to a patent holder on a particular product, which includes exclusionary rights (the third party cannot make, use, offer for sale or import without the consent of the patent holder) and right to assign, transfer or to give licence.[29] However, for any rights to be granted under Article XXVIII, the product should confirm with the conditions provided under Article XXVII.[30] From a bare reading of the Article XXVII(1)[31] together with Article LXX(8),[32] it can easily be deduced that medicines or vaccines fall under a 'patentable subject matter'.[33] Furthermore, Article XXVII (I) also includes the 'non-discrimination' clause, which includes de-facto and de-jure discrimination by the State.[34] Such an interpretation

[26] Slade, Alison, *The Objectives and Principles of the WTO TRIPS Agreement: A Detailed Anatomy*, OSGOODE HALL LAW JOURNAL 53.3 948-998 (2016).

[27] TRIPS Agreement, Art. 7.

[28] TRIPS Agreement, Art. 7 & art. 1.

[29] TRIPS Agreement., Art. 28.

[30] "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.5 Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."
TRIPS Agreement, Art. 27.

[31] Id.

[32] TRIPS Agreement, Art. 70, para (8).

[33] "The introductory clause to Article 70.8 provides that it applies '[w]here a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27 ...' of the TRIPS Agreement. Article 27 requires that patents be made available 'for any inventions, whether products or processes, in all fields of technology', subject to certain exceptions. However, pursuant to paragraphs 1, 2 and 4 of Article 65, a developing country Member may delay providing product patent protection in areas of technology not protectable in its territory on the general date of application of the TRIPS Agreement for that Member until 1 January 2005. Article 70.8 relates specifically and exclusively to situations where a Member does not provide, as of 1 January 1995, patent protection for pharmaceutical and agricultural chemical products." Panel Report-India - Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/R (5 September 1997).

[34] "The primary TRIPS provisions that deal with discrimination, such as the national treatment and most-favoured-nation provisions of Articles 3 and 4, do not use the term 'discrimination'. They speak in more precise terms. The ordinary meaning of the word 'discriminate' is potentially broader than these more specific

dramatically reduces the flexibility available to the State to respond to the health crisis.[35] This leads to the question of how the LDC or developing countries can protect the health of their citizens during times of pandemic. We will discuss a few options available within the framework of TRIPS, below:

EXCEPTIONS UNDER ARTICLE XXVII AND PANDEMIC

Article XXVII not only provides for patentability criterion but under the para (2) it also provides certain exceptions wherein a member state may exclude the patentability of inventions and also prevent the commercial exploitation to 'protect human, animal or plant life or health'.[36] However, this exception comes with a caveat that 'such exclusion is not merely because the exploitation is prohibited by their law'.[37] From a bare reading of this para, it may seem to provide flexibility to the countries; however, its application is nothing but a matter of public policy where specific exclusions are 'necessary' to protect health. The flexibility provided here is that the State is not required to consult other parties if it decides to invoke this clause for exclusion citing 'necessity'. But, due to the requirement of 'necessity', a member state may not be able to use this clause[38] to allow its domestic producers to replicate a particular product to deal with the health crisis because if a product is to be excluded based on morality, order public or even on health ground, it has to be outlawed for not just for the imported/foreign products but also domestic products.[39] Thus, this exception cannot be used to provide access to medicine or vaccine during a pandemic.

One may also look at the Article XXVII (3) which provides that members may also exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals; from patentability.[40] Although, at first instance, Article XXVII (3) provides much flexibility to the LDCs or Developing countries, however, its interpretation is also very narrow especially

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definitions. It certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment. Discrimination may arise from explicitly different treatment, sometimes called 'de jure discrimination', but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called 'de facto discrimination'. Panel Report, Canada - Patent Protection of Pharmaceutical Products, WT/DS114/R (17 March 2000).

[35] Id.

[36] TRIPS Agreement, art. 27, para (2).

[37] Id.

[38] George K. Foster, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and its Aftermath*, 3 UCLA J. INT'L L. & FOREIGN AFF. 283, 290 (1998).

[39] Kevin J Nowak, *Staying Within the Negotiated Framework: Abiding by the Non-Discrimination Clause in Trips Article 27*, 26 MICH. J. INT'L L. 899 (2005) 48.

