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Patents and Sustainable Medical Treatment in Developing Countries: Lessons from COVID-19 Vaccines

Ezgi Demir and Peter M. Bican *

Chair of Technology Management, Universität Erlangen-Nuremberg, 90762 Fürth, Germany
* Correspondence: peter.bican@fau.de

Abstract: COVID-19 has had devastating effects worldwide, and vaccines have become the most efficient solution to address the current pandemic situation thus far. After COVID-19 vaccines had been developed, discussions of the various countries' equality of access gained traction, with patents and pricing forming a significant part of this discourse. Therefore, this study investigates the impact of patents and prices on the accessibility of COVID-19 vaccines in the developing world, using semi-structured interviews with subject-matter experts in this area of focus. Our analysis of these interviews highlights the fact that patents and prices are not the major barriers to accessibility for medical treatments, both generally and specifically in terms of COVID-19; rather, these barriers relate to the lack of local production capacity, technology transfer, infrastructure, local regulations, and supply-chain competencies. These results suggest that rather than focusing on patents and prices, governments should invest more time in improving technology transfer and using compulsory licenses as a negotiation tool. Moreover, the results show that the pricing strategies applied by companies could have different impacts on access, as could accessibility programs such as COVAX.

Keywords: COVID-19 pandemic; patent; intellectual property; vaccines; developing countries; sustainable medication; sustainability; healthcare

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1. Introduction

Throughout its history, the world has faced a variety of crises, such as wars, natural disasters, and pandemics. In December 2019, COVID-19 emerged as the latest such crisis, going on to cause more than 250 million infections and 5 million deaths in just two years [1–3]. Additionally, COVID-19 has adversely affected economic growth, with the International Monetary Fund predicting a decrease in economic growth by 3% in 2020, which was greater than the economic crisis in 2008–2009 [4]. The associated social distancing and lockdown measures were particularly damaging to the travel, tourism, and entertainment sectors [5], which are important factors that affect human psychology and well-being.

To overcome the spread of COVID-19 and its impacts, vaccine development was a global priority and defining the objectives and potential challenges was crucial, leading to multiple innovations before the first vaccines came to market [6,7]. As of January 2023, nine vaccines had been registered for the World Health Organization's (WHO's) Emergency Use Listing [8]. After the first vaccines were approved, the world started to discuss how to distribute them and make them globally accessible. During the distribution phase for a vaccine, equality of distribution becomes vital—especially for those countries that cannot afford it. Therefore, discussions around regulations and patents prompted steps toward equal access to COVID-19 vaccines. Patents provide incentives for pharmaceutical companies' research and development (R&D) operations, as long as the monopoly price is affordable for patients, meaning that patents are among the most important players in the pharmaceutical industry and have a crucial role in vaccine accessibility [9]. Hence, the World Trade Organization (WTO) began a discussion regarding patenting COVID-19 vaccines, to ensure that these vaccines would become more affordable and, eventually, be

accessible to everyone. Thus far, 7 billion doses of COVID-19 vaccines have been registered worldwide, although registration levels vary widely across regions. For instance, North and South America administered 127 vaccines per 100 people, and, in Europe, 199 per 100 people, while those numbers decrease to 11 per 100 people in Africa. How patents and prices affect these numbers, especially in developing countries, is still to be seen [10].

Since vaccines are the most effective solutions (so far) to address COVID-19, our study brings critical new perspectives to the problems of patents, prices, and accessibility in terms of COVID-19 vaccines. We aim at answering the following research question: *"What are the effects of pricing and patents on the accessibility of COVID-19 vaccines in developing countries?"* Therefore, we investigate how patents and prices affect these vaccines' accessibility, as well as discussing practitioners' perspectives on the current and potential solutions, to reveal different aspects of the challenges brought about by the pandemic. Two studies [11,12] have already described accessibility-related challenges related to COVID-19 vaccines; the first study [11] also proposes potential solutions that use innovative approaches to scale up production. However, neither of these studies nor the other existing literature offers practitioner perspectives. Therefore, the current study collects expert perspectives via semi-structured interviews. During these interviews, some participants indicated that patents are a major barrier to access, both generally and specifically amid COVID-19; they also asserted that patents should be waived for COVID-19 vaccines to provide better access for those countries in need, even though this is an imperfect solution. However, the remaining participants argued that production capacity, the availability of local pharmaceutical companies and production facilities, infrastructure, supply chain competencies, and local regulations should be considered before considering the topic of waiving patents for COVID-19 vaccines. Additionally, participants suggested compulsory licensing as a negotiation tool to decrease vaccine prices and, thus, make them more accessible.

This paper first discusses the theoretical background and current status of the research, which includes the patent's role in the pharmaceutical industry, the pricing strategies used in the pharmaceutical industry, and the accessibility discourse around COVID-19 vaccines. Then, it explains the methodological approach (i.e., inductive qualitative research, based on semi-structured interviews), before presenting the results from these expert interviews and discussing the results, as well as the theoretical and practical implications. Finally, the paper provides limitations and recommendations for future avenues of research.

2. Theoretical Background and the State of Research

Patents are one of the most important factors affecting product development in the pharmaceutical industry [13,14]; therefore, a discussion has emerged as to whether the patents for COVID-19 vaccines should be waived or not.

2.1. The Pharmaceutical Industry

Pharmaceutical production is an R&D-based industry; developing new drugs and improving them further is a costly process [15]. Hence, those companies operating in the pharmaceutical industry need an incentive mechanism to encourage the development of new medicines. As one way of providing this incentive [7,16], patents are crucial to the industry [9]. The manufacturers of innovative drugs are at risk during the R&D process, and the patent system incentivizes them with up to 20 years of patent protection [15,17,18]. The innovator company has several rights until the patent expires, including the exclusive right to produce and market a particular drug in a particular country [19], and the monopoly right to decide on their prices. After a generic product is launched on the market, the price of the innovator (or originator) medicine decreases under general conditions [20].

2.2. Intellectual Property Rights and TRIPS

The rights mentioned above were mostly introduced within the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is enforced by the WTO. TRIPS marked an important step toward incentivizing the pharmaceutical industry to

produce innovative new drugs; the WTO has stressed that TRIPS is unique in its comprehensiveness as a multilateral agreement on intellectual property (IP) and that TRIPS is vital to exchanging information, fostering creativity and innovation, and solving international trade and IP disputes [21,22].

