



GDP’S REPORT ON ACCESS TO COVID-19 VACCINES

Research Report (the “**Report**”) prepared by the Law and Poverty Group on the possibility of developing countries accessing COVID-19 vaccines via strategic litigation.

São Paulo

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EXECUTIVE SUMMARY

I. Introduction

The spread of the COVID-19 pandemic (also referred to as “**the Pandemic**”) throughout 2020 has driven governments to adopt rapid institutional responses to prevent the collapse of their national health and economic systems. In this scenario, governmental authorities invested in pharmaceutical companies to develop vaccines and other treatments to deal with the disease.

However, the production and distribution of COVID-19 vaccines are concentrated in developed countries, and developing nations continue to suffer cyclical pandemic waves, which increase the risk of mutations and potentially render the already developed COVID-19 vaccines ineffective. Even the total capacity operation of developed countries’ pharmaceutical companies would still not be able to supply the world’s population at a pace that would allow equitable access to global immunization.

The IP rights protection (including trade secrets) is the single most relevant bottleneck hindering the Global South¹ from manufacturing COVID-19 vaccines to support their populations. Therefore, it would be necessary to grant access to the expertise and technology developed by those pharmaceutical companies. The Law and Poverty Group (“**GDP**”, from its acronym in Portuguese, *Grupo Direito e Pobreza*), presents its conclusions regarding the possibility to expand COVID-19 vaccines manufacturing capacity through IP rights access granted by European courts.

II. COVID-19 vaccines shortage: assessment on the facts

Global tendencies regarding vaccine procurement and manufacturing have taken shape since the beginning of the COVID-19 pandemic, a year after the first official declarations about its nature and severity. It is necessary to introduce the concepts we adopted to investigate procurement and manufacturing landscapes across the world as of April 2021.

¹ This definition will be explained further.



This report opted to use the analytical categories of “**Global North**” and “**Global South**” countries. In synthesis, the Global North refers to developed countries concentrated in the northern hemisphere, characterized by high income and technological advancement levels. In contrast, the Global South refers to developing countries located mainly in the southern hemisphere, with generally low-income and technological advancement levels.

It should be noted that this is not merely a geographical characterization but rather a socio-economic and geopolitical one. North-South terminology is helpful to analyze the COVID-19 vaccine manufacturing landscape across the world because most of the significant COVID-19 vaccine producers (not only developed and marketed ones, but also others in development) so far concentrate their manufacturing activities in Global North locations, as will be demonstrated.

In parallel, this Report adopts The World Bank’s classification of countries by income. They were divided into three groups – high, upper-middle, and lower-middle-income and low-income countries. The income categories are based on a measure of national gross national income per person, or GNI *per capita*, calculated using the World Bank Atlas method.²

Income-related terminology appears the most adequate to assess information regarding vaccine procurement, which concerns each country’s population demand for vaccination activities to begin and unfold as quickly as possible to achieve immunization. High-income countries have been able to secure most vaccines since day one, while fewer doses are to be destined to low- and middle-income countries and for equity-focused partnerships such as the COVID-19 Vaccines Global Access (“**COVAX**”) Facility.

By adopting both classifications, it becomes possible to indicate that Global North’s facilities represent a large percentage of the world’s COVID-19 vaccines manufacturing capacity currently operating, and its doses tend to reach high- and upper-middle-income countries.

² In a few words, as of 1 July 2019, low-income economies are defined as those with a GNI *per capita*, calculated using the World Bank Atlas method, of \$1,025 or less in 2018; lower middle-income economies are those with a GNI per capita between \$1,026 and \$3,995; upper middle-income economies are those between \$3,996 and \$12,375; high-income economies are those with a GNI per capita of \$12,376 or more. More on: <https://datatopics.worldbank.org/world-development-indicators/stories/the-classification-of-countries-by-income.html>.

Meanwhile, as suggested by the results we obtained, the Global South's potential capability in COVID-19 vaccine manufacturing could redound to an overall increase in global COVID-19 vaccine allocation by providing more concrete options for lower-middle- and low-income countries to obtain vaccine shots – through bilateral negotiations, donation initiatives and/or production destined to meet domestic demand.

The current scenario of default of vaccine supply contracts worldwide is the direct result of insufficient production by pharmaceutical companies, as production is concentrated in a few countries in the Global North. Vaccine manufacturing steps face productive bottlenecks that hinder the flow of manufacturing and delay massive distribution.

It should be pointed out how public investment was a key factor for the development of COVID-19 vaccines. Governmental authorities worldwide invested in pharmaceutical companies aiming to develop vaccines and other treatments to deal with the lack of previous knowledge of the disease. These were mainly direct governmental investments in vaccine development, combined with public-private partnerships, within which, in its turn, public investment also dwarfed private investment.

Although not a direct causal link, it is noteworthy that the mRNA vaccines which were proven safe and efficacious and are being widely inoculated (such as Pfizer/BioNTech and Moderna), as well as those which are in late stages of clinical development (such as Curevac) *all* received extremely large sums of public funding. These investments were made by Global North countries directly through awards from governmental agencies or indirectly through the beforehand acquisition of doses intended for the research and development (R&D) of the vaccines³.

³ On the other hand, all mRNA vaccines on pre-clinical development - except one: LNP-mRNA from CanSino Biologics/Precision NanoSystems - did *not* receive public or public-private investment. Furthermore, research for all but two began in early 2020. These are still under development and could never reach the clinical phase despite the long research time ahead. It means that even after almost one year of research, they are yet to begin human tests. As such, a correlation between public funding as a requirement to scale-up, fast-track seems to be demonstrated in the case of mRNA vaccine candidates, which is in line with the most recent literature on innovation in pharmaceutical sectors.

The lack of transparency related to these investments is glaring. Most of the contracts between the pharmaceuticals and governments/public-private partnerships were not available. No contracts of awards were accessible. On the direct purchase ones, only the total amount negotiated was not censored.

Meanwhile, the pharmaceutical sector in the Global South pharmaceutical sector is a pungent one. Besides, it is already very developed. It features large-scale production of generic drugs, high-tech medicines, and vaccines, and great growth avenues. It is essential to say that this production is dedicated both for national supplies and exports, and there is a substantial public investment to develop production and research in this sector as well.

It is also essential to state the adaptative capacity into mRNA production of the production chain of other platforms-based vaccines. Once the vaccine development is completed, production is a less complex and more easily scalable process than in other vaccines⁴. The equipment and machinery used, in their turn, are very similar to the currently being used. The adaptation of production is not an issue from a technical standpoint.

On the last note, Pfizer / BioNTech and CureVac vaccines feature several advantages over other vaccines, demanding closer attention.

Regarding the Pfizer / BioNTech vaccine, its advantages include its effectiveness, the security of the productive process, the possibility of massive production under shorter time frames, the massive public investment to its development, and the possibility of technology replication by other pharmaceutical companies around the world.

The Cure Vac shares similar advantages, such as the high yield potential, and additionally is based on a more stable mRNA, so it can be stored in a standard 5 ° C refrigerator for at least three months and up to 24 hours at room temperature and the huge amount of public investment (it received the third-largest sum of public investment among the vaccine candidates).

⁴ See, for example: <https://mg.co.za/africa/2021-04-15-africa-could-produce-a-covid-19-vaccine-sooner-than-you-think/>.

The inequality in the distribution of vaccines between regions is a way of prolonging this crisis, which, at its turn, enhances the risk of mutations that may harm wealthy and low-income nations alike. For this reason, the only efficient and ethical way to face the pandemic is to promote equitable vaccination. Equitable vaccination will also be positive to the Global North because of less competition for scarce products and the higher and more effective prevention of new mutations.

More than a solution to the current pandemic, mRNA technology can respond to other outbreaks and diseases. It is an unlimited platform for encoding specific desired proteins that stimulate immune responses, so it can be used to create a variety of vaccines and treatments in less time and at lower costs than traditional methods, such as treatments for Malaria, Tuberculosis, Hepatitis B, and various types of cancer. Therefore, the licensing of mRNA technologies is crucial for global health in general.

III. Legal Reasoning and Litigation Scenarios

The third contains the legal reasons supporting a potential claim for expanding COVID-19 vaccines manufacturing capacity through access to IP rights.

On matters of jurisdiction, different avenues can be envisioned. The **first** one would be to start **two proceedings in Germany, one before the Federal Patent Court, to obtain the compulsory license of the vaccine patent, and one before a German civil court regarding the technology and know-how transfer, both protected by trade secret.**

The patents, the know-how, and the technology related to the production of COVID-19 vaccines emerge as “global public goods”. Economically, they present an enormous difficulty of excluding potential beneficiaries, and a high subtractability of use and humanity in its entirety can be considered their beneficiary. Considering these characteristics, IP rights should be mitigated to protect global welfare amid the pandemic through the mechanism of compulsory licensing.

According to German law, there are two mandatory criteria for granting a compulsory patent license, in general: the requirement in question must attend a public interest and must have been the object of previous negotiations between its owner and the license seeker. Another specific possibility for achieving compulsory licenses is the proof that the exercise of an exclusive intellectual property right may involve abusive conduct in the light of competition law provisions.

Regarding the concept of public interest, German jurisprudence indicates that its definition must be filled by the concrete meaning of the case law, taking into account all beneficial and adverse circumstances relevant in the individual case and the interests involved. From the cases of Raltegravir and Alirocumab, it is possible to conclude that the extreme vulnerability in the context of the shortage of COVID-19 vaccines justifies the public interest and urgency for licensing the patent.

Concerning the requirement of preceding negotiations, the recent World Health Organization (“**WHO**”) initiative of organizing a technology access pool of IP rights related to COVID-19, the COVID-19 Technology Access Pool (“**C-TAP**”), has enough legal value to be considered a previous negotiation since it was announced globally and for all COVID-19 patent owners.

The most recent WHO initiative to establish a technological transfer hub for specifically mRNA vaccines (launched on 16 April 2021⁵), searching both candidates to host the hub and companies with mRNA technologies to join it, is additional evidence of this requirement met. There have been no similar cases to interpret in such a manner, but there is no limitation under existing case law regarding the exact contours of how prior negotiations ought to occur.

As it will be demonstrated below, our preliminary understanding is that similar arguments could be envisioned to a request to license all relevant trade secrets in a separate proceeding. Arguments based on the general duties of companies to ensure respect for human rights and the public interest may also be utilized for this particular demand.

⁵ <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing>.

The **second** option would be to address European Courts, such as the **European Court of Human Rights**, since the topic concerned is time-sensitive and there are exceptions to the necessity of exhaustion of national remedies.

Such avenue is based on the international and European human rights instruments applicable to this demand, especially the right to health, on the one hand, and the duties of companies to respect and not create barriers to the attainment of human rights by governments, on the other hand.

Equitable, global access to vaccines is directly related to ensuring the right to health and life. Lack of vaccines outside of Europe may lead to new variants and new pandemic cycles, affecting European citizens and their human rights, which can already be demonstrated. The restrictions by companies to ensure access to the technologies can therefore be framed as a human rights violation and a failure by the States to take adequate measures to ensure such rights.

Specifically, concerning companies' duties and notions of accountability, a strong interpretation of corporate social responsibility and shareholder duties and transparency are additional arguments to be taken into account, as described in this report.

A **third** option would be to file a complaint to the **European Commission** on the grounds of anticompetitive actions by manufacturing companies. The Commission has the autonomy to decide to take investigations further and pursue legal action that may include structural remedies such as access to the technology of the mRNA COVID-19 vaccines. The Commission has since at least 2009 increased its scrutiny in addressing anticompetitive practices in the pharmaceutical sector (e.g., pay-for-delay agreements, abuse of regulatory and patent applications, sham litigation, and excessive pricing).

The pandemic accentuates the oligopoly structure traditionally found in the pharmaceutical market, whose power is held by a handful of pharmaceutical companies that control the whole sector. In the context of COVID-19, only a few companies currently produce and distribute vaccines, and the small offer of different types of vaccines induces the market to an unavoidable concentration.

In the COVID-19 pandemic, these problems are exacerbated due to the high probability that the virus becomes endemic, which will make the secondary market of vaccines for COVID-19 variants also susceptible to those violations. The competitive environment in this secondary market can be negatively affected by potential network and lock-in effects.

In the future, the population's skepticism over certain vaccines, existing logistical and technological path dependency, and contractual obligations of exclusivity between originator companies and sublicensees will likely limit governments' capacity to buy different types of vaccines. These various patterns may *de facto* force countries to purchase only a limited number of potential vaccines once and if production is sufficient.

In other words, increasing manufacturing capacity and the overall number of doses, if needed, may not be enough to curb the pandemic. Furthermore, in the eventual case that one single vaccine or technological platform (e.g., mRNA) proves effective against variants, the dependency may be exacerbated. Besides, this externality is already in evidence as governments are tied up to a specific pharma company after administering the first shot because of the lack of studies proving the safety and effectiveness of mix-and-matching different types of vaccines when applying the first and second doses.

Although studies and countries are exploring such possibilities, they are yet inconclusive and reiterate the overall control of the secondary market of vaccines in the future, if they need to be inoculated yearly as many already predict. The complete control of the "market" for such essential values (in this case, meaning the health and life of people) is, in this case, really possible for the "first movers" if no legal measure is taken.

IV. Conclusion

The patents, know-how, and other trade secrets-protected technology of COVID-19 vaccine manufacturing are the real main impediments to the largely scaling-up vaccine manufacturing and to bring an end to the pandemic. Conditions to quickly repurpose factories and create new facilities and other trade barriers such as import/export licenses and taxes are not impediments to that goal: the refusal to deeply share technologies is.

Not only must COVID-19 vaccines be legally declared as global public goods, but there must also be a set of compulsory licenses of COVID-19 vaccines for both patents, know-how, and trade secrets. Other sanctions and future commitments to involved parties (e.g., better sharing mechanisms of public funding) should also be envisioned.

Looking at the current uncontrollable number of global cases and the possibility that Sars-Cov-2 will become endemic, using a patented invention without the right holder's authorization, the know-how and the technology to manufacture COVID-19 vaccines emerge as a necessary tool to counter the pace of the pandemic. Current voluntary initiatives are not enough and do not address all existing and future issues, which brings a strong public interest to request compulsory licensing of patents and know-how of the COVID-19 vaccines, especially the Pfizer/BioNTech and Curevac ones.

As will be evident in this report, the Global South has well-developed industries in the pharmaceutical sector that can produce mRNA vaccines – precisely those which are potentially easier and quicker to produce once deep technology transfer takes place, which is also better prepared to needed changes, given its more effective adaptive technology.

RESEARCH REPORT

I. Introduction

1. The spread of the COVID-19 pandemic throughout 2020 has driven governments to adopt rapid institutional responses to prevent the collapse of their national health and economic systems. In this scenario, governments made large-scale investments in pharmaceutical companies to develop vaccines and other treatments to deal with the COVID-19 disease.

