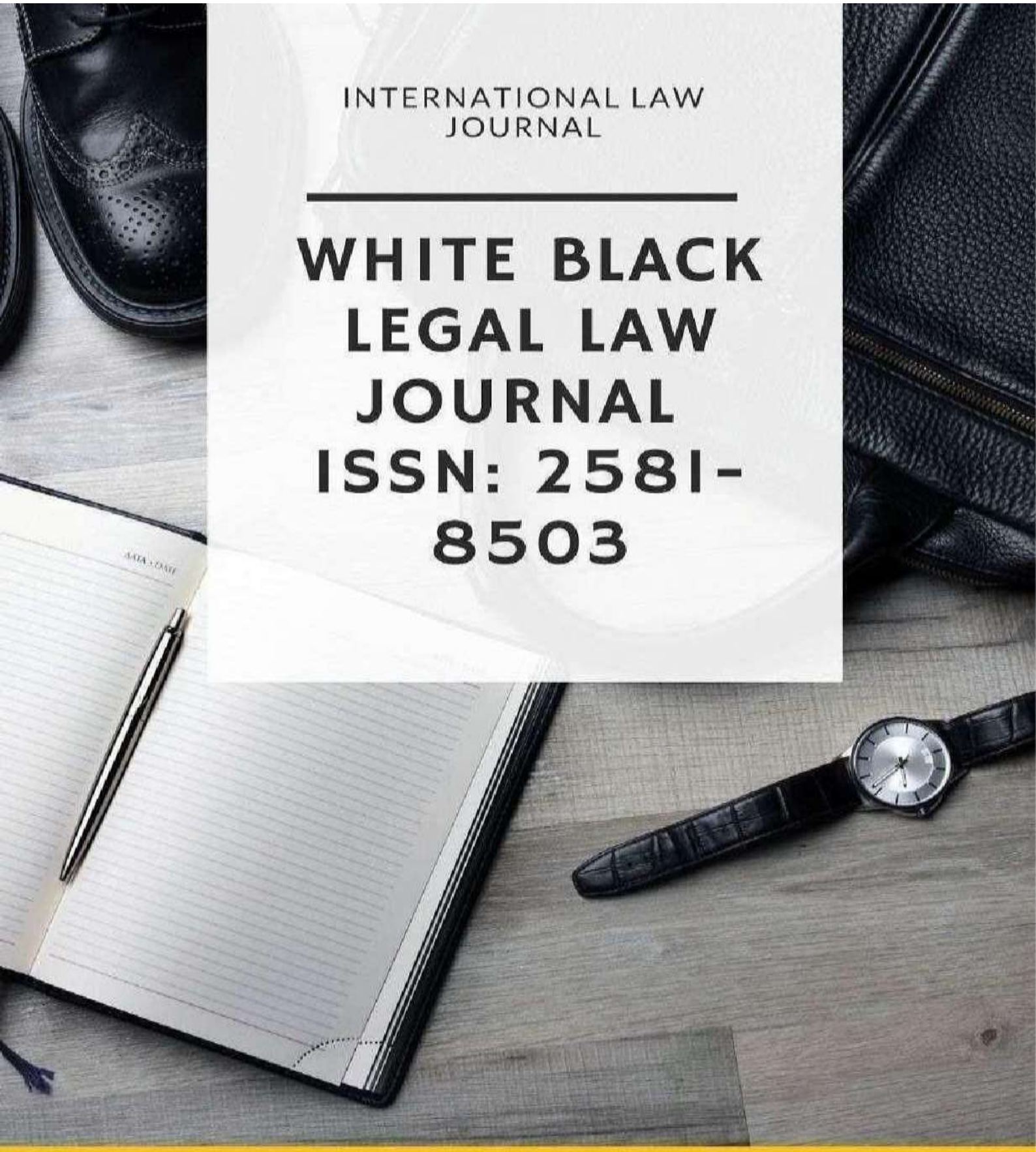

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WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal providededicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

ACCESS TO ESSENTIAL MEDICINES AND INNOVATION- AN INTERSECTION BETWEEN PUBLIC HEALTH AND INTELLECTUAL PROPERTY RIGHTS DURING COVID-19 PANDEMIC.

