An ethical analysis of the impact of covid-19 vaccine patents on the accessibility of vaccines in developing countries.

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A Research Report submitted to the Faculty of Health Sciences, University of the Witwatersrand (Wits), Johannesburg, in fulfilment of the requirements for the degree of Master of Science in Medicine (MSc Med) in Bioethics & Health Law

Steve Biko Centre for Bioethics

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Submitted: 30 September 2025, Johannesburg

Declaration

I, **Lelethu Roto** (Student number: **607533**) declare that this Research Report is my own, unaided work. It is being submitted for the degree of **Master of Science in Medicine (MSc Med) in Bioethics & Health Law** at the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

Signature of candidate: 

On the 30th day of September 2025 in Centurion.

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Abstract

In this thesis, I did a retrospective ethical analysis of the covid-19 pandemic, and specifically did the analysis through the lens of developing countries (LMICs). The thesis question that I aimed to defend was that the patenting of covid-19 vaccines, especially for developing countries during a global pandemic was not ethically justified. One of the components that created bottlenecks and exacerbated vaccine inequity was vaccine patents. In the context of covid-19, high-income countries (HICs) quickly secured competitive agreements with the manufacturers of the new vaccines (Usher, 2020). In contrast, the first vaccine to become available to the first group of South African (a developing country) healthcare workers, which was the Johnson and Johnson (J&J) vaccine, only became available on 17 February 2021 (Mwai, 2022). In this thesis, I argued using rule utilitarianism to illustrate that this led to serious harms that could not be ethically justified. I also argued using distributive justice that LMICs ought to have been prioritised during the distribution of covid-19 vaccines as they had more need for the vaccines, as HICs could afford to pay for the costs of vaccines. I then argued that there are other alternatives to share costs in the event of future pandemics, through the formation of global health partnerships (GHPs). The GHPs would help to subsidize costs for vaccine manufacturers, and ensure that the financial effects of waiving patents are shared.

I used the following keywords to conduct my searches: covid-19, global pandemic, vaccine nationalism, vaccine equity, vaccine innovation, patents ban, patenting, patent waivers, pandemic preparedness etc.

Acknowledgements

Firstly, all praise be to **God**, the most high. Ndiyambulela uThixo kuba kude kwalapha enam.

I would like to express my deepest appreciation to my supervisor, Lizeka Tandwa, for her invaluable patience, feedback and encouragement throughout this journey. She generously provided her time, knowledge and expertise to ensure that I succeed, and believed in me even when I doubted myself. Words cannot truly express how grateful I am that you were a part of my journey.

I would also like to give a special thanks to my mother in heaven, Nondumiso Roto, who walked so that I could soar. Thank you Ma for always being my biggest cheerleader and encouraging me to dream big. Enkosi Mbotho, Thoyana, Mazama.

I also could not have taken this journey without the support of my husband, Ntokozo Mbangwa, and my family and friends who encouraged me to keep going when I felt discouraged. You are my village, and you encouraged me to reach my fullest potential. I love and appreciate you all so much.

I am also grateful to my classmate, Kutlwano Maite, for all the listening and insightful conversations. This was a journey of growth and self-discovery, and I thank you for all the free entertainment and emotional support.

Dedication

This research is dedicated to my family, and all who have supported me throughout this journey. And especially to my husband, who played his part in ensuring that I complete this degree.

And to everyone trying to finish what they have started:

“It does not matter how slowly you go, as long as you do not stop.”

— Confucius

“Our greatest glory is not in never failing, but in rising up every time we fail.”

– Ralph Waldo Emerson

Contents

Chapter 1: Overview

Introduction

It has been several years since the full force of the covid-19 pandemic hit the world in 2020. We are now in a better position to reflect on the effects of the pandemic in terms of the economic, social and health devastation that it caused, and to also reflect on the extraordinary scientific innovation that led to the production of effective covid-19 vaccine interventions within the first year of the pandemic (Lurie et al., 2021). However, at the centre of that extraordinary innovation, was the ethical issue of covid-19 vaccine equity and distribution, especially in developing countries also referred to as low and middle-income countries (or LMICs). It is important to note that the classification used for identifying countries as LMICs or high-income countries (HICs) is based on the World Bank definition, which is based on the country's gross national income (GNI) per capita (World Bank, 2019).

Vaccine equity refers to the act of giving everyone a fair and equal opportunity to access vaccines regardless of their country's economic status (United Nations Development Programme, n.d.). Therefore, vaccine inequity refers to the lack of equity in how the vaccines were acquired and distributed, which contributed towards the prolonged covid-19 pandemic. In this thesis, I retrospectively and ethically analyse the impact of the partial distribution of vaccines during the covid-19 pandemic, with special emphasis on the effect that this had on developing countries, in order to inform what should happen in future should we face a comparable situation.

One of the components that created bottlenecks and exacerbated vaccine inequity was vaccine patents. Patents are intellectual property (IP) rights that allow the holder (owner) of the patent to restrict others from using the invention for the period (usually 20 years) that the patent is valid for (McMahon, 2020). In terms of the international trade law, all countries that are contracted to the World Trade Organisation (WTO) have to make patents available to inventors of technologies, including medicines and health related devices (McMahon, 2020). Patents are an important incentive to individuals and pharmaceutical companies to continue innovating, as patents provide protection against the use of inventions without obtaining authorisation from the original inventors. Without the legal safeguard of patents in place, some medications and other pharmaceutical products could be replicated and sold by competitors who did not contribute to the costly and time intensive research and design process (Grabowski, 2002).

Patent holders have the sole rights over their invention for the designated period that the patent protections are in place, meaning that they have certain powers to decide or control (1) who is granted access, (2) who is granted that access *first*, and (3) the cost of acquiring the access to those particular vaccines, technologies and / or treatments (McMahon, 2020). In the context of covid-19, although patent protection was applied globally, the way it was enforced varied from country to country. High-income countries (HICs) quickly secured competitive agreements with the manufacturers of the new vaccines (Usher, 2020). Even before the Food and Drug Administration (FDA) of the United States of America (USA) approved the first batch of vaccines, the USA and other developed countries (high-income countries) had already made agreements to secure approximately 6 billion doses of vaccines for their citizens (Fischman-Afori, Marcowitz-Bitton and Morris, n.d).

The Pfizer BioNTech vaccine was first administered in the United Kingdom on 8 December 2020 (Gov.uk, 2021), while it was first approved for use in the USA on 14 December 2020 (Galvani, Moghadas and Schneider, 2022). In contrast, the first vaccine to become available to the first group of South African (a developing country) healthcare workers, which was the Johnson and Johnson (J&J) vaccine, only became available on 17 February 2021 (Mwai, 2022). The Pfizer and J&J vaccines only became available to the South African general public after an even longer period. During the waiting period, before vaccines became widely available, South African pharmaceutical companies could not produce vaccines locally due to patent restrictions imposed by Pfizer and J&J (Galal, 2022). The leading covid-19 vaccines such as AstraZeneca, Johnson and Johnson (J&J), Pfizer BioNTech, Moderna were either patented or protected through trade secrets, and these patents were effective worldwide in any jurisdiction where protection was applicable (Alshrari et al., 2021). While waiting for vaccines to be available, it is estimated that South Africa experienced an additional 25 000 covid-19 related deaths (Galal, 2022).

It can be seen that the situation was problematic as the HICs were in a better position to make agreements and acquire patented vaccines as they had financial resources, while some LMICs were either not in a position to afford the costs associated with acquiring vaccines, did not have access to acquire vaccines, and/ or were unable to produce the vaccines locally, without having the necessary permissions (licenses) required from the patent holders. In addition to this, HICs had a surplus of vaccines readily available for administration yet they were unwilling to distribute and share the extra vaccines with LMICs who were struggling to secure vaccines (Yamey et al., 2021). Vaccines were one

of the few (prophylactic) mechanisms that were known to be safe and highly effective against the virus at that time, yet almost one billion the unused vaccines in HICs ended up expiring and being disposed of (Yamey et al., 2021).

It was at this point that low and middle-income countries such as South Africa and India motivated for the WTO to temporarily remove the IP protections that it offers to inventors (i.e. waive patents) in order to maximise access to vaccine during the vaccines (Usher, 2020). This proposal was initially opposed by the European Union, United Kingdom, Germany and the United States of America (HICs), but was partially agreed to at a later stage within a limited scope in 2022 (Amin & Kesselheim, 2022). However, this was obviously ineffective in empowering LMICs as the late timing meant that they were not provided the opportunity to scale up their vaccine production during the peak pandemic period (Amin & Kesselheim, 2022).

Pharmaceutical companies such as Moderna claimed that they would not enforce their patents during the pandemic, however they did not share the technology used for production or assist other pharmaceuticals to scale up their manufacturing (Gold, 2022). Others such as Pfizer BioNTech limited their technology to countries that are wealthy i.e. applied selective licensing (Gold, 2022). Then others such as AstraZeneca did partner with LMICs for manufacture (such as the Serum Institute of India), but they did not do this across the board. This meant that even though there were some LMICs who could participate in the manufacture of vaccines, some were excluded even though they may have had the capacity to fully produce vaccines (Gold, 2022).

Those in support of keeping patents in place argued that doing this would discourage inventions of treatments during a time where it was vital for new vaccines to be created (Usher, 2020). Some such as Santos Rutschman and Barnes-Weise (2021) argued that the waiving of patents would not address the scientific knowledge or skills that LMICs would need to produce the vaccines or provide them with the infrastructure and resources. They say “One or more patents will provide a recipe for a process, or a component needed to produce a vaccine. But, just as with a culinary recipe, the informational power of a patent does not cover any tips or instructions that have not been memorialized in writing, nor does it provide any access to the raw materials needed to put a vaccine together” (Santos Rutschman and Barnes-Weise, 2021). Therefore, their argument was that the patent waiver policies might not be useful in practice.

Others such as Liu et al., (2021) took a more diplomatic approach and argued that as much as patent rights are important, the role which they play under normal circumstances cannot be expected to remain unchanged during a pandemic, and that it is important to balance competing interests with the spirit of humanity and knowledge sharing. Thus, although the purpose of patents in the development of medical treatments is important, there is still a need for a better balance to ensure that people are not compromised in the process (Liu et al., 2021).

Considering the above arguments, I state that patent waivers should not be limited to the acquisition of IP rights only, but that in order to maximise access to vaccines we require an approach that addresses both IP access issues and issues experienced in the vaccine supply chain. Supply chain issues entail (1) inadequate infrastructure to produce, store and transport vaccines and (2) expensive raw material or shortages of raw materials required to produce vaccines. Vaccines are complicated substances that require the correct production facilities, infrastructure, and skill. Therefore, I will be highlighting that the lifting patents alone is not enough, but the pharmaceutical companies who own the intellectual property must also share knowledge and technological resources through global partnerships that will facilitate successful production of vaccines, as a minimum, during a global pandemic. This will help reduce costs involved in producing vaccines while also increasing efficiency in the vaccine development process (Nunes, McKee, Howard, 2024).

1.1. Research Question

Was it ethically justified to impose covid-19 vaccine patents on developing countries, in the context of a global pandemic?

