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Resolved: Equitable Access to Pharmaceuticals Should be prioritized over Protecting Intellectual Property Rights

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I. INTRODUCTION

With pandemics and chronic diseases affecting many, the question of how to ensure access to essential pharmaceuticals, not only becomes a legal debt, but also an important moral imperative. As many international agreements like the TRIPS agreement, and historical health crises demonstrate, all this is a matter of global ethics. By examining the moral obligations enshrined in documents like the Universal Declaration of Human Rights, the limitations of patents, and the lifesaving impact of equitable health access, it is imperative that the right to health must take precedence over IP rights.

II. DEFINING TERMS AND BURDENS

In order to discuss the resolution properly, the affirmative will define a few key terms.

The right to health is an inclusive right, extending not only to timely and appropriate health care, but also to the underlying determinants of health, such as access to safe and potable water and adequate sanitation, healthy occupational and environmental conditions, and access to health-related education and information.

Equitable access refers to ensuring that all individuals, regardless of socio-economic status, geography, gender, race, or nationality, have fair access to life-saving medicines. However, this does not imply equal access,which would mean the same level of access for everyone. Instead, equity recognizes that those facing greater health challenges or with limited resources require greater support to meet their healthcare needs.

As per The World Intellectual Property Organization(WIPO), Intellectual property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names, and images used in commerce.

A generic drug is a prescription drug that has the same active-ingredient formula as a brand-name drug. Generic drugs usually cost less than brand-name drugs. The Food and Drug Administration (FDA) rates these drugs to be as safe and effective as brand-name drugs.

Public health emergency is defined as an urgent situation in which the health status of an area within the territory is adversely affected. It includes localized outbreaks of an infectious disease or a potential outbreak of an infectious disease that has a reasonable possibility of occurring and that poses a significant threat to a community or region in the territory.

"*Prioritizing"* equitable access, here, implies that public health and human well-being are given more importance over profits or exclusive control that companies may have over drug patents. It does not imply that intellectual property rights are discarded entirely. Instead, it means that when the two goals—public health and IP protections—are in tension, public health concerns should take precedence.

"*Protecting"* intellectual property rights, in this debate, refers to the enforcement of legal measures that ensure the creators or patent holders of pharmaceuticals maintain exclusive rights to produce, sell, or distribute their products. This protection is considered paramount; however, it often comes at the expense of public health, as it creates monopolies that prioritize profit over accessibility, restricting the availability of essential medications for those in need.

The affirmative burden is to prove that equitable access to pharmaceuticals is a moral and legal imperative that should outweigh the protection of IP rights. Grounded in international humanitarian frameworks, equitable access is a fundamental right. When patent laws hinder access to life-saving treatments, they violate this fundamental right. Resultantly, by prioritizing equitable access, we are not just addressing a health issue but fulfilling a global moral obligation. Furthermore, the affirmative shall show that equitable access can also be achieved without completely dismantling the International patent frameworks, and also that human life and dignity must take precedence before commercial interests.

The negative burden is to support a system where intellectual property rights are given much more importance than access to life-saving medicines. They endorse a system where monopolies by pharmaceutical companies lead to unjustified high prices of life-saving drugs, reducing their access to people belonging to low-income groups. They must justify protecting companies' interests and profits out of the need to make treatments available to all, and that innovation should be preserved at the cost of public health.

III. MORAL OBLIGATION

Accessibility to healthcare is seen as a basic human right by various international and national organizations. In the Universal Declaration of Human Rights (UDHR), which was adopted in the UN General Assembly, Article 25(1) emphasizes health as a fundamental right. International Covenant on Economic, Social and Cultural Rights (ICESCR): Article 12(1) recognizes everyone's right to the highest attainable standard of physical and mental health and Article 12(2) mandates state parties to ensure access to health-related resources, including medicines and facilities. It is also conspicuously apparent that the World Health Organization recognizes Health as one of the first and foremost rights given to man. General Comment No. 14 was issued by the United Nations Committee on Economic, Social and Cultural Rights (CESCR), it interprets Article 12 of the ICESCR and stipulates that the right to health includes timely access to essential facilities, products, and services necessary for realizing health rights. States are obligated to take appropriate measures to ensure access to essential medicines and to create conditions that support public health.

As implied by the aforementioned prestigious organizations, the importance of healthcare includes providing access to equitable healthcare or at the bare minimum access to equitable pharmaceuticals. Some may believe that intellectual property rights of these pharmaceuticals are also a fundamental human right equal to rival the fundamentality of health as a right. We must understand which right of the 2 is more fundamental to human life. According to some interpretations of human rights provisions, such as those included in the UDHR and ICESCR, intellectual property rights (IPRs), including patents, may be consistent with human rights, especially when it comes to acknowledging the rights of authors. IPRs, according to critics like Schermers, cannot be categorized as fundamental rights.

