I P BULLETIN

Vol. III ISSUE 1 JAN-JUNE 2022, pp. 120-131

PATENTS AND INNOVATION IN PHARMACEUTICAL SECTOR: AN ANALYSIS IN THE COVID-19 CONTEXT

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ABSTRACT

Pharmaceutical innovation is not only related to human health, but also contributes to a country's overall strength in the field of life sciences. However, due to the high investment and unpredictability of success, pharmaceutical companies do not always pursue new drug research. Pharmaceutical innovation is intrinsically connected to the availability of incentives. Intellectual Property becomes a double-edged sword in pharmaceutical innovation. With regard to the current situation of global pandemic there exists many challenges to the access and global distribution of the vaccines predominantly for low and middle-income countries. IP rights more specifically patents have been blamed for being the major hindrance. Alternative manufacturers intending to develop, produce, and supply COVID-19 medical tools to enhance access face a legal labyrinth due to the vast portfolio of existing and emerging patents, non-patent IP, and other exclusivities. Monopoly rights provide MNCs with the power to decide the amount of access and affordability to people and also the power to control further innovation. Alternatively, the pharmaceutical industry claims that without ample IP protection there is no incentive to innovate and for further investment into R&D an ample profit should be gained. While at the instance of a global pandemic patent is in fact standing in the way of access to affordable treatment, taking away the patent rights all at once might do more harm than good.

Keywords: Patent, Pharmaceutical Innovation, COVID-19, Access, Affordability.

Introduction

The unquestionable impact of patents in spurring innovation is widely acknowledged. Nevertheless, it's crucial to recognize that there are certain scenarios where their influence can shift from being a positive driving factor to a potential impediment to innovation. While the

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role of intellectual property rights, particularly patents, in fostering creativity and innovation has remained steadfast over time, it is important to acknowledge that these rights have not been immune to critique. In certain contexts, such as the realm of healthcare, where progress, accessibility, and cost-effectiveness hold immense significance, patents have encountered censure for potentially impeding these vital aspects.

The historical track record of intellectual property rights, especially patents, in igniting the flames of inventive endeavors is well-documented. The assurance of exclusive rights and rewards has consistently acted as a driving force, encouraging individuals and organizations to channel their energies into groundbreaking solutions across a diverse array of industries.

However, this seemingly positive influence can become more complex when viewed within the intricate landscape of healthcare. While intellectual property rights are intended to safeguard innovations and encourage further development, they have come under scrutiny for their potential to hinder progress, particularly in scenarios where human well-being is at stake. This is particularly salient in the healthcare sector, where rapid advancements and unhindered access to life-saving treatments, medications, and technologies are of paramount importance. The concern lies in the potential of patents to create barriers that limit the availability of essential healthcare solutions. The need for swift and widespread distribution clashes with the exclusive nature of patent protection, potentially causing delays in the deployment of critical interventions. Furthermore, the issue of affordability arises, as the costs associated with patented medical advancements can render them inaccessible to a significant portion of the population, particularly in regions with limited resources.

Another facet of the debate centers on the dynamics of innovation within the healthcare sector. Patents, while incentivizing individual inventors and entities, can inadvertently lead to fragmented research efforts. The competition for intellectual property rights can result in duplicated research, inefficient resource allocation, and limited collaboration among researchers. Such fragmentation can hinder the collective progress required to tackle complex health challenges efficiently.

In light of these complexities, it becomes imperative to strike a delicate balance between the advantages of intellectual property rights and the broader societal interests, especially in critical sectors like healthcare. While patents undoubtedly serve as a driving force for innovation, they must be examined critically and adapted to align with the unique demands of sectors where accessibility, affordability, and rapid progress are essential. This involves reimagining patent systems that incentivize innovation while fostering an environment of collaboration and equitable access to healthcare advancements. By doing so, we can harness the positive potential of patents while mitigating the potential barriers they may pose to advancement, availability,

and cost-effectiveness, thus creating a more inclusive and impactful landscape for healthcare innovation.