AUTHORED BY - INSHA QUYOOM
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Abstract

The COVID-19 pandemic's shortages of essential medications in various countries have rekindled discussions about universal access to expensive, patent-protected life-saving drugs. Many proponents of global health justice have stated that patents worsen the issue of access to cost-effective medical care globally by adding new legal impediments to it and have a substantial impact on the availability or scarcity of pharmaceutical products. This paper seeks to address the role of intellectual property (IP) law in addressing the problem of the COVID-19 pandemic. This paper adopts an IP perspective on the COVID-19 pandemic to highlight pandemic-related IP considerations and IP problems. It addresses the main research question, which is whether the current international IP system can be seen as a barrier to innovation and access to essential medicines and should be changed as a result to speed up the development of the vaccine. It also argues that, notwithstanding the restrictions that patents may impose on universal access to generic COVID-19 medicines, the TRIPS framework is an integral part of an equitable global solution to the pandemic. It also highlights that there are several other issues regarding vaccine development or access to live saving drugs, apart from patents, that needs to be addressed.

Key Words: Public Health, Patents, Covid-19, TRIPS, Compulsory licensing, Vaccines.

Introduction

Since the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) entered into force in 1995, disputes over IPRs have become more prevalent in international economic and political relations, particularly in the North-South context. All World Trade Organisation (WTO) members are mandated by the Trips Agreement to establish basic criteria for the protection of intellectual property rights (IPRs) . The idea that IPRs would need to be enforced and extended to all nations sparked profound concerns that the developing world may be further disadvantaged. IPR protection requirements that are close to those in advanced countries could harm developing nations' chances of gaining from the transformation of contemporary society into "knowledge societies," where information is valued highly. In the public discussions surrounding IPRs, the TRIPS Agreement's apparent injustice and the "widening of the North-South gap" play a significant role. The issue of "Access to Essential Medicines" is the one that has perhaps most clearly crystallised the problems. Undoubtedly, one of the primary objectives of public policy is to guarantee that patients have access to reasonably priced medications. One could even argue that governments have a responsibility to give such access in light of the Declaration of Universal Human Rights, which recognises a right to healthcare. As mentioned before, intellectual property rights are meant to balance private interests (such as incentives and rewards for inventors) with public ones (such as research and innovation, economic growth, and prosperity). If the economy is to be “embedded,” the balance will have to be “right”, and this amounts to saying that the competing functional imperatives implied in IPRs have to relativize one another. The TRIPS Agreement was also created as a compromise construction where the protection of private interests is expected to be compatible with and, in fact, supportive of public interests (health policy objectives). In general, patent law attempts to establish a compromise between private and public interests.

The Research paper will deliberate upon the interaction between patents and access to medicines and whether the current international IP system can be seen as a barrier to innovation and access to essential medicines and must be revised if one is to cope with negative impacts of patents on access to medicines. It also discusses if current IPR regime is an impediment to the access to the essential medicines, what could be the measures to mitigate or avoid negative impacts of patents on the access to medicines by taking recourse to short term or long term measures.

Research Methodology

A non-structured narrative review of the evidence addressing interaction between Intellectual property rights and access to essential medicines and innovation was conducted. Non-systematic reviews are crucial for addressing a topic in broader contexts, even though systematic reviews are prioritised higher in the hierarchy of evidence-based public health when it comes to addressing particular research issues. The purpose of choosing a narrative review for this study is to summarise what has already been written on the subject and look for new, unexplored study areas. To find relevant papers, the literature databases PubMed (MEDLINE), Scopus, and Google scholar were searched without regard to the publication date or the location of the works. Additional gray literature and scholarly materials, including working papers, dissertations, and book sections, were manually searched using institutional websites, Google Scholar, and snowballing through review of references in the identified publications. Full information on All publications that reported results from an original quantitative or qualitative research study on the impact of IP regime on the access to medicines were included

An Intersection between Public Health and Intellectual Property Rights during Covid-19 Pandemic.