Human rights are inherently protected and cannot be revoked by legislation, whereas patents are statutory creations. Intellectual property rights are temporary, revocable, and primarily serve the interests of corporations rather than individual inventors. Unlike human rights, which are universal and perpetual, IPRs are territorial and limited in time. The Committee highlights that although human rights are inalienable, the main purpose of intellectual property rights (IPR) is to encourage innovation and creativity for the good of society. Individuals are entitled to human rights, but intellectual property rights (IPRs) might be owned by businesses or other legal entities, making it more difficult to classify them as such. While IPR may acknowledge inventors' interests, they do not offer the same level of protection as human rights. The overlap exists, but one can exist without the other. While patents can support human rights goals, they should not be equated with fundamental human rights. IPR protections lack the same enforcement strength as rights like the right to health.

The TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) is an international legal framework governing intellectual property (IP) rights. According to Article 8 of the TRIPS agreement, "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement." Moreover, Article 27 (2) "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law." The presence of these articles goes on to prove that this agreement about Intellectual property rights itself not only acknowledges but emphasizes the importance of equitable access to healthcare over the protection of intellectual property rights.

The comparison between IPR and basic health rights can analogically be compared to the comparison between the usage of the intellect for gaining money and the usage of the intellect for saving lives.

The case of South Africa is a testament to this. South Africa has one of the highest rates of Human Immunodeficiency Virus (HIV) in the world. By the late 1990s, approximately 10% of the adult population was living with HIV, leading to significant public health challenges. Antiretroviral (ARV) medications, crucial for treating HIV, were prohibitively expensive. In the late 1990s, a year's supply of some ARVs could cost as much as 10,000 USD, making them inaccessible to most South Africans. As a result, the means to stay alive were snatched away from thousands.

Therefore, it is morally incumbent upon societies to prioritize equitable access to healthcare, ensuring that all individuals can exercise their right to health and have access to necessary pharmaceuticals.

IV. INTELLECTUAL PROPERTY RIGHTS CREDIBILITY AND MISUSE

While intellectual property laws are stringent in legislation and application, there are many cases where they are undermined to focus on social welfare or various factors. This raises the question of credibility, application and ambiguities in legislation. Moreover, the legal lacunae provides less importance to the economic benefits that some believe intellectual property rights give the creators.

Pursuant to Article 31 of the TRIPS Agreement and relevant national legislation, Member States retain the authority to grant compulsory licenses. Compulsory licenses permit the use of a patented pharmaceutical without the consent of the patent holder under circumstances deemed to constitute a national emergency or public health crisis, provided that adequate remuneration is ensured to the patent owner. While many argue that the existence of such provisions is helpful for the masses, they fail to acknowledge certain gaps in the same created. The contrarians may argue that since compulsory licenses exist, the need for prioritization of equitable access may be redundant as governments have the choice to employ a compulsory license in times of need. However, what is not realized is the fact that compulsory licenses fully deem IPRs to be superfluous. They give the intrinsic right of an IPR, that is, the recognition and sole ownership of the pharmaceuticals to another party for production. At the ground level, compulsory licensing is evidently not for the protection of IP, but rather for equitable access of IP in times of need.

The utility of compulsory licenses is not the same for all countries. While countries that have manufacturing ability in the pharmaceutical sector can effectively employ compulsory licenses, a large number of least-developed countries do not have such capability. Even developing countries that can use compulsory licenses to produce patented drugs are always under pressure from developed countries not to issue such licenses. For instance, India was subjected to relentless attacks by the US government when it issued a compulsory license in 2012 to produce a generic version of Bayer's cancer drug. Furthermore, Article 31(f) of the TRIPS Agreement clearly states that a compulsory license may be issued predominantly for the domestic market of the country issuing the license. Thus, generic medicines produced under a compulsory license cannot be exported. As a result, countries that have limited manufacturing ability in the pharmaceutical sector will simply not be able to benefit from the provision on compulsory licensing given in Article 31 of the TRIPS Agreement, which is highly ironic given that these countries are the ones in dire need of such resources. This is relevant here as it contradicts the very purpose of the existence of compulsory licenses.