The intricate interplay between patents and innovation stems from their dual roles as catalyst and limitation. On one hand, patents furnish inventors and innovators with the assurance of exclusivity over their novel creations, creating an environment where individuals and entities are motivated to invest their resources, time, and expertise in pioneering solutions. The alluring prospect of reaping rewards through the safeguarding of intellectual property rights serves as a potent driving force that propels innovation across diverse domains. However, this incentivizing effect can sometimes transform into a hindrance, particularly in critical sectors like healthcare. The healthcare arena, marked by its immediate impact on human well-being and the urgency to address public health concerns, introduces complexities that may clash with the conventional patent framework. While intellectual property rights effectively safeguard innovations, they can inadvertently lead to restricted access to life-saving treatments, medications, and technologies. The excessive costs linked to patented medical solutions can create barriers that curtail accessibility, consequently obstructing the widespread distribution of vital interventions to those who require them the most. Moreover, the intricate relationship between patents and healthcare innovation extends beyond financial considerations. The patent system can result in fragmented research endeavors, where duplicated efforts and limited exchange of information hinder collective advancement. This fragmentation can undermine collaborative approaches to tackling intricate health challenges, potentially causing delays in progress and impeding the swift development of solutions.

As we navigate the intricate landscape of intellectual property rights, it is imperative to strike a nuanced balance between fostering innovation and ensuring the broader societal benefit. While patents undeniably provide a mechanism to reward inventors and ignite imaginative thinking, they should be approached with a discerning viewpoint that takes into account their potential drawbacks. Particularly in the healthcare domain, the importance of accessibility, affordability, and timely interventions should guide conversations concerning patent protection. By nurturing an environment that encourages innovation while concurrently prioritizing equitable access to crucial healthcare solutions, we can chart a course towards a future where the affirmative potential of patents is harnessed while concurrently mitigating their prospective hindrances to progress.

In light of the current global pandemic crisis, there are numerous barriers with regard to access and global distribution of vaccines, predominantly for low and middle-income countries. There are two sides to the discussion regarding patent and innovation especially in the pharmaceutical sector. On one hand the broad array of existing and emerging patents, non-

patent IP, and other exclusivities creates a legal labyrinth for alternative manufacturers attempting to develop, produce, and supply COVID-19 medical tools to enhance access.[2] While on the other hand the pharmaceutical industry claims that without ample IP protection there is no incentive to innovate and also that for further investment into R&D an ample profit should be gained.

Patent as a Barrier

There is widespread concern that patents may stymie the swift development of vaccines and therapeutics for Covid -19, making it inaccessible and unaffordable to third-world countries. These concerns are not always unfounded. There are circumstances where the existences of patents block further innovation. The IP holders have utmost control over the distribution of vaccines, medications, and treatments, which they may withhold according to their discretion thereby limiting access to such vaccines and medicine. The major issue is that the companies who holds the IP rights to the vaccines sells the vaccines to such developed and middle-income countries leaving the low-income countries hopeless. The intellectual property rights allow firms to demand exorbitant prices and profit from the pandemic, or to prioritise wealthy countries over those with less financial capacity.[3]

The vaccine R&D and manufacturing is often concentrated in such developed and sometimes developing countries as well. The pharmaceutical industry argues that even in the absence of patent protection in the case of COVID-19, the developing and least developed countries will not be able to manufacture the required vaccines and drugs due to the lack of manufacturing capacity and hence they point out that patents are not the main impediment for access and affordability, manufacturing capacity is. It is of course true that patent is not the only barrier. As a counter argument to this, the Indian Representative pointed out in the TRIPS Council meeting pointed out that if the developing and least developed countries which doesn't have enough manufacturing capacity to produce the required vaccines and therapeutics protected by IP, then the interest of such IP holders will not suffer and hence, the argument of lack of manufacturing capacity doesn't make sense.