2. Even though scientists had already been studying the SARS-CoV virus variants long before the pandemic⁶, the world was far from ready to offer a proper response. For one, the state of the art of vaccine technology, the mRNA vaccines, was yet to be invented.⁷ Thus, only the massive and predominantly public investment in the pharmaceutical sector allowed for the rapid progress of research, clinical trials, and the large-scale manufacturing of vaccines at a reduced risk.⁸

3. However, despite the current global pandemic scenario, the global investment in COVID-19 vaccines manufacturing and distribution was concentrated in the Global North, while the Global South continues to suffer from cyclical pandemic waves⁹. This segregation increases the spread of the virus and the likelihood of mutations that may render the already developed COVID-19 vaccines, the global investment, and the Global North's effort in securing their vaccines ineffective.¹⁰

⁶ See: Yen-Der Li et al, *Coronavirus Vaccine Development: from SARS and MERS to COVID-19*, Journal of Biomedical Science 27 (2020): 4.

⁷ Angela Desmond and Paul A. Offit, *On the Shoulders of Giants – From Jenner's Cowpox to mRNA Covid Vaccines*, The New England Journal of Medicine 384 (2021): 1081-1083.

⁸ Section 2.3 will discuss the relationship between public investments and the development of COVID-19 vaccines.

⁹ See on Brazilian and Indian scenarios, respectively: Lise Alves, *Brazilian ICUs short of drugs and beds amid COVID-19 surge*, The Lancet World Report 397 (10283), apr. 2021, 1431-1432, available at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00836-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00836-9/fulltext); Siladitya Ray, *India Records 200,000 New Covid-19 Cases For First Time As Second Wave Continues to Surge*, Forbes, apr. 15, 2021, available at: <https://www.forbes.com/sites/siladityaray/2021/04/15/india-records-200000-new-covid-19-cases-for-first-time-as-second-wave-continues-to-surge/?sh=5da22abd260d>.

¹⁰ For the purpose of this Report, GDP is considering all the vaccines that are being offered in the Global North.

4. The need to reflect upon the situation becomes even more glaring as a growing number of pharmaceutical companies fail to supply the global demand for immunization while producing countries are holding up contracted doses.¹¹ Even the first agreements executed with national governments are on default – and the subsequent should follow the same path, demonstrating that this shortage situation is structural, not momentaneous.

5. In other words, even if the pharmaceutical companies of the Global North were operating at their full capacity and expanding their manufacturing sites, they still would not be able to provide COVID-19 vaccines to the world's population at a reasonable pace, i.e., one that would allow equitable access to global immunization to end the pandemic for good.

6. As a result, the populations of the Global South are experiencing and will continue to experience alarming death rates even though effective COVID-19 vaccines are already being offered in the Global North. Hence, pressure for a global initiative towards vaccination and the dispersion of manufacturing sites has rapidly risen. Governments are the main actors that must step up and account for their investments that made the vaccine endeavor feasible.

7. That being so, governmental action might be a catalyst for vaccine production by granting access to the expertise and technology developed by those pharmaceutical companies that received the public investments.

8. As will be further discussed in this report, IP rights protection is one of the most significant bottlenecks blocking the Global South's access from manufacturing COVID-19 vaccines to support their populations. In a scenario where there are not enough COVID-19 shots available even for the countries that host pharmaceutical companies themselves, coming up with ways to expand COVID-19 vaccines manufacturing capacity across the globe becomes a duty.

¹¹ For an example, the European Union introduced export controls on COVID-19 vaccines made within the bloc, as a way of denying authorization for vaccine exports if the manufacturing company is at default with European countries: European Commission, *Commission extend transparency and authorization mechanism for exports of COVID-19 vaccines*, last updated on March 11, 2021, https://ec.europa.eu/commission/presscorner/detail/en/IP_21_1121.



9. That said, the Law and Poverty Group (“**GDP**”, from its acronym in Portuguese, *Grupo Direito e Pobreza*), a research center aiming to provide public agencies with relevant information on the impact of economic power structures on developing societies, now presents its conclusions regarding the possibility to expand COVID-19 vaccines manufacturing capacity through IP rights access granted by European courts.

10. GDP has focused primarily on COVID-19 vaccines that are not currently available for production on the Global South on a large scale due to lack of access to the technology needed to manufacture COVID-19 vaccines or absence of supply contracts – focusing primarily on the Pfizer / BioNTech COVID-19 vaccine (“**the Pfizer / BioNTech vaccine**”)¹², and the CureVac COVID-19 vaccine (“**the CureVac vaccine**” or “**the CVnCoV vaccine**” and, together with the Pfizer / BioNTech vaccine, “**the Vaccines**”).

11. Deepening research, GDP has decided to focus on vaccines developed and produced by European-based companies to provide input on the possibility of granting access to the needed IP rights. Thus, the following chapters of this Report mainly focus on Vaccines and on viable ways to allow developing countries to produce them.

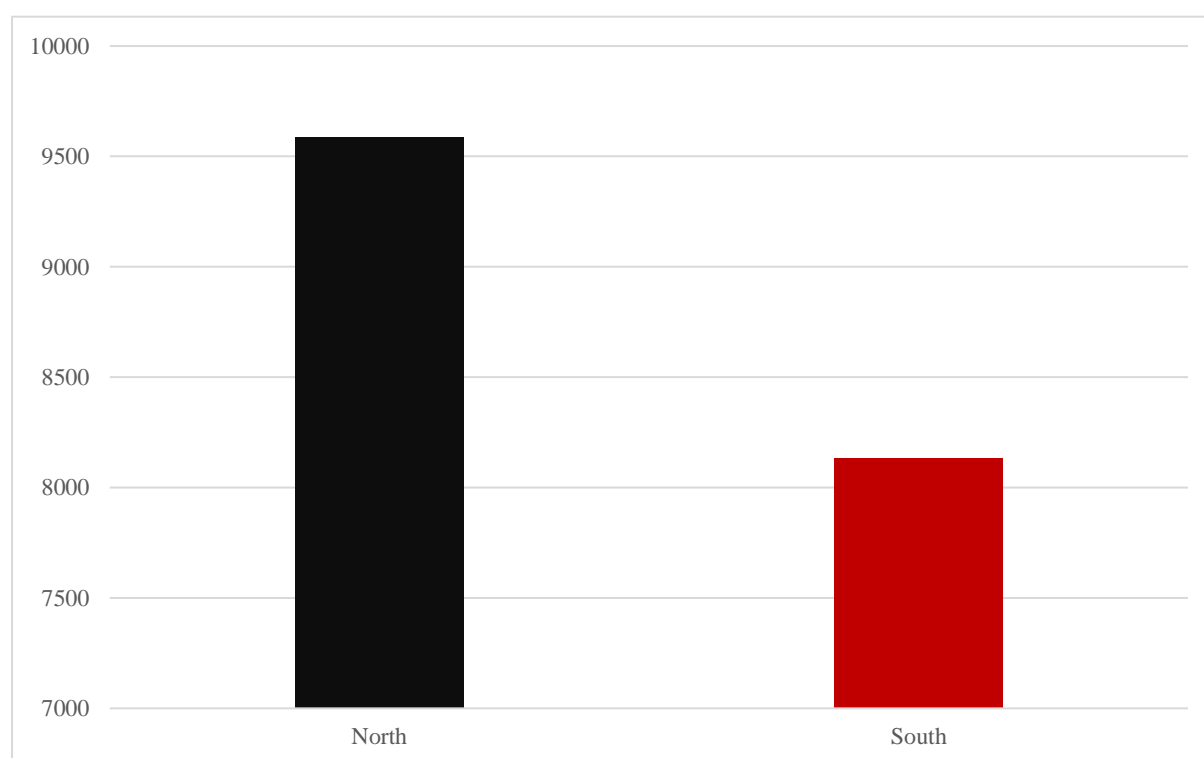
¹² See: <https://www.pfizer.com/science/coronavirus/vaccine-efforts>, and <https://investors.BioNTech.de/news-releases/news-release-details/pfizer-and-BioNTech-receive-authorization-european-union-covid>. Access on April 10, 2021.

II. Vaccine shortage: the new inequality dilemma for the Global South

2.1. COVID-19 Vaccine Doses Scarcity in Global South

12. The vast majority of the Global South countries face an alarming COVID-19 vaccine shortage and cannot guarantee enough doses to fulfill internal demand. It is crucial to begin this debate by seizing the Global North and the Global South countries' total manufacturing capacity installed to operate in 2021, in millions of doses, *based on the most recent declarations by pharmaceutical companies*.

Image 1. Sum of Vaccine Capacity Declaration per Region (in millions of doses)



Source: Table C, Graph 4.

13. Global South's facilities have mainly been assigned to fill and finish vaccine patches in the global production chains. In these countries, bulk manufacturing tends to occur only when a national vaccine is developed due to tech-transfer contracts with the Global North pharmaceuticals. Nonetheless, as discussed later in this Report, many South countries' fill and finishing programs state that production capabilities could be updated to produce vaccine bulk.

14. While the Global South is still unable to manufacture bulk using its available and projected means, despite its investment and manufacturing capacity, the Global North's keep struggling to satisfy its populations' demands due to the current insufficient pace of COVID-19 vaccine doses production.

15. Unexpected supply shortages and other unforeseen difficulties have hampered production in most developed countries, and major vaccine programs have been facing problems that require more time invested in development, testing, and production, and some have been canceled.¹³

16. Uncertainty over production stability has led to massive public investment towards expanding manufacturing capacity by constructing new facilities or increasing the existing ones. In that regard, the Table below compiles the declared projected manufacturing capacity in the Global North countries.

Table 1. COVID-19 manufacturing and procurement by the central Global North countries

Country	Projected manufacturing capacity (in millions of doses per year)	Main companies and institutions	Total bulk manufacturing facilities	Total fill and finishing-only facilities	Due to be fully operational in (estimated date)
France	250	CordenPharma, Delpharm, Fareva, Recipharm, Sanofi	2	4	Jun-21
Germany	2,910	Allergopharma, Baxter, BioNTech, CureVac, Dermapharm, IDT Biologika, R-Pharm, Rentschler, Sanofi, Siegfried	11	2	May-22

¹³ Two brief examples: the Sanofi-GSK vaccine showed an insufficient immune response in older patients, and would be delayed at least six months. Canada, the US, and the UK had ordered the largest stocks of this vaccine. Meanwhile, on 11 December 2020, the University of Queensland cancelled the development of its COVID-19 vaccine, due to false positive HIV test results in Phase 1 trial participants. Information available at: <https://www.bmj.com/content/371/bmj.m4809> and <https://www.uq.edu.au/news/article/2020/12/update-uq-covid-19-vaccine>.

Country	Projected manufacturing capacity (in millions of doses per year)	Main companies and institutions	Total bulk manufacturing facilities	Total fill and finishing-only facilities	Due to be fully operational in (estimated date)
Japan	400	Daichi Sankyo, JCR Pharmaceuticals, KM Biologics Co., Takara Bio, Takeda Pharmaceutical Co., Shionogi Pharma	2	3	Jan-22
Switzerland	300	CordenPharma, Lonza, Novartis	2	1	Sep-21
UK	750	CG MIC, Croda, Fujifilm Diosynth Biotechnologies, GSK, Oxford Biomedica, Valneva, VMIC, Wockhardt	11	3	Jan-22
USA	1,204	Catalent, Emergent BioSolutions, Grand River Aseptic, Janssen/Johnson and Johnson, Lonza, Merck, Moderna, Pfizer	7	5	Jun-21

Source: Table E, Graph 4.¹⁴

17. The Global North has actively put efforts into reducing its COVID-19 vaccine doses shortage. Meanwhile, the Global South's demand for vaccines mostly remains unanswered.

18. On March 21, 2021, EU Commission President Ursula von der Leyen announced that the European Union ("EU") would not export COVID-19 vaccine doses until there was "*a better production situation*." "There is quite a bit of pressure on member states to obtain the vaccine for themselves," she told Germany's Funke Media Group.¹⁵

¹⁴ The actual capacity may be higher than the collected data, as some companies or institutions' information is undisclosed as of April 9th, 2021. Also, these production chains may feature partnerships with facilities located on other countries.

¹⁵ Deutsche Welle, *Coronavirus: EU 'not ready' to share COVID vaccines with poorer countries*, March 21st, 2021. Available at: <https://www.dw.com/en/coronavirus-eu-not-ready-to-share-covid-vaccines-with-poorer-countries/a-56944274>.

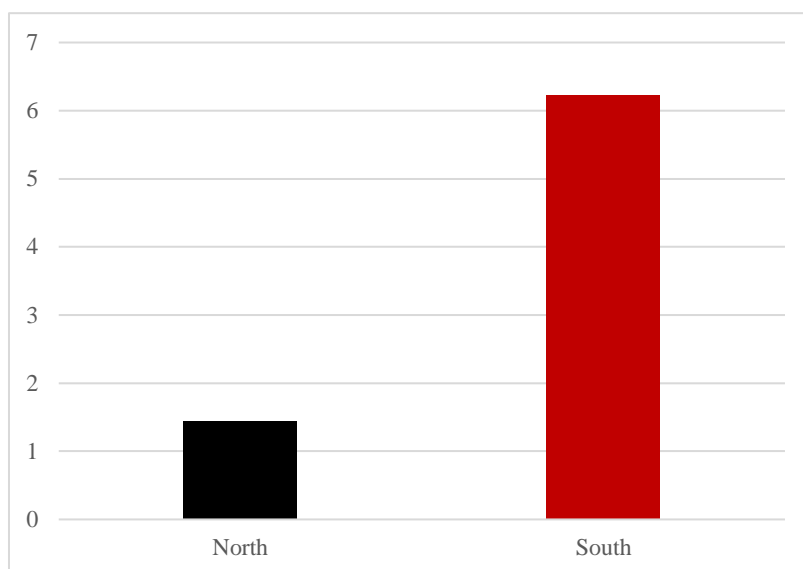
19. On April 1st, Germany's Health Minister Jens Spahn said Berlin might seek to secure its vaccines by 2022, which means being *“ready to act independently.”* *“For now, we do not know how long protection will last. Nobody has been immunized longer than 12 months, according to the first clinical studies. And nobody knows how long it will last — 12, 24 months, five years, ten years.”*, said Spahn.¹⁶

20. Governments keep trying to vaccinate their citizens as soon as possible, but the concentration of COVID-19 vaccine manufacturing is hardly necessary to ensure this. The current global COVID-19 vaccine scarcity can be traced to such concentration in the Global North, as southern countries usually depend entirely on the North for every dose administered, making it almost impossible to address internal demand completely. For that reason, bilateral negotiation options between the Global South countries remain scarce.

21. The impact of the concentration of COVID-19 vaccine manufacturing sites is noteworthy by exploring the contrast between the Global North and South countries' populations and the average percentage of doses administered and available as of April 2021 and available doses per citizen, as can be seen in graphs below:

¹⁶ Deutsche Welle, *Germany considers break with EU on 2022 vaccine orders*, April 1st, 2021. Available at: <https://www.dw.com/en/germany-considers-break-with-eu-on-2022-vaccine-orders/a-57074107>. Access on: April 17, 2021.