1.2. Rationale for the Study

Patents play a significant role in stimulating technological inventions as the inventor gains financially through licensing out their invention to others (Mitnovetski, 2004; Corrick, Watson and Budhdeo, 2011). The covid-19 pandemic had a serious impact on public health and the economy on a global scale, and this was even more pronounced in developing countries due to limited resources.

Current covid-19 statistics (as of December 2024) show a total of 7 083 246 million deaths globally, with 3 044 779 deaths in North and South America, 2 280 421 in Europe, 808 867 in South East Asia, 421 659 Western Pacific, and 175 532 in Africa (Worldometer, n.d). Furthermore, some studies on excess mortality have found that the total deaths on account of covid-19 could be more than currently

reported (especially in LICs) but that these deaths have been under-reported due to insufficient testing, challenges with and non-uniformity of reporting, lack of access to health facilities and other resources (Wang et al., 2022).

In this report, I argue that the temporary lifting of patents during public health emergencies such as a global pandemic is a necessary measure that must be put in place, in order to ensure the equitable distribution of vaccines or other pandemic response mechanisms globally. As HICs are in an advantaged position to secure agreements with patent holders do to financial capabilities, there is a need for this access to be managed by ensuring that LMICs are given the opportunity to manufacture their own vaccines using local resources which will in turn reduce the waiting time for them to acquire vaccines and other treatments.

In this report, I am not questioning the validity of patents under all circumstances, but I am questioning their ethical justification in a global public health emergency, such as the covid-19 pandemic. In the place of patents, I recommend Global Health Partnerships (GHPs) for product development and GHPs for improved access. GHPs for product development use money obtained from the public to lower risks for private companies that are conducting the expensive research to develop a vaccine, or other relevant treatments. The GHPs focused on product development also ensure that they subsidise the processes for developing and commercialising vaccines. Examples of successful GHPs for product development include International AIDS Vaccine Initiative (IAVI), and the Malaria Vaccine Initiative (MVI).

Although the focus of my argument will be on the covid-19 vaccines, the findings of my proposal can be generalised to apply to any other medical conditions (all things equal) that result in a pandemic in the future. Therefore, this research project could play a valuable part in informing pandemic policies in the future.

1.3. Thesis

I argue that patenting of covid-19 vaccines during a global pandemic was not ethically justified, especially for the developing countries who participated in the covid-19 research, and there ought to be an obligation to provide vaccines along with the necessary equipment and storage in order to ensure that people have access to the vaccine.

1.4. Research Aim

I aim to articulate and defend the thesis that patenting of covid-19 vaccines, especially in developing countries during a global pandemic was not ethically justified.

1.5. Research Objectives

a) To defend the position that the inaccessibility of covid-19 vaccines, as a result of patent restrictions, contributed to harms (severe illness, death) that could have been mitigated through vaccination.

b) To defend the position that developing countries who participated in the covid-19 vaccine research such as South Africa, India etc. should have received a fair opportunity to receive vaccines and the necessary equipment to store and distribute the vaccines as part of solidarity and reciprocity.

c) To defend the position for equitable distribution of vaccines and the provision of necessary equipment and storage by global alliances such as COVAX, through cost sharing that is funded by participating countries and other donors to contribute towards vaccine costs.

1.6. Research Design

I am doing a type 1 purely normative bioethical project where I argue in defence of my thesis.

1.7. Research Methods

I conducted library and desktop-based searches as per the methods and standards usually applicable to philosophical work. There was no analysis or collection of any new empirical data during the research project. No human participants were involved in the research project and therefore no ethics approval was required. I analysed and discussed literature findings through a bioethical lens.

I used the following keywords to conduct my searches: covid-19, global pandemic, vaccine nationalism, vaccine equity, vaccine innovation, patents ban, patenting, patent waivers, pandemic preparedness etc.

1.8. Argumentative Strategy

Premise (P) 1: The inaccessibility of covid-19 vaccines, as a result of patent restrictions, contributed to harms (severe illness, death) that could have been mitigated through vaccination. This is more so as there were no medicines available to cure covid-19 infection.

P2: Developing countries who participated in the covid-19 vaccine research such as South Africa, India etc. should have received a fair opportunity to receive vaccines and the necessary equipment to store and distribute the vaccines as part of solidarity and reciprocity.

P3: There should be cost sharing that is funded by participating countries and other donors to contribute towards vaccine costs and the provision of necessary equipment and storage in order to ensure equitable distribution of vaccines.

Conclusion: Patenting of covid-19 vaccines, especially to the disadvantage of developing countries during a global pandemic was not ethically justified.

Premise 1:

I make the case that the patenting of covid-19 vaccines during a global pandemic made the vaccine inaccessible to some countries, especially developing countries. As a result of this, some developing countries such as South Africa and India pushed for covid-19 vaccine patent waivers (Usher, 2020). The lack of timeous access contributed to some of the harms that could have been mitigated had the vaccines been available to those countries, especially as there were no other medicines available in the market proven to effectively cure or manage covid-19.

The harms caused could be direct harms in the form of serious physical illness, psychological harms as a result of strict isolation and social distancing, financial harms owing to the impact of covid-19 on the economy and deaths. There were also indirect harms for example, in the form of illness or death of family members, colleagues etc., inability to access health resources due to prioritisation of covid-19 cases at clinics and hospitals etc.

However, some authors such as Le and Samson (2021) argue that weakening protections on patents could lead to more harms than the harms resulting from waiving patents in place. This is because waiving patents disincentivises research in the vaccine industry, and that the removal of rules on intellectual property could lead to an increase in counterfeit goods being produced (Le and Samson, 2021). Le and Samson (2021) further argue that the main focus should not be on whether patents should be waived or not, but should be on tackling trade restrictions, fostering partnerships between the different developers of vaccines, and strengthening supply chains across borders.

I argue using rule utilitarianism theory, where I emphasize that spread of a global pandemic affects everyone, therefore, it is in the best interests of everyone (in terms of health, the cost to the economy, the liberty of people etc.) to have vaccine options available to all countries, regardless of whether they are in developing or developed environment. Rule utilitarianism, is applicable in this context because we cannot leave it to patent holders to decide (use their discretion) what the right thing to do is in terms of sharing their knowledge and expertise, or rely on HICs to share their excess vaccines (as we have already seen that this is not effective). Therefore, we need to provide compulsory measures and limitations in place to ensure knowledge sharing initiatives between manufacturers and scientists in LMICs, and the holders of vaccine patents.

Some may object that it is unrealistic to expect patent holders to agree to the lifting of their patents during pandemics as the costs and risks involved in developing new vaccines are very high. However, I respond that the cost and risk to human life due to a prolonged pandemic is even higher in terms of health and the economy in the long term, for all countries.

Premise 2:

I make the case that the patenting of vaccines proved to be a barrier or obstruction for many countries, especially developing countries, as these countries did not have an equal opportunity to access (or produce) the vaccines once they became available. Ramachandran, Ross and Miller (2021) did a study on the access of covid-19 vaccines in lower middle-income countries, upper middle-income and high-income countries (HICs) that hosted clinical trials. They (Ramachandran, Ross and Miller, 2021) found that there were 25 completed trials, with 3 in lower MICs, 11 in upper MICs and 11 in HICs. However, when it came to the distribution of vaccine doses the upper and lower MICs received proportionately lower doses (14.9% and 31.0%, respectively) compared to HICs, which received more doses such that they could vaccinate 51.7% of their populations. This is not an uncommon finding, as it often reported in other literature that trials conducted in developing countries result in host communities not being able to afford treatments (hence benefit from the research studies) for which they had carried the burdens (Dhai, 2019).

Distributive justice, which refers to the *"fair, equitable, and appropriate distribution of benefits and burdens determined by norms that structure the terms of social cooperation"* (Beauchamp & Childress, 2013, p. 250), requires that the community that assumed the burdens of research should be among

those who benefit from it. Therefore, I argue that developing countries that were involved in the development of vaccines ought to have been given a chance to be among the first countries to receive the vaccines, and I argue on the basis of distributive justice (Dhai, 2019).

Some might object that even if the vaccines were made available to the developing countries, these countries may not necessarily have the correct infrastructure to store and distribute the vaccines to the masses. To this, I respond that the distributive justice should not be limited to the vaccines themselves but should also include the necessary equipment required to make the vaccines available, as this is an integral part of closing the equity gap. Others might also object that the number of deaths were higher in HICs than in LMICs. To this, I respond that the published covid-19 statistics were based on the reporting submitted by the individual countries, and therefore there was a probability of under reporting due to LICs not having the necessary infrastructure to conduct covid-19 tests and document and maintain the necessary data (World Health Organisation, 2024).

Premise 3:

Lastly, we have established that patent holders offering intellectual property alone is insufficient, as there were additional supply chain issues that further obstructed vaccine equity. The effective application of distributive justice requires that the patent waivers must be accompanied by the necessary supply chain resources and knowledge sharing in order to be able to produce quality localised vaccines. Covid-19 affected and continues to affect the entire world, as shown by the statistics above, therefore the cost of funding the development of vaccines and purchasing vaccines should be carried by an international organisation that is funded by participating countries and/or other donors and not solely the pharmaceutical companies which develop the vaccines or individual countries that require the vaccine.

Some might object that there were existing initiatives already in place that were launched by the World Health Organisation, such as covid-19 vaccine global access facility (COVAX) and the C-TAP patent pool, which assisted in financing the manufacturing of covid-19 vaccines. Since these organisations had still not been able to overcome the vaccine inequity issue, how would this organisation be any different? I respond that GHPs would be different as they would not only ensure the financing of the procurement of the actual vaccines, but it would also finance the supply of technological equipment, raw materials etc. (Fischman-Afori, Marcowitz-Bitton and Morris, n.d).This would ensure equitable

access for all countries regardless of financial standing of individual countries. The GHP would also need to have the necessary authority to enforce equity measures against patent holders and HICs.

1.9. Research Outcomes

The envisaged outcomes for this project are for it to be presented at workshops and conferences to highlight the negative effects that the patenting of vaccines during a global pandemic has on the developing world, and to hopefully contribute towards pandemic policies of the future.

1.10. Overview of Chapters

Chapter 1: Overview

This chapter gave an introduction and background to the research topic, and gave a brief literature overview. It also gave an outline of the research question, rational for the study, the thesis, the research aim, objectives, design, methods, argumentative strategy and the research outcomes.

Chapter 2: Avoidable harms during the covid-19 pandemic through vaccine access

In this chapter, I described the avoidable harms that were caused to people during the covid-19 pandemic and used rule utilitarianism to show why the harms were indefensible and could not be ethically justified.

Chapter 3: Distributive justice and reciprocity for the covid-19 vaccine

In this chapter, I used the principles of distributive justice and reciprocity to argue that the distribution of covid-19 vaccines towards LMICs was unjust, and even more unjust for those countries that had participated towards finding a vaccine for the illness.

Chapter 4: Cost sharing for vaccine access and equity

This chapter gave an analysis of the different cost-sharing methods in order to improve access to vaccines and ensure that such access is equitable.