[40] TRIPS Agreement, Art. 27, Para 3.

when we consider the word *'may also'*, which suggest a connection between Article XXVII

(1) & (2). By invoking this article, a country may not be able to refuse the patentability of the pharmaceutical product since this article also requires that the test of 'necessity and non-discrimination'[41] should be fulfilled.[42] Further, if the interpretation of Article XXVII (3) includes blanket exception towards pharmaceuticals products, then it will make Article LXX

(8)132 redundant. Hence, para 3 under Article XXVII can be used for dissemination of medical procedure and techniques but not to exclude pharmaceutical patents.

PATENT RIGHTS EXCEPTIONS & TRIPS

Article XXX[43] provides exceptions to certain rights conferred under Article XXVIII. However, there are conditions attached as to when a state may invoke this Article. Essentially there are three conditions which need to be fulfilled for patent rights exceptions according to Article XXX; a) the exception to rights conferred should be limited, b) that it should not create unreasonable conflict with a normal exploitation of a patent and c) that it should not unreasonably prejudice the legitimate interest of the patent owner.[44] The objective of this article is to provide flexibility to a member state in balancing the public health with patents rights and promotion of transfer of technology. The best example of the applicability of this article is 'Bolar Exception' which means that the State may allow a non-patent owner to start working on the patent,[45] so as to introduce the product in the market later in future once the patent has expired. Similarly, it may also be applied for scientific studies, but it will have limited use in providing access to the vaccine.

COMPULSORY LICENSING & TRIPS

According to the Paris Convention,[46] a compulsory license is granted "to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for

[41] Canada-Generic Medicines WTO case

[42] George K. Foster, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and its Aftermath*, 3 UCLA J. INT'L L. & FOREIGN AFF. 283, 290 (1998).

[43] TRIPS Agreement, Art. 30.

[44] Panel Report, Canada - Patent Protection of Pharmaceutical Products, WT/DS114/R (17 March 2000).

[45] WTO | Intellectual property (TRIPS) - fact sheet - pharmaceuticals - 2, WTO.ORG , https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited Jul 19, 2020).

[46] Paris Convention for the Protection of Industrial Property, Mar. 20, 1883 21 U.S.T. 1583; 828 U.N.T.S. 305. (hereinafter as Paris Convention)

example, failure to work".[47] Simply put, compulsory licensing is a method by which a state may grant the right of use to any third party (including government) without the consent of the patent owner.[48] Similar to the Paris Convention, Article XXXI of TRIPS provides that under certain circumstance.

'*Where the law of a Member allows for other use of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government, the following provisions shall be respected:*'[49]

Although Article XXXI doesn't use the term 'compulsory licensing' but its use in such a way is implied. However, there are certain conditions attached along with this Article. A member state may not grant a blanket authorisation but rather all authorisations should be considered on its individual merits (a), State should hold prior talks with the patent holder, and only if no mutual consensus is reached based on reasonable commercial term, then only any authorisation may be granted (b) however, adherence to this rule might lead to delay in cases of a public health crisis. Hence, the second part of para (b) allows the State to skip this rule in case of a national emergency. Flexibility to developing and LDCs was also augmented with regards to the interpretation of 'national emergency' after the adoption of Doha Declaration[50] Para 5(c), which provides that each member has a right to determine what constitutes a national emergency and it includes public health crisis.[51] Further, the authorisation should only be to satisfy the needs of the domestic market. However, after the Doha Declaration and the adoption of Article XXXI (bis),[52] there are certain exceptions provided to this rule, especially in cases of LDCs with no pharmaceutical manufacturing capability[53] and Regional Trade Block.[54] Interestingly, under Article XXXI and Article XXXI (bis), both suggest that the original patent holder should receive

[47] Paris Convention, Art. 5A (2).
[48] Id.
[49] TRIPS Agreement, Art. 31.
[50] Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001 WT/MIN(01)/DEC/2 (hereinafter as Doha Declaration).
[51] Doha Declaration, Para 5(c).
[52] 'The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.' TRIPS Agreement, Art. 31 *bis.*
[53] "Confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector" TRIPS Agreement Annex Para 1, sub para 2 (a) (ii).
[54] Similar meaning as in GATT 1994: General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994)
(hereinafter GATT 1994)

adequate compensation; however, what is adequate compensation is left to the discretion of members states.[55]