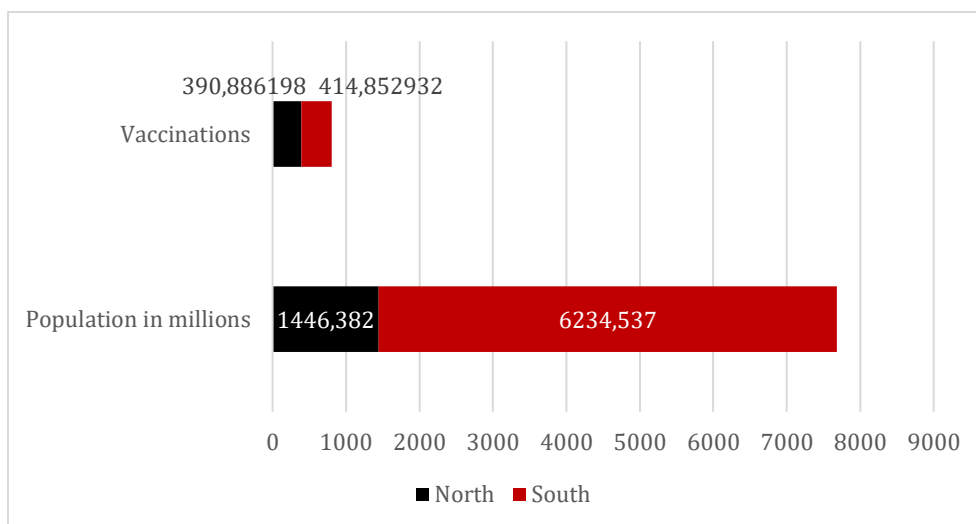
Image 2. Total population per region (the Global North and the Global South) (in billions of people)



Source: Table M, Population Graph. Based on the 2020 population reported by Worldometers.¹⁷

¹⁷ Available at: <https://www.worldometers.info/world-population/population-by-country/>.

Image 3. Total vaccine shots *versus* populations, per region (in millions of people)

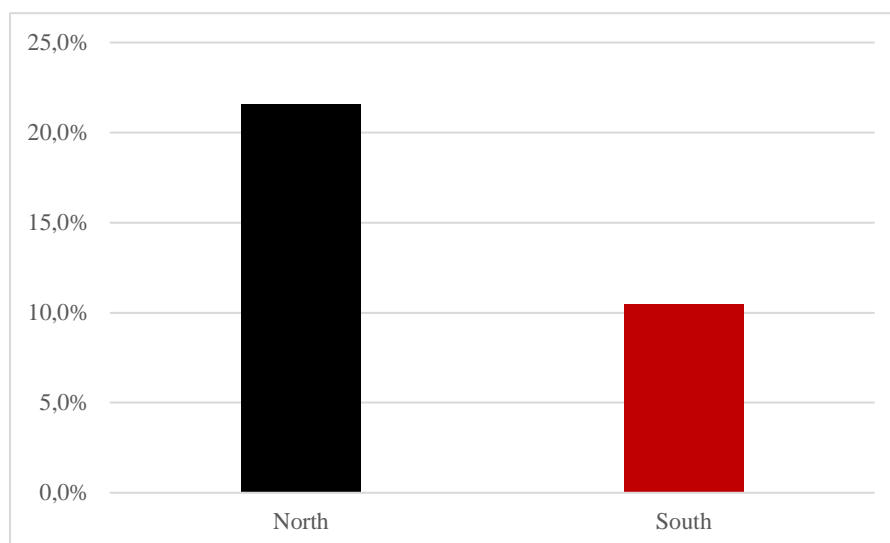


Source: Table M, Vaccination Graph. Total vaccinations, based on the first column named “total vaccinations” or “total doses applied” in Our World in Data.^{18 - 19}

¹⁸ Available at <https://ourworldindata.org/grapher/cumulative-covid-vaccinations>.

¹⁹ GDP was not able to find some countries’ vaccinations information, such as Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Comoros, Congo, Cuba, Djibouti, East Timor, Eritrea, Ethiopia, Fiji, Guinea-Bissau, Haiti, Kiribati, Lesotho, Liberia, Libya, Madagascar, Nauru, Nicaragua, Niger, North Korea, Samoa, Somalia, South Sudan, Tajikistan, Tanzania, Tonga, Turkmenistan, Tuvalu, Vanuatu, Yemen, Zambia. All of them are part of the Global South.

Image 4. Average of COVID-19 vaccine doses available for countries population, per region (in percentage)



Source: Table M, Average % Graph. GDP. The average percentage of the vaccinated population for each country was calculated by the total doses available for the country's population.²⁰

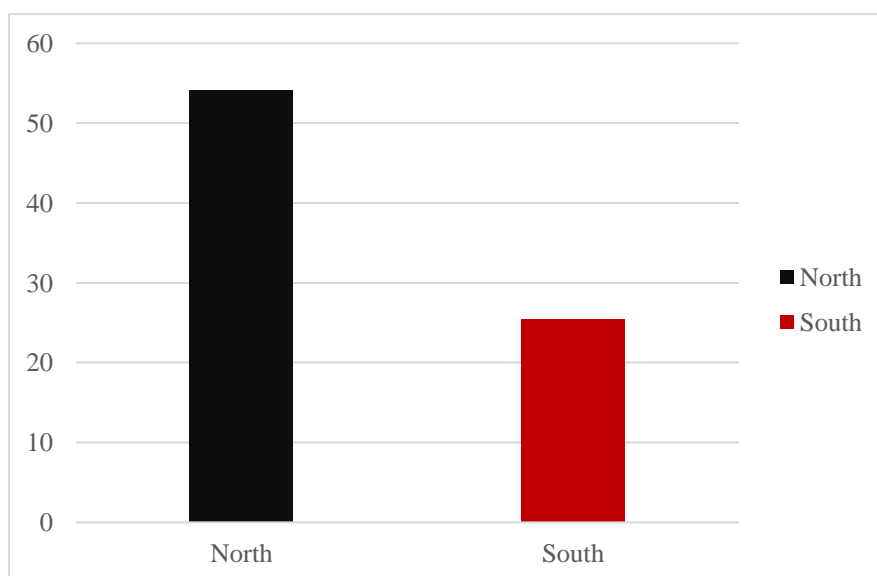
22. According to their income conditions, one can better understand the Global South's low vaccination pace by looking at COVID-19 vaccine distribution throughout countries. For this purpose, this Report divided countries into three categories based on their average income: (i) high-income countries; (ii) upper-middle-income countries; and (iii) lower-middle-income countries and low-income countries.

23. The following Table presents the destination of the purchased doses of ten COVID-19 vaccines²¹ based on the purchasing countries' economic situation. As of April 2021, Moderna, Pfizer-BioNTech, CureVac, and other COVID-19 vaccines developed in the Global North have not reached lower-middle and low-income countries. Moreover, in cases such as the Pfizer / BioNTech and the CureVac's vaccines, upper-middle-income countries have also secured much less than half of their total purchased doses.

²⁰ It is necessary to say that there are COVID-19 vaccines that demand two shots while others demand only one. Hence, GDP could not find the total of people vaccinated per country. The pointed-out percentage takes into account the total amount of COVID-19 shots that were applied for the population.

²¹ These figures include marketed vaccines, as the Moderna and the Pfizer-BioNTech ones, and also candidates that were purchased by countries, as the Sanofi/GSK one.

Table 2. COVID-19 Committed per Region

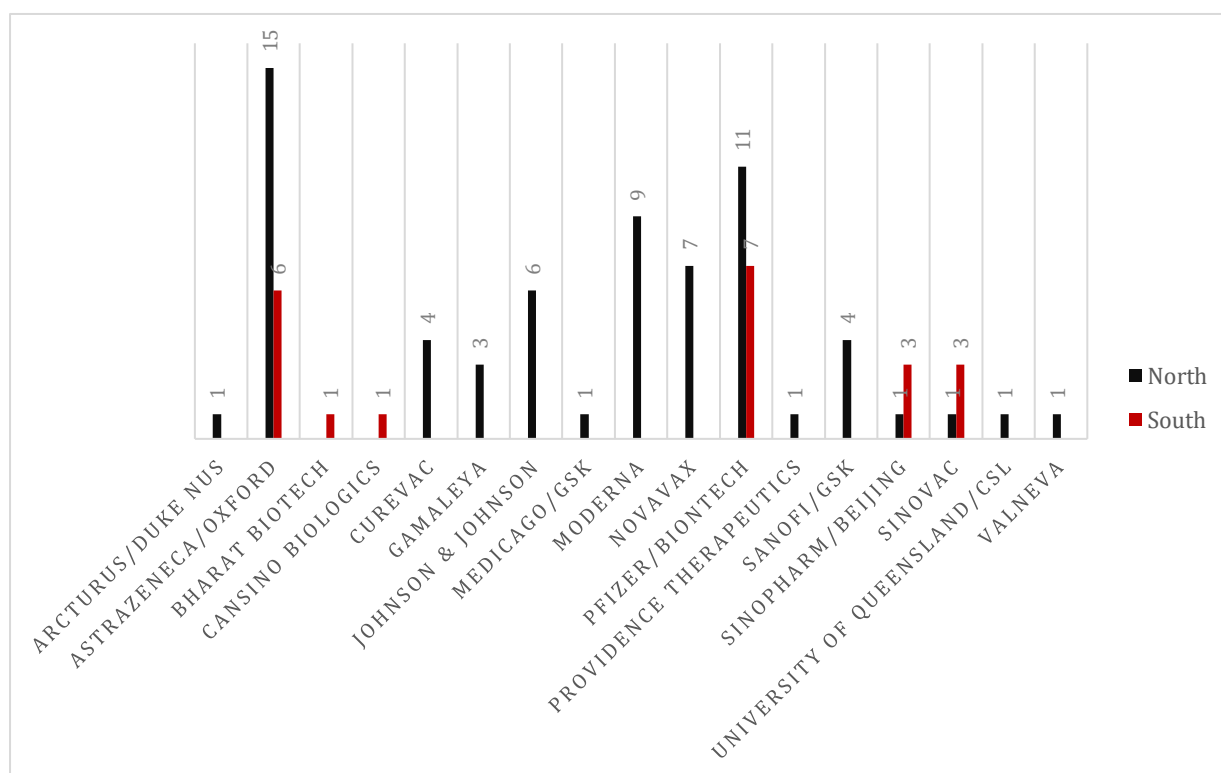


Source: Table E, Graph “Doses Committed per Region”.²²

24. By securing a vast percentage of the produced doses of vaccines, high-income countries have vaccinated much greater percentages of their populations. Meanwhile, doses reserved to upper-middle-income, lower-middle-income, and low-income countries have not been sufficient to satisfy their populations’ urgent demands for vaccination.

²² Database available at: https://public.tableau.com/views/COVID-19VaccineDealsFebruary2021/CandidateTrialPhase?:language=en&:increment_view_count=no&:embed=y&:embed_code_version=3&:loadOrderID=0&:display_count=y&:origin=viz_share_link.

Table 3. COVID-19 vaccination per countries' categories



Source: Table E, Graph 7.²³

25. These figures show why vaccine supplies under COVAX for African countries (mainly distributed in the lower-middle-income and low-income categories) started only in February 2021. The COVAX initiative aims to supply 600 million doses to the continent, enough to vaccinate approximately 20% of the population, but has barely delivered more than 16 million vaccine doses to 31 African countries.²⁴

²³ Database available at: https://public.tableau.com/views/COVID-19VaccineDealsFebruary2021/Story1?:language=en&:increment_view_count=no&:embed=y&:embed_code_version=3&:loadOrderID=0&:display_count=y&:origin=viz_share_link.

²⁴ Peter Mwai, *Covid-19 Africa: What is happening with vaccines*. *BBC News*, April 13th, 2021. Available at: <https://www.bbc.com/news/56100076>.



26. Besides COVAX, some African countries have directly purchased vaccine doses from manufacturing pharmaceuticals or have received direct donations. China has donated vaccine shots to 16 countries, India to 15, and the United Arab Emirates also donated to some countries, mainly in North Africa. Nearly half doses received by African countries came from donations.²⁵

27. However, even the ones that received initial shipments could be soon running out of doses. Rwanda has already exhausted the initial shipment it had received from COVAX, and Ghana, the first country in Africa to obtain vaccines from the initiative, now has little more than 100,000 doses left.²⁶

28. Moreover, limited stocks and supply bottlenecks are putting COVID-19 vaccines out of the continent's reach. The Serum Institute of India, for instance, has claimed its production capacity is "very stressed", directly impacting African countries' vaccination schedules. Most of the continent does not have enough vaccines for adequate coverage of even health workers or all at-risk groups.²⁷

29. Moreover, most Latin American and Caribbean countries also rely on COVAX, which aims to distribute 280 million doses to the region by the end of 2021. However, as of April, these countries have barely started vaccinating. Several countries have not secured enough COVID-19 vaccines to cover their total populations through COVAX, like Honduras, Venezuela, El Salvador, Ecuador, Guatemala, Bolivia, Costa Rica, Colombia, Uruguay, and Argentina.²⁸ Some are deciding not to wait for COVID-19 vaccines donations and have started to settle their purchase deals.²⁹

²⁵ Peter Mwai, *Covid-19 Africa: What is happening with vaccines*. *BBC News*, April 13th, 2021. Available at: <https://www.bbc.com/news/56100076>.

²⁶ Peter Mwai, *Covid-19 Africa: What is happening with vaccines*. *BBC News*, April 13th, 2021. Available at: <https://www.bbc.com/news/56100076>.

²⁷ AlJazeera, *Developing nations demand equal access to coronavirus vaccines*, March 10th 2021. Available at: <https://www.aljazeera.com/news/2021/3/10/countries-continue-push-for-equal-access-to-coronavirus-vaccines>.

²⁸ AS/COA, *Timeline: tracking Latin America's Road to Vaccination*, April 12th, 2021. Available at <https://www.as-coa.org/articles/timeline-tracking-latin-americas-road-vaccination>.

²⁹ Honduras is one clear example. Juan Carlos Sikaffy, president of the Honduran Private Business Council, told the Associated Press that Honduras "cannot wait on bureaucratic processes or misguided decisions" to give citizens "the peace of mind" offered by COVID-19 vaccines. The Honduran Private Business Council participated in a vaccine-buying deal for the Central American country by providing a bank guarantee. More in VOA News, *Poor countries begin to buy vaccines*, February 6th, 2021. Available at: <https://www.voanews.com/covid-19-pandemic/poor-countries-begin-buy-vaccines>.



30. Even the countries that in theory have already secured enough doses to cover their total populations – Chile (219.2%), Peru (183.5%), Brazil (141%), Dominican Republic (132.4%), Mexico (129.1%), and Panama (105.3%) – have been facing delays in the fulfillment of supply agreements.