Chapter 5: Conclusion

This chapter gave a conclusion of the research report and provided recommendations for how to proactively prepare for future pandemics, in order to prevent unnecessary harms to people, especially the most vulnerable.

1.11. Ethics Approval

This research report does not involve any human participants and therefore no ethics clearance certificate was required from the Human Research Ethics Committee.

Chapter 2: Avoidable harms during the covid-19 pandemic through vaccine access

Introduction

The covid-19 pandemic caused a strain in the global healthcare system by creating limitations on health resources, medications, life-saving equipment and even things we take for granted such as physical space (through social distancing). The pandemic also highlighted the already existing challenges of inequitable access to life-saving interventions, such as vaccines, in the different parts of the world. Equitable access to vaccines (also known as vaccine equity) refers to giving everyone, regardless of their country's economic status, an opportunity to access vaccines in an equal and fair manner (United Nations Development Programme, n.d.). Thus, inequitable access to vaccines refers to the inability to access vaccines in an equal and fair manner. In a non-crisis setting, patents (which are intellectual property rights) are one of the useful tools for incentivising creators of new medical inventions and methods (McMahon, 2020).

The main factors that contributed to the inequitable access of vaccines included (1) high-income countries (HICs) wanting to put themselves first and hoarding vaccines, patent restrictions, (2) vaccine hesitancy, (3) limitations on the capacity to manufacture vaccines, and (4) the weak public health systems (Ferranna, 2023). In a crisis such as a global pandemic, patents can cause further limitations in an already limited environment, resulting in harms that could have been mitigated. These harms could be direct and/ or indirect. The direct harms could be in the form of serious physical illness, psychological harms due to strict isolation and social distancing, financial harms due to the impact of covid-19 on the economy, and deaths (Emanuel et al.,2020). Indirect harms could be in the form of illness or death of family members, colleagues etc., or the inability to access health resources due to prioritisation of covid-19 cases at health facilities etc. (Emanuel et al., 2020).

In this chapter, I will be arguing using rule utilitarianism that the patenting of covid-19 vaccines during a global pandemic contributed to harms, such as severe illness, death, adverse effects on the global economy, and major disruptions on the global education system. This could have been mitigated with the use of vaccinations. This was more so, as vaccines were one of the few prophylactic mechanisms that were known to be safe and highly effective against the covid-19 virus at that time. For the purposes of this thesis, we will be focusing on the impact that patenting of vaccines had on the accessibility and availability of vaccines and will not directly address other contributors such as vaccine hesitancy.

Although I make specific reference to covid-19 virus, which is the most recent pandemic that we have experienced, this argument is applicable to all contexts of public health emergencies. Thereafter, I will complete my argument by addressing some obvious objections that can be made against it.

2.1 Utility and Utilitarianism

The issue of patents and its contribution to the inaccessibility of vaccine treatments during a global pandemic brings to the surface the principle of utility. Historically, utility was understood as experiencing "pleasure" and "the absence of suffering" (Bentham, 1961). However, modern definitions have evolved to describe it along the lines of "maximising benefit and minimising harms for the greatest number" (Bellefleur & Keeling, 2016). Therefore, according to utilitarianism, the good or right action is judged in terms of how much utility it provides. Utilitarianism is a normative ethical theory that is a form of consequentialism, as the wrongness of an action or practice or even a policy is judged based on its outcome i.e. the consequences (The University of Texas at Austin, 2023). In ethics, a normative or moral theory is a systematic moral approach that is used to determine, from a moral perspective, what we should or should not do (or ought to do and not do), both as individuals and as a society (Bellefleur & Keeling, 2016).

Utilitarianism seeks to ask the question of what action should be taken in order to create the most happiness over unhappiness, for the largest number of people. The advantages of this normative theory is that it can be used to decide the moral course of actions in difficult matters, such as issues of public health, military warfare etc. (The University of Texas at Austin, 2023). One of the reasons why it is a good fit for such complex matters is that it takes into account the costs and benefits that are associated with each decision, and the associated harms (The University of Texas at Austin, 2023). For example, if there is a multi-vehicle accident and the nearest hospital is flooded with patients, the directive given to doctors may be to do a triage, where patients with highest chance of survival are prioritised in order to maximise the number of survivors, and hence create the greatest happiness over unhappiness.

Utilitarianism can be distinguished into two types: (1) the classical utilitarian theory and the (2) rule utilitarian theory. The classical utilitarian theory refers to the original version of the theory (act utilitarianism), and the rule utilitarian is a modification of the classical theory. Act utilitarianism has three main propositions i.e. (1) The morality of an act is dependent solely on the resulting consequences, everything else is irrelevant, (2) The consequences resulting from an act are only relevant to the extent

to which they affect the happiness or unhappiness of someone else, and (3) When morally assessing the consequences of actions, everyone's happiness counts the same (Rachels & Rachels, 2015). An important characteristic of act utilitarianism is that it operates on a case-by-case basis taking into account the specific context, which is what distinguishes it from rule utilitarianism. Before we move into the discussion of rule utilitarianism, let us first look at some of the issues of act utilitarianism.

There are some issues that ethicists have argued against the act utilitarian approach. For example, when looking at point (1) and (2) above, one might think that surely consequences alone are not the only thing that matters when considering the morality of an action? Also, can we ever be 100% certain that the outcome of certain actions will have the expected good or bad consequences (The University of Texas at Austin, 2023)? One of the arguments that ethicists often make against act utilitarianism is that it cannot account for justice. A common example of this is one where a person has to choose between being a false witness in order to do good for more people, versus telling the truth in order to do good for one person. According to act utilitarianism, choosing to be a false witness would be the correct action although instinctively we know that it would not be the right thing to do (The University of Texas at Austin, 2023).

A second issue with act utilitarianism is that the rights of an individual will always be infringed on if they have to compete with a group of people who may stand to gain from the infringement of that individual's rights. An example of this is the peeping Tom illustration, where Tom secretly spies on his neighbour and it makes him happy. Many of us would argue that Tom is violating his neighbour's right to privacy (whether the neighbour is aware of his actions or not) and that this action is wrong. However, in the act utilitarian perspective it could be argued that Tom's actions are good as they are increasing the general happiness (Rachels & Rachels, 2015). In order to address the concerns expressed in the above examples, the rule utilitarianism approach was introduced (Rachels & Rachels, 2015).

Rule utilitarianism is based on the requirement that moral actions are those actions that comply with that rules that have been set. Therefore, actions are morally correct not only when they maximise the happiness within a specific set of circumstances (the case with act utilitarianism), but rather when the actions align with the rules which generally maximise utility or happiness (Hooker, 2023). An example that illustrates the difference between rule and act utilitarianism is one of crossing a red traffic light. In specific circumstances, such as when rushing a sick friend to the hospital, crossing a red traffic light in

a quiet area could be considered to be an option that maximises utility as it could save a person's life and there is a lower risk of being caught.

According to act utilitarianism, based on the specific details around the scenario, it could be concluded that it is necessary to cross a red traffic light when driving in a quiet area when trying to save your friend's life. However, rule utilitarianism would ask us the following question: if there was a rule stating that people are allowed to cross red traffic lights in whatever circumstances that they see as valid, versus a rule that prohibits the crossing of red traffic lights under all circumstances, would that generally maximise the utility or overall happiness? A rule utilitarian may decide that red traffic lights should never be crossed, even in circumstances where crossing them could possibly produce more utility, as following that rule generally maximises the utility.

Another everyday example of rule utilitarianism is the rule that it is illegal to drink alcohol and drive. As much as individuals have a right to consume alcohol, studies have shown that alcohol leads to mental impairment, making it dangerous for them (and other members of society) to drink alcohol and drive afterwards. The rule is set in place to protect the rights of everyone in society (i.e. accounting for justice), and not just the individuals who stand to gain from performing a certain act. An important thing to note is that in some scenarios there can be conditions or exceptions to the utilitarian rule that has been set.

Reverting to the previous example about crossing a red traffic light, it would be a reasonable exception to modify the rule to include that ambulances, for example, are allowed to cross a red traffic light when carrying a patient in need of urgent medical intervention, or when police services are chasing after a person who is a danger to society. Adding this condition to the rule would surely still produce the highest utility in most circumstances. The importance of moral theories such as utilitarianism is that they can help us make decisions, and provide a way for us to justify the morality of actions that are taken or not taken, and policies that are implemented.

2.2 Applying utilitarianism

In the previous section, I explained the different types of utilitarianism and explained the different contexts where they apply. In this section, I illustrate that a rule (policy) ought to be set for moral dilemmas such as global pandemics, in order to ensure that treatment benefits such as vaccines (insofar as the vaccines are proven to be safe and efficacious) are accessible to the greatest number of people. In the context of the covid-19 pandemic, the issue of equitable access to vaccines is an

important one, as the lack of equity resulted in harms that could have been prevented. Therefore, I make the claim that these harms minimised the utility and are morally indefensible.

I state that if we were to find ourselves in a pandemic again, the following rule ought to be applied:

During global pandemics or global health emergencies, where a vaccine or similar resource yields the most benefits (happiness) and is proven to be safe and effective, and avoids the most harms (unhappiness), there should be patent waivers in place such that there is maximum access to the life-saving resources.

Some may ask why there should be a rule in the first place instead of allowing each country to figure out a solution for themselves. To this, I respond that as much as countries have borders, contagious illnesses such as covid-19 go beyond borders and threaten the health of everyone regardless of their geographic location. Therefore, rules on how lifesaving treatments should be managed during a pandemic are a necessity, as people (organisations) in general cannot always be trusted to make decisions that are in the best interests of the greater community. As stated in the previous section on rule utilitarianism, following set rules or policies is one of the ways to ensure that harms are minimised and utility is maximised in the long-term for the greatest number of people in society.

Before I go into details about the harms caused, I will proceed by first clarifying the harms that I am referring to in this thesis. There are a few definitions of what "harm" is in the bioethics literature, as the term is quite subjective. Beauchamp and Childress (2013, p.153) do provide a definition of harm as part of their principle of non-maleficence, and they define it as "…a thwarting, defeating, or setting back of some party's interests". Therefore, it is an act that reduces an individual's welfare and puts them in a position that is worse off. When describing the types of harms that are covered by the non-maleficence principle, they also include "significant loss of or damage to life, health, or some other basic interest" (Beauchamp and Childress, 2013, 207). In the legal sense, harm can be described as "the loss of or damage to a person's rights, property, physical or mental well-being" (Merriam-Webster's Dictionary of Law, 1996). Therefore, a person is said to be "harmed" when their physical and/ or mental well-being is adversely impacted by certain actions, inactions or situations (Brereton, Flynn and Kemp, 2024).

In the literature, the harms are typically dissected into *direct* and *indirect harms.* Van den Berg et al (2021) defines *direct harms* as harms that occur directly in or on a person, while *indirect harms* are harms that occur outside of person e.g. harms to their belongings, other people that they care about,

their environment and surroundings. *Direct harms* can be in the form of (1) physical harms e.g. contracting a virus and getting ill, injured or dying etc., and (2) psychological or emotional harm e.g. experiencing trauma due to strict quarantine measures (Van den Berg et al, 2021). As *indirect harms* are harms that result from an indirect action or decision, they are usually more subtle and only become noticeable over time (Van den Berg et al, 2021). These harms can be financial, social or economic harms e.g. loss of employment because of the impact of covid-19 on the economy.