The right to health is a fundamental and universal human right. One key component of the right to health is access to medicines and health technologies.[1] It is widely accepted that intellectual property legal requirements such as patents can affect access to medicines[2]. Access to essential drugs has been adversely affected by the monopoly rights conferred by patent laws and regulatory exclusivities, particularly for poor patients in low-income nations.[3] The COVID-19 pandemic, which has taken millions of lives, has once again highlighted the need to address the tension between the right to health and IPRs.[4] Following the implementation of TRIPS regulations, the establishment of patents and pharmaceutical-related TRIPS-plus IP provisions are linked to an increase in drug prices, losses to consumer welfare, and higher prices for both pharmaceutical consumers and national governments.[5]

[1]Joe Chen, "Balancing Intellectual Property Rights and Public Health to Cope with the COVID-19 Pandemic", *eRepository @ Seton Hall* 3 (2021).
[2] Tenni, B., Moir, H.V.J., Townsend, B., "What is the impact of intellectual property rules on access to medicines? A systematic review", 18 *Global Health* 40 (2022).
[3] *Supra note* 1.
[4] *Ibid.*
[5] *Supra note* 2.

On one side are the pharmaceutical companies that research, develop, and manufacture treatments for a host of illnesses and diseases. The pharmaceutical industry often acts as a monolith and advocates for strict IP protections to safeguard patents and competitive secrets. Pharmaceutical companies tend to maximize profit margins by prioritizing developing treatments for medical issues that affect large demographics of people with the financial means to pay for treatment. On the other side are developing countries, also known as lower-middle-income countries ("LMICs"), with citizens who often cannot afford those pharmaceuticals. Strong intellectual property schemes are perceived as a substantial impediment to access to drugs that their citizens badly require in these countries. Most citizens in these LMICs cannot afford to pay hundreds of dollars for a patented drug, nor can these countries subsidise such therapies effectively to safeguard all, or even a majority, of their citizens.[6] This changed in 1995, when the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS') came into effect, requiring all WTO members to extend patent protection to all forms of technologies, including medicines. These new international norms, together with bilateral treaties that provide protection even further, as well as patent-related initiatives by pharmaceutical corporations aimed at 'evergreening' their market monopoly, are all contributing to the increased protection.[7] Since TRIPS' implementation, much of literature on the international framework and its policy implications has centred on the "Doha Declaration on the TRIPS Agreement and Public Health," which was endorsed by the WTO Ministerial Conference in 2001. The Doha Declaration actually made no changes to the TRIPS Agreement; it is merely a seven-paragraph declaration that confirms what was already in TRIPS. However, the Doha Declaration attempted to ease the use of flexibilities by refining the regulations and removing ambiguity about what procedures were permitted under TRIPS, and most crucially, by emphasising governments' rights to implement their new international IP responsibilities in health-supportive ways. The Doha Declaration was a following agreement that addressed specific issues of nations with insufficient manufacturing capabilities by addressing the circumstances under which drugs might be transferred from patent-holding countries to explicitly specified countries.[8]

Given the context, this section of the research paper will argue that, while patents can impose

[6] Arjun Padmanabhan, "Coronavirus, Compulsory Licensing, and Collaboration: Analyzing the 2020 Global Vaccine Response with 20/20 Hindsight", *Texas A&M Law Scholarship* 776-108 (2021).

[7] Olga Gurgula and Wen H Lee, "COVID-19, IP and access: Will the current system of medical innovation and access to medicines meet global expectations? ", 17(2) *Journal of Generic Medicines* 61–70(2021).