COMPULSORY LICENSING & INTERNATIONAL PERSPECTIVE

In response to the COVID pandemic, several countries have taken initiatives to find potential cure and affordable medical treatment to combat the pandemic. *Israel* for the first time has invoked Section 104[56] and Section 105[57] of *Israeli Patents Law, 1967* by issuing compulsory license for public non-commercial use. Israel became the first country to grant permission to exploit patent granted on Kaletra by Abbvie (Patent no: 173939, 207260, 185390) by importing generic version of Kaletra from Hetero pharmaceuticals.[58]

Ecuador has also taken bold steps by passing a resolution by a Committee of National Assembly which has approved grant of compulsory license to provide affordable medical treatment related to preventive, diagnostic and treatment technologies to deal with COVID. The resolution passed by the committee has also granted permission to collect any important information for the purposes of research and development to fight COVID.

Chile has taken a strong initiative towards strengthening the existing laws on compulsory licensing to provide affordable access to medical care to fight the pandemic. The chamber of deputies in the lower house passed a resolution for the issuing of compulsory license mentioned as under Article 51º Nº 2 of Industrial Property law.

The resolution passed with good majority in lower house states that international treaties such as ICESCR (International Covenant on Economic, Social and Cultural Rights) ratified by the Chile government mandates the state to fulfil non-derogable obligations which are mainly Right of access to health centers, Right of access to essential medicines and Right to equitable distribution of health facilities. Furthermore, obligation on the state to adopt a good action plan and public health strategy in times public health crises. In accordance with the WHO resolution and ICESCR the state has fulfilled its obligations by providing access

[55] Antony Taubman, *Rethinking TRIPS: "Adequate Remuneration" for Non-voluntary Patent Licensing*, 11 JOURNAL OF INTERNATIONAL ECONOMIC LAW 927–970 (2008).

[56] Section 104: Right of State to exploit invention
The Minister may permit the exploitation of an invention by Government departments or by an enterprise or agency of the State, whether a patent for it has or has not already been granted or has or has not already been applied for, if he finds that that is necessary in the interests of the National security or of the maintenance of essential supplies and services.

[57] Section105: Right of State to permit exploitation of invention The Minister may, if he finds that that is necessary for the purposes enumerated in section 104, grant a permit under that section to a person who operates under contract with the State, in order to ensure or facilitate the implementation of that contract and for the requirements of the State only.

[58] Swaraj Paul Barooah, Corona and IP – Looking for the Right(s) Answers (2020), SPICY IP, 2020 https://spicyip.com/2020/03/corona_and_ip_rights_answers.html (last visited on 16 July).

to essential medicines, vaccine, diagnostics, medical supplies and other technologies which can be viable for prevention, detection, surveillance and medical treatment of COVID patients in Chile.

Germany has been a frontrunner by passing a new legislature *Prevention and Control of Infectious Diseases in Humans Act* which provides some extensive powers to the government, as mentioned under Section 13(1) of the act, which mainly includes the issue of compulsory licensing. It permits even if it circumvents any patent rights in the interest of public welfare. All the government orders pertaining to corona will automatically be revoked at the end of the pandemic or when the law expires in March 2021.

*Canada i*s another country which has passed a new legislature *COVID-19 Emergency Response Act*. This act provides wide powers to the government, which can supersede patent laws. Under this, the government can manufacture, sell and use a patented invention for the public interest in the times of public health emergency. The government can obtain the patent even without the consent of the patent holder. Such licenses as issued by the government are non-assignable and shall be revoked once the pandemic is over.[59]

United States of America has also passed some legislations to deal with the pandemic. Coronavirus Aid, Relief, and Economic Security (CARES) Act and Coronavirus Preparedness and Response Supplemental Appropriations Act (CPRSA). Under CPRSA, it contains two provisions which related to the affordability of medical access. It states that the vaccines, therapeutics and diagnostics purchased by the federal government shall be in accordance with federal acquisition regulation guidance on fair and reasonable pricing. [60]

BALANCING TRIPS AND PUBLIC HEALTY

From the above discussion, we can see that the member states, especially the LDCs, have greater flexibility when it comes to acting for the protection of public health. Further, under Article VIII (1) of TRIPS provides the principle of health, whereby members may adopt or amend laws to protect public health when necessary, in conformity with the provisions of TRIPS.[61] The position of LDC under TRIPS was especially strengthened after the Doha

[59] Adam Houldsworth, *The Key Covid-19 Compulsory Licensing Developments So Far*, IAM, Iam-media.com, 2020 https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far (last visited on 16 July).