Before the TRIPS agreement, IP rights were not well-regulated worldwide [23], and patent protections varied—indeed, more than 40 countries were not providing patent protection at all [24]. For example, a pre-TRIPS study analyzing the Indian pharmaceutical industry described how India had a strict, colonial-era patent system and argued that relaxing this system would be beneficial for India [25]. However, that is the opposite of the idea proposed in a study by the authors of [24], in which they stated that TRIPS established minimum international standards and created a balance between the accessibility of necessary medicines and the need to incentivize pharmaceutical production [24]. Furthermore, TRIPS provided countries with the flexibility to determine their own steps to put patents in place [25].

Clearly, TRIPS instituted important changes in the pharmaceutical industry. However, there are two schools of thought on how TRIPS has affected accessibility. Some researchers say that innovative drugs must be protected via patents since IP rights provide incentives to pharmaceutical companies. Others (e.g., Ref. [24]) see patents as a barrier to access and argue that patents should not be so crucial to the pharmaceutical process since they provide exclusive rights to the innovator companies. In that sense, it is important to analyze the opportunities offered by compulsory licensing, to better understand how TRIPS has affected access to medicines, as well as the opportunities for flexibility that are provided by the TRIPS agreement.

2.3. Compulsory Licensing and Patent Waivers

Compulsory licensing came into force following the WTO's Doha Declaration in 2001, which revised the regulatory framework for IP rights [9]. It is a mandatory, government-enforced process, allowing a third party to use the patented drug without the permission of the innovator company [26]. According to another study [27], the Doha Declaration reshaped TRIPS implementation in a way that supports the decisions and rights of WTO members to protect public health and provide better access to medicines for all, as covered in Article 31 of TRIPS. Additionally, the use of compulsory licenses without negotiation can be implemented only for non-commercial use, in national or extreme emergencies, and for the purposes of being anti-competitive [27]. As emphasized by the authors of [26], before starting negotiations regarding a compulsory license, the interested parties should first discuss the potential for a voluntary license.

Some scholars argue that compulsory licensing is an efficient way to improve access, especially in developing countries where the necessary production capabilities are available [24]. In addition, compulsory licensing can be used to increase economies of scale by exporting medicines, according to the amendment to Article 31 [24]. However, compulsory licensing depends heavily on the developing countries' manufacturing capabilities and technological competencies [26,28]. Moreover, it could also diminish R&D returns and the return on investment since it decreases drug prices [20].

Currently, one of the main global discussions regarding COVID-19 vaccines relates to waiving patents to improve the vaccines' accessibility and make them more affordable for countries in need. According to Médecins Sans Frontières, India and South Africa were the main countries proposing patent waivers to the WTO, gaining the support of 58 sponsoring states [29] and the US President, Joseph R. Biden Jr. This decision could have a significant impact on further discussions at the WTO [30]. However, some European Union leaders, as well as the president of the European Commission, argue that increasing production capacity, eliminating export barriers, and sharing current vaccine doses are more crucial than waiving patents [31]. When it comes to the pharmaceutical companies' opinions, Moderna published on its website that it will not enforce patents for COVID-19 vaccines [32], while the Pfizer CEO, Albert Bourla, emphasized the importance of patents

and said that the company would not waive patents and allow other countries to produce Pfizer-BioNTech vaccines [33].

2.4. Pricing of Pharmaceuticals

As was emphasized earlier, the pharmaceutical industry depends heavily on its R&D activities, and to cover these R&D costs, pharmaceutical companies apply different pricing schemes. At the same time, the pricing structure of medicines depends heavily on drug patent protection, since patents provide a temporary monopoly to pharmaceutical companies [34]. After the patent expires, generic drugs can enter the market and create free competition, with prices that tend to be 20% to 80% lower than the originator drugs [17].

According to [35], the pricing schemes most often applied by pharmaceutical companies in industrialized countries are therapeutic reference pricing, international/external reference pricing, and value-based pricing. Therapeutic reference pricing is an internal reference pricing that compares the prices of therapeutically equivalent remedies (for similar or for the same medicines), while value-based pricing uses the medicine's therapeutic value, based on health technology assessments [35]. According to the glossary of Pharmaceutical Pricing and Reimbursement Information [36], international/external reference pricing uses the prices of a medicine sold in several other countries as a benchmark to set or negotiate the prices of that medicine in a particular country.

However, when it comes to COVID-19 vaccines, companies have mostly applied differential and at-cost pricing. Pfizer's CEO recently said that wealthier nations would pay higher prices than lower-income countries would need to pay [37], as seen in the United Nations' Children's Fund's COVID-19 Vaccine Market Dashboard (see Table 1). In contrast, AstraZeneca announced that it would supply its vaccines as a not-for-profit scheme, regardless of the particular country's income level [38].

Table 1. Reported Pfizer-BioNTech vaccine price per dose, based on [39].

Country/Entity	Price per Dose (USD)
African Union	6.75
Tunisia	7.00
Brazil	10.00
South Africa	10.00
Argentina	12.00
Colombia	12.00
United States of America	19.50
European Commission	23.15

2.5. Accessibility

Scholars have promoted different approaches to creating greater global accessibility for COVID-19 vaccines. For example, the authors of [11] promote a 3Ds (development, dissemination, and deployment) framework that includes 11 challenges of policy for a successful outcome, including sustaining R&D incentives, controlling vaccine deployment, securing global access to COVID-19 vaccines, ensuring adequate production numbers, and delivering vaccines securely (see Figure 1). Additionally, another study [12] suggests important dimensions to achieving global immunity that are related to development, manufacturing, pricing, distribution, and allocation.

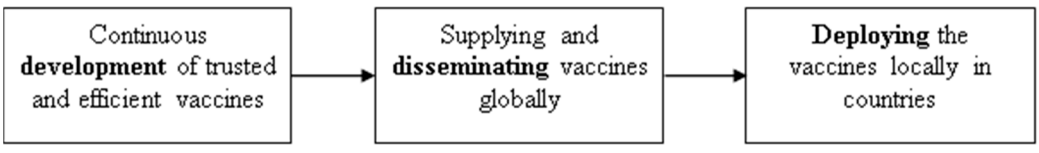

Figure 1. Framework for understanding the challenges of implementing COVID-19 vaccination campaigns. Adapted from [11].