- Brazil has reserved 541.4 million COVID-19 doses from several suppliers³⁰ but has already only received less than 30 million doses for a population of 210 million people and, so far, has managed to apply the first dose on only 5.61% of its population.³¹
- Mexico, the first Latin American country to receive COVID-19 vaccines, purchased more than 234 million doses but has received only 1.7% of those.³²
- Chile has received 9.8% of its purchased shots; Peru, 1.5%; Dominican Republic, 4.6%; and Panama, 8.2%.³³

31. According to current models, Global South will not address its populations' demands for vaccination for at least the next three years.³⁴ These predict that the rollout of vaccines will not happen until 2023 or 2024 for a considerable portion of the Global South, despite the Global South's considerable manufacturing capability potential.

³⁰ In March, Brazil's Ministry of Health settled a purchase contract with Pfizer on 100 million doses. The first patch of 2 million doses should arrive between April and June, but the most part is scheduled to be delivered only in the second half of the year. O Globo, *Pfizer antecipará entrega de 2 milhões de doses de vacina para o Brasil, diz ministro da Saúde*, April 14th 2021. Available at: <https://oglobo.globo.com/sociedade/vacina/pfizer-antecipara-entrega-de-2-milhoes-de-doses-de-vacina-para-brasil-diz-ministro-da-saude-24970424>.

³¹ CNN Brasil, *Brasil aplicou mais de 16 milhões de doses da vacina contra a Covid-19*, March 22nd 2021. Available at: <https://www.cnnbrasil.com.br/saude/2021/03/22/brasil-aplicou-mais-de-16-milhoes-de-doses-da-vacina-contr-a-covid-19>.

³² EL País, *Escassez de vacinas contra a covid-19 na América Latina escancara desigualdade brutal entre países ricos e pobres*, March 7th 2021. Available at: < <https://brasil.elpais.com/internacional/2021-03-07/escassez-de-vacinas-contr-a-covid-19-na-america-latina-escancara-desigualdade-brutal-entre-paises-ricos-e-pobres.html>.

³³ EL País, *Escassez de vacinas contra a covid-19 na América Latina escancara desigualdade brutal entre países ricos e pobres*, March 7th 2021. Available at: < <https://brasil.elpais.com/internacional/2021-03-07/escassez-de-vacinas-contr-a-covid-19-na-america-latina-escancara-desigualdade-brutal-entre-paises-ricos-e-pobres.html>.

³⁴ Duke Global Health Innovation Center. *Tracking Covid-19 vaccine purchases across the globe* (updated weekly). Available at: <https://launchandscalefaster.org/covid-19/vaccineprocurement> >. See also: The Economist Intelligence Unit, *Q1 global forecast 2021 Coronavirus vaccines: expect delays*, January 22nd, 2021, p. 5. Available at: <https://www.eiu.com/n/campaigns/q1-global-forecast-2021/>.

32. The coronavirus will likely become endemic, meaning that it will continue to circulate across the global population for years to come. If immunity (from vaccines or infections) does wane, as most scientists predict, a periodic COVID-19 vaccine shot will be needed to block transmission. Only mass immunization policies are capable of containing never-ending cycles of contamination.³⁵

33. The data above helps comprehend the quick adherence of the majority of countries from the Global South to South Africa and India’s Trade-Related Aspects of Intellectual Property Rights (“**TRIPS**”) waiver proposal of the implementation, application, and enforcement of the IP rights of products and their underlying technologies related to COVID-19 vaccines, until “*widespread vaccination is in place globally, and the majority of the world population has developed immunity.*”³⁶

34. Without going into detail on the proposal’s merits and the critical observations that have been raised, it should be noted that Kenya and Eswatini immediately subscribed to it, and later seven other countries signed on as co-sponsors.

35. At the TRIPS Council Meeting held on October 16, 2020, 13 other Member States – including Bangladesh, Nepal, Pakistan, and Sri Lanka – fully subscribed to the proposal; 14 others gave qualified support, including China and Nigeria; and approximately 50 countries formally supported the proposal.³⁷

36. Support continued to be reiterated in subsequent informal and formal meetings of the TRIPS Council, although agreement on the issue has been stalled and a ‘third-way’ approach based on fostering voluntary agreements was proposed by the new Director-General of the WTO, Ms. Ngozi Okonjo-Iweala.

³⁵ Nature, *The coronavirus is here to stay – here’s what that means*, February 16th, 2021. Available at: <https://www.nature.com/articles/d41586-021-00396-2>.

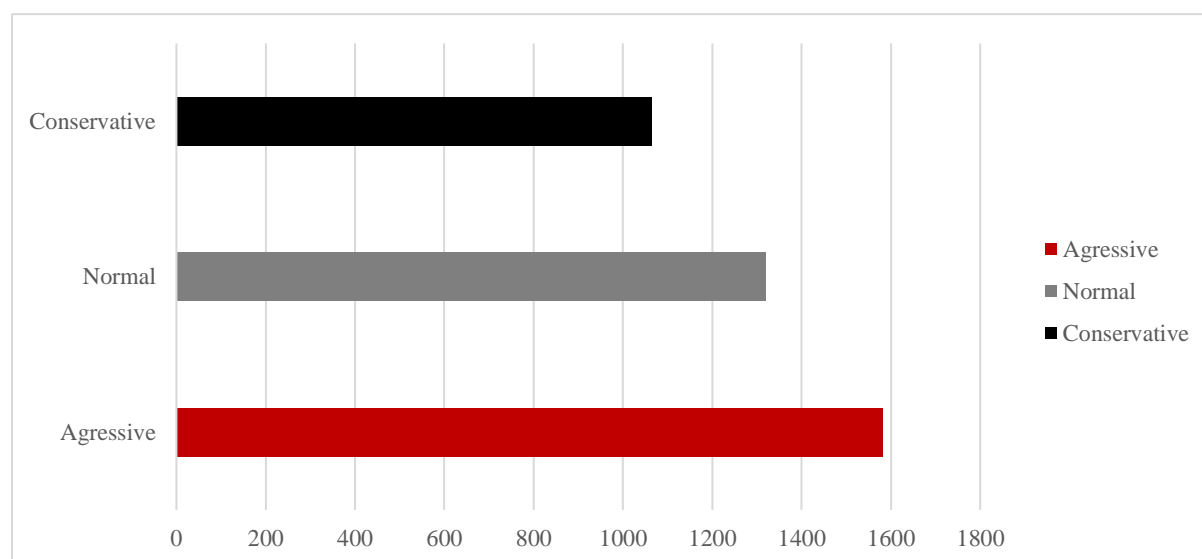
³⁶ Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19: communication from India and South Africa, § 13. Available at: <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>.

³⁷ Argentina, Bangladesh, Egypt, Honduras, Indonesia, Mali, Mauritius, Mozambique, Nepal, Nicaragua, Pakistan, Sri Lanka, Tunisia and Venezuela supported the proposal. Other countries such as Chad (Least Developed Countries Group), Chile, China, Colombia, Costa Rica, Ecuador, El Salvador, Jamaica (Africa, Caribbean and Pacific Countries Group), Nigeria, the Philippines, Senegal, Tanzania (African Group), Thailand, and Turkey.

37. Besides, 380 civil society organizations submitted a document calling on World Trade Organization (“WTO”) to adopt the waiver measure.³⁸ The Global South is fully aware of the urgency of the matter and the need for swift action.

38. The ratio of deaths that could be avoided by ensuring vaccination to Global South is also crucial data. The GDP worked with external statistic consultants to develop the graphic presented below as Image 5 – with complete calculation annexed into this Report as **Annex 1**. It contains three projection scenarios (aggressive, conservative, and average/normal) of deaths that could be avoided if the IP rights related to the Vaccines are shared with the most significant five developing countries (i.e., China, Brazil, India, Mexico, and South Africa):

Image 5. Saved lives *per day* if IP rights related to the Vaccines are available to developing countries (estimation for Brazil)



Source: Table F, Graph 1.³⁹

39. Table 4 consolidates these calculations:

Saved Lives per Day	Scenario Projection
1583	Aggressive
1320	Normal

³⁸ Henrique Zeferino Menezes. *The TRIPS waiver proposal: an urgent measure to expand access to the Covid-19 vaccines*, South Centre, Research Paper no. 129, March 2021. Available at: <https://www.southcentre.int/wp-content/uploads/2021/03/RP-129.pdf>.

³⁹ A methodological note explaining the rationale of Image 5 is presented with Annex 1.



Saved Lives per Day	Scenario Projection
1066	Conservative

Source: Table F, Database Graph 1.⁴⁰

40. These figures show the importance of sharing the IP rights connected to COVID-19 manufacturing to ensure that developing countries may fight the pandemic with the right tools. Sections below demonstrate that this licensing of IP rights would meet the worldwide community's interest.

2.2. Access to vaccines through contractual agreements is not a viable option.

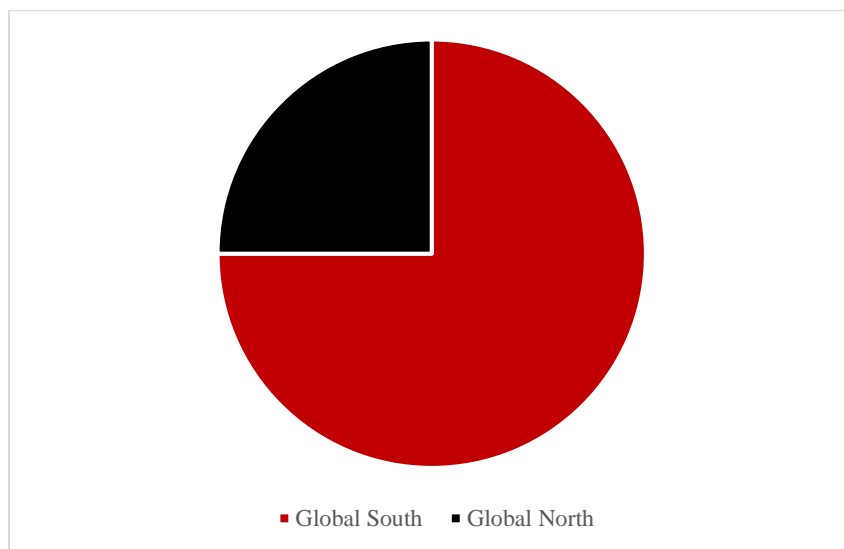
41. Agreements entered into by governments and/or international entities and celebrated with COVID-19 vaccine manufacturers are the available approaches for states to access vaccines, the world's most effective answer to the Coronavirus pandemic. However, as we will showcase in this chapter, this scenario is unsustainable and will cost many more lives than have already been lost if maintained without structural changes to the current vaccine production chain.

42. This is especially so for countries of the Global South, which, despite representing over 75% of the world's most populous countries, have individually secured approximately 40% fewer vaccine doses than countries of the Global North, and, even when doses acquired by international institutions⁴¹ are considered, the number of vaccines destined to southern countries is still approximately 17% less than northern countries', as seen below:

⁴⁰ A methodological note explaining the rationale of Image 5 is presented with **Annex 1**.

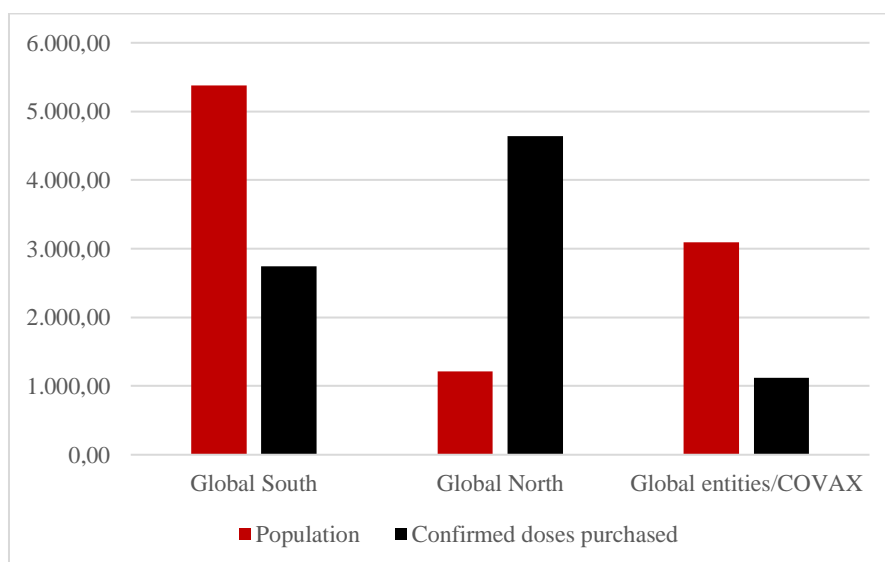
⁴¹ Namely, the COVAX Facility, an initiative coordinated by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and the World Health Organization (WHO), and dedicated to supporting the development, manufacturing and distribution of COVID-19 vaccines, namely to lower-income nations. S. Berkley, *Gavi, The Vaccine Alliance, COVAX explained*, viewed on April 5th, 2021 <<https://www.gavi.org/vaccineswork/covax-explained>>

Image 6. North and South countries' presence in the 100 most populous countries (2020)



Source: Table H, Graph 2.

Image 7. Comparison between population and vaccine procurement (in millions)



Source: Table H, Graph 1.

43. Such data also visually highlights the disproportion of the number of doses acquired by the Global North concerning their own population and the population of southern countries. These numbers would be worrying even if where every single dose purchased was rightfully delivered as scheduled. This, however, is not the case, as mentioned above.

44. Regardless of the global slow vaccination pace, decentralization of vaccine production is barely in sight as pharmaceuticals are only investing in expanding production sights that will, at the very least, remain geographically centralized. In that regard, investments and programs directed at the acceleration of development, manufacturing, and deployment of vaccines, such as the European Strategy for COVID-19 vaccines⁴², do not encompass southern countries' capable pharmaceutical manufacturing plants, which remain secluded from the majority of today's COVID-19 vaccine production chains.

2.2.1. Overview of purchase agreements and contract defaults

45. As has been introduced above, contractual vaccine procurement is currently the primary way for nations to implement vaccination programs. In this topic, we will provide an overview of some of the many agreements settled between COVID-19 vaccine manufacturers and state governments and/or global entities to showcase the relevance of these instruments in the current fight against the Coronavirus pandemic.

46. This will then be followed by an overview of a central problem faced by all countries that have procured vaccines – even if it is a problem faced most cruelly by countries of the Global South: *contract default*, the various delays in delivering COVID-19 vaccines doses.