Considering these definitions, there is substantial evidence that people were harmed during the covid-19 pandemic (in health-related and non-health related ways), and the most severe harm caused during the covid-19 pandemic was the death of millions of people worldwide. The utilitarian's aim is always to benefit (or save in this context) the greatest number of people, which did not happen during the pandemic. Below I describe some of the moderate to severe outcomes that occurred to people and society during covid-19, to remind us how serious/ grave and probable these harms were.

a. Health and well-being

As at December 2024, the World Health Organisation had recorded the total number of deaths, an irreversible direct harm, to be approximately 7.1 million people (World Health Organisation, 2024). As the covid-19 vaccines had been proven safe and effective at the time, the vaccines were able to minimise direct harms such as death, hospitalisations, disabilities etc., and to minimise the long-term illnesses that people experienced as a result of contracting covid-19 (Ferranna, 2023). The argument here is not that people died due to the covid-19 virus, but rather that the death toll did not have to be the recorded 7.1 million people, especially because there were effective vaccines available in some parts of the world that could have reduced the extent of the harm.

In addition to the above official death count, there are more deaths that were caused due to indirect harms caused during the covid-19 pandemic. For example, many people globally experienced delays in accessing treatments for their chronic conditions since the focus of most health facilities was on managing covid-19 patients (Ferranna, 2023). This was more so for those individuals who had no medical aid (health insurance) and who relied solely on the public health resources, which is common for populations in LMICs. In addition, some people were fearful and unwilling to go to health facilities as they were scared of contracting covid-19, and this led to the disruption of screening measures and medical testing for serious conditions such as cancer (Ferranna, 2023).

Moreover, immunisation practices for childhood conditions such as measles, polio etc. were also disrupted which led to post covid-19 outbreaks in immunisable conditions such as measles and mumps (World Health Organisation, 2024). Lockdowns also had negative effects on the physical and mental health of individuals and their loved ones. For example, health workers had to continue to work while also having to social distance or quarantine away from their families for fear of infecting their children and vulnerable family members. Rajkumar et al. (2022) found that quarantined individuals experienced psychological and emotional conditions such as depression and anxiety, symptoms of post-traumatic stress, sleep difficulties, obsessive behaviour and hoarding of resources for fear of food shortages amongst other issues. In countries such as South Africa, it was reported that there was a surge in cases of gender-based violence, which was exacerbated by financial stress experienced within households, reduced physical activity due to lockdown, and lack of excess to counselling services (Mbunge, 2020).

b. Global economic impact

In order to control the spread of infection, many countries put in place isolation and quarantine measures (i.e. lockdowns) that led to closures of businesses and schools. This negatively affected the financial performance of most businesses, leading to some businesses shutting down permanently. As such, this led to large rates of unemployment, which had devastating effects on the livelihood of individuals and their families. It also exacerbated matters in LMICs which already have very high unemployment rates in comparison to HICs. According to estimates provided by the International Monetary Fund (IMF) the global gross domestic product (GDP), which is broadly described as an indicator of a country's economic health, had decreased by 3.1% in 2020 (International Monetary Fund, 2021). The sub-Saharan African region experienced a recession for the first time in 25 years, which led to approximately 40 million people living in extreme poverty (World Bank, 2021). In 2021, the Global GDP increased again by 6% due to the availability of vaccines and the reduction in isolation and travel restrictions (International Monetary Fund, 2021).

The introduction of vaccines not only enabled countries to manage the spread of covid-19 infection, which translated to the reduction of people getting sick to the point of hospitalisation. It also enabled the reduction of isolation restrictions, which majorly improved economic activity. Since there was a direct correlation between access to vaccines and the resumption of economic activity, the delayed access to

vaccinations slowed down the process for economic recovery and caused economic harms that could have been avoided.

c. Public health system

The covid-19 pandemic had major negative effects on the public health systems throughout the world, as most countries were overwhelmed and not adequately prepared for the volumes of covid-19 patients (Ferranna, 2023). Under normal non-pandemic conditions, there is a sparsity of health workers in both HICs and LMICs, and there is an unequal distribution of health resources in rural and urban areas (Mbunge, 2020). The situation in LMICs is even more unfavourable as there are consistent shortages in healthcare professionals, specialist health workers, and health infrastructure (Mbunge, 2020). Therefore, under covid-19 conditions, the strain to the public health system was overwhelming for both HICs and LMICs, and the LMICs who were already disadvantaged were in a direr situation. I will elaborate further on this issue when I discuss distributive justice in Chapter 3.

In reality, harms are rarely experienced in isolation, but they typically accumulate to result in even greater harms (Van den Berg et al., (2021). For example, a person that got ill from covid-19 (physical harm) and was hospitalised, could have also lost their job due to incapacity to work while ill, which would result in a combination of the above scenarios such financial and psychological harms (indirect harms) to them and their dependents. Therefore, as illustrated by the above examples, the harms caused during the covid-19 pandemic were serious and were bad harms.

2.3 Bad harms

Not all harms are equal, there are good and bad harms. In order for a harm to be classified as a good harm, it has to be a harm that can be morally justified (Elliot, n.d). For example, if a doctor is to conduct a painful surgery on a patient, the patient would have to consent to that surgery with the understanding that they must experience that initial harm (injury from being cut open and operated) so that they can prevent a worse harm from happening in the future should the operation not be conducted. In the context of covid-19, and example of a good harm is if a patient was given the covid-19 vaccine, and they experienced some mild side-effects from it. Although the patient experienced side effects (some harm) from the vaccine, that harm was justified because it was with the purpose of ensuring that the patient stood a better chance of surviving should they get infected with the covid-19 virus in future. Thus, what

separates a good harm from a bad harm is the corresponding justifications and outcomes (Brereton, Flynn and Kemp, 2024).

In the instance of covid-19, some may assert that the harms that occurred were justified because they were not intentional, but occurred because of poor management of resources, poor planning, crisis mismanagement etc. However, intent is never a sufficient justification for causing harm as the consequences of the actions or inactions are still significant on the populations impacted by those harms. Therefore, the harms caused were not only bad harms, but they could not be ethically justified. Which is why it is important to have moral rules in place, which aim to prevent similar harms from happening in future. One of the significant contributors to the bad harms mentioned above is the enforcements of patents during a pandemic situation. In the next section, I analyse the impact of patents in more detail.

2.4 Patents contributing to bad harms

In this section, I argue that the inaccessibility of vaccines further contributed to the avoidable direct and indirect harms. I make the claim that patent waivers were a necessary part in ensuring that there was maximum access to life-saving vaccine (treatments) in order to benefit the most people. As was detailed in the previous chapter, patents are intellectual property (IP) rights that allow the owner or holder of the patent to restrict others from using their invention for the specific period of time (usually 20 years) that the patent is valid for (McMahon, 2020). This means that if a product is patented, within those 20 years other people are prohibited from commercially making, using, distributing or selling that product without consent from the original patent holder (McMahon, 2020).

Under normal circumstances, having patent restrictions is not an issue, as patents can encourage innovation, which is beneficial to science and health communities. However, when the patented inventions happen to be amongst the few proven life-saving prophylactic interventions available in the entire world during a global pandemic, then the use of patents becomes a moral issue. In our context, patent restrictions brought about the following issues: (1) Patent holders had the power to decide or influence who was granted access to their inventions, and (2) they could decide who was granted access to their inventions *first*, which meant that they could give preference to certain countries over others e.g. HICs over LMICs. This was problematic as that preference was usually motivated by

financial gain, and not by need, which disadvantaged LMICs who may not have been able to compete financially or otherwise.

Therefore, even if a country had a surplus of vaccines, so long as they have the financial muscle to pay for preferential access, they were likely to get treatments before others who were in much greater need for it (Heuberger, Forster and Frewer, 2023). As implied above, the other issue was their (3) ability to control the price or costs associated with acquiring the required vaccine processes, technical solutions etc. These issues enabled the stated harms, and they created bottlenecks that exacerbated those harms. For example, patents limited vaccine hubs such as India from being able to produce the much needed vaccines, although they were well-known vaccine hubs with a proven track record. For example, India is the largest producer of HPV, rotavirus and pneumococcal vaccines and the Serum Institute of India produces 60% of vaccines worldwide (Nunes, McKee, Howard, 2024). Similarly, South African vaccine manufacturers such as *Aspen* had a limited scope to produce vaccines locally due to patent restrictions imposed by Pfizer and J&J (Galal, 2022).

By the end of 2021 covid-19 vaccines were widely available in HICs, to such an extent that there were discussions regarding the necessity of administering third vaccine doses in some HICs (due to the threats brought by mutations of the covid-19 viruses). However, some LMICs had not been able to administer even a single vaccine dose to their citizens ever since the pandemic started (Heuberger, Forster and Frewer, 2023). This was because although some HICs were receiving vaccines from the covid-19 vaccine global access (COVAX) initiative, they were primarily receiving vaccines via private contracts that they had secured with the patented vaccine producers (Heuberger, Forster and Frewer, 2023).

The World Health Organisation (WHO) in partnership with GAVI (Global Alliance for Vaccines and Immunisation) and CEPI (Coalition for Epidemic Preparedness Innovations) established the COVAX initiative in response to the rapidly spreading pandemic, and the main aim of COVAX was to ensure that a safe and effective vaccine was developed, and to ensure that the vaccine was distributed in a fast and fair manner throughout the globe (Heuberger, Forster and Frewer, 2023). However, of the vaccines that COVAX delivered to the participating countries, the vaccines accounted for less than 1% of those received by HICs while it accounted for 80% of the vaccines that were received in LMICs (World Health Organization, 2021). An important thing to note is that this does not mean that each LMIC got

80% of the vaccines that they required, but rather highlights that LMICs were highly dependent on receiving donations from COVAX as compared to HICs who did not necessarily need it. This was because LMICs were not in a position to compete with HICs in securing the required vaccines privately from vaccine producers (United Nations, 2021).

This illustrated that although collaboration through facilities such as COVAX could yield positive results, patents still promoted vaccine inequity between HICs and LMICs. Patent holders also did not treat countries in the same fair manner when making procurement agreements for vaccines, which created further harms and thus went against utility. For example, patent holders had differential treatment in how they treated LMICs and HICs by demanding that LMICs indemnify them against any litigation that could arise as a result of adverse effects, while this requirement was not the same for HICs (Gorodensky and Kohler, 2022). In order for a country to be in a position to indemnify a pharmaceutical company, this requirement must be included in the national legislation of that country. In countries where this is not already in law, then that means they have to first sign that requirement into law before being able to sign vaccine procurement contracts (Gorodensky and Kohler, 2022).

This type of treatment disadvantaged LMICs, and further strengthened the argument for the necessity of patent waivers. Therefore, it is clear that without intervention from governments and other influential organisations, patent owners will continue to enjoy the rights they have to sell vaccines to the highest bidder during global health emergencies.