[60] Hickey, K. *Legal Issues in COVID-19 Vaccine Development*, 2020; Ariel Cohen, Senators *Worry About COVID-19 Vaccine Affordability, Distribution*, INSIDE HEALTH POLICY https://insidehealthpolicy.com/daily-news/senators-worry-about-covid- 1 9-vaccine-affordability distribution (last visited on May 14, 2020)

[61] TRIPS Agreement, Art. 8.

Declaration on Health,[62] and recently in 2015 when more extension was granted to them with respect to patents obligations.[63] LDCs have the flexibility to grant a compulsory license, to provide affordable medicine and access to health in instances of a public health crisis, and a pandemic of the proportion of Covid-19 inevitably falls under that category.[64] However, when one looks at the history of the use of compulsory licensing, then one may only find a few instances where it was granted by the members.[65] There has not been optimal use of the compulsory licensing, which was envisioned by many academicians. Interestingly, even during COVID-19 (at least almost after five months when the initial spread was reported), there has not been a single compulsory license which was granted by any country.[66] Even for the past pandemics like HIV, the use of compulsory licensing by the African nation (most prone to the pandemic) was unsatisfactory.

The reason for such a lacklustre record of 'compulsory licensing' to meet its objective are plenty. The first reason is the ambiguous nature of the requirement to grant compulsory licensing under TRIPS, which the Doha declaration tried to resolve.[67] The second reason may be attributed to the geopolitical reality where the Western and more developed countries (like the USA) have sway over other less developed countries. Members, especially countries in the global south, are acompulsory retaliation by the more developed countries.[68] There also has been a trend to target the pharmaceuticals manufacturers of the developing counties with sanction by the more developed countries.[69] As a result, many manufacturers are afraid of applying for a compulsory licensing within their own countries. Few countries also tried to use compulsory licensing as a bargaining chip to force the developed countries to come to the table for trade negotiations.[70] There is a new reality where the LDCs or developing countries are afraid of retaliation, and hence they are moving

[62] Doha Declaration 2001.
[63] WTO | intellectual property (TRIPS)—Responding to least developed countries' special needs in intellectual property, , https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm (last visited Jul 19, 2020).
[64] Coronavirus: What is a pandemic and why use the term now?, BBC NEWS, March 11, 2020, https://www.bbc.com/news/health-51358459 (last visited Jul 19, 2020).
[65] Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLOS MEDICINE e1001154 (2012).
[66] COVID-19 IP Policy Tracker, WIPO, https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access (last visited Jul 19, 2020).
[67] Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents*, 4 AMERICAN UNIVERSITY INTERNATIONAL LAW REVIEW 15, 941-974. (2000).
[68] Dina Halajian, *Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem*, 38 BROOK. J. INT'L L. (2013).
[69] Id.
[70] Jennifer Bjornberg, *Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation*, 27 NW. J. INT'L L. & BUS. 199 (2007).

towards a new model of 'voluntary licensing'[71] which is even espoused by the WIPO. However, there must be a change in status quo within the TRIPS framework, considering that 'voluntary licensing' model is not the most efficient[72] during a Pandemic like COVID-19 as not only it requires a lot of negotiations but the success rate of 'voluntary license negotiations' has been inadequate.[73] WTO should look at the model adopted by the WHO, especially the Pandemic influenza preparedness framework (PIP).[74] The objective of the PIP framework is to prepare against a pandemic with a global outlook. It further reaffirms that the issue of public health is superior to IP rights and thus should be given more preference.[75] Para 6 of the PIP framework provides a benefit-sharing model, which includes sharing the vaccine amongst the member states and transfer of technology.[76] In such a circumstance, the members of TRIPS should work towards the inclusion of a PIP like the model within TRIPS framework for an efficient global response against a pandemic, by creating a collective pool of vaccines which all states may use.[77] Only by veering towards a collective approach, in case of a pandemic,[78] we can ensure that public health and innovation are protected, for there will be innovation only when the humankind is alive and prospers.