⁴² Access the European Strategy for COVID-19 vaccines on: <<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1597339415327&uri=CELEX:52020DC0245>>

47. In line with the scenario above, and to clearly illustrate the relevance of contracts related to vaccine procurement, the European Commission (“EC”) has secured, through contractual agreements with Pfizer / BioNTech, and in the course of the last five months, a total of 604 million doses of the Pfizer / BioNTech vaccine^{43 44-45}, as well as 400 million doses of the AZD1222, the COVID-19 vaccine developed by AstraZeneca⁴⁶ (“**the AstraZeneca vaccine**”), 300 (three hundred) million doses of the Moderna COVID-19 vaccine (“**mRNA-1273**” or “**the Moderna vaccine**”), developed by Moderna⁴⁷⁴⁸, and another 400 million doses of the Johnson & Johnson vaccine, Janssen⁴⁹ (“**the Janssen vaccine**”).

⁴³ In November 2020, the European Commission approved a fourth contract with BioNTech and Pfizer, providing for the initial purchase of 200 million doses on behalf of all EU Member States, plus an option to request up to a further 100 million doses. *The European Commission, Coronavirus: Commission approves contract with BioNTech-Pfizer alliance to ensure access to a potential vaccine*, viewed on March 25th, 2021 < https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2081>

⁴⁴ In February 2021, Pfizer and BioNTech announced a new agreement with the European Commission, through which the companies agreed to provide an additional of 200 million doses to the 27 European Union member states. An option for the European Commission to request and additional supply of 100 million doses was also established. *Pfizer Inc., Pfizer and BioNTech to supply the European Union with 200 million additional doses of Comirnaty*, viewed on March 25th, 2021 < <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-BioNTech-supply-european-union-200-million>>

⁴⁵ In March 2021, the European Commission announced another agreement with Pfizer and BioNTech, in order to supply the EU member states with additional 4 million doses of the Comirnaty vaccine. *The European Commission, Commission supports Member States in tackling coronavirus hotspots with offer of four million additional doses of BioNTech-Pfizer vaccine to be delivered this month*, viewed on March 25th, 2021 < https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1101>

⁴⁶ In August 2020, the European Commission announced that it had reached an agreement with AstraZeneca for the purchase of 300 million doses of the company’s vaccine, with an option to purchase 100 million more. *The European Commission, Coronavirus: Commission reaches first agreement on a potential vaccine*, viewed on March 25th, 2021 < https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1438>

⁴⁷ <https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19>. Access on April 10, 2021.

⁴⁸ In February 2021, the European Commission approved a second contract with Moderna, approving an additional purchase of 300 million doses (150 million in 2021 and an option to purchase an additional 150 million in 2022) on behalf of all EU member states. *The European Commission, Coronavirus: Commission approves second contract with Moderna to ensure up to additional 300 million doses*, viewed on April 2nd, 2021 < https://ec.europa.eu/commission/presscorner/detail/en/IP_21_655>

⁴⁹ In October 2020, Johnson & Johnson announced an agreement with the European Commission, through which the Janssen Pharmaceutical Companies will supply 200 million doses of its COVID-19 vaccine to EU member states, with a secured option of an additional 200 million doses. *Johnson & Johnson Services, Inc., Johnson & Johnson announces European Commission Approval of Agreement to supply 200 million doses of Janssen’s COVID-19 vaccine candidate*, viewed on April 3rd, 2021 <https://www.jnj.com/johnson-johnson-announces-european-commission-approval-of-agreement-to-supply-200-million-doses-of-janssens-covid-19-vaccine-candidate>



48. The United States of America (“USA”), in its turn, has managed to secure 700 (seven hundred) million doses of the Pfizer / BioNTech vaccine^{50 51}, as well as over 500 (five hundred) million doses of the mRNA-1273 vaccine⁵² and 400 (four hundred) million doses of the Janssen vaccine⁵³.

49. The Global South has been trying to procure vaccine shots as well. The African Union⁵⁴ has secured, through agreements with companies providing COVID-19 vaccines, a total of 270 (two hundred and seventy) million doses to be distributed to its member states, 50 (fifty) million of which are to be provided by Pfizer-BioNTech, 100 (one hundred) million to be provided by AstraZeneca and the remaining 120 (one hundred and twenty) million doses will be supplied by Johnson & Johnson⁵⁵.

⁵⁰ In July 2020, the U.S. government entered into an agreement with Pfizer and BioNTech, through which the companies agreed to supply 100 million doses, with an option for the government to acquire an additional of up to 500 million doses. *Pfizer Inc., Pfizer and BioNTech announce an agreement with U.S. government for up to 600 million doses of mRNA-based vaccine candidate against SARS-COV-2*, viewed on March 21st, 2021 <<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-BioNTech-announce-agreement-us-government-600>>

⁵¹ In December 2020, Pfizer and BioNTech announced a second agreement with the U.S. government, providing an additional 100 million doses of the companies’ Comirnaty vaccine against COVID-19. *Pfizer Inc., Pfizer and BioNTech to supply the U.S. government with 100 million additional doses of COVID-19 vaccine*, viewed on March 21st, 2021 <<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-BioNTech-supply-us-100-million-additional-doses>>

⁵² U.S. government has already agreed to buy 200 million doses of the mRNA-1273 vaccine, developed and manufactured by Moderna, in a contract that establishes the option to secure an additional 300 million doses. *N. Higgins-Dunn, CNBC, Health and Science, Moderna increases minimum 2021 Covid vaccine production by 20% to 600 million doses*, viewed on April 3rd, 2021 <<https://www.cnbc.com/2021/01/04/moderna-says-increases-2021-covid-vaccine-production-by-20percent-to-6doses-this-year.html>>

⁵³ In March 2021, the U.S. government announced the purchase of an additional 100 million doses of the J&J vaccine, which are now summed to the 100 million the U.S. had already purchased in a deal that also established an option to purchase an additional 200 million doses. *J. Mason, M. Erman and A. Shalal, Reuters, Biden prepares for “challenges” with extra 100 million doses of J&J COVID-19 vaccine*, viewed on April 2nd, 2021 <<https://www.reuters.com/article/health-coronavirus-biden/update-5-biden-prepares-for-challenges-with-extra-100-mln-doses-of-jj-covid-19-vaccine-idUSL1N2L814X>>

⁵⁴ The African Union currently encompasses 55 member states: Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cabo Verde, Central African Republic, Chad, Comoros, Congo, the Democratic Republic of Congo, Cote d’Ivoire, Djibouti, Equatorial Guinea, Egypt, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, the Kingdom of Lesotho, Liberia, Libya, Madagascar, Malawi, Mali, Mauritania, Mauritius, Morocco, Mozambique, Namibia, Niger, Nigeria, Rwanda, Saharawi Arab Democratic Republic, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Kingdom of Swaziland, Tanzania, Togo, Tunisia, Uganda, Zambia and Zimbabwe. *NTI, African Union (AU)*, viewed on April 3rd, 2021, <<https://www.nti.org/learn/treaties-and-regimes/african-union-au/#:~:text=Membership,%2C%20Guinea%2C%20Guinea%2DBissau,>>

⁵⁵ *D. Lewis, A. Winning, Reuters, Healthcare & Pharma, COVID-19 shots to cost \$3 to \$10 under African Union vaccine plan*, viewed on March 24th, 2021 <<https://www.reuters.com/article/health-coronavirus-africa-vaccine/exclusive-covid-19-shots-to-cost-3-to-10-under-african-union-vaccine-plan-idUSL1N2JU2WH>>

50. The Mexican government, which has also entered into agreements with the companies, managed to secure over 34 (thirty-four) million doses of the Pfizer / BioNTech vaccine⁵⁶, while the Peruvian government signed a deal with Pfizer and BioNTech for the supply of 20 million doses of the vaccine⁵⁷.

51. When it comes to international entities, the COVAX Facility has managed to secure 40 (forty) million doses of the Pfizer / BioNTech vaccine⁵⁸. The Facility has also struck deals with AstraZeneca, having procured over 700 million doses of their vaccine, with Johnson & Johnson, who committed to provide 500 million vaccine doses⁵⁹, and with Novavax, who, in alliance with the Serum Institute of India, promised to deliver up to 1.1 billion doses of the company's COVID-19 vaccine, NVX-CoV2373⁶⁰.

52. These are only a few of the numerous agreements celebrated between governments or political union's commissions and COVID-19 vaccine pharmaceuticals: according to Duke Global Health Innovation Center's "*Launch & Scale Speedometer*", **over 15.4 billion doses of existing COVID-19 vaccines have been the object of contracts signed or to-be-signed by manufacturers and national and international entities**⁶¹.

53. This strategy of tackling the Coronavirus pandemic via contracts, however, faces a – literally – life-threatening obstacle: with COVID-19 still spreading rapidly and the demand for vaccines not slowing down in the foreseeable future, pharmaceuticals are delaying deliveries agreed to.

⁵⁶ Reuters, Mexico signs deal with Pfizer for 34.4 million doses of COVID-19 vaccine, viewed on March 24th, 2021 <<https://www.reuters.com/article/us-health-coronavirus-mexico-idUKKBN28C2VK>>

⁵⁷ Reuters, Peru inks deal with Pfizer for 20 million doses of coronavirus vaccine, viewed on March 24th, 2021 <<https://www.reuters.com/article/us-health-coronavirus-peru-idUSKBN2A42MZ>>

⁵⁸ In February 2021, UNICEF signed on behalf of the COVAX Facility, an agreement with Pfizer and BioNTech for the supply of 40 million doses of the Comirnaty vaccine through 2021. UNICEF, UNICEF signs supply agreement for Pfizer/BioNTech COVID-19 vaccine, viewed on March 24th, 2021 <<https://www.unicef.org/press-releases/unicef-signs-supply-agreement-pfizerBioNTech-covid-19-vaccine>>

⁵⁹ P. Adepoju, Health Policy Watch, Ambitious global COVAX Facility delivers first doses in Accra Ghana, viewed on April 6th, 2021 <<https://healthpolicy-watch.news/ambitious-global-covax-facility-delivers-first-doses>>

⁶⁰ Novavax, Inc., Novavax announces Memorandum of Understanding with Gavi for Cumulative Supply to COVAX Facility of 1.1 billion doses of COVID-19 vaccine, viewed on March 27th, 2021 <<https://ir.novavax.com/news-releases/news-release-details/novavax-announces-memorandum-understanding-gavi-cumulative>>

⁶¹ Access Duke Global Health Innovation Center's "*Launch & Scale Speedometer*" here: <<https://launchandscalefaster.org/covid-19/vaccineprocurement>>

54. In January 2021, EU member states had to experience setbacks in their immunization schedules due to the delay of shipments of the Pfizer / BioNTech⁶² and Moderna⁶³ vaccines. In February, the EU faced new delays in deliveries of the Pfizer / BioNTech vaccine: by the second week of the month, Pfizer had not yet delivered around 10 million vaccine doses that had been originally due in December⁶⁴.

55. In March, the EU member states experienced new shortfalls in supply, this time from manufacturer AstraZeneca, who announced it would deliver only a third of the 90 million doses provided for the month in the agreement settled between the European Commission and AstraZeneca⁶⁵.

56. In March 2021, a publication in Germany's Business Insider reported that over 850 thousand doses of the Moderna vaccine, due to be delivered from April 26th to May 2nd, might end up not happening due to delivery delays⁶⁶. In North America, the U.S. and Canada have also experienced setbacks in vaccination due to delays in COVID-19 vaccine shipments⁶⁷⁻⁶⁸.

⁶² BBC News, *Coronavirus: EU anger over delayed Pfizer vaccine deliveries*, viewed on March 28th, 2021, <https://www.bbc.com/news/world-europe-55666399>.

⁶³ E. Parodi, Reuters, *Moderna COVID vaccines delayed in Europe and elsewhere, adding to shortfalls*, viewed on April 4th, 2021 <https://www.reuters.com/article/us-health-coronavirus-italy-vaccine-idUKKBN29Y1CD>.

⁶⁴ F. Guarascio, Reuters, *Exclusive: Pfizer COVID-19 vaccine supply to the EU about 10 million doses short of plan*, viewed on April 1st, 2021 <https://www.reuters.com/article/us-health-coronavirus-eu-pfizer-exclusiv-idUSKBN2AH1E3>.

⁶⁵ P. Laurent, *Sortir A Paris*, *AstraZeneca vaccine: new shipping delays in the EU*, viewed on March 29th, 2021 <https://www.sortiraparis.com/news/coronavirus/articles/241757-astrazeneca-vaccine-new-shipping-delays-in-the-eu/lang/en>.

⁶⁶ J. Miller, Reuters, *Moderna says Europe-bound COVID-19 vaccine deliveries are on track*, viewed on April 10th, 2021 <https://www.reuters.com/article/us-health-coronavirus-moderna-vaccine-idUSKBN2BU15I>.

⁶⁷ In January 2021, the city of New York had to postpone over 100.000 doses, which were delayed due to problems with transportation. *The Straits Times*, *Temperature issues delay shipments of Moderna Covid-19 vaccine in the US*, viewed on March 31st, 2021 <https://www.straitstimes.com/world/united-states/shipments-of-moderna-vaccine-lag-in-the-us-due-to-temperature-issues>.

⁶⁸ In March 2021, Moderna Inc. announced it would have to delay the shipment of over half a million doses of its vaccine, which were to be delivered to Canada. *U.S. News*, *Moderna delays shipment of about 600.000 Covid-19 vaccine doses to Canada*, viewed on April 3rd, 2021 <https://www.usnews.com/news/top-news/articles/2021-03-25/moderna-delays-shipment-of-about-600-000-covid-19-vaccine-doses-to-canada>.

57. This situation is even more critical when it comes to vaccine doses to be sent to developing countries. As reported by *Health Policy Watch*, of the 270 million vaccine doses acquired by the African Union, the first batch of 50 million doses is yet to be delivered, and, by March, only an approximate 14.5 million doses had been delivered in the African continent⁶⁹.

58. In March, the COVAX Facility lamented the delay of over 90 million doses of the AstraZeneca vaccine⁷⁰, causing the COVAX Program to be set back in weeks and aggravating the slow pace of vaccine deliveries destined to the Facility. By the end of March, COVAX had only been able to distribute about 30 million COVID-19 vaccine doses⁷¹, having also faced delays in shots to be delivered by Pfizer and BioNTech, due to additional requirements set by the companies regarding the COVAX vaccine-program⁷².

59. In Mexico, of the 34 million doses provided for in the agreement the government entered into with Pfizer, less than a tenth of the total promised has been delivered so far⁷³. On March 18, 2021, Argentinian president Alberto Fernández admitted that the country had only received 6% of all vaccine doses ordered, a little over 4 million doses⁷⁴.

60. In Indonesia, the Health Minister announced that, of the 50 million AstraZeneca vaccine doses procured by the country, only 20 million would be delivered in 2021 – the remaining 30 million doses having been delayed for the second quarter of 2022⁷⁵.