To overcome the challenges of implementing vaccination, the Coalition for Epidemic Preparedness Innovations, along with Gavi, the Vaccine Alliance, established COVAX with the aim of delivering various COVID-19 vaccines to all countries of the world [12]. COVAX supplies vaccines to at least 20% of the population of a particular country and promises to end the COVID-19 pandemic [40], striving to ensure access for countries with limited economic resources by purchasing vaccines from firms and negotiating pricing deals with governments so that countries can potentially purchase vaccines on their own behalf [41].

COVAX's fair distribution mechanism includes two steps. In the first phase, all participating nations will receive enough doses to vaccinate 3% of their population, with the first doses being distributed to front-line health and social care professionals. In the second phase, doses will be supplied to all countries until 20% of each country's population is vaccinated; the WHO anticipates that those doses will be given to those people who are most vulnerable to COVID-19, such as older adults and those with pre-existing illnesses [42]. COVAX has more than USD 2 billion in commitments from almost 100 developed countries, foundations, and corporations, but only a small portion of that money is cash in hand, and it was predicted that USD 5 billion would be necessary by the end of 2021. However, even if there are not enough vaccine doses to immunize the approximately 8 billion people in the world, Richard Hatchett (head of the Coalition for Epidemic Preparedness Innovations) believed supply and demand would "get into equilibrium" by 2022 [41].

3. Methodology

The literature review conducted prior to this study did not uncover opinions from experts in the pharmaceutical industry and non-governmental organizations (NGOs) on how patents and prices affect the accessibility of pharmaceutical drugs and COVID-19 vaccines. Therefore, we formulated our research question, to be addressed via semi-structured interviews with experts from the pharmaceutical industry: *"What are the effects of pricing and patents on the accessibility of COVID-19 vaccines in developing countries?"*

This study has defined "developing countries" in line with the United Nations' country classifications [43], and we used three categories for grouping countries: developed economies, economies in transition, and developing economies. "Developed countries", "high-income countries", and "Western countries" are used interchangeably, but "industrialized countries" is not used due to a lack of specificity.

3.1. Data Collection

This study used several methods to find and contact experts on the research question, reaching 167 people via LinkedIn, ResearchGate, emails, and contact forms. Ultimately, we conducted 12 interviews between August and October 2021 to address the research question, although one interview was excluded from the data analysis due to unrelated answers to the interview questions. Following prior research [44], the interviews were conducted remotely via calls to ensure safety during the COVID-19 pandemic and to avoid distress from the interviewee being influenced by the researchers' presence and the question options [45]. Some of the experts requested to remain anonymous; therefore, they are presented here by number (e.g., E1, E2). The experts have diverse positions and areas of focus, as Table 2 shows, and they work in pharmaceutical companies, NGOs, law firms, and universities. Their most common area of expertise is IP rights. Due to the strong correlation between patents and pricing strategies in the pharmaceutical industry, we discussed with them not only the impact of patents but also how different pricing schemes for COVID-19 vaccines affect accessibility.

According to an earlier study [46], both closed- and open-ended questions can be found in semi-structured interviews; semi-structured interviews are more interactive and relaxed than surveys and focus groups. Therefore, we decided to use open-ended questions with semi-structured interviews in this study, to explore the experts' opinions. The interview questions were mostly more general, to allow both interviewee and interviewer to explain and discuss the question more fully (see the Appendix A). The main topics discussed

during the interviews included the main challenges/barriers to COVID-19 vaccine access in the developing world, the patents' impact on COVID-19 vaccine accessibility, the effects of different pricing strategies on COVID-19 vaccine accessibility, and possible solutions to overcome this access problem.

Table 2. Demographic overview of the interview partners.

Expert	Job Position	Focus Area
E1	Senior director	Global public policy, international trade, and IP issues
E2	Strategy lead	COVID-19 response strategies and the supply chain
E3	University professor and NGO president	Global healthcare policy and IP protection
E4	Lawyer and lecturer	Patent rights for pharmaceutical and medical technology
E5	Manager	Global market access and pricing
E6	Patent agent	IP rights for biotechnology
E7	Lawyer and researcher	IP rights, new technologies, and technology transfer
E8	University professor	Pharmaceutical IP law and patents of COVID-19 vaccines
E9	Commercial and corporate paralegal	IP rights in healthcare and COVID-19 vaccines
E10	Lawyer and lecturer	IP rights, TRIPS agreement, and health innovations
E11	Lawyer	IP rights and access to medicines

3.2. Data Analysis

To code the qualitative data, we used an inductive category application (previously employed by Mayring [47]), based mostly on the research question. Inductive analysis is defined as "approaches that primarily use detailed readings of raw data to derive concepts, themes, or a model through interpretations made from the raw data by an evaluator or researcher" [48]. Unlike structural approaches, this method allows researchers to find common, prevalent, and/or significant topics in the raw data, without any restriction [48].

Figure 2 depicts an overview of the applied coding process. We first read the interview transcripts several times (after transcriptions were made with the support of the transcription tools, Trint and Otter.ai). The theoretical background, research question, and systematic reading of the interview text allowed us to establish the major themes and codes for the analysis. During this categorization, we used the support software, MAXQDA, with memos added to specify and define the subthemes. As a result of this reading process, we were able to conduct an analysis to understand the differences and similarities among interviews and find the relationships between the different code segments.

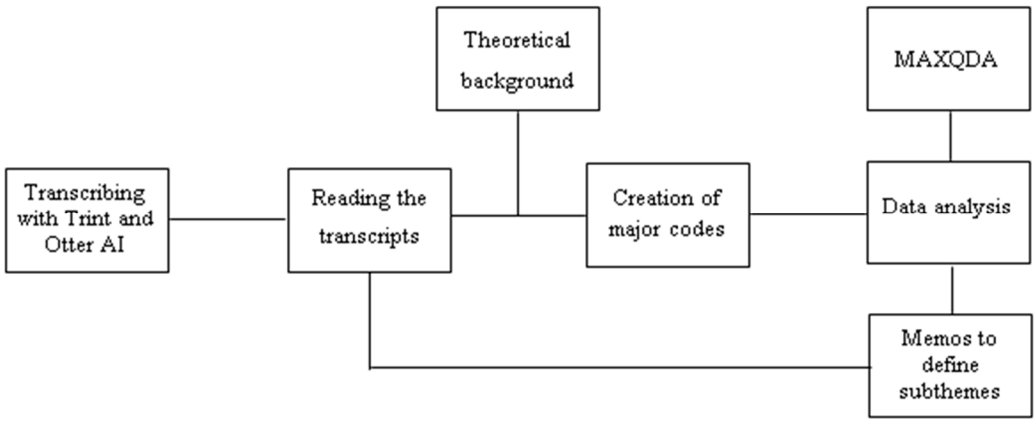

Figure 2. Coding process for the interviews (authors' own representation).