The pharmaceutical companies state the example where even after Moderna announced that it will not exercise its patent rights, no other firm has manufactured the vaccine to show that patent protection might not be a barrier after all. In this particular case the mRNA technology used by Moderna to manufacture the vaccine is protected by numerous patents. Moderna has

[2] MSF, *Removing Intellectual-Property Barriers from COVID-19 Vaccines and Treatments for People in South Africa*, March 2022.

[3] Council for Trade-Related Aspects of Intellectual Property Rights, *Examples of IP Issues and Barriers in Covid-19 - Pandemic Communication from South Africa* (WTO, 23 November 2020).

stated that they will not enforce their patent rights in relation to the vaccine but will do so in relation to the surrounding patents, and they are also hesitant to licence it out.[4]

Examples of IP being a barrier and hindering development, production and supply -

a. Therapeutics:

Gilead Sciences signed a restrictive voluntary licence on its Remdesivir by excluding around half the world population.[5] The licence was with five generic manufacturers to enable more production and distribution of Remdesivir, an experimental treatment for COVID-19. The licence permitted the five generic producers to sell the drug in certain countries, but more than 70 countries were excluded. This meant that these 70 countries which were excluded would have to buy the medicine from Gilead at its monopoly pricing, and they would be blocked from accessing the generic version until 2031. Some other monoclonal antibodies like sarilumab and tocilizumab that are being tested for its potential to treat COVID-19 are under patent protection in many countries, this means that even if such antibodies show efficacy, the access to it might be challenging.[6]

b. Vaccines

Allele Biotech sued Regeneron, Pfizer and BioNTech for the patent infringement of the mNeonGreen fluorescent protein it used to develop COVID-19 vaccine. The alleged infringement was that that Pfizer and BioNTech for its COVID-19 vaccine BNT162 and Regeneron for its REGN-COV2 used the above-mentioned fluorescent protein without Allele's permission. These fluorescent proteins which is one of the most stable and brightest ones are utilised to view the molecular changes in order to comprehend the cell's response to therapies.[7]

Testing kit reagents [8]

Another example is that of the testing kit reagents. Roche provides testing kit reagents which is used as the buffer for running COVID-19 tests. Many COVID-19 labs in Netherlands which uses this testing kit reagent was not able to conduct mass COVID-19 tests during the initial stages of the pandemic due to the buffer shortage. Roche's refusal to make available the recipe for the buffer blocked the labs from manufacturing their own buffer and thereby increasing the

[4] Sudip Chaudhuri, "Patent Protection and Access to COVID-19 Medical Products in Developing Countries" *SSRN Electronic Journal* (2021).
[5] "Remdesivir Should Be in the Public Domain; Gilead's Licensing Deal Picks Winners and Losers," *Public Citizen*, 12 May 2020.
[6] MSF, *Proposal for a TRIPS Waiver from Intellectual Property Protections for COVID-19-Related Medicines, Vaccines, Diagnostics and Other Health Technologies*, 27 May 2021.
[7] Angus Liu, "Pfizer-BioNTech, Regeneron sued for patent infringement with COVID-19 products" *FiercePharma*, 6 October 2020.
[8] Supra 6.

testing capability. Later on, due to the pressure from the government the company had to agree to release the recipe.

N95 respirators[9]

There has been a shortage of N95 respirators, a type of protective mask which is protected by several patents held by the multinational company 3M, other healthcare companies, the US government and universities. The Governor of Kentucky in the United States called upon the 3M Company in early 2020 to release the patents to avoid the shortage. IP obstacles, such as patents, have intensified shortages of N95 respirators in hospital around the world.