[8] Chorev, Nitsan and Shadlen, Kenneth C, "Intellectual property, access to medicines, and health: new research horizons", 50 (2), Studies in Comparative International Development 143-156 (2015).

significant impediments to universal access to generic COVID-19 medicines, the TRIPS system is an essential component of an equitable global solution to the pandemic.[9] The analysis in the paper is both positive and normative. The multidisciplinary methodology used can expand a theoretical and comparative study of this type by assisting in the development of better regulations in day-to-day law policymaking. On the one side, there are arguments that patents grant patent holders exclusive monopoly rights, providing barriers to access to medicines and the development of covid-19 vaccines. However, there is evidence that the TRIPS Agreement is not an insurmountable barrier to acquiring an effective COVID19 vaccination. The paper attempts to answer both questions by analysing relevant literature. Although there is evidence that TRIPS flexibilities can help with access to medicines, their use is restricted and their implementation can be challenging - they cannot alone be a panacea to IP provisions that increase monopolies. They can, however, provide countries with some flexibility and bargaining power with pharmaceutical companies when it comes to determining access and pricing in national markets. The same can be claimed for several national measures aimed at increasing access to low-cost generic pharmaceuticals. Intellectual property rules do not work independently of social, political, and economic circumstances, whether at the local or global levels. They interact, in particular, with a variety of other legislation that are likely to effect access to medicines in a specific jurisdiction. [10]

The Doha Declaration, a historic WTO declaration adopted in 2001, restated the TRIPS aims and principles as recommendations for applying TRIPS provisions in accordance with public health policy. The Doha Declaration provides a set of flexibilities within the TRIPS legal framework.[11] One of such flexibilities is compulsory licensing. Compulsory licencing is when the government permits someone else to produce a patented product or process without the approval of the patent owner, or when the government intends to exploit the patent-protected invention itself. Specific scenarios under which compulsory licences may be given are specified in each patent system's law and differ between systems. A compulsory licence may be granted in the following circumstances: failure to work in the territory of the patent for an extended period of time, inventions funded by the government, failure or inability of a patentee to meet a demand for a patented product, and where refusal to grant a licence results in the inability to exploit an important technological advance or a further patent. TRIPs also

[9] *Supra note* 6.
[10] *Supra note* 5.
[11] The Doha Declaration on TRIPS and Public Health, 2001.

states that in certain circumstances, such as a national emergency or extraordinary urgency, or in cases of public non-commercial usage, the criteria for a compulsory licence may be removed. Article 31.f of TRIPS requires that compulsory licenses be used "predominantly" for local markets, a requirement that complicates the ability of countries to import drugs manufactured overseas.[12] Compulsory licences are not a long-term sustainable answer to the problem of ensuring universal access to medicines since they gradually undermine long-term incentives for R&D. Nonetheless, by reducing exclusivity, such licences stimulate competition among generic drug makers, resulting in drastically cheaper short-term prices for certain treatments.[13] In various empirical studies conducted, researchers have found no uniform decline in innovation by companies affected by compulsory licences and very little evidence of a negative impact on their innovation activity[14]. Additionally, corporations may choose not to file a patent for a successful vaccine and/or manufacturing process in order to avoid having to reveal how the specific invention works in precise terms.[15] Thus, due to unique circumstances posed by the COVID-19, the motivations behind a patent holder to enforce its patent might not be as significant as compared to more orthodox circumstances.[16]

Coming to the second preposition that publicly advocated change or even abolition of the current patent law regime under serious information asymmetries, might prove to be counterproductive and distortive. Namely, the greater the uncertainty, the greater the cost of giving up the option of waiting; and the greater the expected value of the law over time, the greater the value of waiting. Of course, one may regard the COVID-19 pandemic as a necessary stressor for achieving the resilience and antifragility of the IP law.[17]

The current vaccination race, in which over 200 companies are competing to find a vaccine, may also be taken as circumstantial evidence that today's IP regime should not be viewed as an impediment to vaccination innovation. Specifically, the current rapid rate of medical research on COVID19, which far outpaces that seen in any previous epidemic, may imply that the earlier vaccine R&D' failures' in