4. Results and Findings

Five main points emerged from the interviews: general barriers to accessing all medicines in the developing world, barriers to accessing COVID-19 vaccines in the developing world, the impact of patents on COVID-19 vaccines, the pricing of COVID-19 vaccines and its impacts, and current and/or possible solutions.

4.1. General Barriers to Accessing Medicines in the Developing World

All the interviews began with a question about the general barriers to accessing medicines in the developing world. It is important to understand the overall situation since it gives us an idea of the general conditions that are currently in place, which also apply to the context of COVID-19. The participants' answers to this question also helped to differentiate between the barriers regarding COVID-19 vaccines, specifically, and more general barriers regarding access to medicines.

The respondents described a variety of barriers, with four of the experts mentioning the lack of infrastructure capacity and/or health facilities as a key impediment to providing access to healthcare. For example:

> "Many countries do not have the same infrastructure, and when I say infrastructure . . . connections, roads, railways to bring medicine, new vaccines, and whatever is needed to the patients." (E10)

> "The capacity is limited, e.g., the number of hospitals we have built . . . and the number of trained personnel in this access to health facilities." (E7)

Respondent E1 gave an example demonstrating the problem of infrastructure scarcity. In African countries, the respondent said the first point of contact in case of an illness is pharmacies since most communities generally do not have access to a doctor. Therefore, the company for which the respondent is working now has a program that provides rural pharmacies in Africa with better access to medicine.

Another access issue is pricing, which was mentioned by three interviewees. E11 identified three "A"s to this accessibility problem in developing countries: availability, affordability, and accessibility. When the product is available and affordable, it automatically becomes accessible in that developing country. During the pricing discussion, the respondent mentioned the importance of competition in the pharmaceutical market, due to the rapidly evolving technology:

> "So, as a person who invented that or a company, he knows that this is a potential market for me to earn profits or earn money. So, what he will do, he will keep the prices high so that he can earn profits in a smaller period of time . . . The problem here is that people cannot buy it because, in developing countries, the income of people and its [gross domestic product] is not as high as developed nations." (E11)

Respondent E5 mentioned how international reference pricing affects accessibility, describing how countries determine a floor price to ensure that the drug price is not too low when a developing country is referenced. Sometimes, E5 said, this floor price is much higher than the country's health budget allows. However, E3 opposed this idea of seeing prices as a barrier, saying that "the most expensive healthcare technology is the one that doesn't work." The respondent also said that low- and middle-income countries prefer buying low-quality medicines that have no value but that are sold at a low price—the wrong tactic.

Four respondents mentioned patents in response to this question. Two (E11 and E2) saw them as a barrier, while E4 did not. E11 explained that companies apply for a patent in India even if they do not have a reason to sell it, which means that drugs are unavailable even though as much as 10% of the population is suffering from that disease. Additionally, E2 mentioned that IP has been an important issue for Southeast Asian countries, which the respondent said possess the manufacturing capacity, formulations, and drugs but cannot produce these medicines since they do not know the underlying technology, due to patents. However, E6 stressed that patent laws block young pharmaceutical companies from producing innovative drugs. It is also noteworthy that E4 commented that the lack of an appropriate IP law system in a country could result in fewer companies doing business there:

> "Italy is an example of a country in which … I believe, until the 1980s—'70s, '80s—there were no patents granted on pharmaceutical products. So, it was one industry that there were not patents [for], but for all other industries—for automotive and everything [there were patents], but not for pharmaceutical products. Again, the idea was they should be free. And if you then take a look at today's map, where … the big pharmaceutical companies [are], and you can see, there are many in Germany and France, in the UK, in Switzerland, but there aren't so many in Italy." (E4)

Two participants mentioned limited budgets as a barrier to access. E2 and E5 commented that developing countries have issues with scaling up production, due to the limited budget given to the health authorities because of those countries' economic conditions. E5 emphasized that governments generally provide a larger budget for defense than for education and healthcare. E2 and E5 also discussed vaccine supply to the actual patient as a problem. According to E2, the problem is mostly about the workforce and working conditions. Behavior in society is steered toward trusting female healthcare workers more when it comes to vaccination at home, even when the healthcare community is mostly composed of women in poor working conditions, due to the lack of workplace safety, which is usually not provided by their respective governments. Additionally, E5 commented that doctors sometimes do not follow the latest developments in medical science and prefer not to prescribe innovative drugs, which may have fewer side effects for patients.

Several issues were raised by just one participant each. For example, E2 discussed how health education in India is clinically oriented, rather than investigation-oriented, and how false information spreads rapidly—in more than 200 languages—through WhatsApp; she described how this rapid, multilingual spread of false information has created hesitancy regarding vaccination. Additionally, E5 discussed how counterfeiting can cause drugs to not be delivered to patients, and how a lack of over-the-counter medicines could shift the financial burden from governments to patients, so that the government can increase the budget for health authorities. Finally, E8 described a lack of research into the diseases that affect developing countries.

4.2. Barriers to Accessing COVID-19 Vaccines in the Developing World

For the second question, participants were asked to narrow the discussion of barriers down to the COVID-19 pandemic, specifically. The most common answer was related to the production capacity needed to meet the demand for COVID-19 vaccines. For example:

> "So, I think the problem [was] … last year, in terms of access and availability, or early this year, there was really just no existing physical capacity to produce the vaccines at the scale that we needed." (E1)

In addition, E6 said that developing countries do not have any local pharmaceutical capabilities to produce the vaccines, even though the patents are waived, and E10 elaborated that a patent waiver would not solve this problem of limited production capacity.