From the above example it is quite clear that even though IP is not the only factor that might be a barrier to access and affordability as well as innovation, it most certainly plays a huge role as a block. An environment with no patent obstacles and no threat of lawsuit is more encouraging to product development and manufacturing.[10]

Patent - Not a Barrier

There are various factors that leads to innovation and similarly there are various factors that might affect access, affordability and innovation. Lack of manufacturing capacity, import duties, lack of infrastructure, stringent laws, in this case IP laws, are some of the factors that acts as a barrier to access, affordability and innovation.

Providing protection to innovations and later at the expiry of the term disclosing it to the world is a way to kindle people's creativity. According to Mansfield's (1986) study it was concluded that without a patent system 60% of medical inventions could not have been developed and 65% could not have been commercially introduced.

Because of the vaccine industry's inherent vulnerability due to the uncertain outcomes of clinical trials, changes in epidemiology, and a variety of other factors, intellectual property rights, patents in particular have long been regarded as a guarantee of return on R&D investment, but that too only if the vaccine is proven successful.[11] In the absence of patent protection, the problem of free riders arise and their incentive to invest in the filed decreases. The innovation ecosystem is not as simple as it seems; it encompasses several actors, policies, initiatives, and programmes. The Global Innovation Index, for example, uses over 80 indicators to measure innovation capacity and performance, covering areas such as educational systems and institutions, research and development expenditure, scientific publications, IP applications,

[9] Id.
[10] Supra 4.
[11] Van Anh Le and Leah Samson, "Are IPRs and Patents the Real Barriers to COVID-19 Vaccine Supplies?," 18 *SSRN Electronic Journal* (2021).

access to capital markets, regulatory frameworks and business and market sophistication.[12] When there are so many factors involved it would be a misjudgement to emphasis on a single factor, that is, IP alone.

When the innovation provides effective results and if the people are not able to get their hands on it on affordable terms, in such cases patents acts a barrier.[13] The chances that absence of patent protection disincentivising pharmaceutical industry is high. It will also lead to a rise in counterfeit products. Counterfeit products in the health sector can be quite dangerous. The WHO has determined that counterfeiting is facilitated where "[…] there is lack of effective intellectual property protection".[14] There have been examples in Cameroon and Uganda where fake Covid-related treatment has been found.[15]

Often the argument of tragedy of common goods are also taken to support the patent system. The tragedy of common goods is a circumstance in which a person who has access to shared resources (common) will act purely in their own interests, resulting in resource depletion. When the patent protection is removed and when the goods come to the public domain and not properly allocated, this will result in the ripple effect of the tragedy of common goods.

The TRIPS waiver proposal was a cry for a complete waiver of all IP rights relating to COVID-19 which has the potential of backfiring on the society if as a result of it the patent holders decided to halt their current researches. Suspension of IP rights altogether need not necessarily result in speedy innovation and manufacture of vaccines and therapeutics.

Rajinder Suri, the Chief Executive Officer of Developing Countries Vaccine Manufactures Network (DCVMN) and Sai Prasad, the President of Bharat Biotech, an Indian vaccine manufacturer opined that removing IP Rights would not solve vaccine production concerns since practical issues lay in non-IP aspects such as manufacturing capacity, human resources, and know-how.[16]

The Max Planck Institute for Innovation and Competition in their recent position statement also endorses the view that "IP rights might so far have played an enabling and facilitating rather than hindering role in overcoming Covid-19, and that the global community might not be better off by waiving IP rights, neither during nor after the pandemic".[17]

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[12] Francis Gurry, "Some Considerations on Intellectual Property, Innovation, Access and COVID-19" *WIPO*, 2020*available at*: https://www.wipo.int/about-wipo/en/dg_gurry/news/2020/news_0025.html (last visited March 13, 2023).

[13] Francis Gurry, "Intellectual Property, Innovation, Access and COVID-19" *WIPO*, 2020*available at*: https://www.wipo.int/wipo_magazine/en/2020/02/article_0002.html (last visited March 6, 2023).