I acknowledge that inventors of life-saving treatments, equipment and vaccines seek to maximise on financial gains that they make because of their inventions, and from a practical view point, temporarily removing patent protections would limit profit mechanisms for the producers of COVID-19 vaccines. I also acknowledge that there could be some harms that could result from the waiving of patents, for example, it could end up setting a precedence in terms of the development of future vaccines and treatments beyond covid-19. Pharmaceutical companies could be discouraged from investing in research involving other emerging public health emergencies. However, patent holders ought to agree to temporarily make less profits in order to ensure that everyone's interests are promoted, and to ensure justice. This is especially if the vaccines are funded by the public funds i.e. taxpayers, which was the case for Pfizer and Moderna covid-19 vaccines (Gold, 2022). This further reinforces the immorality of prioritising profits above securing global health. The aim of temporarily waiving patents is not to

overburden patent holders with moral demands on their inventions and resources, but the requirement is for them to concern themselves with the consequences of their actions. Their actions have adverse impact on the global community, and lower the utility overall.

Patent holders and some HICs may feel that this rule infringes on their right to choose what to do with their financial resources. However, a prolonged pandemic does not maximise the good for anyone (including them and their families), and regardless of whether they are from LMICs or HICs. The World Health Organization (2020) stated, “A global pandemic requires a world effort to end it. None of us will be safe until everyone is safe”. Authors such as Le and Samson (2021) maintain that suspending patent protections may result in greater harms than those that could arise from keeping patents in effect, as this may discourage research in the vaccine industry. Furthermore, Le and Samson (2021) maintain that the primary focus or strategy should not be on the question of whether to waive patents or not, but rather on addressing trade restrictions, promoting collaboration among vaccine developers, and strengthening cross-border supply chains.

To this I respond, that there are many alternatives to the current patent system, to ensure that patent holders do not lose out. For example, such alternatives include Global Health Partnerships (GHPs), which can ensure that the financial risk is shared and innovation is maintained. These can be (1) GHPs for *product development* and (2) GHPs for *improved access*. GHPs for product development use money received from the public to lower risks for private companies that are conducting costly scientific research. They also ensure to subsidise the processes for developing and commercialising vaccines (Nunes, McKee, Howard, 2024). Well-known and successful GHPs for product innovation include the International AIDS Vaccine Initiative (IAVI) and Malaria Vaccine Initiative (MVI) amongst others (Nunes, McKee, Howard, 2024).

GHPs for improved access focus on the procurement and delivery of technologies for vaccines, and they use advance market commitments (AMCs) in order to incentivise vaccine producers that develop vaccines that are required in LMICs. Successful GHPs for access include GAVI vaccine alliance (Nunes, McKee, Howard, 2024). These partnerships could help to address the concerns that patent holders have about recovering costs and ensuring sustainability for their inventions. They would also ensure that LMICs receive the necessary technological support required to be able to transport and store the vaccines received.

2.5 Conclusion

During the Covid-19 pandemic there were direct and indirect harms that occurred to people globally, and these harms could have been avoided, or at least mitigated. These harms lowered utility and were morally indefensible, as they could not be justified. Vaccine patents contributed to these harms as the patents created unnecessary bottlenecks, which limited access to the only known safe and efficacious prophylactic mechanism at the time. Therefore, patent waivers could have assisted or prevented what was already a bad situation from becoming worse. I acknowledged that some authors feel that waiving patents would inhibit innovation and invention. However, patent waivers are an important part of remedying the issue of inaccessibility of vaccines during global crises, and global health partnerships (GHPs) can be key in helping to address the concerns that patent holders have about recovering costs for their inventions.

Chapter 3: Distributive justice and reciprocity for the covid-19 vaccine

Introduction

In the previous chapter, we established that patents caused more harm than good during the covid-19 pandemic. In this chapter, I will be arguing that LMICs that participated in covid-19 vaccine research ought to have been prioritised to receive vaccines on the basis of need, and should have been provided with the necessary equipment for the storage and distribution of such vaccines. I will be approaching my argument in two ways, in terms of (1) distributive justice and (2) reciprocity. Distributive justice relates to the "fair and appropriate" manner in which resources and burdens are distributed in society, while reciprocity is a principle of fairness, which refers to what individuals deserve due to their contribution to a cause, society, or an organisation (Sofaer, 2014).

Importantly, I acknowledge that all LMICs ought to have had equal moral concern through equitable access to vaccines, and therefore, I am not implying that only those LMICs who contributed to vaccine trials had the right to obtain vaccines, or that they should not have been considered within the "scope of justice". My position is that all LMICs should have been prioritised to receive vaccines as they had the greatest need for them, and on the basis of solidarity. This was even more so for some LMICs who participated in clinical trials, as they should have been able to benefit from their involvement in clinical trials as their contribution and effort made it possible for everyone else in the world to benefit from the final vaccine product. It is a well-known fact that some LMICs were not in a position to acquire vaccines on their own due to socio-economic constraints. Other LMICs such as Mauritius, Morroco, Botswana and South Africa were able to finance their participation in COVAX, but their vaccine orders were not prioritised due to unfair supply approaches (Brown and Rosier, 2023).

3.1 Distributive Justice

Justice can be described as giving each person what is due to him or her (Degrazia and Millum, 2021, pp.138). Degrazia and Millum (2021, pp.138) describe distributive justice as the appropriate and fair distribution of valuable resources (benefits) and burdens to the diverse members of society e.g. the distribution of work opportunities, health resources, legal rights, taxes etc. Similarly, Beauchamp & Childress (2013, p. 250) describe distributive justice as the "fair, equitable, and appropriate distribution of benefits and burdens determined by norms that structure the terms of social cooperation". Therefore,

according to distributive justice, an injustice occurs when individuals are denied benefits that they ought to be entitled to or when they are unfairly imposed with a burden that is not due to them.

John Rawls, in *The Theory of Justice* made the claim that where one is born, and their societal and familial status are a result of "*luck*", and therefore these unearned factors should not unreasonably influence the benefits that people receive in life (Krejci, 2022). Consequently, he asserted that the function of distributive justice is to limit the effect of this "*luck*", such that resources can be more fairly distributed and to the advantage of everyone in society (Krejci, 2022). Considering the above, this then raises the question of how this fairness ought to be determined, as there are limited resources in the world. In order for the fair allocation of resources to occur, certain factors are taken into account such as the total amount of resources available, the process for the distribution, whom the resources must be distributed to etc. Beauchamp and Childress (2019) have four famous principles that they use for the distribution of health resources namely: (1) respect for autonomy, (2) nonmaleficence, (3) beneficence and (4) justice. In Chapter 7 of Beauchamp and Childress (2019, p.3), they further analysed the *justice* principle into a sub-list of "material principles" that can be used to implement distributive justice:

(1) "To each person according to rules and actions that maximize social utility (utilitarianism)

(2) To each person a maximum of liberty and property resulting from the exercise of liberty rights and participation in free-market exchanges (libertarianism)

(3) To each person according to principles of fair distribution derived from conceptions of the good developed in moral communities (communitarianism)

(4) To each person an equal measure of liberty and equal access to the goods in life that every rational person values (egalitarianism)

(5) To each person the means necessary for the exercise of capabilities essential for a flourishing life (capability theories)

(6) To each person the means necessary for the realization of core elements of well-being (well-being theories)".

Depending on the context, the principles put forward by Beauchamp and Childress can be used individually or as a combination because sometimes the principles conflict with each other. Different distribution principles are used to promote different goals e.g. creating equal outcomes, creating equal opportunities etc. In the next sections, I will analyse some of the above principles, focusing on the principles that we encounter the most when it comes to debates about the sharing of resources, and are the most relevant for our purposes.

3.2 Equality vs Need

Equality refers to the notion that everyone within a society has a right to be given the same rights, opportunities and social status as other people belonging to that society (Krejci, 2022). Therefore, if we were to use equality as the principle to determine how resources ought to be distributed, then resources would be shared equally (proportionally) amongst all the people in society, i.e. everyone would get exactly the same amount but any additional requirements that individuals have beyond that would be disregarded. As a result, the outcome of equality may not produce equal results or outcomes for everyone because diverse people in a society have diverse needs.

For example, the government of a particular country can decide to provide financial assistance to low-income families or child-headed households in order to ensure that those families are able to buy basic needs such as food. If we analyse this social grant scenario from an equality perspective, then every household ought to receive an equivalent amount of financial assistance from the government, as that is what treating people equally dictates. However, if we look at it from the basis of what each person in that society needs, then the fair or just action is to give assistance to the low-income households so that an equal *outcome* is achieved (i.e. having food to eat) for all households regardless of their financial situation. This is because *need* based distribution requires that the government must prioritise the people who are in the most need of assistance i.e. special treatment is given to those with the highest level of need.

Now if we apply the principles of *equality* and *need* in the context of covid-19, the principle of equality would require that all countries, regardless of their socio-economic conditions be given an equal amount of vaccines. However, if we apply the principle of *need* instead, then we would be required to consider the individual needs of those countries. How then do we decide which principle should take priority over the other? To help us decide the best approach, let us consider which action would bring about the most utility. As mentioned in Chapter 2, the utilitarian theory requires that we promote the action that maximises the benefits (happiness) and reduces the harms overall for the greatest number of people.

There are two issues with the equality approach: (1) in reality it is virtually impossible to have an equal share of vaccines as the majority of vaccines are developed in HICs, and as such their governments are in a position to secure exclusive contracts with the producers of vaccines or patent holders. Secondly, (2) trying to apply the equality principle in this context will result in variable outcomes in terms

of how efficiently the vaccines reach the end users (citizens) as LMICs and HICs do not have the same financial, storage and transport capabilities (Ferranna, 2023).

According to a study that was conducted by the World Health Organisation (WHO), of its 194 member states, HICs had a health worker density of 170 per 10 000 population while MICs and LICs had around 65 and 26 per 10 000 population respectively (Boniol et al., 2022). The health worker density is determined based on the number of nurses, midwives and physicians that exist in a country as a ratio of the country's population per 10 000 population (Ahmat et al., 2022). This shows that as at 2020, HICs had a health worker density that was around 2.6 times more than that of MICs and 6.5 times more than that of LICs. In another 2019 study conducted by the WHO Office for Africa Region across 47 African countries, it was found that the African regional density of nurses, midwives and physicians per 10 000 is 15.5. In South Africa, this was found to be around 44.5 per 10 000, which is higher than the regional average, but still 3.8 times lower than the average of 170 per 10 000 in HICs.

The general findings from the study were that the densities of health workers in most African countries are very low in comparison to the rest of the world, and that there are shortages of health workers across all worker categories i.e. nurses, midwives, physicians, dentists, laboratory technicians and pharmacists (Ahmat et al., 2022). In India, it was found that there are nine (9) physicians per 10 000 population and around 17 nurses and midwives per 10 000 populations (Minhas, 2023). The relevance of health worker densities in this discussion is that there is a positive correlation between low health worker density and a high rate of illness and premature death within a population (i.e. the disease burden) and high rate of bad health outcomes (Ahmat et al., 2022). Therefore, citizens from LMICs have an even higher risk of covid-19 mortality due to fewer treatment options and the under-resourced healthcare systems in their countries (Heuberger, Forster and Frewer, 2023).