Three respondents mentioned technology transfer, namely that countries need the technology behind the production of these vaccines more than the actual ingredients needed to manufacture them. E11 said that most patent laws only provide the right to produce the medicine and do not discuss technology transfer, which makes producing a vaccine in a developing country more difficult. E6 noted that the companies would not provide technological knowledge since they need to enforce their IP rights to cover their other major investments. Therefore, as E5 mentioned, pharmaceutical companies have production sites in different places and can only stabilize the technology in those locations.

Several answers were given by only one participant each. E1, for example, discussed the moral failure of Western governments and pharmaceutical companies; he argued that Western countries bought the vaccines that they needed and only tended to think about the rest of the world's countries later. However, E3 stated that this is just the reality of the situation since the West has more resources with which to buy vaccines than developing

countries do. Furthermore, E7 mentioned how regulatory restrictions in his country only allow a compulsory license to be issued three years after a patent is issued. Finally, E11 discussed the unavailability of public insurance schemes in developing countries since neither public nor private health insurance is compulsory.

4.3. Impact of Patents on COVID-19 Vaccines

Two views about the impact of patents on COVID-19 vaccines emerged among participants. While some believed that a patent waiver could address the accessibility issue to some extent, others did not. E1 said that COVID-19 has become the new HIV crisis (which, he said, created a platform enabling more people to blame the patent system); he believes that there is fundamental opposition to the patent system. E9 and E8 also said that there has always been a debate around patents, which have previously been seen as a barrier. However, according to E8, the problem is that many people are only just recognizing the discussions concerning the patent system.

Moreover, E9 and E3 discussed the difficulty of producing COVID-19 vaccines, saying that companies would not be willing to produce these vaccines without the protection of the patent system. E3 explained that the first step is to build factories before a patent expires, to avoid losing time, while E9 commented:

> "Everything that's been put into patents is the reason why we are here now. And without patents, we wouldn't have a vaccine because who's going to produce the vaccines if no one is going to get a reward for it?" (E9)

Another reason mentioned by E8 is the continuous development of vaccines to address new variants of the virus. Therefore, even though there is the symbolic "prize" of the patent, the onus is all on the patent owner, since they are the ones who developed the product in the first place and need to develop it in the future. Furthermore, when the interviewer asked questions about the Moderna vaccine specifically (since they developed and produced one of the first effective vaccines against COVID-19), E1 said that there had to be enough information given in the patent to produce the vaccine, while E8 commented that there were many disclaimers when Moderna published their patents.

However, E10 remarked that patents are an important factor—but not the only one—in terms of accessibility. Therefore, he continued, waiving patents might be a good way to start, and maintaining discussions around this topic would facilitate accessibility. However, he also said that patent waivers would not be enough; the world would also need to improve the supply and distribution. Additionally, E7 commented that there are two ways to look at how patents affect accessibility; while patents are an incentive mechanism for the pharmaceutical industry, they have a monopolistic nature that is recognized worldwide (e.g., in the TRIPS agreement).

4.4. Pricing of COVID-19 Vaccines and Its Impact

In terms of pricing COVID-19 vaccines, the participants mentioned various companies' pricing strategies, the different countries' economic situations, and compulsory licensing as important factors affecting access. Johnson & Johnson and AstraZeneca apply at-cost pricing, which E1 called a charitable endeavor for Western countries. He questioned whether companies could sell vaccines at a higher price to developed countries and at cost (or even slightly below cost) to developing countries:

> "I mean, it's a simple, morally appealing thing, where something [is] at cost to everyone, but I think you're giving something to people who don't need it." (E1)

Another point mentioned by E7 was the lack of discussion around compulsory licensing. He said that creating a discussion around possible compulsory licensing could be used as a negotiating tactic and could, eventually, lower vaccine prices. He also mentioned the developing countries' weak currencies, which makes it even more difficult for them to buy the vaccines. In addition, E11 discussed high production costs in developed countries as a factor that increases vaccine prices; he commented that the material and production costs

are lower in developing countries and that companies could make even greater profits should they decide to manufacture in developing countries.

4.5. Current and/or Possible Solutions

The final interview question sought participants' opinions on possible solutions to the accessibility problem, in terms of the impact of patents and prices. When it came to the current solutions, participants mainly discussed COVAX; most felt that such institutions could be helpful and that COVAX was a good concept. However, some argued that this benefit is not universal:

> "Let the countries that really need COVAX use COVAX, and let the rich countries that have already healthcare system that can deal directly with pharma companies, let them deal directly with the pharma companies." (E1)

In terms of production-related solutions, participants discussed increasing the number of production sites, as well as production collaborations with developing countries. E1 described the need to look at the available production facilities. E4 explained that if there is no production facility in a particular country, it is more difficult to build up and begin production; she also said that the world needs to increase the number of local pharmaceutical companies in developing countries in the long run. In addition to production, E8 and E9 proposed that countries should invest more in the health infrastructure (e.g., strategic planning and supply chains).

Participants also discussed the roles of governments and universities. E2 recommended that governments invest more in public-sector research (such as building public labs) to increase the pressure on companies to provide better access and more affordable prices. Furthermore, E5 suggested that governments need to subsidize public R&D in terms of topics such as pandemics; these areas receive relatively little attention since pandemics happen so infrequently. Moreover, E5 said that governments could have pandemic preparedness plans and that companies should transparently price their vaccines to avoid misunderstandings among a public that already holds misconceptions about pharmaceutical manufacturers, especially when it comes to the pricing and accessibility of medicines.

However, E2 mentioned that waiving patents could be an imperfect solution. She also added that even though it is not a sustainable solution, it is necessary until there is government support available for public research. In addition, E7 suggested suspending IP rights only for COVID-19 vaccines. He also mentioned that compulsory licensing could be the most obvious solution to overcome this accessibility problem. Table 3 provides a summary of the five main points, as presented above, that emerged from the interviews.

Table 3. The main topics and findings from the interviews.

Topic	Results and Findings
General Barriers to Accessing Medicines in the Developing World	- Missing infrastructure in developing countries, e.g., number of hospitals and doctors. - Pricing and pricing strategies applied in developing countries, e.g., keeping the floor price high during international reference pricing. - Patented drugs, especially in countries where they do not have potential to be sold; thus, patents limit accessibility. - Lack of knowledge about the technology, due to the limitations caused by patents. - Limited budgets of governments' health divisions.