[14] WHO, *Counterfeit Drugs: Report of a WHO/IFPMA Workshop WHO IRIS*, 1992.

[15] Marius Schneider and Nora Ho Tu Nam, "Africa and counterfeit pharmaceuticals in the times of COVID- 19," 15 *Journal of Intellectual Property Law & Practice* 417–8 (2020).

[16] Supra 11.

[17] Reto M. Hilty et al., *Covid-19 and the Role of Intellectual Property - Position Statement of the Max Planck Institute for Innovation and Competition*, 7 May 2021.

In circumstances where patent holders refuse to license their intellectual property and when such refusal cannot be justified on objective grounds, such issues can be resolved by using available remedies like compulsory license for example, instead of holding all right holders. There is without a doubt a risk of excessive pricing and hence the issue access to vaccines but nothing which cannot be addressed by proper government interference.

Absence of IP rights might push the research institutes to abandon their researches. In the case of COVID-19 with the emerging new variants, such a situation will expose the humanity to mutated viruses without a solution to battle it. This shows that intellectual property is, in reality, a promoter of future breakthrough innovations, which in this case may even help rescue mankind. Lack of Intellectual rights may not be in the best interests of today's society, as it may function as a deterrent for researchers and pharmaceutical firms to do more research.

The treatments currently available for COVID-19 are based on researches and technologies of the past which was the result of the proper IP protection then. Even with researches willing to invest and face the risk, these technologies took decades to be developed. Given the circumstances, IP may be considered as the base on which the COVID-19 vaccine has been developed. The swift establishment of various partnerships surrounding COVID-19 was a result of the IP system where even the commercial rivals were ready to cooperate and share capital and intellectual resources.[18] It can be said that proper IP protection encourages the researchers and makes them comfortable to collaborate and share their knowledge and know how without the fear of free rider issues by ensuring that the information they shared will only be used for the agreed purposes.

When the patent rights and information are out in the public domain it helps the drug developers to fish out those players with the knowledge and technical expertise preferred by them. Equating the term "monopoly" to patent according to Prof. Edmund Kitch is one of the "elementary and persistent errors in the economic analysis of Intellectual Property", when in reality IP rights result in competing products in the market and thereby putting a cap on the ability of the manufacturers of the products to charge arbitrary and unaffordable prices.[19]

The polio vaccine model [20]

The polio vaccine model is an example quoted by those who argues against IP rights during

[18] Philip Stevens and Mark Schultz, "Why intellectual property rights matter for COVID-19 - Geneva Network - Intellectual Property Rights and Covid-19" *Geneva Network*, 2021*available at*: https://geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/ (last visited March 8, 2023).

[19] *Ibid.*

[20] Ami Neuberger and Ilan Noy, "The big barriers to global vaccination: patent rights, national self-interest and the wealth gap" *The Conversation*, 2021*available at*: https://theconversation.com/the-big-barriers-to-global-vaccination-patent-rights-national-self-interest-and-the-wealth-gap-153443 (last visited March 9, 2023).

the pandemic. The polio vaccine which took around 15 years to be developed by Jonas Salk in 1955 was not patented by its inventor. The decision for the inventor to not patent the vaccine was to maximise its distribution. Several philanthropic donations were used to support polio vaccine development, and the endeavour was communal, which was trialed largely by volunteers.

The National Foundation for Infantile Paralysis looked into patenting the polio vaccine but concluded that it couldn't be patented due to prior art and that it would not have been considered a patentable invention by standards of the day. Given all the facts and circumstances the polio vaccine model cannot be used in the current pandemic context as the polio vaccine was developed in around 15 years whereas the pandemic situation is fairly new and also the vaccine development which is mainly done by big pharmaceutical companies focus more on profit than on philanthropic goals.