Intellectual property rights are often misused as well. The practice of evergreening shows this. Evergreening is the practice used by patent holders to extend the duration of their patent protections beyond the original term. They typically do this through minor modifications or new formulations of existing drugs. This leads to the creation of a monopolistic control that stays put for far too long. Consequently, it delays the entry of generics into markets, thus, keeping certain sections from having access to drugs they can't otherwise afford. This lack of affordability stems from the fact that due to evergreening, prices typically remain high. This is a major risk to the universal availability of healthcare in developing countries specifically. When access to medications is restricted for long periods of time, it hinders access to healthcare for all and exacerbates inequalities even further.

The misuse of these rights to restrict access to essential medications not only contravenes the objectives of IP protection as a whole but also goes against the very people they were intended to *benefit.*

V. HURDLES TO FUNDAMENTAL HEALTHCARE FROM IP LAWS

Situations that occurred during COVID-19 are prime examples of drastic disease calamities that couldn't be avoided due to IP laws, one such example was India's development of vaccines.

During the COVID-19 pandemic, several vaccines, including those developed by Pfizer-BioNTech and Moderna, were subject to stringent patent protections under national and international IP frameworks, including the TRIPS Agreement. The Committee highlights that although human rights are inalienable, the main purpose of intellectual property rights (IPR) is to encourage innovation and creativity for the good of society. Individuals are entitled to human rights, but intellectual property rights (IPRs) might be owned by businesses or other legal entities, making it more difficult to classify them as such. Despite India's manufacturing capacity, the country was still unable to produce drugs on a larger and faster basis due to this need for consent. IP rights forbade the production of generic vaccines as first, the procurement of the licenses required to use necessary technologies for the generation of similar vaccines led to extended deliberations and limited manufacturing periods. Second, the availability of necessary components and raw materials, which are often controlled by patent holders, was also impacted by patent restrictions, further restricting production capacities. Lastly, further complexity and delays were caused by the need to comply with regulatory standards for vaccination licensure, which frequently call for using proprietary compositions and procedures. Given these challenges, there have been substantial demands both in India and the international community for reforms to intellectual property laws, including suggestions for the temporary suspension of specific IP rights under the TRIPS Agreement.

Proposals at the WTO, supported by India, Argentina, Brazil, South Africa, Russia , and China, have been made to temporarily suspend or waive patent rights, allowing countries to produce generic versions of patented medicines and vaccines without the need for authorization from patent holders. Furthermore, in order to promote local manufacture of vaccines and treatments, reform proposals frequently include steps to enhance transparency and facilitate the exchange of trade secrets, such as formulations, manufacturing processes, clinical trial data, and other production-related information. Additionally, in certain jurisdictions, Supplementary Protection Certificates (SPCs) prolong patent protection for pharmaceuticals beyond the usual 20-year term to account for regulatory delays. Some proposals suggest limiting or suspending these extensions during health emergencies.

The short-term exemptions granted during emergencies emphasize how urgent it is to give equal access to necessary medications precedence over intellectual property (IP) laws in extraordinary situations. Numerous impacted countries, mostly developing ones, were forced to temporarily renounce their international commitments to secure vaccine supplies and their established intellectual property rights. These countries were forced to rely on the kindness of wealthy nations to safeguard the health of their citizens because they lacked the scientific capability and required patented consent to manufacture their own vaccines. "The waiver of patent rights is essential for ensuring that vaccines are accessible to all nations, particularly those with limited resources."

This was stated by Argentine representatives in support of the proposal at the WTO.

On the other hand, the reluctance of some high-income and developed nations to endorse this waiver underscored the disparities between wealthier and poorer countries, revealing the tension between IP rights and global public health imperatives. This reveals the hidden disparities between developing and developed countries, clearly revealing the dispassionate and mercenary approach taken by individuals who prioritize IP protection over equity. Developed countries that opposed this waiver consisted of the United States of America, the European Union, Switzerland, Germany, and the United Kingdom.

Fair access to pharmaceuticals acknowledges that rural regions and low-income groups typically require reasonably priced drugs, which are mostly unattainable because of strict intellectual property regulations. This idea prioritizes the needs of marginalized individuals before financial interests, which is consistent with global health goals like Universal Health Coverage (UHC).

VI. THE NEED FOR VALUE ASSESSMENT

At this stage, it is crucial for us to acknowledge and act upon the need to confer priority upon equitable access to healthcare facilities and medications. This must be reflected in reforms introduced to assuage the hurdles presented due to IP laws and their misuse. These may include regulatory laws against evergreening. Moreover, the legal framework should be strengthened further such that there is no room for economic discrimination in the aforementioned ways. They should be centered around the development of different sources of incentivization for innovation, and equitable resource allocation and must not ignore the significance of accessible healthcare while also showing regard for the reassuring security granted to innovators by IPRs.