Table 3. *Cont.*

Topic	Results and Findings
Barriers to Accessing COVID-19 Vaccines in the Developing World	- Production capacity and the availability of local production sites. - Technology transfer and the limitations due to IP rights on this transfer.
Impact of Patents on COVID-19 Vaccines	- In general, there is a claim that there are more important factors than patents, such as the difficulty of producing vaccines, building factories before the patent expires, and the continuous development of vaccines. - On the other hand, patents have a monopolistic nature and a discussion around them would facilitate their accessibility.
Pricing of COVID-19 Vaccines and Its Impacts	- The pricing strategies of companies and the various countries' economic situations have an important impact on pricing. - There is a lack of discussion around compulsory licensing, which could actually be used as a tool for negotiation. - Moreover, the production costs for pharmaceuticals in developing countries affect the prices.
Current and/or Possible Solutions	- Limited availability of institutions such as COVAX in the developing world; their sufficiency for solving the accessibility problem remains controversial.

5. Discussion

This study aims to answer the research question, *"What are the effects of pricing and patents on the accessibility of COVID-19 vaccines in developing countries?"* The results indicate that there are both commonalities and differences between the general barriers to access to healthcare in developing countries and those related specifically to COVID-19. Moreover, the results show that patents do not have a major impact on COVID-19 vaccines' accessibility and that a potential patent waiver could be a solution, but this would be only to an extent. In addition to patents, companies' pricing strategies might relate to accessibility issues in terms of COVID-19 vaccines.

5.1. Patents and Compulsory Licensing

Two of the 11 participants felt that patents are a general barrier to access. However, when it comes to COVID-19, participants largely remarked that problems other than patents needed to be addressed, regardless of a patent waiver. In terms of why a patent waiver would not overcome the accessibility issues in developing countries, participants mentioned the companies' unwillingness to share the technologies behind production, even when sharing the patents. Indeed, technology transfer represents an important dilemma for companies; when companies try to report the technologies that they use and make that information simpler to understand, they also deal with the possibility of imitation [49]. In addition, technology transfer depends on factors such as people and management practices, as well as patenting and commercial strategies [50]. The process of transferring technological knowledge is also complex because multiple players are involved and the firm's knowledge (including internal and external learning) continues to grow [49]. Therefore, transferring technological knowledge depends heavily on systemizing human know-how, which is a difficult task.

Moreover, technology transfer can speed up manufacturing, not only for these companies that already have the vaccines under patent protection but also for other companies that are attempting to develop a vaccine [51]. However, even when pharmaceutical companies transfer the know-how and technologies used to produce the vaccines, developing

countries still face a lack of production facilities and limited capacity, due to fewer available pharmaceutical companies. Thus, a patent waiver alone cannot solve the accessibility problem [52]. To illustrate the point that this is an issue for the developing world, it is important to mention the United Nations Industrial Development Organization, which has been providing assistance for developing countries to increase local pharmaceutical production capacity [53]. According to a study conducted for the WHO [54], despite the high demand for safe, effective, and affordable medicines, Africa relies heavily on imported medicines due to a lack of local pharmaceutical production capacity. The same study proposes that local pharmaceutical production capacity could offer a long-term solution to overcome this accessibility issue in developing countries, especially for life-saving drugs [54]. Therefore, local pharmaceutical production capacity could be valuable to discuss before arguing about the impact of patents on COVID-19 vaccines.

Another important point relates to issuing a compulsory license when companies do not want to publish their patents [55]. As the participants discussed, compulsory licensing could be used as a tool in negotiating vaccine prices with companies; there are examples of this type of negotiation being successful for developing countries that need to access life-saving drugs. For example, looking at Brazil's national HIV/AIDS program, the Brazilian government said that compulsory licenses would be issued if the suppliers did not decrease the prices of medications [28]; it applied such a strategy since the medicines and treatments for HIV/AIDS represented a significant segment of the Ministry of Health's budget.

However, participants also said that vaccine production is difficult and requires complex manufacturing systems. Therefore, production capacity and technology transfer are also important issues for compulsory licensing, since most developing countries do not have enough manufacturing capacity, technical know-how, or raw materials; they also sometimes have the capacity to produce medicines but do not have the active ingredients [28]. Thus, one should also not ignore the importance of production capacity and technology transfer for compulsory licensing. Moreover, it is crucial to calculate the costs of production against the conditions of compulsory licensing. One study assumed that it would be more affordable for developing countries to regulate drug prices instead of entering into a discussion with the WTO on compulsory licensing. This study found that the lower the cost of the compulsory license, the bigger a threat it becomes to decreasing prices; if the cost goes up, the importance of the compulsory licensing declines, and the manufacturer continues to supply the medicines without limitations [26].

Consequently, an increase in the cost of compulsory licenses also affects the incentive scheme of the pharmaceutical industry—patents. Since their patents will become less viable with the threat of compulsory licensing, companies will begin spending less on their R&D activities as they start to feel insecure about recouping their upfront investments. This is because pharmaceutical companies invest heavily in their R&D activities. E9 articulated that patents are the reason why we have medicines and treatments today, not only for COVID-19 but also for many other (life-saving) medical treatments; the analysis by the authors of [26] demonstrates this incentive mechanism for the pharmaceutical industry by showing how companies decreased their R&D investment in the case of a price reduction due to a compulsory license. Therefore, a possible price reduction for COVID-19 vaccines could lead to reduced investments in pharmaceutical R&D in the future, affecting the development of future medical treatments, an issue far beyond the matter of COVID-19.

5.2. Pricing Strategies

As mentioned by participants and explained in the theoretical background, pharmaceutical companies apply different pricing strategies, which have different impacts on the accessibility of medicines—in this case, COVID-19 vaccines. In the interviews, pricing was not mentioned as a barrier to access for COVID-19 vaccines; however, when specifically asked about these vaccines' pricing, some participants argued that pricing schemes in the pharmaceutical industry vary across countries, thereby affecting local prices differently. However, according to the author of [34], prices are a significant barrier to access and

can cause difficulties for patients, although the same study argues that it would be too difficult to discuss how high the effect of prices on pharmaceuticals might be in developing countries. Hence, it would be difficult to say that price is a barrier to access for COVID-19 vaccines since different determinants affect access throughout the process until they reach the end user (i.e., patients).