INDIAN PERSPECTIVE: PANDEMIC AND PATENT LAWS

We know patent laws in India have its roots in the British era, and it start taking shape in 1911. Later, some significant committees were set up in 1949 Justice Tek Chand committee and in 1957 Justice N. Rajagopala Ayyangar Committee.[79] These committees scrutinised the

[71] K D Raju, *Compulsory v Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries, 22* JOURNAL OF INTELLECTUAL PROPERTY RIGHTS (2017).

[72] Anusuya Nigam & Vrinda Pathak, Affordable access to Covid-19 drugs: Are voluntary patent licences here to stay? ,2020,ECONOMICTIMES,https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/affordable-access-to-covid-19-drugs-are-voluntary-patent-licences-here-to-stay/articleshow/75756605.cms?from=mdr (last visited 19 July, 2020).

[73] Kyung-Bok Son & Tae-Jin Lee, *Compulsory licensing of pharmaceuticals reconsidered: Current situation and implications for access to medicines*, 13 GLOBAL PUBLIC HEALTH 1430–1440 (2018).

[74] WHO, Pandemic Influenza Preparedness Framework, WHA 64.5 Agenda item 13.1 24 May 2011. (hereinafter as PIP)

[75] Id.

[76] PIP, Para 6.

[77] Christopher Garrison, *Urgent collective action to meet the challenge of this pandemic crisis: a coronavirus related intellectual property pool,* MEDICINES LAW & POLICY, https://medicineslawandpolicy.org/2020/03/urgent-collective-action-to-meet-the-challenge-of-this-pandemic-crisis-a-coronavirus-related-intellectual-property-pool/ (last visited Jul 20, 2020).

[78] Prathiba M. Singh, Needed: A Pandemic Patent Pool, THE HINDU, May 1, 2020, https://www.thehindu.com/opinion/lead/needed-a-pandemic-patent-pool/article31475628.ece (last visited Jul 20, 2020)

[79] Justice Ayyangar Committee Report 1959, IPINDIA.NIC.IN,

existing patent laws and acted as the catalyst in the formation of the present-day Indian Patent Act, 1970. These committees formed the backbone for strong laws which are conducive to the public interest and compulsory licensing regime.[80]

In India, the concept of the compulsory license is not new as it was incorporated in the Patent Act, 1970 from the very inception. However, the use of compulsory licensing provisions is unsatisfactory and dismal. The first time it got invoked was after four long decades in 2011. In a landmark case *Bayer Corporation v. Natco Pharma limited,* it was granted to Natco pharmaceutical company for an anti-cancer drug named Nexavar.[81] Though, granting of this license came with a severe backlash from developed nations claiming that compulsory licensing should only be invoked in situations of public health crisis and not otherwise.[82] Due to intense criticism and severe scrutiny by International forums, all the applications for compulsory licenses have been rejected by the Controller General of Patent. Cases such as Roche's breast cancer drug Herceptin was rejected.[83] In 2013, BDR's application for a compulsory licence for Squibb cancer drug SPRYCEL was rejected merely on technical grounds. In a recent case of 2015, Lee Pharma filed for a compulsory license for diabetes management drug Saxagliptin which was again rejected by Controller as it did not meet the criteria for application. This is a reaffirmation of India's insipid performance when it comes to granting compulsory licenses.

Though, it does not mean that 'Public interest' has not been discussed widely in various landmark judgements. *In F. Hoffmann LA Roche Limited v. Cipla Limited*,[84] the court opined that the patent granted should be beneficial to the public and serve the public interest as per section 83(g). It was said that generic drugs should be affordable and should fulfil public interest. In another landmark case, *Novartis v. Union of India*[85] In this court observes that as per TRIPS agreement, members have the power to adopt measures and incorporate

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http://www.ipindia.nic.in/writereaddata/Portal/Images/pdf/1959Justice_N_R_Ayyangar_committee_report.pdf (last visited Jul 19, 2020).

[80] Uday S Racherla. *Historical Evolution of India's Patent Regime And Its Impact On Innovation In The Indian Pharmaceutical Industry.* INNOVATION, ECONOMIC DEVELOPMENT, AND INTELLECTUAL PROPERTY IN INDIA AND CHINA. ARCIALA SERIES ON INTELLECTUAL ASSETS AND LAW IN ASIA. SPRINGER, Singapore (2019)

[81] Sood, M*, Natco Pharma Ltd. v. Bayer Corporation and the compulsory licensing regime in India,* 104 NUJS LAW REVIEW 99 (2013).