⁶⁹ P. Adepoju, *Health Policy Watch*, *Delayed delivery of vaccines procured by Africa CDC threatens timeline for achieving “herd immunity”*, viewed on April 3rd, 2021 <<https://healthpolicy-watch.news/delayed-vaccine-delivery-threatens-africas-herd-immunity-target/>>

⁷⁰ Euronews, *COVAX chief disappointed with slow vaccine exports to world’s poorest*, viewed on April 3rd, 2021 <<https://www.euronews.com/2021/03/26/covax-chief-disappointed-with-slow-vaccine-exports-to-world-s-poorest>>

⁷¹ CTV News, *UN-backed vaccine delivery program warns of supply delays*, viewed on April 3rd, 2021 <<https://www.ctvnews.ca/health/coronavirus/un-backed-vaccine-delivery-program-warns-of-supply-delays-1.5362163>>

⁷² Reuters, *Pfizer requirements causing delays in COVAX deliveries: GAVI*, viewed on March 29th, 2021 <<https://www.reuters.com/article/health-coronavirus-who-vaccines-pfizer-i-idUSKBN2AU1GP>>

⁷³ KTLA5, *Mexico to rely heavily on Chinese-made coronavirus vaccines, even with lack of data*, viewed on March 27th, 2021 <<https://ktla.com/news/nationworld/mexico-to-rely-heavily-on-chinese-made-coronavirus-vaccines-even-with-lack-of-public-data/>>

⁷⁴ Buenos Aires Times, *Vaccine delays force government onto defensive, Fernández preaches caution*, viewed on April 4th, 2021 <<https://www.batimes.com.ar/news/argentina/vaccine-delays-force-government-onto-defensive-as-fernandez-preaches-caution.phtml>>

⁷⁵ ABC News, *Indonesia turns to China for more vaccines after AstraZeneca delays*, viewed on April 8th, 2021 <<https://www.abc.net.au/news/2021-04-09/indonesia-china-vaccines-astrazeneca-supply-problems/100057448>>

61. The situation becomes even more threatening – especially for the Global South – due to the retention mechanisms implemented by countries that host vaccine production. The scenario of contractual default presented above led European leaders to subject vaccines produced in the EU to export authorizations, meaning that companies with which the EU has concluded Advanced Purchase Agreements (“**APAs**”) must deliver the pre-contracted doses before exporting to other countries⁷⁶.

62. Moreover, even though the EU has recently dismissed export restrictions⁷⁷, the mechanism was responsible for diplomatic tensions and delays in worldwide vaccination schedules⁷⁸. It showcases yet another risk to having contractual agreements as the sole mechanism for access to vaccines.

63. The foreboding context of vaccine production and delivery depicted above showcases the great difficulties the world faces to access COVID-19 vaccines and how only recurring to a contractual solution will not and cannot be sufficient for overcoming the Coronavirus pandemic.

64. After all, as stated by the EC itself in its “*EU Strategy for COVID-19 vaccines*” (despite clearly opposing any measures to accelerate access and manufacturing of COVID-19 vaccines globally, including via sharing of IP and know-how):

“This is not only a European challenge, it is also a global one. All regions of the world are affected. The spread of the virus has shown that no region is safe until the virus is under control everywhere. In addition to it being in their clear self-interest to do so, high-income countries have a responsibility to accelerate the development and production of a safe and effective vaccine and make it accessible for all the regions of the world. The EU recognizes this task as its responsibility.”

⁷⁶ European Commission, *Commission extends transparency and authorization mechanisms for exports of COVID-19 vaccines*, viewed on April 17th, 2021 <https://ec.europa.eu/commission/presscorner/detail/en/IP_21_1121>.

⁷⁷ BBC News, *Coronavirus: EU stops short of vaccine export ban*, viewed on April 17th, 2021 <<https://www.bbc.com/news/world-europe-56529868>>.

⁷⁸ BBC News, *Covid: Italy blocks AstraZeneca vaccine shipment to Australia*, viewed on April 17th, 2021 <<https://www.bbc.com/news/world-europe-56279202>>.

2.2.2. Contractual default as a result of the insufficient production and production concentration

2.2.2.1 Insufficient production

65. The current scenario of default of vaccine supply contracts worldwide is the direct result of insufficient production by pharmaceutical companies, as production is concentrated in a few countries in the Global North. Vaccine manufacturing steps face productive bottlenecks that hinder the flow of production and delay massive distribution.

66. Specifically, the Pfizer / BioNTech, Moderna, and CureVac vaccines⁷⁹, the mRNA vaccines, have productive bottlenecks in the fill and finish stages due to the high volume produced during the bulk manufacturing, and the small number of companies that carry out the final part of the production⁸⁰. It creates a discrepancy among the manufacturing stages, and accordingly, the quantity of shots produced does not reflect the expected production capacity.

67. Vaccines that use other platforms, such as the viral vector AstraZeneca or Jansen vaccines, have productive bottlenecks in the first steps on account of the necessary processes and materials to obtain the active pharmaceutical ingredient (API).⁸¹⁸² These processes require a complex production structure for large-scale manufacturing, and the concentration of production makes it more difficult.⁸⁴

⁷⁹ Out of the three companies aforementioned, it is worth noting that CureVac has not yet perceived profits. Nevertheless, CureVac already raised USD 450 million on a follow-on public offering of shares that took place in February 2021. See: "CureVac Announces Closing of \$450 million Follow-on Public Offering of Common Shares", Updated February 2, 2021, <<https://www.curevac.com/en/2021/02/02/curevac-announces-closing-of-450-million-follow-on-public-offering-of-common-shares/>>. In this sense, and especially due to the fact that CureVac is a Biotech Unicorn, it is possible that the company follows the same path traced by Moderna, which was able to rapidly grow and reach a USD 4.7 billion valuation due to vaccine development, highlighting the growth potential perceived by the market for CureVac amidst the Pandemic. A close parallel can be drawn with what happened with Moderna, a company founded in 2010 that has the recently developed Moderna vaccine as its most important product and experienced a 215% increase in price of its stocks in the past year.

⁸⁰ "With billions spent and 'wartime' declared, why are vaccines still in short supply?", Updated on 23 fev. 2021, <https://fortune.com/2021/02/23/covid-vaccine-supply-manufacturing-pfizer-moderna-defense-production-act/>.

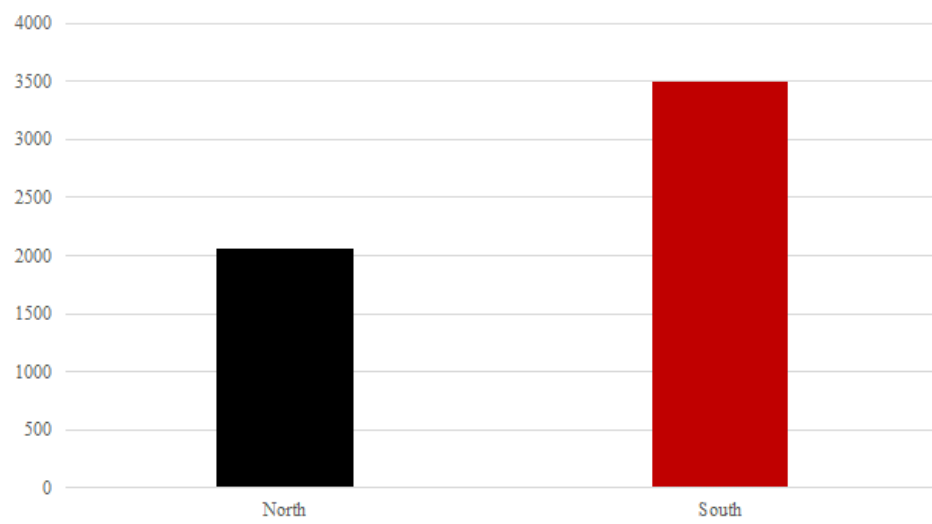
⁸¹ API (Active Pharmaceutical Ingredient) means the active ingredient which is contained in medicine. Katsura Chemical, "What is API?", <https://www.katsura-chemical.co.jp/en/drugs/>

⁸² "How are Covid vaccines produced and why have there been delays?", Updated 19 Mar. 2021, <https://www.theguardian.com/society/2021/mar/19/how-are-covid-vaccines-produced-and-why-have-there-been-delays>.

⁸³ "AstraZeneca's and J&J's COVID-19 vaccines manufacturing face viral vector shortages", Updated 24 Mar. 2021, <https://www.globaldata.com/astrazenecas-jjs-covid-19-vaccines-manufacturing-face-viral-vector-shortages/>.

⁸⁴ "AstraZeneca COVID vaccine's complex EU supply chain", Updated 02 Feb., 2021, <https://p.dw.com/p/3olUR>.

Image 8. Sum of Production Expansion Capacity per Region (in millions of doses)



Source: Table C, Graph 1.

68. According to the graph above and the “Image 1. Sum of Vaccine Capacity Declaration per Region (in millions of doses)”, given the need to increase production, the main vaccine producers would get better results if they expanded their production chains to the Global South. Projections demonstrate that there will not be enough vaccines to cover the world's population until 2023.⁸⁵ The current distribution of the production process will not supply the global demand for vaccination, as this requires unprecedented and impossible productivity.⁸⁶

69. The retention of technology for the manufacture of vaccines by a small part of the pharmaceutical industry has only one result: insufficient production. As the amount of vaccine produced is insufficient for the equitable vaccination of all countries, a scenario of artificial vaccine shortages is created as companies prioritize the North's supply⁸⁷. That is why it is necessary to include the Global South⁸⁸ in the productive process.

⁸⁵ McDonnell, Van Exan, Lloyd, Subramanian, Chalkidou, La Porta, Li, Maiza, Reader, Rosenberg, Scannell, Thomas, Weintraub, and Yadav, 2020. “COVID-19 Vaccine Predictions: Using Mathematical Modelling and Expert Opinions to Estimate Timelines and Probabilities of Success of COVID-19 Vaccines.” CGD Policy Paper 183. Washington, DC: Center for Global Development. <https://www.cgdev.org/publication/covid-19-vaccine-predictions>.

⁸⁶ “What it will take to vaccinate the world against COVID-19”, Updated 24 Mar. 2021, <https://www.nature.com/articles/d41586-021-00727-3>.

⁸⁷ “Covid vaccine tracker: How’s my country and the rest of the world doing?”, Updated 12 Feb., 20201, <https://www.bbc.com/news/world-56025355>.

⁸⁸ W. Nicholson Price II, Arti K. Rai, Timo Minssen, “Knowledge transfer for large-scale vaccine manufacturing”, Science, 21 Aug 2020, <https://science.sciencemag.org/content/369/6506/912.full>.

2.2.2.2 Concentration of production

70. The report produced by the Global Health Innovation Center, edition "*Deciphering the Manufacturing Landscape for Covid-19 Vaccines*" (2021), demonstrates the close relationship between concentration of production and distribution of vaccines.⁸⁹

71. Because of the need to increase production, the expansion of production capacity is not evenly distributed among manufacturers, and the most widely supplied vaccines are the AstraZeneca Pfizer / BioNTech vaccines. While the first takes a distributed manufacturing approach, with many technology transfer businesses, the second operates under a centralized approach, with internal manufacturing in few regions.⁹⁰

⁸⁹ "Issue Brief: Deciphering the Manufacturing Landscape for Covid-19 Vaccines", Updated 19 Mar. 2021, <https://launchandscalefaster.org/sites/default/files/documents/Speedometer%20Issue%20Brief-COVID%20Manufacturing%20Landscape%2019%20March%2021.pdf>.

⁹⁰ "Manufacturing Data per Vaccine", Updated 02 Apr. 2021, <https://public.tableau.com/profile/duke.global.health.innovation.center#!/vizhome/ManufacturingDataperVaccine/ManufacturingLocationsperVaccine>.

72. The graph below demonstrates the distribution configuration of the AstraZeneca and Pfizer vaccine productions, respectively, which represent the platforms with the highest productive potential today. The data for elaborating the maps were obtained through press releases and information of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).⁹¹⁻⁹²⁻⁹³⁻⁹⁴⁻⁹⁵⁻⁹⁶⁻⁹⁷⁻⁹⁸⁻⁹⁹⁻¹⁰⁰

⁹¹ "Landscape of Current COVID-19 Supply Chain and Manufacturing Capacity, Potential Challenges, Initial Responses, and Possible 'Solution Space': a Discussion Document", Updated 09 Mar., 2021, https://www.dcvmn.org/IMG/pdf/landscape_of_current_c19_supply_chain_manufacturing_capacity_embargo_9_march_2021.pdf.

⁹² "Production, Distribution and Technology Incorporation in Bio-Manguinhos, Nov. 2020, https://www.arca.fiocruz.br/bitstream/icict/44795/2/i_oficina_sobre_a_vacina_para_covid-19_producao_distribuicao_e_tt.pdf.

⁹³ "Japanese drugmaker starts AstraZeneca vaccine production", 12 Mar. 2021, <https://www.japantimes.co.jp/news/2021/03/12/national/astrazeneca-vaccine-japan/>.

⁹⁴ "Argentina sends to Mexico supplies for AstraZeneca vaccine", Updated 19 Feb., 2021, <https://www.folhapse.com.br/noticias/argentina-envia-ao-mexico-insumo-para-vacina-da-astrazeneca/169486/>.

⁹⁵ "Spanish group Insud Pharma signs agreement with AstraZeneca to manufacture COVID-19 vaccine candidate", Updated 20 Jan. 2021, <https://www.insudpharma.com/spanish-group-insud-pharma-signs-agreement-astrazeneca-manufacture-covid-19-vaccine-candidate>.

⁹⁶ "A COVID-19 vaccine life cycle: from DNA to doses", Updated 08 Feb. 2021, <https://www.usatoday.com/in-depth/news/health/2021/02/07/how-covid-vaccine-made-step-step-journey-pfizer-dose/4371693001/>.

⁹⁷ "The Austrian firm Polymun has been playing a key role in developing a vaccine", Updated 30 Dec. 2020, https://www.advantageaustria.org/om/news/20201230_Polymun.en.html.