As E11 noted, insurance schemes play an important role in the pricing and affordability of medicines. The level of public funding is also crucial to affordability since these funds decide the cost to the patient; the level of coverage by public health insurance depends on regulation and competition in that country [56,57]. In addition to reimbursement mechanisms and public funds, out-of-pocket payments are another key aspect of public insurance mechanisms and will impact the medicines' affordability. According to the author of [34], developing countries depend heavily on private payments by patients; those countries have an unequal income distribution, which, in turn, affects access to medicines. Moreover, a study by [58] found that it was less difficult for more equal-income countries to fight the COVID-19 pandemic.

Vaccine producers' different pricing strategies might affect the accessibility of COVID-19 vaccines in different ways. As mentioned in the theoretical background, companies claim to apply differential and at-cost pricing for COVID-19 vaccines; differential pricing could be a tool to create greater affordability and, in turn, accessibility. A study by [59] found that price discrimination—in other words, differential pricing—could ease the problem of the medicines' lack of availability. However, some have criticized differential pricing, arguing that, as monopolists with the patent rights, pharmaceutical companies could price their products higher in developing countries [60]. This makes the products accessible to fewer, higher-income people since developing countries are likely to have an unequal economic structure [60]. In addition to differential pricing, some companies have applied at-cost pricing for COVID-19 vaccines, as mentioned both in the theoretical background and by participant E1. According to one study [28], the prices of pharmaceutical products can improve or restrict accessibility, even if the medicines are priced at cost. Furthermore, when COVID-19 vaccines are provided at cost to developed countries, companies cannot make a profit and invest in R&D, which was also noted by E1.

5.3. Accessibility Programs

When it comes to COVID-19 vaccines, COVAX is the institution that began the process of providing greater accessibility, especially to developing countries. Indeed, COVAX has proven to be an optimal way to start solving the accessibility problem, providing 435 million vaccines to 144 participating countries [61]. As some interviewees indicated, COVAX was planned as a necessary, functional institution with the objective of providing countries with equal access to various vaccines [12].

However, COVAX has been criticized for distributing vaccines to high-income countries; in our interviews, E1 described this as a particular problem. In addition, COVAX has been criticized since many countries purchased more vaccines than they needed, even though they were excluded from buying vaccines from COVAX [12]. Furthermore, COVAX lacks a budget, despite its achievements [11]. Thus, COVAX, arguably, could solve the problem of accessibility. However, in the long run, it could be an indirect solution since having this type of institution serves to maintain the discussion around the problems of accessibility and affordability.

5.4. Implications for Theory and Practice

As the interviewees discussed, possible solutions to the problem of COVID-19 accessibility could have implications for theory and practice. According to most of the participants, production capacity needs to increase in developing countries to improve accessibility. One previous study [11] argues that there are two important factors regarding achieving the successful supply and distribution of COVID-19 vaccines: (1) equal accessibility and producing an adequate number of vaccines, and (2) durable supply chain systems. Moreover,

another study [62] found that increasing the production capacity for vaccine development by 1 billion (over a baseline of 2 billion) could result in a growth of global financial benefits of between USD 1.3 billion and USD 1.9 billion over a period of 9 months. This additional capacity could create greater benefits; the baseline for manufacturing the vaccines is lower for developing versus developed countries and increasing the production capacity would work as an insurance mechanism, since it is in preparation for a potential worsening of the COVID-19 pandemic [62].

When it comes to the ways in which governments or companies can increase production capacity, especially in developing countries, one solution could be collaborating with global players in the pharmaceutical industry. One example is the collaboration between Pfizer and the South African company, Biovac, to complete the final step of the manufacturing process, which is called "fill and finish". The project has already started and the first doses were produced in September 2022 [63]. Even though this is only one initiative, it represents an important step for similar collaborations to sustainably address COVID-19 vaccine accessibility and potential accessibility situations in the future.

Governments and public funds also play an important role in increasing production capacity. As the participants discussed, governments can invest more in public facilities, such as public laboratories and university R&D centers. If governments invest more in state universities, R&D centers, and laboratories, their countries will become more prepared to fight pandemics since they will have the necessary research before the pandemic occurs. A well-known example is the Oxford/AstraZeneca COVID-19 vaccine, which was 97% publicly funded by taxpayers and charities [64]. Moreover, the University of Oxford had been working on vaccine development since the Ebola outbreak began in 2014 [65]. When these two facts are combined, we can clearly see how public funds are important to the rapid development of vaccines.

Additionally, pandemic preparedness plans could play a crucial role in fighting the next pandemic. Since pandemics have not only happened recently but have occurred throughout history, the world must be prepared for their future return [66]. As the WHO notes, COVID-19 will not be the world's last pandemic [67]. Even though there are different measures provided by WHO in the case of pandemics, the lessons learned from the COVID-19 pandemic should prepare countries for future infectious disease outbreaks [67]. Thereby, digitalization and technologies such as artificial intelligence could substantially improve the detection and reaction processes [68,69]. Agile methods could speed up the development process [70,71]. Indeed, the WHO's full emergency cycle (Figure 3) includes preparedness for pandemics; preparing for health emergencies is important to achieve the sustainable capacity of health systems [67]. To achieve this, countries need to invest more in their health systems. An example of a pandemic preparedness plan is Uganda's work prior to the Ebola outbreak in 2018. Since Uganda had been experiencing this disease for many years, the country developed a pandemic preparedness plan to rapidly prevent the spread of the Ebola virus [72].

Returning to the topic of COVID-19 vaccines, transparency is another problem, especially when it comes to pricing. The Max Planck Institute for Innovation and Competition indicates that concerns around the extreme prices of COVID-19 vaccines are due to the lack of transparency [52]. The WHO also states that there is a lack of vaccine transparency and that greater transparency could aid in decision-making and the introduction of new vaccines [73]. As E5 mentioned during the interviews, the public hold misperceptions about pharmaceutical companies. This has always been an issue because pharmaceutical producers have an important role in providing access to medicines. Therefore, discussions were already occurring pre-COVID-19 regarding how pharmaceutical companies should price their products transparently to ensure equality; for example, according to one study [24], prices have been an important factor restricting access to life-saving drugs, such as those for HIV/AIDS. However, we must not forget that pharmaceutical companies are for-profit organizations that need to increase their income to invest more in their R&D. Without pharmaceutical R&D, we would not have achieved a COVID-19 vaccine as quickly

as we did. Members of the public can overlook this element and may see pharmaceutical companies as non-profit organizations.