[12] The Agreement on Trade-Related aspects of Intellectual Property Rights, 1994, art. 31.f.
[13] Thana c. De Cmpos-rudinsky, "Intellectual property and essential medicines in the COVID-19 pandemic", International *Affairs* (2021).
[14] Chien Colleen, "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation" 18 *BTLJ* 853 (2003).
[15] Benjamin Tham, and Mark James Findlay, "COVID-19 Vaccine Research, Development, Regulation and Access", *ZBW* (2020), available at: <https://ssrn.com/abstract=3640153>
[16] Chorev, Nitsan and Shadlen, Kenneth C, "Intellectual property, access to medicines, and health: new research horizons", 50 (2), Studies in Comparative International Development 143-156 (2015).
[17] *Ibid.*

the Ebola, Zika, SARS, and MERS epidemics were driven by the relatively small demand for such vaccines (and thus were not due to an insufficient IP-incentive stream) —the demand side, not the supply side of the market problem. The earlier epidemics infected a very small number of people and were also successfully contained before they became a global pandemic. In these circumstances, low-cost containment measures appeared to be more effective than extensive R&D vaccine expenditures. As a result, the low rate of vaccine R&D expenditure observed in the Ebola, Zika, and H1N1 outbreaks may not be due to extremely exclusive property like protection, as frequently suggested in the literature, but may be a manifestation of restricted demand and rapid containment.[18]

Obstacles to vaccine research and commercialization (and thus public availability) may not be caused by flaws in current IP legislation, but rather by potential deficiencies or defects in regulatory authorities. Namely, policymakers and vaccine-approving authorities might be prone to 'type I and type II errors'[19]. For example, a vaccine-approving authority can make two types of error: (a) type I error —approving vaccines that are too dangerous to be put in the market (sanction negligence criterion); or (b) type II error—not approving drugs that should be allowed (sanction gross negligence criterion). Consequently, a vaccine- approving authority might play it on the safe side and approve too little (type I error) and too late/too much (type II error). Literature suggest that, for example, the drug approval system might put enormous stress on Type I errors and largely ignores Type II errors, thereby raising the cost of drug testing and delaying the availability of safe and effective drugs.[20] Hence, a more balanced set of regulatory vaccine approval standards, accounting for the consequences of both Type I and Type II errors, could result in reducing high costs and long delays of introducing new vaccines and could also lower the costs of clinical testing.[21]

Second, substantial social costs arising from COVID-19 might have been avoided with proper ex ante investments in infectious disease basic/fundamental research (a traditional public good) if earlier

[18] Mitja Kovac and Lana Rakovec, "The COVID-19 pandemic and long-term incentives for developing vaccines: Patent law under stress", *25, J World Intellect Prop.* 292-316 (2022).
[19] Type I error, also known as a 'false positive', is the error of rejecting a null hypothesis when it is actually true. In other words, this is the error of accepting an alternative hypothesis (the real hypothesis of interest) when the results can be attributed to chance. Plainly speaking, it occurs when we are observing a difference when in truth there is none (more specifically, no statistically significant difference). Type II error, also known as a 'false negative', is the error of not rejecting a null hypothesis when the alternative hypothesis is the true state of nature. Namely, this is the error of failing to accept an alternative hypothesis when you do not have adequate justification. Put simply, it occurs when we fail to observe a difference when in truth one exists.
[20] See https://escholarship.org/uc/item/5fg9n284 (Visited on August 13, 2023).
[21] *Supra note* 17.

coronavirus vaccine research had not been shut down due to a lack of funding.[22]

Thus, contemporary shortages of existing life-saving treatments—more precisely, shortages of both medicines and some of their active pharmaceutical ingredients—are the result of a rapid surge in demand for these drugs during the COVID-19 epidemic, rather than patent protection. This means that patents are not directly responsible for either the existing shortages of essential drugs or the current disruptions in global pharmaceutical supply chains. If this is the case, then the most immediate remedy to the COVID-19 disaster would clearly be the rapid expansion of manufacturing capacity for critical life-saving and life-sustaining pharmaceuticals, paired with a reform of global drug supply chains.[23]