In non-pandemic circumstances, countries such as South Africa already have significant challenges in the delivery of health care services due to insufficient budget and funding, and thus resulting in insufficient health facilities and number of healthcare workers in both urban and rural areas, and both private and public sectors (Mbunge, 2020). Secondly, LMICs carry an excessively high burden of global deaths caused by chronic respiratory diseases (CRDs), including post-tuberculosis lung disease, bronchiectasis, asthma etc., and CRDs are correlated to poverty and socioeconomic wellbeing (Meghji et al., 2021). This means that patients with respiratory conditions in LMICs have lower rates of recovery

due to limited resources. As such, this outcome is worsened during a global pandemic and the severity of the situation would be more. Thus, that if a person in a LMIC became moderately or severely ill during the covid-19 pandemic, their chances of dying were significantly higher because of environmental factors.

LMICs have multiple social challenges (as mentioned above) that affect their ability to respond to the pandemic, and it would take them significantly longer than their HIC counterparts to recover from the direct and indirect harms once the pandemic is over. Although HICs inevitably also experienced a shortage of resources such as ventilators and personal protective equipment (PPEs) and became worse off too, however LMICs who started in worse circumstances were further disadvantaged. While all countries were in need during the pandemic, some were in worse conditions due to social determinants of health.

Sharma et al (2021) conducted epidemiological modelling which demonstrated that if the distribution of vaccines was done by prioritising the local infection rates of covid-19 in that particular region (i.e. take into account the need) then the most deaths could have been prevented. It was also found that a person living in LMICs such as Bolivia, Peru or Brazil was 10 times more likely to die from covid-19 (at a minimum) than a person living in HICs such as New Zealand, Australia and South Korea due to socio-economic factors and limited access to health resources (Sharma et al., 2021). Sharma et al. (2021) estimated that after the initial round of vaccines were distributed, more than 200 deaths per day were prevented in Brazil in comparison to New Zealand. Therefore, it is estimated that had the COVAX facility delivered vaccines earlier to Brazil, instead of distributing to HICs who did not need them, roughly 40 thousand deaths could have been avoided (Victora et al., 2021).

I argue that treating LMICs and HICs in the same manner when distributing vaccines without taking into account their unique circumstances (i.e. their pre-existing healthcare challenges and excessive disease burden) did not result in vaccine equity, but it instead resulted in further harms and went against utilitarianism (Heuberger, Forster and Frewer, 2023). Herzog et al. (2021) emphasized the limitations that came with the equal allocation of vaccines, because differences in need could not be adequately addressed if the individual impact of covid-19 on each country, pre-existing vulnerabilities and epidemic risks for each country were not considered. It can be seen from the above examples that there was a

great need for vaccines in LMICs, and that had the vaccines from COVAX been received sooner, the vaccines would have had a positive impact on the death rates experienced in LMICs.

Secondly, it illustrates that there was a mismatch between the (1) availability of vaccines, (2) the need for vaccines and (3) the access to vaccines in LMICs. Obviously, the pandemic affected the lives of people worldwide, and citizens of every country had similar needs. However, due to the confounding factors that came with covid-19 (such as the strain to the public health system and health workers, disruptions to the global supply chains, shortage of PPE and ventilators etc. as mentioned above), the need in LMICs was more and therefore those countries ought to have been prioritised on that basis.

Some may argue that it is not the responsibility of HICs to ensure that LMICs have equitable access to vaccines. To this, I respond that the fair distribution of health resources according to each country's needs, especially during a pandemic is necessary for the sustenance of the health of everyone in the global society in order for the world to function in an effective manner. Another way we can assess the issue is if we consider the covid-19 pandemic in terms of the (1) locus of control and (2) prevalence. The "*locus of control"* addresses the question whether people (in LMICs) are in themselves responsible for their "needy" situation and whether they are undeserving of generous support from others i.e. HICs (Hootegem, Abts and Meuleman, 2020).

Considering how the covid-19 pandemic arose so unexpectedly and spread so rapidly, I do not think it would be fair to conclude that LMICs could have predicted the situation that they are in and therefore could have caused or even prevented it in any way. Therefore, it was beyond their locus of control as covid-19 was one of the worst pandemics since the influenza pandemic in 1918 (Morens et al., 2021). Secondly, prevalence addresses the factor of who within the population was affected by the particular illness or circumstance (Hootegem, Abts and Meuleman, 2020). In the case of covid-19, the disease was widespread and affected the entire world population.

Therefore, we can conclude from the above answers that it was morally relevant to assist LMICs in a timely manner as covid-19 was prevalent and the pandemic was not self-inflicted. Another consideration is that beyond the direct harms of a prolonged pandemic due to the inaccessibility of vaccines in LMICs, most countries are dependent on each other for other reasons as well, such as for the trade of goods and services, skills exchange, economic stability etc. As such, it was in the best interests of everyone

to collaborate towards a common goal of ending the pandemic as soon as possible. In the following section, I consider the principle of contribution.

3.3 Contribution & Effort

While “need” dictates that we should consider the systematic inequalities that exist in society so that everyone is able to have access to the same benefits, the principle of contribution addresses the effect that those inequalities have on being able to attain certain resources (Timmermann, 2018). Contributive justice (as some refer to it) requires that contributions made by members of society such as effort, contribution towards common good, work ethic etc. are measured and rewarded (Timmermann, 2018). From this understanding, the contribution principle can be understood as equity, as equity requires that in order to have access to society’s resources, an individual must contribute to it in some way (Maiese, 2020). Therefore, those people who have contributed more to the society (i.e. have been more productive) must receive better pensions, state healthcare etc.

The principle of effort is connected to the principle of contribution, because some people believe that it would be fairer to give people an income that is proportional to the amount of effort that they have spent in fulfilling their contribution. Therefore, according to these principles, there is a moral obligation or duty to reward productive members of society. However, the principles of contribution and effort can be seen as competitive and thus exclude those who are not in a position to compete e.g. people with congenital disabilities that prevent them from contributing to society (Maiese, 2020). In order to address this concern, contribution can be combined with the principle of need to ensure that people who contribute are rewarded, while those who are unable to still have their basic needs met within society (Maiese, 2020). In the context of covid-19, this should have been implemented by giving those who participated in vaccine trials, and who also happened to have the greatest *need*, priority when allocating vaccines i.e. those who were at the intersection of principles of *contribution* and *need*.

Some might argue that the taxonomy of contribution is complex and clinical trials were not the only measure of contribution, as there were many possible contribution methods during the covid-19 pandemic. For example, there were:

(1) Countries that contributed towards vaccine manufacture, the COVAX initiative and clinical trials (mostly HICs)
(2) Countries that contributed to COVAX and clinical trials (such as South Africa and Botswana)

(3) Countries that contributed towards clinical trials only
(4) Countries that contributed to the COVAX initiative only (such as Bangladesh, Mauritius and Morocco)
(5) Countries who could not contribute even if they wanted to due to sanctions and/or other political reasons
(6) Some just chose not to contribute

To that I respond that although there were other contribution methods that could have been considered, those methods were self-serving, and were not really motivated by benefitting the common good. For example, those that contributed towards vaccine manufacture or the COVAX initiative were most likely doing it so that they could secure preferential treatment during vaccine acquisition and allocation. As much as someone could say the same about participation in clinical trials, the risk involved is different as there are no guarantees that the trials will convert into successful vaccines. Participation in clinical trials also entails a great level of sacrifice while also beneficial to the common good. I will elaborate on this in chapter 4.

Ramachandran, Ross and Miller (2021) conducted a study on the access of covid-19 vaccines in lower middle-income countries, upper middle-income and high-income countries that hosted clinical trials. The authors found that there were 25 completed trials in total, with 3 in lower MICs, 11 in upper MICs and 11 in HICs. Then when it came to the allocation of the vaccines that had been authorised from the *completed* trials, the lower and upper MICs received proportionately fewer vaccines (14.9% and 31.0%, respectively) compared to HICs which received more doses and were able to vaccinate 51.7% of their people. When the authors also took into account the ongoing trials, they found 37 trials in total, which consisted of 1 trial in a LIC, 6 in lower MICs, 12 in upper Mics and 18 in HICs. When comparing the COVAX delivery of vaccines against the countries that had participated in the vaccine trials, they found that a median of 15.4% doses of vaccines tested in LICs, 48.8% of doses in lower MICs, and 78.8%of does in upper MICs (Ramachandran, Ross and Miller, 2021).

This is not an unexpected finding, as it often reported in other literature that trials conducted in developing countries (LICs, lower and upper MICs) result in host communities not being able to afford treatments (hence benefit from the research studies) for which they had carried the burdens (Dhai, 2019). Another example is when the vaccines by Johnson and Johnson (J&J), which were made in

South Africa (after the pharmaceutical company entered into an agreement with Aspen Pharmacare), were being exported to already vaccinated HICs in Europe while only 7% of the South African population had been able to get vaccinated (Yamey et al., 2021). Based on the principles of contribution and effort the way in which the vaccines were distributed was unjust, as the LMICs had made efforts to enable vaccine development by hosting vaccine trials, and countries such as South Africa had entered into agreements to produce vaccines locally only for J&J not to reciprocate, but choose to distribute the vaccines elsewhere.

3.4 Justice and Reciprocity

The connection between distributive justice and reciprocity is that they both aim to address the evident imbalances in how costs and benefits of research are distributed (Sofaer, 2014). In public health ethics literature, distributive justice and reciprocity are typically used in the context of participants in clinical trials. The two can be used together as principles to justify the prioritisation of limited resources and are a vital component for redressing some of the harms caused during the participation in covid-19 trials (Fenton, 2021). In the literature, reciprocity is often defined from a virtue ethics perspective as drawn from Lawrence Becker's (1986, p.3; 2005) interpretation, where he defines it as "the disposition to return 'good' in proportion to the good we receive, and to make reparations for the harm we have done".

According to Becker, as humans we have the duty to reciprocate whether we have asked for the good that we have received or not, as reciprocating the good received leads to better connectedness and solidarity in society (Becker, 1986). He argues that it is a moral value that should be nurtured and is an integral part of the conditions that contribute to human flourishing. In *The theory of Justice,* Rawls (1971, pp 494 - 495) defined reciprocity as "a tendency to answer in kind" and argued that successful social cooperation would be weak and unimaginable without reciprocity. Silva, Dawson and Upshur (2016) also put forward that since reciprocating helps to make our lives go well, and from a consequentialist perspective it contributes towards maximising the good.

Obligations of justice require a fair distribution of benefits and burdens. In the case of LMICs that participated in vaccine trials to treat a global pandemic, this means that a proportional and fitting return must be provided to them for taking on the risk when they are already disadvantaged is a sacrifice on their part for the greater good. As previously stated, caring about LMICs who participated in vaccine trials and other public health programs was in the best interest of everyone, as it was in the best interests

of everyone to find an effective vaccine. Participation in vaccine trials required the individuals to provide a good to the public at a great sacrifice to themselves, even if they would also benefit from the outcome (this does not make it any less of a sacrifice).