VII. CONCLUSION

While preferential treatment of Intellectual Property Rights over equitable access may supposedly lead to more incentive for innovation, we must also realize that the equitable access of pharmaceuticals in itself, is a salient incentive for development. Moreover, as recognized by many international organizations, it is essential to devote more resources and focus on equitable access to pharmaceuticals to elude disastrous circumstances costing us lives and trauma. This debate is not merely between access to pharmaceuticals and IP rights. At stake here is the bedrock of human rights as a whole, ie, the right to health. Therefore, we must prioritize human well-being over commercial interests.

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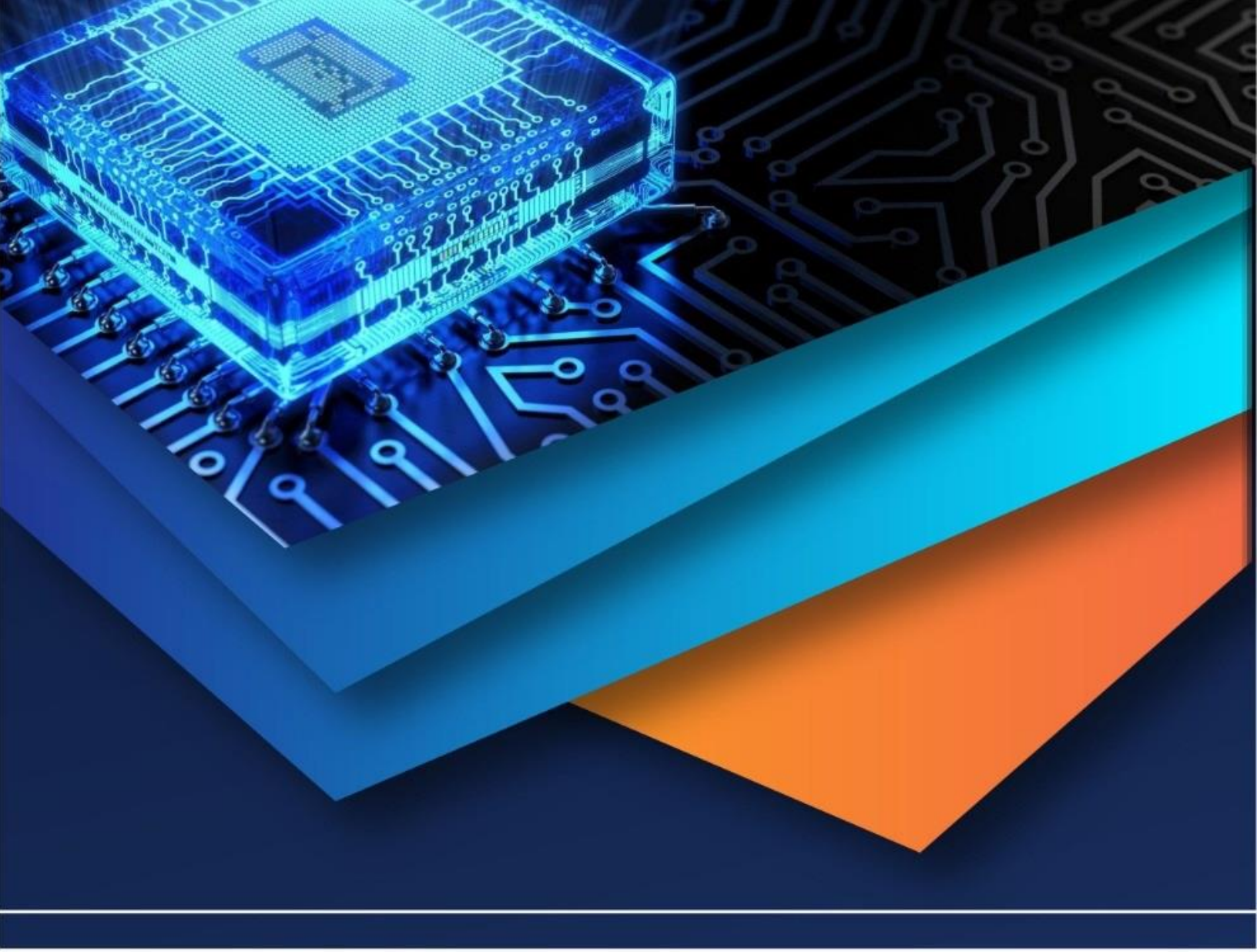

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