Proposals to Address Future Pandemics

While the strategies identified above may provide a short-term solution for inexpensive access to specific COVID-19 treatments, they will not fix the overall access problem. This unprecedented global epidemic is the outcome of a global market failure that requires immediate intervention. To prevent the worldwide problem of access to COVID-19 treatments and to prepare for future pandemics, the current system must undergo radical modifications. There are several alternatives for making such adjustments available today. These include, for example, state-coordinated research and manufacture of pandemic-fighting drugs, as well as the development of a new open-access model.[24]

The first approach simply implies that the state should adopt the function and duty for health-related threats such as pandemics. A complete infrastructure should be established to cover both the research and manufacture of medications required for health security.[25] Therefore, the establishment of new specifically designated research centres to investigate and prepare for new pandemics, and setting up the infrastructures for the development and manufacture of medicines by countries, may help to reduce the risks of new pandemics.[26]

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[22] *Ibid.*
[23] Thana c. De Cmpos-rudinsky, "Intellectual property and essential medicines in the COVID-19 pandemic", International *Affairs* (2021).
[24] Olga Gurgula and Wen H Lee, "COVID-19, IP and access: Will the current system of medical innovation and access to medicines meet global expectations? ", 17(2) *Journal of Generic Medicines* 61–70(2021).
[25] Brown D. Medicine for all: the case for a public option in the pharmaceutical industry. The next system project, available at: https://thenextsystem.org/medicineforall (visited on August 10, 2023).
[26] *Supra note* 24.

Another approach is to establish an open innovation system in which access to information, data, and technology is openly available. 'While innovation is vital, the traditional process of managing innovation does not appear to function any longer'. Chesbrough articulated this viewpoint about 20 years ago, and it is still applicable today. He highlighted that the old paradigm of innovation was based on the closed model, in which corporations generated their own ideas, developed, built, marketed, and financed them.[27] One of the model's implicit criteria is that "we should control our IP so that our competitors do not profit from our ideas." He further argued that this paradigm generated a 'virtuous circle' in which corporations invested in R&D, which led to discoveries, increased revenues, which were then spent back into internal R&D. Because intellectual property was zealously safeguarded, others could not profit from it. According to Chesbrough, this paradigm, which worked for the majority of the twentieth century, has become unsustainable in the twenty-first century, and the pharmaceutical industry is realising that the closed model of innovation in this field is no longer viable. Pharmaceutical companies are increasingly turning to external sources of innovation.[28] Pharmaceutical companies have established collaborations with academic centres of excellence, built innovation centres, formed joint ventures with academic institutions (public-private partnerships), formed precompetitive consortia, or experimented with crowdsourcing and virtual R&D, in recent years. Despite the enormous promise that the open innovation model holds in this field, the pharmaceutical industry has been cautious to use it. One of the primary reasons is that this will necessitate adjustments to their old techniques, as well as the fear of losing control of their precious intellectual property assets. This system, which is based on the closed (or semi-closed) model of innovation that relies on strong IP protection and has already proven to be ineffective in the past, poses a risk to humanity by preventing researchers from accessing valuable information about COVID-19 therapeutics that is currently being generated in hundreds of laboratories around the world. The open innovation approach, if implemented, would minimise "the fragmentation of knowledge that is inherent in the IP-driven pharma industry" and allow for the free flow of information, allowing for more efficient use of resources and speedier development of medications, including for COVID-19.

The COVID- 19 pandemic has caused “the most severe contraction of the global economy since

[27] Henry W. Chesbrough, “*Open Innovation: The New Imperative for Creating and Profiting from Technology*”, (Harvard Business School Press, Boston, Massachusetts,2003).
[28] Schuhmacher A, Gassmann O, McCracken N, “Open innovation and external sources of innovation. An opportunity to fuel the R&D pipeline and enhance decision making?”, 2 *J Transl Med* 119 (2018).