[82] Devika Agarwal, Radhika Agarwal , The Dismal History of Compulsory Licences In India, (Indian Institute of Technology, Madras) 2016, http://patentblog.kluweriplaw.com/2016/04/21/the-dismal-historycompulsorylicencesindia/?doing_wp_cron=1594499575.3004329204559326171875#:~:text=In%20the% 20first%20four%20decades, anti%2Dcancer%20drug%2C%20Nexavar. (last visited on 18 July).

[83] *Id.*

[84] 2009 (40) PTC 125 (Del.) (DB).

[85] (2013) 6 SCC 1.

provisions which are essential in protecting public health and promoting the public interest. The dichotomy between the monopoly and public interest was highlighted, it explained that the monopoly is being granted to the patent holder as a quid pro quo to the knowledge of the invention which is disseminated for the benefit of the larger public.

However, due to the unique situation presented before us, i.e., COVID pandemic, there is an ongoing debate to revisit IP laws which can be conducive in developing medical miracles and reach masses at an affordable price. For this, it is pertinent to shed light on pivotal provisions under Indian patent Act, 1970, which can be invoked in such times of public health crises.

Compulsory licensing forms a large part of Indian patent laws, i.e., Section 84 till section 92. Compulsory license, as discussed under section 84,[86] can be granted only after expiration of three years from the date of grant of the patent. Any interested person or company can apply only when they have failed to negotiate a voluntary licensing agreement with the patentee. For granting, following criteria needs to be fulfilled: reasonable requirements of the public not met, non-availability at a low price and the patented invention not worked in the territory of India. This provision cannot be invoked as three years have not been elapsed since the grant of the patent.[87]

The proximate option available under the compulsory license regime is under section 92(3). This section does away with the need to negotiate a voluntary license with the patent holder and three years expiration to grant a compulsory license. In this case, the Controller can issue a compulsory license in circumstances such as National emergency or extreme urgency, public non-commercial or during a public health crisis like an epidemic.[88] This provision can be invoked in the present times to do away with the monopoly rights at the same time provides a viable solution in providing affordable drugs. Apart from compulsory licensing, patent laws give immense authority to the government to exercise the rights of the

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[86] Section 84 (1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:
(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
(b) that the patented invention is not available to the public at a reasonably affordable price, or
(c) that the patented invention is not worked in the territory of India.

[87] R Beall and R Kuhn, *Trends in compulsory licensing of pharmaceuticals since the Doha Declaration: A database analysis, 106 PLOS Medicine Journal 2012, D* Harris, *TRIPS after fifteen years: success or failure, as measured by compulsory licensing,* 18 387 Journal on Intellectual Property Law (2010).

[88] Juan, H. E., *INDIAN PATENT LAW AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY: WHAT CHINA CAN LEARN FROM INDIA? IN INNOVATION, ECONOMIC DEVELOPMENT, AND INTELLECTUAL PROPERTY IN INDIA AND CHINA.* Springer Singapore (2019).

patent holder by itself or through the third party in the name of public interest. Under section 100[89], the government can issue a license and use an invention to itself or third party for the purposes of public interest. Lastly, under section 102[90] government also has an option to acquire the patent from the patent holder.

International pharmaceutical companies are conducting trials and R& D activities and launching various drugs with properties to cure the coronavirus. In such a scenario, section 107A known as bolar exemptions can be invoked. This provision enables the Indian generic pharmaceutical companies to conduct research and trials on the existing patented pharmaceutical drug. This is a defence to the patent infringement suit and enables generic companies for an early launch of the generic version of the drug. This provision enables clinical trials of the patented drugs such as Remdesivir and Favipiravir without the prior authorisation of the patent holder. There are numerous options to defeat the monopoly of the patentee in the pharmaceutical industry and make it available to the masses.