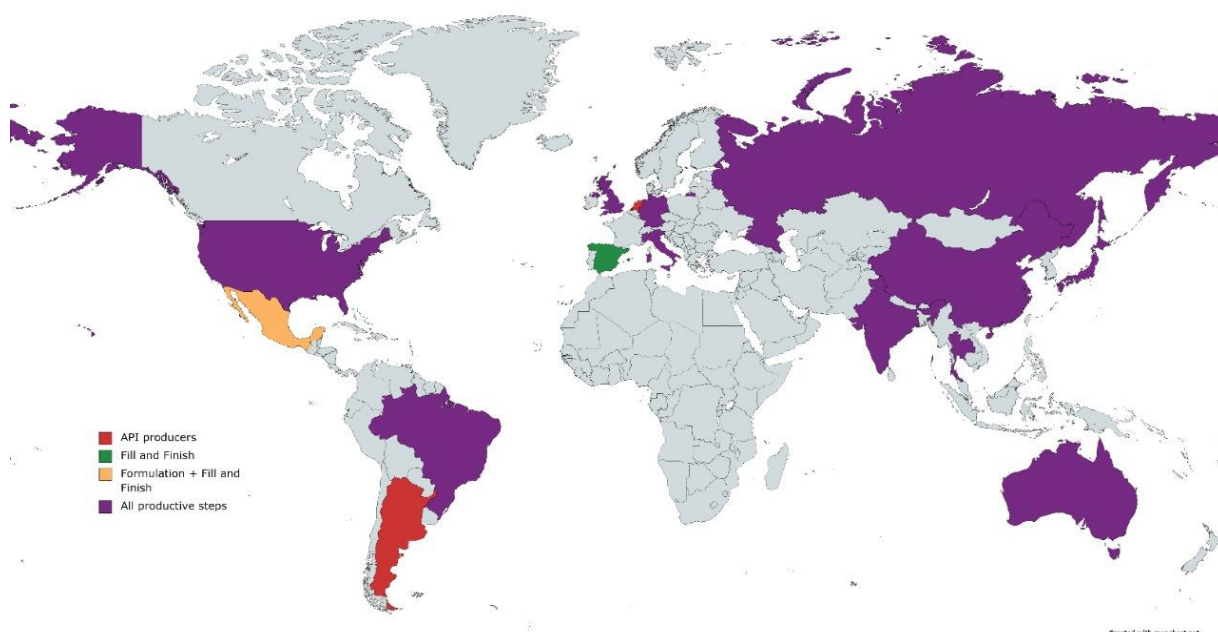
⁹⁸ "Novartis Signs Initial Agreement to Provide Manufacturing Capability for the Pfizer-BioNTech COVID-19 Vaccine", Updated 09 Feb. 2021, <https://www.novartis.com.br/news/media-releases/novartis-assina-acordo-inicial-para-fornecer-capacidade-de-fabricacao-para>.

⁹⁹ "BioNTech provides Update on Vaccine Production Status at Marburg Manufacturing Site", Updated 26 Mar., 2021, <https://www.globenewswire.com/news-release/2021/03/26/2200134/0/en/BioNTech-provides-Update-on-Vaccine-Production-Status-at-Marburg-Manufacturing-Site.html>.

¹⁰⁰ "BioNTech provides Update on Vaccine Production Status at Marburg Manufacturing Site", Updated 26 Mar., 2021, <https://www.globenewswire.com/news-release/2021/03/26/2200134/0/en/BioNTech-provides-Update-on-Vaccine-Production-Status-at-Marburg-Manufacturing-Site.html>.



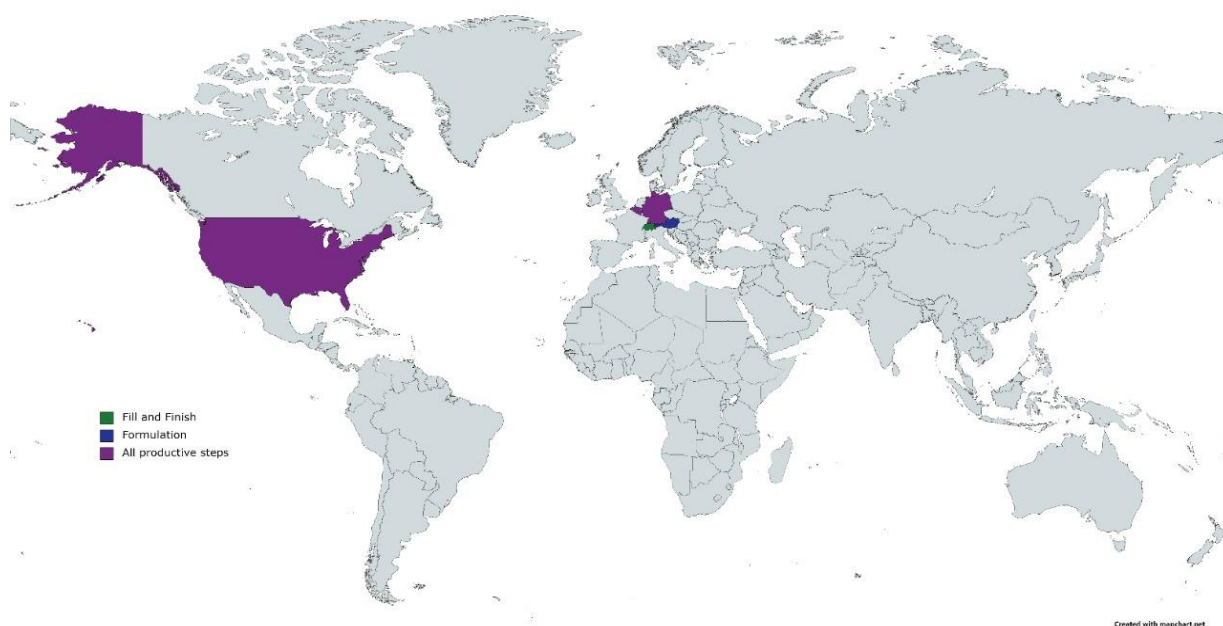
Image 9. Distribution of Oxford-AstraZeneca vaccine manufacturing



Source: Table G, Graph 1.

73. According to the same report, global purchasing patterns tend to reflect the manufacturing approach. Manufacturers with a centralized production approach, such as Pfizer and BioNTech, prioritize their manufacturing sites for sales and deliveries. In general, the analysis shows the concentration of mRNA vaccine production in the Global North, as can be seen below.

Image 10. Distribution of Pfizer-BioNTech vaccine manufacturing



Source: Table G, Graph 2.

74. These graphs highlight the differences in the production of vaccines and, especially, the great concentration of production of the Pfizer / BioNTech vaccine, representing the production of mRNA vaccines.

2.2.2.3. Distribution of mRNA vaccines production

75. Pfizer and BioNTech and Moderna and CureVac indicate, through the spatial distribution of production and the destination of reserved vaccines, a preference for supply to the Global North¹⁰¹.

76. Both have independent supply chains in Europe and the USA. Pfizer (US) distributes the manufacturing of the stages among the factories located in different US cities to make better use of the facilities and identify and solve possible productive bottlenecks.¹⁰²

¹⁰¹ "Total Purchases by Country Income Level Classification and Manufacturing Projection (2021)", Updated 02 Apr. 2021, <https://public.tableau.com/profile/duke.global.health.innovation.center#!/vizhome/TotalPurchasesbyCountryIncomeLevelClassificationandManufacturingProjection2021/Dashboard1>.

¹⁰² "A COVID-19 vaccine life cycle: from DNA to doses", Updated 07 Feb. 2021, <https://www.usatoday.com/in-depth/news/health/2021/02/07/how-covid-vaccine-made-step-step-journey-pfizer-dose/4371693001/>.

77. However, Pfizer (BE) performs all the production stages, with the help of four companies in the bulk manufacturing stage (BioNTech, Dermapharm, Rentschler Biopharma, and Polymun Scientific) and four companies for the fill-finish stage (Dermapharm, Novartis, Siegfried, and Sanofi).¹⁰³⁻¹⁰⁴⁻¹⁰⁵⁻¹⁰⁶⁻¹⁰⁷⁻¹⁰⁸⁻¹⁰⁹⁻¹¹⁰⁻¹¹¹⁻¹¹² In this way, the European production is concentrated in only four countries (Germany, Austria, Belgium, and Switzerland).

¹⁰³ "Pfizer and Belgium: coup de foudre?", Undated, <https://yes2belgium.be/pfizer-and-belgium-coup-de-foudre/>.

¹⁰⁴ "Update on vaccine production at BioNTech's manufacturing site in Marburg" Updated 10 Feb., 2021, <https://investors.BioNTech.de/news-releases/news-release-details/update-vaccine-production-BioNTechs-manufacturing-site-marburg/>.

¹⁰⁵ "A vial, a vaccine and hopes for slowing a pandemic — how a shot comes to be", Updated 17 Nov. 2020, <https://www.washingtonpost.com/health/2020/11/17/coronavirus-vaccine-manufacturing/>.

¹⁰⁶ "Dermapharm aims to start making Pfizer shot at second site by May", Updated 09 Feb., 2021, <https://www.reuters.com/article/us-health-coronavirus-germany-dermapharm-idUSKBN2A91CK>.

¹⁰⁷ "Joining forces against SARS-CoV-2", Updated 07 Oct. 2020, <https://www.rentschler-biopharma.com/news/press-releases-and-announcements/detail/view/joining-forces-against-sars-cov-2/>.

¹⁰⁸ "The Austrian Firm Polymun Has Been Playing a Key Role in Developing a Vaccine", Updated 30 Dec. 2020, https://www.advantageaustria.org/om/news/20201230_Polymun.en.html.

¹⁰⁹ "Dermapharm expands COVID-19 vaccine production capacity at ex-Merck site", Updated 15 Feb. 2021, <https://www.cphi-online.com/dermapharm-expands-covid19-vaccine-production-news110840.html>.

¹¹⁰ "Novartis Signs Initial Agreement to Provide Manufacturing Capacity for Pfizer-BioNTech COVID-19 Vaccine", Updated 09 Feb., 2021, <https://www.novartis.com.br/news/media-releases/novartis-assina-acordo-inicial-para-fornecer-capacidade-de-fabricacao-para>.

¹¹¹ "Siegfried and BioNTech Sign Contract for the Aseptic Fill & Finish of a COVID-19 Vaccine", Updated 14 Set., 2020, <https://www.siegfried.ch/siegfried+and+BioNTech+sign+contract+for+the+aseptic+fill+%2526+finish+of+a+covid-19+vaccine/news-en/5746>.

¹¹² "Sanofi steps up to deliver 125m doses of Pfizer's COVID-19 vaccine", Updated 27 Jan. 2021, <https://bioprocessintl.com/bioprocess-insider/global-markets/sanofi-steps-up-to-deliver-125m-doses-of-pfizers-covid-19-vaccine/>.

78. While Pfizer itself carries out all the steps, Moderna outsources the entire bulk manufacturing production process only to Lonza (US) and Lonza (CH), and five other companies do the filling and finishing step (Baxter, Catalant, GCPharma, Recipharm, and ROVI).¹¹³⁻¹¹⁴⁻¹¹⁵⁻¹¹⁶⁻¹¹⁷⁻¹¹⁸ Production location is concentrated in five countries (USA, Switzerland, Spain, France, and South Korea).

¹¹³ "Moderna and Lonza Announce Worldwide Strategic Collaboration to Manufacture Moderna's Vaccine (mRNA-1273) Against Novel Coronavirus", Cambridge (MA), USA and Basel, Switzerland, 1 May 2020, https://www7.lonza.com/~media/Files/japan/News/200501_Press_Release__Moderna_Lonza_COVID_FINAL.pdf.

¹¹⁴ "Baxter BioPharma Solutions and Moderna Announce Agreement for Fill/Finish Manufacturing of the Moderna COVID-19 Vaccine in the U.S.", 8 Mar. 2021, <https://www.baxter.com/baxter-newsroom/baxter-biopharma-solutions-and-moderna-announce-agreement-fillfinish-manufacturing>.

¹¹⁵ "Moderna and Catalent Announce Collaboration for Fill-Finish Manufacturing of Moderna's COVID-19 Vaccine Candidate", CAMBRIDGE, M.A. and SOMERSET, N.J.— 25 Jun. 2020, <https://www.catalent.com/catalent-news/moderna-and-catalent-announce-collaboration-for-fill-finish-manufacturing-of-modernas-covid-19-vaccine-candidate/>.

¹¹⁶ "Which company to produce Moderna Covid-19 vaccines in Korea?", Updated 08 Apr. 2021, <https://www.koreabiomed.com/news/articleView.html?idxno=10077>.

¹¹⁷ "Recipharm and Moderna finalize agreement for aseptic drug product manufacturing and fill-finish for supply to countries outside the U.S.", Updated 30 Dec. 2020, <https://www.recipharm.com/press/recipharm-and-moderna-finalize-agreement-aseptic-drug-product-manufacturing-and-fill-finish>.

¹¹⁸ "Moderna and ROVI Announce Collaboration for OUS Fill-Finish Manufacturing of Moderna's COVID-19 Vaccine Candidate", Updated 09 Jul. 2020, <https://investors.modernatx.com/news-releases/news-release-details/moderna-and-rovi-announce-collaboration-ous-fill-finish/>.

79. The CureVac vaccine is another mRNA vaccine with a production concentrated in the Global North: France, Germany, Austria, and The Netherlands¹¹⁹. Celonic, Novartis, Warcker, and Rentschler Biopharma are CureVac's production partners in bulk manufacturing, and the fill and finish stage is done only by the Fareva company¹²⁰⁻¹²¹⁻¹²²⁻¹²³⁻¹²⁴. It will be necessary to expand this last step to prevent a production bottleneck on account of its high performance.

80. Therefore, the productive approach of mRNA vaccine manufacturers seems to prioritize the supply of the Global North. The low number of companies participating in the production process indicates a lack of interest in expanding production towards regions without sufficient vaccine access. So, the technology of this highly productive platform tends to be restricted to high-income countries while the Global South faces a shortage of vaccines.

2.2.2.4. Technology transfer

81. Pharmaceutical companies that manufacture mRNA vaccines have been failing to follow the example of manufacturers of other platforms, which have signed deals on clinical trials, manufacturing, and technology transfer to countries in the South, such as Oxford/AstraZeneca, Sinovac, and Johnson & Johnson.

¹¹⁹ "Manufacturing Data per Vaccine", Updated 09 Apr. 2021, <https://launchandscalefaster.org/covid-19/vaccinemanufacturing>.

¹²⁰ "Celonic and CureVac Announce Agreement to Manufacture over 100 Million Doses of CureVac's COVID-19 Vaccine Candidate, CVnCoV", Updated 30 Mar. 2021, <https://www.curevac.com/en/2021/03/30/celonic-and-curevac-announce-agreement-to-manufacture-over-100-million-doses-of-curevacs-covid-19-vaccine-candidate-cvncov/>.

¹²¹ "Novartis Signs Initial Agreement with CureVac to Produce COVID-19 Vaccine Candidate", 23 Mar. 2021, <https://www.novartis.com.br/news/media-releases/novartis-assina-acordo-inicial-com-curevac-para-produzir-vacina-candidata-da-0>.

¹²² "CureVac and WACKER sign contract for the production of the COVID-19 vaccine candidate CVnCoV" Updated 23 Nov. 2020, <https://www.wacker.com/cms/de-de/about-wacker/press-and-media/press/press-releases/detail-150656.html>.

¹²³ "CureVac and Rentschler Biopharma ramp up Manufacturing of COVID-19 Vaccine, CVnCoV - joint press release", Updated 01 Feb., 2021, <https://www.curevac.com/en/2021/02/01/curevac-and-rentschler-biopharma-ramp-up-manufacturing-of-covid-19-vaccine-cvncov/>.

¹²⁴ "CureVac and Fareva Sign Agreement for Fill & Finish Manufacturing of CureVac's COVID-19 Vaccine Candidate, CVnCoV - joint press release", Updated 09 Dec. 2020, <https://www.curevac.com/en/2020/12/09/curevac-and-fareva-sign-agreement-for-fill-finish-manufacturing-of-curevacs-covid-19-vaccine-candidate-cvncov-joint-press-release/>.