World War II," with a resultant "terrible impact on the poorest and emerging economies."[29] Because this is a worldwide pandemic, the reaction must be global as well. Inter-national cooperation is essential for resolving the problem as quickly as possible by ensuring that all countries have access to the vaccine. However, while global access to the vaccine may resolve this particular pandemic, it does not safeguard the globe from being held captive by the next global health disaster.[30]

Below are the four proposals aimed at improving international collaboration and vaccine distribution for this and future pandemics:

1. establishing a Trilateral council to enforce TRIPS obligatory licencing clauses,
2. reimbursing R&D costs retrospectively,
3. rewarding voluntary licencing as an alternative to compulsory licencing, and
4. enhancing competitiveness through non-exclusive voluntary licences.

Although the TRIPS Agreement contains guidelines for dealing with emergencies, none of them specify how to construct a global response to a global health calamity such as COVID-19. Individual countries and alliances must consequently decide how to best work together to counter the threat. This strategy is weak, because the lack of clear standards and guidelines leads to countries dealing with the threat in their individual ways rather than as a global collective. As a result, it is critical that the WHO collaborate with other intergovernmental organisations to establish a governing body capable of dealing with global crises and coordinating a coordinated response to them.31 While the TRIPS Agreement provides the groundwork for compulsory licencing measures that can aid the world during global health crises, the WHO lacks a regulatory authority that can effectively apply them when such crises occur. The Doha Declaration permits member states to make decisions on compulsory licencing while making no provisions to aid in the formation of international initiatives. The international community may mainly address this shortcoming by amending the TRIPS Agreement to create a body capable of acting and enforcing compulsory licencing clauses to gather research endeavours from around the world once a pandemic has been identified. COVAX and the ASEAN Special Summit are examples of ongoing initiatives that can serve as templates for a permanent body that achieves the same goal.

[29]See,https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc (Visited on August 13, 2023).
[30] *Supra Note* 6.
[31] The Agreement on Trade-Related aspects of Intellectual Property Rights, 1994.

Voluntary licencing is another alternative that, when properly leveraged, can achieve the same purpose as compulsory licences while avoiding most of the ill will associated with a government having to intervene and infringe on a citizen's property rights.[32] This can be achieved by:

1. Retroactive Remuneration of R&D Costs for Proportional Licensing Rights
2. Incentivize Voluntary Licensing as an Alternative to Compulsory Licensing
3. Increase Competition Through Non-Exclusive Voluntary Licenses

Conclusion:

Access to essential medicines is one component of the global health issue that confronts many developing countries. Many factors influence access to pharmaceuticals, including intellectual property rights (particularly patents). In this regard, there is broad agreement among representatives of the most varied organisations. The precise significance of patents, i.e. the extent to which they genuinely affect access to medicines, and whether such impact warrants (or necessitates) the change of current intellectual property systems, particularly the TRIPS agreement, are contentious questions. The assessment of the significance of IPRs has both a factual and a normative dimension. In the factual dimension crucial questions seems to be whether patents because they lead to higher prices will make essential medicines unaffordable for poor people. This paper contends that today's patent law framework and the TRIPS Agreement are not insurmountable barriers to the development of an effective COVID-19 vaccine. Promoting IP exchanges to collaborate against health crises such as COVID-19 should be the world's key goal in the future. Whether via encouraging voluntary licences, enforcing compulsory licences, or other means, global actors such as countries and commercial pharmaceutical developers must be prepared to engage in dialogue in order to share knowledge and information about treatment or cures. While it is impossible to predict when the next global pandemic will occur, there is one certainty: it will occur, and a swift, coordinated response will be required. Only by investigating and learning from the current plagues can we ensure the health of our future generations.

[32] Arjun Padmanabhan, "Coronavirus, Compulsory Licensing, and Collaboration: Analyzing the 2020 Global Vaccine Response with 20/20 Hindsight", *Texas A&M Law Scholarship* 776-108 (2021).