As such, there was a moral obligation for reciprocation on the part of pharmaceutical companies that tested their vaccines in LMICs to ensure that those participants did not only bear the burdens but also enjoyed the benefits as well through justified preferential treatment. The Council for International Organisations of Medical Sciences (CIOMS) in its Guideline 2 states that researchers in LMICs (and their sponsors) must ensure that they make the interventions that were on trial available to the research participants and their communities as part of benefit sharing (Dhai, 2019). If this is not done, then it can be considered exploitation of the participants and their communities (Dhai, 2019). The CIOMS also states that in exchange, those communities also need to be provided with additional benefits such as being assisted with building their own research capacity (Dhai, 2019). Therefore, benefit sharing is an important way of establishing distributive justice, and the reciprocity of the interventions / vaccines developed after the research is important.

As mentioned earlier, justice and reciprocation do not always require everyone to be treated equally, as equal treatment can sometimes create even greater injustices (Emanuel et al., 2020), as each country has its own level of threats and vulnerabilities due to the robustness of their public health systems. Frameworks for allocating vaccines must also take into consideration the specific circumstances of the countries involved (their *need*, as was mentioned in the previous section). Some may argue that prioritising the LMICs who participated in covid-19 trials may have caused more harm than good and is a form of discrimination. Discrimination is not always an injustice as it may be acceptable if there is a morally relevant reason (Savulescu and Cameron, 2020).

Savulescu and Cameron (2020) illustrated this using an example of how governments spend millions on breast cancer screening for women, but do not do the same for men although men can also get breast cancer. They state that this is because breast cancer is less likely to occur in men as compared to women i.e. the women have a greater ***need*** for the screening, which is a morally relevant reason to justify that action. Similarly, LMICs have pre-existing public health challenges, which made them have a greater *need* for access to vaccines, therefore the preferential treatment from pharmaceutical companies that tested their vaccines in LMICs would have been justified as the likelihood of adverse

harms would be higher. Moreover, as was mentioned in chapter 2, patent intellectual property rights also contributed to a state of monopoly pricing that allowed for vaccine treatments to be inaccessible for the majority of LMICs, and thus making them unattainable to the citizens of those countries. Therefore, I argue that *not* allocating a benefit where it is due can be a form of injustice.

Considering another example, if we consider health workers (or other workers providing essential services) during the peak of the covid-19 pandemic in an attempt to sustain our lives, was it not justified that they got higher priority in receiving the necessary personal protective equipment (PPE) and vaccines when they first became available? I think intuitively we can all agree those benefits were justified in comparison to the burdens they carried in ensuring that they provided the essential services at a great risk to themselves. However, even if the LMICs had not participated in any clinical trial or made any significant contribution towards the development of acovid-29 vaccines, I argue that HICs still have a responsibility towards *Solidarity*. Therefore, on this basis, LMICs ought to have been prioritised as doing so would promote the general well-being of all and ensure social justice.

3.5 Conclusion

One of the issues that came about during peak covid-19 pandemic was the issue of the inequitable distribution of vaccines. There was the issue of patents, which created bottlenecks in the vaccine manufacturing process, and thus affecting access to vaccines in LMICs. In addition to that, there was the issue of the equitable distribution of vaccines to LMICs. I argued that LMICs who contributed to the solution of the vaccine by participating in clinical trials ought to have been prioritised based on need, reciprocity and solidarity. I established that LMICs had more need for the vaccines based on the pre-existing socio-economic conditions, and those that had participated in vaccine trials should have been prioritised as a form of reciprocation. Moreover, it was in the best interests of everyone to be in solidarity with LMICs as countries are inter-dependent on each other.

Chapter 4: Cost sharing for vaccine access and equity

Introduction

In the previous chapters, I argued using rule utilitarianism that during the covid-19 pandemic harms were caused to people due to inequitable distribution of vaccines, and that the harms could have been mitigated. I made the claim that patent restrictions further contributed to the harms that were caused. I also argued using distributive justice that LMICs ought to have been prioritised during the allocation of covid-19 vaccines as they had the greatest need. Furthermore, those that had contributed towards vaccine development by participating in clinical trials ought to have been prioritised based on reciprocity and benefit sharing.

In this chapter, I argue that patent holders offering IP only to vaccine manufacturers in LMICs is not sufficient, as there are additional supply chain issues that obstruct equitable access to vaccines. In order to effectively apply distributive justice, the requirement is that the necessary supply chain resources and knowledge sharing must accompany the patent waivers in future. This can be achieved through cost sharing that is funded by participating countries in order to provide the necessary equipment and storage of vaccines. This is to make certain that vaccines are distributed equitably, and that access issues in LMICs can be mitigated in future pandemics. As we have already established, one of the best tools to manage and or eliminate infectious diseases is through vaccination (Nonvignon et al., 2022).

As such, diseases that require vaccines are diseases that need international cooperation in order to get the best results since they are extremely contagious. Therefore, it is our collective responsibility to promote public health policies that encourage solidarity. In the next section, I will commence my discussion by providing an overview of the vaccine manufacturing process, so that we can have a high-level understanding of why vaccine costs and processes tend to be a barrier that prevents LMICs from establishing their own vaccine supplies.

4.1 Overview of Vaccine Manufacturing

The industry of manufacturing of vaccines is a challenging one, as the steps that are required to produce a safe and effective vaccine are complex to execute even for the most basic manufacturing processes. There are a myriad of variables in the vaccine starting materials, in the actual microorganism used, the

dependency on the expertise of the lab technicians involved in manufacturing process, and the purification steps that are involved (Plotkin et al., 2017). These variabilities then result in risks, as any variations to the process could result in very different outcomes compared to what was intended. Therefore, if these risks are not adequately managed, they could result in situations where products have to be recalled due to safety and efficacy issues, resulting in penalties for the manufacturers if supply agreements are breached (Plotkin et al., 2017).

There are also strict regulatory requirements that must be complied with in order to ensure that the correct microorganism is used, that a particular process is followed to produce the specific microorganism or antigen, and that it is tested and released for usage according to the regulatory standards (Plotkin et al., 2017). Examples of regulatory bodies include the United States Food and Drug Administrator (FDA) and SAHPRA (South African Health Products Regulatory Authority). The complexities of the vaccine production process are the reason why most patents are actually on the vaccine manufacturing process itself and not on the materials used. This also highlights why I make the claim that it is a necessity for pharmaceutical companies who hold vaccine patents to not only share the IP for the vaccine, but to also share the accompanying knowledge, skills and supply chain resources in order to ensure better chances of success.

After the manufacturing process and lab testing is done, and before commercial production can begin, there are regulatory requirements for clinical trials phases to be conducted to test the efficacy, safety and life-cycle of the vaccine (Privor-Dumm et al., 2023). These clinical trials need to be approved by regulatory bodies before they can commence. Pharmaceutical companies manufacturing vaccines therefore have to balance trying to optimise the process, while also moving fast enough to take the vaccine to the market in order to generate revenue (Wen et al., 2014). Another element that has to be accounted for is the consistent and sustainable supply of the raw materials that are required to make the vaccines. Moreover, manufacturers must also maintain the stability of the vaccine through the correct storage and transportation conditions, to ensure that the vaccine remains highly effective throughout its lifecycle (Privor-Dumm et al., 2023).

From the above overview, it is quite clear that the vaccine manufacturing process is quite involved, and that funding is required to support the associated costs. The costs for manufacturing a vaccine may include product development, equipment and facilities costs, labour costs, regulatory licensing costs,

clinical trials, maintenance of the production line etc. (Wen et al., 2014). Additionally, the required equipment and the professionals who have the necessary skills may not be available in LMICs. Therefore, if LMICs want to start producing vaccines locally, they will have to acquire funding or ways to share the costs of the above mentioned expenses.

Therefore, the cost issue faced by LMICs is two-fold, there is (1) the costs associated with buying an already completed vaccine product, and then there are (2) the costs involved should they want to produce vaccines locally. There are also political factors that affect the vaccine manufacturing process, as the governments for the participating countries have to be willing partners to ensure successful outcomes. In the next section, I discuss cost-sharing options for both scenarios.

4.2 Cost sharing through Global Health Partnerships

The concept of global health partnerships (GHPs) is not a novel one, as they started emerging towards the end of the twentieth century, when concerns about access to vaccines and essential medications increased (Nunes, McKee and Howard, 2024). These partnerships usually comprise of non-governmental organisations (NGOs), governments, universities, international agencies, private philanthropic foundations and governments collaborating for complex global health challenges (Nunes, McKee and Howard, 2024). Global health partnerships all work in a similar way, in the sense that they use funds obtained from public institutions to reduce the risks that are undertaken by private companies when developing health products such as vaccines (Mahoney, 2011). The risks that are involved are risks in the manufacture of new products, from the early stages until the product is commercialised.

GHPs also make use of advance market commitments (AMCs) where they pledge to subsidise or purchase the vaccine products should they be developed successfully (Gilchrist and Nanni, 2012). In order to reciprocate, the vaccine manufacturers then pledge to sell the vaccines to the GHPs at a fixed rate. As a result of these mutually beneficial relationships, GHPs are usually a good motivator for the innovation of new health products as they encourage vaccine manufacturers/ pharmaceuticals to spend money on vaccine development with the incentive that a certain amount of vaccines is already sold. They can be categorised into two groups, namely (1) GHPs for product development and (2) GHPs for improved access. Examples of successful GHPs for product development include Malaria Vaccine Initiative (MVI), the International AIDS Vaccine Initiative (IAVI), and Drugs for Neglected Diseases Initiative (DNDi) etc. (Nunes, McKee and Howard, 2024).

Examples of successful GHPs for improved access include GAVI and arguably COVAX (although some may argue that it failed due to funding and supply issues). The benefits that have been reported about GHPs is that they encourage LMICs to have globally competitive vaccine manufacturers through funding and subsidisation. An example of this is the *Serum Institute of India* (SII), which was established through global partnerships with the Bi*ll and Melinda Gates Foundation* (BMGF) and PATH, which is the *Program for Appropriate Technology in Health* (Nunes, McKee and Howard, 2024). However, some authors have reported that a large portion of GHPs tend to undermine the health systems in the communities that they are meant to serve, they go beyond their operating scope and end up not benefitting the local communities in a sustainable manner i.e. they focus on providing donations instead of ensuring long-term benefits (Prasad et al., 2022). Therefore, this highlights that there is a requirement for guiding principles on how GHPs should engage with the LMICs that they seek to empower, and which address the ethical issues that arise in such situations.

A meeting for global health leaders for global leaders in health was held in 2020 in order to formulate the guiding principles for successful GHPs. The principles as stated by Prasad et al., (2022) are as follows:

(1) "Mutual partnership with bi-directional input and learning,
(2) Empowered host country and community define needs and activities,
(3) Sustainable programs and capacity building,
(4) Compliance with applicable laws, ethical standards, and code of conduct
(5) Humility, cultural sensitivity, and respect for all involved
(6) Accountability for actions."