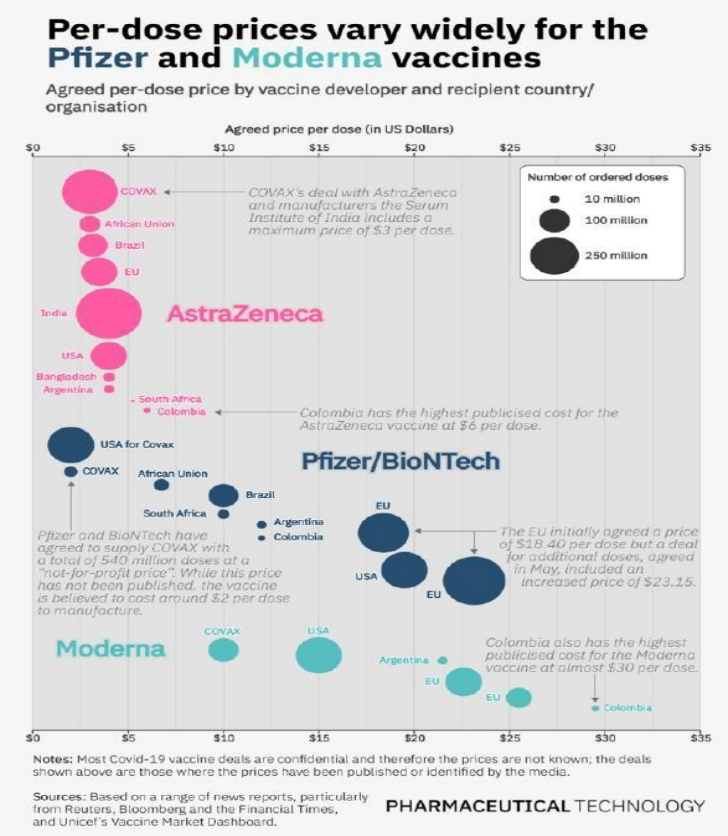
Pricing

The temporary monopoly rights that is granted to the patent holders gives them the power of pricing as well. In many countries the citizens do not have to pay for the vaccines but the government acquires these vaccines from the companies at a price which is sometime unaffordable to developing and least developed country governments. The companies sell the vaccines to the developed countries at a lesser cost than they sell it to developing and least developed countries. The reason for this might be the involvement of the developed countries in the research of vaccines.

Based on computational process modelling, the expert analysts estimate that setting up regional hubs to transfer the successful technology and manufacture 8 billion doses of the mRNA vaccines in one year would cost $22.8 billion for the Moderna vaccine ($2.85 per dose), and $9.4 billion for the Pfizer/BioNTech vaccine ($1.18 per dose).[21]

The below figure shows the price various countries had to pay for obtaining vaccines from AstraZeneca, Pfizer, BioNTech and Moderna and the estimated number of ordered doses. The price that various countries paid are drastically different, for example, in the case of Moderna wherein US had to pay around $15 dollars for a dose of vaccine whereas Columbia had to pay almost $30 dollars that is twice the amount US paid.

[21] Zoltan Kis and Zain Rizvi, "How to Make Enough Vaccine for the World in One Year" *Public Citizen*, 2021*available at*: https://www.citizen.org/article/how-to-make-enough-vaccine-for-the-world-in-one-year/ (last visited February 26, 2023).



There might be various causes for this price discrepancy, including as a country's participation and investment in vaccine research and development, which could lower the price for them. The issue is that developing and least developed countries may lack the necessary capital and technology to fund R&D. As a result, the condition of affairs in such nations must be taken into account while determining the price for them.

Conclusion

The question to be asked is whether suspension of patent rights will act as a disincentive for the development of new innovations in this case, medical products? Stimulating R&D for innovation is the key economic justification for granting patents which is the anticipated outcome. But, when the aforementioned patents begin to prevent others from producing such a product, as in the instance of COVID - 19, the number of individuals who profit from the invention decreases, which is a negative outcome.