PRESENT INDIAN POSITION: PANDEMIC AND PATENT LAWS

Despite the fact that patent laws provide umpteen provisions as discussed in the previous chapter, voluntary licensing is being adopted over compulsory licensing yet again. In May 2020 Gilead life sciences entered into non-exclusive voluntary licenses with numerous generic pharmaceutical companies to allow distribution and production of Remdesivir drug at affordable rates in 127 countries, including India. Several firms such as Cipla, Jubilant Life Sciences, Hetero, BRD and Mylan have signed a voluntary licensing agreement with Gilead Life Sciences.[91] Another drug Fabiflu, is the first oral favipiravir launched by

[89] Section 100 (1) of the Indian Patents Act states –
Power of Central Government to use invention for purposes of Government. - (1) Notwithstanding anything contained in this Act, at any time after an application for a patent has been filed at the patent office or a patent has been granted, the Central Government and any person authorized in writing by it, may use the invention for the purposes of Government in accordance with the provisions of this Chapter.

[90] Section 102 of The Indian Patent Act states that
1) The Central Government may, if satisfied that it is necessary that an invention which is the subject of an application for a patent or a patent should be acquired from the applicant or the patentee for a public purpose, publish a notification to that effect in the Official Gazette, and thereupon the invention or patent and all rights in respect of the invention or patent shall, by force of this section, stand transferred to and be vested in the Central Government.
(2) Notice of the acquisition shall be given to the applicant, and, where a patent has been granted, to the patentee and other persons, if any, appearing in the register as having an interest in the patent.
(3) The Central Government shall pay to the applicant, or, as the case may be, the patentee and other persons appearing on the register as having an interest in the patent such compensation as may be agreed upon between the Central Government and the applicant, or the patentee and other persons

[91] Teena Thacker, Covid-19 treatment: *Cipla, Hetero Lab get nod to manufacture and sell Remdesivir,* ECONOMIC TIMES, 2020, https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/cipla- hetero-

Glenmark Pharmaceuticals which will be used to treat COVID-19. The Drug Controller General of India has granted permission to Cipla and Hetero pharma companies to launch generic versions of Remdesivir and Glenmark pharmaceuticals to manufacture favipiravir for restricted emergency use to treat Covid-19.[92]

International Pharmaceutical companies entering into a voluntary licensing agreement is not per se a benevolent move but rather a calculated move. It is to protect its patent from being exploited under the compulsory licensing regime and other possible scenarios where the government can take control over the patent. Furthermore, it safeguards the company from any potential allegations of misuse of its patent monopoly and monetising in such global public health crisis.

CONCLUSION

The current global health crisis has again resurfaced the public interest and proprietary rights dichotomy under patent laws. Historically speaking, there are umpteen theories and philosophical justifications of IP laws which favours public interest over patent rights. International Organization such as TRIPS aims to strike a balance between IP obligations and social obligations to serve the public interest. TRIPS also mandates other member states to conform to its obligations and incorporates such provisions which aims to curtail monopoly rights to serve public interest. International organization and national laws also incorporate several provisions which supersede patent rights in case of public health crisis and to protect the public interest.

In the first chapter, the author tries to justify with the help of the philosophical underpinnings of IP laws that the patent rights are not sacrosanct. Patent holders are incentivized only to maximize public utility, and hence the ultimate goal is not creating monopoly rights but to promote the larger public interest. The author elucidates the philosophical justification with the help of several theories which restrict monopoly rights to promote larger public welfare. Utilitarian theory which posits that the exclusive monopoly rights are granted to the creators solely to promote larger goal of public interest.

getsellremdesivir/articleshow/75958389.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst (last visited on 18 July,2020)

[92] Meenakshi Ray, *Glenmark's Covid-19 drug to nod to Hetero and Cipla for remdesivir: Latest on coronavirus treatment,* HINDUSTAN TIMES, 2020, https://www.hindustantimes.com/india-news/glenmark-s- covid-19-drug-to-nod-to-hetero-and-cipla-for-remdesivir-latest-on-india-s-fight-against-coronavirus/story- t2vOApAZQRpxG (last visited on 17 July)

Bargaining theory which emphasize on the fact that monopoly rights on the invention is granted to further serve public Interest by disclosing the invention for the public use. Social Contract Theory advocates that monopoly rights are not absolute and can be curtailed by the state to serve public interest.