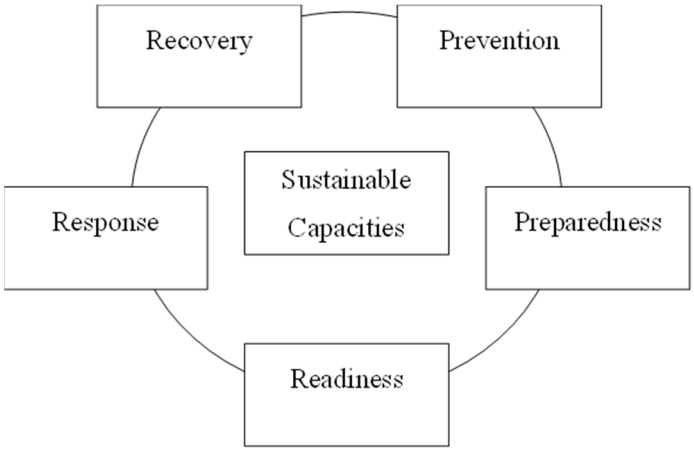

Figure 3. The WHO full emergency management cycle, adapted from [67], p. 4.

However, being a for-profit organization does not mean that pharmaceutical companies can set prices at whatever they want and make unethical profits. To overcome this problem, companies could apply transparency, including transparent pricing. When they show the steps (to the extent that contracts allow) regarding how they price their medicines—including COVID-19 vaccines—these companies could win the trust of society.

A potential patent waiver could also be an imperfect solution to the problem of COVID-19 vaccine accessibility, as E2 mentioned in the interviews. Additionally, E7 suggested waiving patents only for COVID-19 vaccines for these periods of acute emergency. However, patents are a temporary monopoly power for pharmaceutical firms, especially for the innovator pharmaceutical companies, and removing patents completely could harm the incentive mechanism for the pharmaceutical industry and its ability to invest in R&D activities, which could then lead to fewer innovative drugs. Additionally, waiving patents only for COVID-19 vaccines could be a starting point for discussions to remove patents for all pharmaceutical products. Before starting negotiations for any potential patent waiver, the flexibility in the TRIPS agreement should be evaluated.

Compulsory licensing could be a potential solution for governments to access COVID-19 vaccines at a more affordable price, although compulsory licensing requires adequate production capacity, a procedure for receiving a compulsory license, adequate payment for a compulsory license, and know-how and technology transfer [52]. There are also local regulatory issues in developing countries, such as requirements around the number of years the patent must have been in place before compulsory licensing is allowed [52]. Therefore, the optimal solution for developing countries to have more accessible and affordable products could be to use compulsory licensing as a negotiation tool, as E7 proposed during the interviews. For that, developing countries would need to prove that they have the production capacity, the budget to pay for the compulsory license, and the ability to handle the process of obtaining a compulsory license. In this way, they could decrease the prices of COVID-19 vaccines, while ensuring that the incentive mechanism for the pharmaceutical industry (i.e., patents) remains intact.

5.5. Limitations and Suggestions for Further Research

COVID-19 has been in our lives since December 2019, and the discourse on COVID-19 vaccines and the associated patents remains an ongoing topic. This qualitative study has used semi-structured interviews to examine how patents and prices affect the accessibility of COVID-19 vaccines. This study combined the perspectives of experts from several different backgrounds to mitigate the subjectivity of the individual participants [74,75].

This study was conducted and finalized during COVID-19, meaning that the literature was still scarce on the impact of COVID-19 vaccine patents and prices. Thus, future research on the accessibility of COVID-19 vaccines should involve a review of the literature when more scholarly work is available on the topic. This limitation also affects the generalizability of the results. The topic of accessibility is always ongoing and, as a result, this study could not explore additional, specific cases with the interview partners. Rather, these discussions focused on general issues related to vaccine accessibility for developing countries, within the context of COVID-19.

Additionally, this study did not analyze the impact of parallel trade, an area often mentioned in similar situations, because parallel trade has not been discussed widely within the context of the COVID-19 vaccine. Parallel trade could be a mechanism to reduce prices since countries can import medicine from lower-cost countries, although TRIPS incorporates restrictions around parallel trade. Therefore, it could be valuable for future research to discuss parallel trade opportunities and challenges for COVID-19 vaccines.

When it comes to the interview process, this study is limited to experts from the pharmaceutical industry and qualified lawyers. However, different participants could address the research question differently (e.g., NGO representatives), and it could be meaningful to include experts from institutions such as the WHO and WTO to analyze patents and prices, both generally and specifically, in the context of COVID-19. Future research might also consider building on our work by comparing our study's results with insights from other economically important European countries, such as France, Italy, and Spain, or by using other research designs, e.g., quantitative approaches based on secondary data [76]. Herein, technology landscaping via patents may serve as a valuable means to contribute additional insights [22]. However, despite all these limitations and new research opportunities created, this study does analyze the current situation of patents and pricing within the context of COVID-19 vaccines and, by following a top-down approach, ensured interviewees' answers were appropriate for answering the research question.

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Appendix A. Interview Guideline for the Semi-Structured Interviews

How would you describe the main struggles and barriers to access in the developing world?

- First, thinking about it in general.
- Then, narrowing it down to the topic of COVID-19.

Moving to the discussion of patents and prices:

Patents:

- How do patents affect access in developing countries?
- How would you analyze their impact on COVID-19 vaccine accessibility?
- How can some companies open access to patents and why not others?
- The case of Moderna: Moderna, which said in October that it would not enforce patents on its vaccine during the pandemic, noted the lack of companies who were able to rapidly scale up the complex manufacturing of a similar vaccine to meet surging global demand.

Prices:

- Do you think there is a fair pricing strategy for COVID-19 vaccines?
- Is tiered pricing enough?
- How do they affect access?
- After-pandemic prices => Are they going to be higher or lower, in your opinion?
    - Opinion on Pfizer and Moderna vaccines => Prices might be increased after the pandemic.

What could be the potential solutions? Waiving patents is not a sustainable solution, it will not be temporary, and it can affect the pharmaceutical patenting system.
Is it enough to have international organizations or collaborations, such as COVAX, to provide equal access?
Does waiving patents constitute a sustainable solution in the long term?

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