One of the most prominent complaints regarding suspending patent and other intellectual property protection in the context of COVID-19 vaccines and therapeutics is that it would jeopardize future medical advancements and leave us vulnerable to other diseases if the firms stopped research and innovation due to the lack of incentive to innovate. Innovation in pharmaceutical industry is risky and quite expensive, in such a case the lack of incentive and without the power to set the prices so as to gain profit, the pharmaceutical firms may not find

it practical to spend on R&D for new drugs. The argument against this is that the current vaccines and therapeutics is not the result of the investment and the research the pharmaceutical companies alone, public funding and global collaborations between various research institutions and the pharmaceutical industry had a huge role in the sift development of the vaccines.

Patent protection does have its advantages and disadvantages. It is a commonly held belief that patent protection serves as a significant catalyst for fostering innovation within various industries. This mechanism provides inventors and creators with a safeguard, assuring them of exclusive rights to their inventions for a specified period. This exclusivity, in turn, incentivizes investment in research and development, as individuals and companies strive to create groundbreaking solutions that can be patented, thereby reaping the benefits of their ingenuity. However, the dynamics surrounding patent protection become more complex when viewed through the lens of extraordinary circumstances, such as a global pandemic. In such dire situations, where rapid and widespread access to life-saving innovations is of paramount importance, the traditional emphasis on exclusive rights and commercial gains may warrant reconsideration.

A pandemic, characterized by its swift and extensive impact on public health, necessitates a different set of priorities. The availability and affordability of essential medical treatments, vaccines, and technologies take precedence over conventional notions of intellectual property rights. The urgency to mitigate the widespread suffering and loss of life requires collaborative efforts, rapid information sharing, and unfettered access to vital resources. Patent protection, while crucial in ordinary times, can inadvertently impede progress in a pandemic scenario. By limiting the dissemination of critical knowledge and hindering the widespread production of necessary medical interventions, patents can inadvertently prolong the time it takes for solutions to reach those in need. This delay can be particularly detrimental when time is of the essence and countless lives are at stake.

Furthermore, the ethics of prioritizing profit over human well-being come into question during a pandemic. The patent system, designed to incentivize innovation through financial gain, may clash with the moral imperative to ensure that life-saving interventions are promptly accessible to all, regardless of their economic or geographical circumstances.

In essence, while patent protection undeniably fuels innovation in ordinary times, its limitations become glaringly evident when faced with a global crisis like a pandemic. The crisis underscores the need for a nuanced and adaptable approach to intellectual property rights, one that balances innovation incentives with the immediate and widespread well-being of humanity. As we navigate the complexities of the modern world, it becomes essential to

reevaluate and perhaps even adjust our perspectives on patents to better align with the collective good, especially when availability and affordability stand as crucial cornerstones in the face of unprecedented challenges.

Innovations therein can be incentivised via patent alternatives with lesser importance to patent but not wiping it off altogether. To fix the innovation, access and affordability issues for COVID-19, the pharmaceutical monopoly on vaccines and therapeutics should be broken and thereby the technology and know-how should be transferred to more manufacturers in developing and least developed countries.[22] This might result in increase of supply and decrease in price. It is obvious that patents grant firms monopolistic rights, which they utilise to control prices. The monopoly rights provide such multi-national corporations the power to decide how much access and affordability individuals have, as well as the capacity to restrict future innovation. During a pandemic, such power in the hands of profit-hungry MNCs would do no benefit to the people or the global health. Taking away the patent rights all at once might do more harm than good. Patent alone cannot work for better and faster innovation, access and affordability. Patent rights can be made less stringent and patent alternatives may be introduced to work alongside patents.

In conclusion we can say that IP in particular patent is both facilitator and a barrier and hence a complete absence of it altogether might not be ideal. At the instance of a global pandemic patent is in fact standing in the way of access to affordable treatment.

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[22] Anna Marriott and Alex Maitland, *Policy Brief - the Great Vaccine Robbery,* 29 July 2021.