The main outcome from the above principles was that GHPs should respect the knowledge and expertise in the different health domains that they work in, in order to ensure that the long-term objectives for justice worldwide are achieved, and costs for health developments are shared in an optimal manner.

4.3 Unpacking COVAX

The GHP that was a major role player during the covid-19 pandemic was the *Covid-19 Vaccines Global Access* (COVAX). The COVAX is a GHP that was founded in 2020 by the World Health Organisation,

in collaboration with GAVI and CEPI (Coalition for Epidemic Preparedness Innovations) in an effort to tackle the covid-19 pandemic (Heuberger et al., 2023).

The COVAX initiative was established based on the principle of solidarity, where it aimed to supply the covid-19 vaccines to have at least 20% of each of its member country's population vaccinated by December 2021. The COVAX planned to do this by managing the costs of acquiring and delivering an already completed vaccine product to all its member countries (World Health Organisation,2020). The COVAX GHP had 192 member countries, which consisted of both HIC and LMICs, with 92 LMICs and 100 HICs. Initially, the COVAX used a cost sharing method where it pooled together funding from donors such that participating countries could be fully funded (i.e. 92 LMICs donated to it), or they could self-fund where possible, which was the case for the 100 HICs (Heuberger et al., 2023). The GHP was able to acquire vaccines through funding from private foundations such as the Bill and Melinda Gates Foundation (BMGF), funds from HICs, and by collecting left over vaccines from HICs and then redistributing those resources to LMICs (Heuberger et al., 2023).

In mid-2021, when the projections for vaccines improved, the COVAX GHP then provided an option for countries who required more vaccines (than the initial donations provided by COVAX) to self-fund (World Health Organisation, 2020). The main requirement from COVAX was for each country to formulate a readiness plan for their country before the donations could be provided to them, in order to make sure that once that country received the vaccines they would be able to efficiently handle the vaccination process and minimise wastage or misuse (World Health Organisation, 2020). The first vaccines that were supplied by COVAX were delivered to Ghana in February 2021, and by December 2021, 721.7 million doses were delivered by the initiative (Heuberger et al., 2023). However, this translated to only 9% of the people in LMICs who received vaccines, while HICs had 66.3% of their populations vaccinated since they had access to other vaccines resources outside of the COVAX partnership (United Nations Data Futures Platform, 2021).

During the first phase of vaccine distribution, the COVAX allocated vaccines in proportion to the country's population and did not take into account other factors such as the individual country's level of need. The GHP was highly criticised for this as some authors felt that the vaccines should have been allocated according to need and not according to the equality (Heuberger et al., 2023). The challenge that COVAX structure faced was that the initiative was heavily dependent on donations, and the issue

with donations is that recipients are at the mercy of the donors. Therefore, COVAX as a GHP was not in a position to challenge HICs in terms of the allocation framework, because from a justice perspective, HICs should not have been receiving vaccines from COVAX while also getting vaccines from other contracts.

The dilemma was that without the buy-in and donations from HICs the initiative was at risk of collapse (without sufficient funding). Therefore, rather be able to provide a few vaccines to LMICs rather than not being able to supply vaccines at all. Although COVAX GHP did improve access for LMICs that otherwise would have not stood a chance in getting the vaccines, it was not sustainable as it only improved the short-term vaccine equity goals which were necessary during the pandemic. Secondly, the COVAX did nothing to challenge the IP issues and patent holders overpricing vaccines. This shows that for a GHP to be able to achieve the desired outcomes, all parties involved must have the same goal and ensure that solutions are cost-effective for all. For future GHPs to be successful, they need to be proactive, in the sense that they need to ensure that they also address the gap of the lack of vaccine manufacturers in LMICs, as it will promote justice in the long-term.

It has been reported that other GHPs such as IAVI have found a way to ensure that patent holders do not overprice vaccines for LMICs (Moran and Stevenson, 2013). They have done this by allowing patent holders to keep their patents, but reserving the right to be able to enter into contracts with other manufacturers, should the original manufacturers choose not to produce vaccines at reasonable prices and volumes (Moran and Stevenson, 2013). This shows that it is important for GHPs to address IP issues, and ensure that they negotiate terms that are favourable for the LMICs.

As I have mentioned in previous sections, there were great inequalities in the accessibility of vaccines between HICs and LMICs. Therefore, it is important to note that the moral importance of GHPs goes beyond the practicalities of the cost-sharing required for the development of vaccines. The aim is also to facilitate global solidarity, and facilitate a shared sense of moral responsibility during a public health emergency. GHPs would also help to address the historical injustices and injustices that occurred in the distribution of covid-19 vaccines and other health resources in the past. This would be done in ensuring that HICs and LMICs pool together their resources in ensuring that all countries in need receive the necessary assistance during a public health emergency.

4.4 Conclusion

GHPs are one of the best ways to ensure that distributive justice is achieved in the domain of public health. They do this by ensuring that costs with vaccine manufacturers are subsidised, or they enter into AMCs with the manufacturers which give them a financial guarantee of buyers should they develop the vaccines successfully. The advantages of GHPs is that they provide assistance to LMICs and enable them to have access to health resources such as vaccines, which they would not otherwise be able to afford. However, some criticism against GHPs is that they tend to focus on unsustainable solutions such as donations, instead of solutions that provide long-term benefits such as helping LMICs develop their own vaccine hubs such as India did. Some GHPs also shy away from negotiating contracts that hold IP/ patent holders accountable, so that the vaccines produced are still affordable for LMICs. Therefore, the critical components for creating successful GHPs is to create ones that not only solution for the present, but also consider the future possibilities for the communities that they assist.

Chapter 5: Conclusion & Recommendations

It is now five years since the covid-19 virus was declared as a pandemic and the world that we knew came to a dramatic halt. The pandemic highlighted the weaknesses in the public health system globally, and exposed some of the ethical issues that need to be proactively resolved, in order to prevent the repeat of injustices from occurring in the future. One of the major injustices that came out was the issue of distributing vaccines equitably, so that low and middle-income countries are not disadvantaged. Thus, in this thesis, I did a retrospective ethical analysis of the covid-19 pandemic, and specifically did the analysis though the lens of developing countries i.e. (LMICs). The thesis that I aimed to defend was that the patenting of covid-19 vaccines, especially in developing countries during a global pandemic was not ethically justified.

In this analysis, it was clear that there were harms that occurred to people in LMICs that could have been mitigated, because there was already a safe and effective vaccine available in other parts of the world. I used rule utilitarianism to illustrate that the harms caused were bad, and that the harms were not morally defensible. The harms were bad harms as they could not be ethically justified, and these harms included direct and indirect harms. The harms affected health and well-being, the state of the economy, and had devastating effects on the public health system itself. I then argued that there needs to be a rule in place that we used as a guideline in the context of public health emergencies. The rule stated that during public health emergencies there should be patent waivers in place in order to minimise harms and maximise the good, provided that the treatment is proven to be safe and effective.

This rule was necessary because one of the factors that made an already bad situation much worse, was the patent restrictions. Patents aggravated the situation because they created bottlenecks in the vaccine equity and distribution process, which affected the access to life-saving treatments for the majority of people in LMICs, and possibly even some people in HICs. Although patents waivers by themselves would not have eradicated the pandemic, they would have provided some assistance in ensuring that the vaccine reached people in LMICs at a faster rate, and saved lives. The other issue that was revealed in the thesis is the amount of control that patent holders have because they can choose whom to sell the vaccine to, and at what cost, which greatly disadvantages those countries that cannot compete financially.

In this thesis, I acknowledged that many people believe that patents are beneficial because they encourage scientific invention and innovation, and therefore without patents the scientific and pharmaceutical communities would be negatively affected. However, to this I argued that it is in fact beneficial to all to eradicate contagious conditions, as a longer pandemic negatively affects everyone including the patent holders. I then analysed the issue of vaccine access using the principles of distributive justice and reciprocity. Gaining insight from Beauchamp and Childress' criteria for distributive justice, I specified the distribution of the covid-19 vaccine. I argued that using the principle of equality to distribute vaccines was inadequate, as equality requires that vaccines be distributed proportionally, instead of taking into account the different circumstances that LMICs face in comparison to HICs for example.

I then argued that the vaccines ought to have been distributed according to need, as that would make the distribution equitable. I also considered other options such as effort and contribution, and taking that into account meant that we also had to consider LMICs that participated in covid-29 vaccine trials. According to Ramachandran, Ross and Miller (2021) there were LICs, MICs and HICs that participated in vaccine trials, indicating that some LICs also played a part in finding a solution to the pandemic. Therefore, taking that into account, they also should have been prioritised during the distribution of vaccines on the basis of reciprocation. If not on the basis of reciprocation, then at least they should have been prioritised on the basis of solidarity. I then also argued that there are alternatives that can be explored to recover manufacturing costs for vaccines without solely depending on patents, through the use of Global Health Partnerships (GHPs).

Global health partnerships comprise of different role players such as governments, universities, NGOs, international agencies etc., which work together with a goal of solving a specific, complex public health issue. These GHPs obtain funding from donors, and use the funds to share costs with manufactures of vaccines, for example. I acknowledged that the process for manufacturing vaccines is complex and expensive as it is a process that requires skill and perfection. Moreover, it is also a highly regulated industry, and a vaccine has to go through multiple steps before it can be licensed for commercialisation.

Therefore, the advantage of GHPs is that they are able to incentivise the production of vaccines for LMICs, as the GHPs are able to negotiate contracts that are mutually beneficial for all interested parties. I highlighted that some of the disadvantages of these GHPs is that they can focus on short-term justice

goals, instead of also considering the longer-term goals that will solve the complex public health issues. An example of a long-term goal was for GHPs to support the development of vaccine manufacturing facilities in LMICs, similar to the vaccine centre that was built in India. Considering all the above factors, we can conclude that there were other alternatives available, which could have enabled the waiving of patents without fully disadvantaging patent holders. It showed that patenting of covid-19 vaccines, especially on developing countries during a global pandemic was not ethically justified.

I recommend that countries recognise that although we have different borders, we are a global village. This means that we are all dependent on one another, and LMICs and HICs have a symbiotic relationship that must be nurtured for the flourishing of all. I also recommend that countries make use of GHPs, as public health issues are easier to solve as a collective and with a wider pool of skills and expertise. Future GHPs also have to be intentional about addressing IP/ patent restrictions when entering into contracts with vaccine manufacturers, in order to make sure that their objectives are not compromised in the process. Patents create a barrier, especially for small vaccine manufacturers that want to break into the market.

I also recommend that future GHPs should go beyond the practicalities of cost-sharing, but also focus on fostering global solidarity and international co-operation. This is why it is important for policy changes to be made to the current legislations in terms of patent use during a pandemic. I recognise that the issue of patents is not an easy one to resolve, as there are also political issues at play that affect relationships between countries, and between donors. However, I would recommend that future GHPs take notes from IAVI, and negotiate the vaccine costs in such a way that they are able to find alternative manufacturers, should the original manufacturers dictate terms that are unreasonable to the GHP.

6. References

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