In the second chapter, the author analyses the provisions under TRIPS which are favourable in times of public health crisis and access to affordable medical care. Interestingly, TRIPS and Doha Declaration provides several provisions relating to compulsory licensing and Bolar Exemptions which can be invoked by the member states in times of public health crisis. There has been a poor implementation of these provisions due to severe backlash and staunch opposition by highly developed countries. The author has also highlighted the legal reforms taken by various countries to deal with COVID. Countries such as Israel which has invoked Section 104 and Section 105 of *Israeli Patents Law, 1967* by issuing compulsory license, Ecuador and Chile has passed resolutions to grant compulsory license. Germany has passed *Prevention and Control of Infectious Diseases in Humans Act* to deal with COVID and has given approval for granting compulsory license to provide affordable access to medicines. Canada has passed *COVID-19 Emergency Response Act* which gives wide powers to government to sell, manufacture patented invention to serve public interest. It is time to learn from other countries by invoking appropriate provisions and strengthening the existing laws to deal with COVID effectively.

In the third chapter, the author sheds light on the relevant provisions under Indian patent laws which can be invoked to combat the pandemic. The author elucidates the legal provisions as covered under Section 84 to Section 92 of Indian Patent Act which encompasses compulsory licensing regime and its procedure. The author sheds light on Section 92(3) which can prove to be the most viable solution to provide affordable medical care during times of public health crises and can be invoked to deal with COVID. Due to mounting pressure from the international pharmaceutical companies, developed nations and international organization, has led to lackluster performance of these legal provisions. The author highlights the present position of India where Gilead and other international pharma companies have entered into voluntary licenses with Cipla, Hetero and other generic pharma companies established in India to manufacture remedesivir drug. Such measures by international pharma companies are clear indicator of exploitation of exclusive monopoly rights and non-fulfillment of public interest. As government won't be in a position to regulate the terms of voluntary licenses and as a result will have dire

consequences. Therefore, it becomes all the more pertinent to take strong measures by invoking appropriate provisions dealing with compulsory licensing to provide accessibility and affordability of medicines to the masses.

RECOMMENDATIONS: A WAY FORWARD

A. GLOBAL PATENT POOLING FUND AND FAIR USES

World leaders are also taking a wide array of initiatives to collaborate and fight collectively against the virus. WHO has launched a patent pool to conduct clinical trials, collect patent rights, regulate test data and other technologies which can be conducive to develop drugs and combat COVID -19. Collect patent rights, regulatory test data, and other information that could be shared for developing drugs, vaccines, and diagnostics to combat COVID-19.[93] Pharmaceuticals patent pool is being established for multiple players such as Universities, research institutes, drug makers, and non-profit organisation to work collectively and share information about research, development and production of vaccine to fight the pandemic.[94] This initiative helps in global dialogue among different stakeholders and dissemination of health-related technology, intellectual property rights and other relevant data for fighting COVID-19.

B. PATENT SHARING AND CURBING MONOPOLY

It is pertinent that the giant pharmaceutical companies to not claim their monopoly rights of excluding others for making the drug more accessible and affordable. Private pharmaceutical companies have acted in a non-competitive manner for the benefit of public interest and to provide effective medical care. Gilead has cancelled its seven-year orphan drug period for Remdesivir. Similarly, Abbvie Pharma company in Israel has foregone its monopoly rights

over Kaletra, which is being tested to treat COVID 19. However, the role of government is vital to act as a watchdog and observe the effective implementation of such policies.

[93] COVID-19 Technology Access Pool, WHO, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool (last visited on 17 July 2020).

[94] Ed Silverman ,*The WHO launched a Voluntary Covid-19 Product Pool. What happens next?,* STATNEWS.COM, 2020, https://www.statnews.com/pharmalot/2020/05/29/who-covid19-coronavirus-patents/ (last visited 20 July).

C. PUBLIC PRIVATE PARTNERSHIP

Development of vaccine requires an ample amount of R& D investment. Public, private partnerships among all the stakeholders becomes pivotal to mitigate the disastrous effects of the pandemic in the future. Such partnerships would spur innovation, provide long term funding, capacity building, and legal compliance. Stakeholders such as policymakers, international organisations, big pharma companies, universities and other R&D centres can collaborate and work effectively to provide research funding and rapid development of effective technologies to fight the pandemic.

This shall prove to be a useful tool not only to address the global pandemic problem at hand but also would promote industrial growth considering the economic slowdown in the current times. This initiative will accelerate the development of advanced technologies and drugs and would reach to the people in need at a fast pace due to less legal complication and faster compliance by governing bodies.

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