82. However, even such agreements contain little transparency and are reported to contain exclusivity clauses (i.e., sub-licensing is not possible). It demonstrates the productive capacity and some interest in partnering with the Global South. Manufacturers of mRNA vaccines do not even follow this path, representing an even more restricted model for the time being.

83. AstraZeneca has set up a global supply chain for COVID-19 vaccines to distribute doses worldwide and partnered with India's Serum Institute. The Institute aims to produce one billion doses of the vaccine developed by AstraZeneca for low-income and medium-income countries and deliver 240 million doses to COVAX.¹²⁵

84. On account of the technology for this vaccine production, between January and February 2021, India exported more than 60 million doses to 77 different countries.¹²⁶ In this process, the Serum Institute of India supplies part of the demand for vaccines and acts as a productive booster for AstraZeneca. However, reliance on a single producer has proven to be problematic, and despite being the single largest vaccine manufacturer in the world, SII is not enough to address global demand and not even the Indian market.

85. Another example of vaccine technology supply, production, and licensing agreements is the partnership between Bio Farma, an Indonesian company, and Sinovac Biotech, the developer of the COVID-19 vaccine Coronavac.

86. The idea is still at an early stage and includes cooperation for vaccine development research, raw material development, and increased national production capacity, according to an interview with Indonesian Chancellor Retno Marsudi.¹²⁷ If the agreement between the companies works, Indonesia could become Southeast Asia's production hub for Chinese-developed vaccines.¹²⁸

¹²⁵ "U.K. inspects AstraZeneca vaccine partner's India manufacturing, setting stage for supply boost", updated 16 Feb., 2021, <https://www.fiercepharma.com/manufacturing/serum-institute-india-up-for-british-audit-as-astrazeneca-looks-to-boost-covid-19>.

¹²⁶ "India Suspends Covid-19 Vaccine Exports to Focus on Domestic Immunization", updated 25 Mar. 2021, <https://www.wsj.com/articles/india-suspends-covid-19-vaccine-exports-to-focus-on-domestic-immunization-116166908> 59.

¹²⁷ "Indonesia to Receive 10 Million Doses of Sinovac Vaccine This April", 04 Apr. 2021, <https://en.tempo.co/read/1449186/indonesia-to-receive-10-million-doses-of-sinovac-vaccine-this-april>

¹²⁸ "Bio Farma: Sinovac's Indonesian partner sets sights on making Chinese vaccines for Southeast Asia", updated 15 Jan., 2021, <https://www.scmp.com/week-asia/politics/article/3117840/bio-farma-sinovacs-indonesian-partner-sets-sights-making-chinese>.

87. A similar and reportedly deeper partnership has taken place between Sinovac and Instituto Butantan, São Paulo, which accounts for more than 80% of all vaccines inoculated in the country as of April 2021. Total production of Coronavac in Brazil, including APIs, is expected to be available in early 2022. Until then, Butantan conducts fill and finish for the manufacturing of the vaccine.

88. In South Africa, Aspen Pharmacare is part of the Jansen vaccine production chain in the formulation and fill-finish stages. Most of the doses will be distributed internationally, and Aspen Pharmacare will contribute with shipments to African Union member states¹²⁹⁻¹³⁰. According to the agreement between the companies, 220 million doses will be exported to the entire African continent, 30 million for South Africa alone¹³¹⁻¹³². However, again, production in the African continent is mainly taking place to benefit the Global North markets.

89. As seen, the current production capacity for COVID-19 vaccines is not enough to supply the entire world. Further steps for the distribution of vaccine production must be taken, and mRNA vaccines must follow the example of other manufacturers.

90. In this context, multiple discussions and initiatives on ensuring technology transfer and manufacturing capacity have taken place. However, most of them end up being prospective plans, and without access to know-how and trade secrets of mRNA vaccines, reverse engineering is consensually deemed impossible. In other words, mechanisms to ensure that companies that hold mRNA vaccines share their technology are essential.

¹²⁹ "Vaccine production in South Africa: how an industry in its infancy can be developed", Updated 20 Jan., 2021, <https://theconversation.com/vaccine-production-in-south-africa-how-an-industry-in-its-infancy-can-be-developed-153204>.

¹³⁰ "Johnson & Johnson pledges 400M single-dose COVID-19 vaccines to African Union", Updated 29 Mar., 2021, <https://www.fiercepharma.com/pharma/johnson-johnson-pledges-400m-single-dose-covid-19-vaccines-to-african-union>.

¹³¹ "SA secures 30 million Johnson & Johnson vaccines", Updated 29 Mar. 2021, <https://www.sanews.gov.za/south-africa/sa-secures-30-million-johnson-johnson-vaccines>.

¹³² "About 30 million J&J vaccines to be produced at Aspen Facility - Ramaphosa", Updated 29 Mar. 2021, <https://ewn.co.za/2021/03/29/about-30-million-j-and-j-vaccines-to-be-produced-at-aspen-facility-ramaphosa>.

2.3. Public Investment and Transparency

2.3.1 Assessing the type of investments for vaccine development

91. It is vital to highlight how public investment was a crucial factor in developing COVID-19 vaccines in such a context. To deal with the lack of previous knowledge of the disease, governmental authorities worldwide invested in pharmaceutical companies to subsidize the development of vaccines. These were mainly direct governmental investments in vaccine development, combined with public-private partnerships.

92. What our data reveals is that public investment was not only necessary for the very existence of COVID-19 vaccines, but it withal impacted the development of pre-clinical and clinical development. Another important remark is that the sum each vaccine receives from public and public-private contributions implies, at least in terms of a correlation, how far the vaccine has come in terms of clinical trials and R&D.

93. Given the scope of this Report, we analyzed mRNA vaccines and vaccine candidates. The sample consisted of twelve (12) candidate mRNA vaccines on pre-clinical development and eleven (11) on clinical development. GDP has analyzed the sum of public investment each received and the time spent in each clinical trial phase.¹³³

94. Even though their studies mostly started concurrently, results differed vastly depending on the investment received. The non-mRNA vaccines analyzed are Covishield, developed by AstraZeneca and University of Oxford, and Sputnik V, recombinant adenovirus vaccine developed by Gamaleya Center.

Table 4. Public investment on mRNA vaccines

Development	Public Investment	mRNA vaccine	Developer	Public Investment (USD)
Clinical	Yes	SARS-CoV-2 mRNA vaccine (ARCoV) ChiCTR2000034112	Academy of Military Science (AMS), Walvax Biotechnology and Suzhou Abogen Biosciences	Undisclosed

¹³³ The monetary information collected was found on the pharmaceuticals and governments' official websites. Still, the time used for clinical evaluation of each vaccine was gathered from "ClinicalTrials.gov", a database of privately and publicly funded clinical studies conducted around the world.

Development	Public Investment	mRNA vaccine	Developer	Public Investment (USD)
Clinical	Yes	LUNAR-COV19 - ARCT-021 NCT04480957	Arcturus Therapeutics	\$46.6M
Clinical	Yes	ChulaCov19 mRNA vaccine NCT04566276	Chulalongkorn University	Undisclosed
Clinical	Yes	CVnCoV Vaccine NCT04449276	CureVac AG	\$299M
Clinical	Undisclosed	mRNA	FBRI SRC VB VECTOR, Rospotrebnadzor, Koltsovo	Undisclosed
Clinical	Undisclosed	LNP-encapsulated mRNA cocktail encoding VLP	Fudan University/ Shanghai JiaoTong University/RNACure Biopharma	Undisclosed
Clinical	Yes	CoV2 SAM (LNP) NCT04758962	GlaxoSmithKline	Undisclosed
Clinical	Yes	LNP-nCoVsaRNA ISRCTN17072692	Imperial College London	\$22M
Clinical	Yes	mRNA-1273 NCT04283461	Moderna + National Institute of Allergy and Infectious Diseases (NIAID)	\$2,480M
Clinical	Yes	mRNA-1273.351 NCT04785144	Moderna + National Institute of Allergy and Infectious Diseases (NIAID)	Undisclosed
Clinical	Yes	Comirnaty - BNT162b2 NCT04368728	Pfizer/BioNTech	\$2,508M
Clinical	Yes	PTX-COVID19-B NCT04765436	Providence Therapeutics	\$4.7M
Clinical	Yes	MRT5500	Translate Bio/Sanofi Pasteur	Undisclosed
Clinical	Undisclosed	LNP-encapsulated mRNA	University of Tokyo / Daiichi-Sankyo	Undisclosed

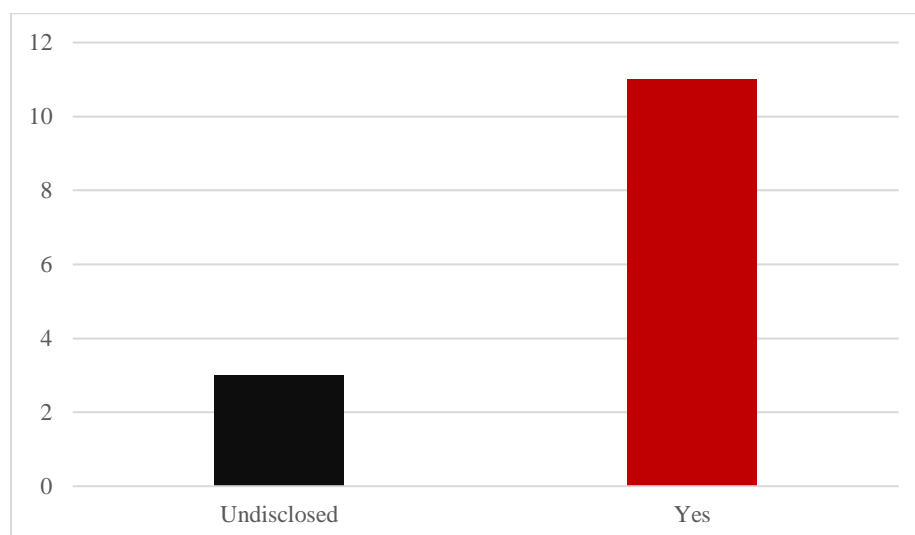
Source: Table I, Graph 1.

95. All mRNA vaccines that are still in pre-clinical development except one (LNP-mRNA from CanSino Biologics/Precision NanoSystems) did not declare to have received public or public-private investment. Furthermore, research for all but two began in early 2020. That means that even after more than a year, these are still under development and are yet to reach the clinical trials phase conducted on humans.

96. In contrast, most of the mRNA vaccines currently on or past clinical development received public investment. These investments were made by the Global North directly through awards from governmental agencies or indirectly through the beforehand acquisition of doses intended not only as a way of procuring shots but also to finance the research and development (“**R&D**”) of vaccines.

97. In other words, the vaccines which reached conclusive stages of R&D, including those that are already being inoculated, all received wide public funding. Those who did *not* receive such a boost have been unable for the time being to pursue trials, highlighting – in line with evidence presented by current literature on health innovation - the reliance on public investment in its various forms.

Image 11. Public Investment for Clinical-stage Vaccines (in units)¹³⁴



Source: Table “Summary Board on mRNA Vaccines”, Graph 5.

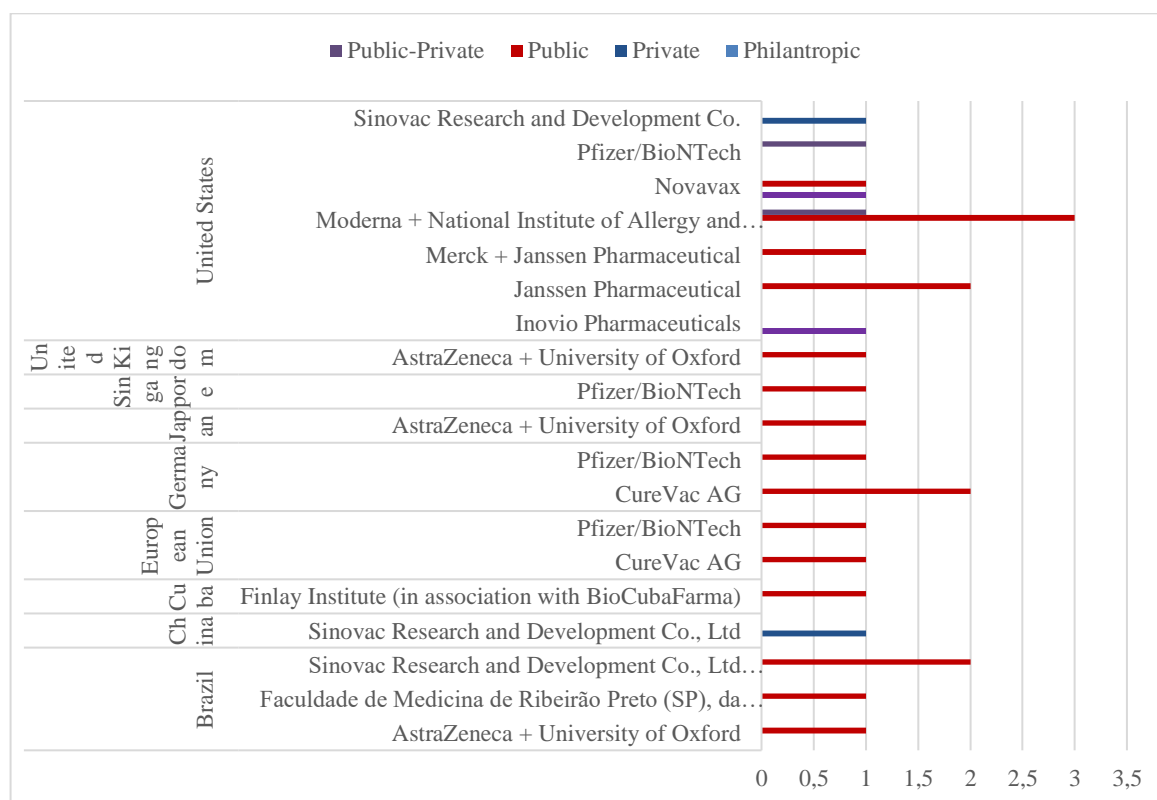
¹³⁴ Even though some information was undisclosed, there are indications that even the Vaccines that did not disclose their investment profile received public investment at some point of their development path, especially through APAs.

98. In the same timeframe, vaccines on clinical development conducted the initial research, human tests, and clinical evaluation, while the pre-clinical vaccines never went further than the initial research. It means that human tests and clinical evaluation were only achieved with the help of public investment.

99. As mentioned, the second largest investment received by vaccines was from public-private investments. Even within this pool of investments, the sum contributed by the governments was much larger than from private parties. In third and last place sits the private only investment.

100. The amount of each type of investment made for the development of every vaccine analyzed is presented below in Image 12 that is the visual representation of the discrepancy between public and private investments mentioned above.

Image 12. Amount of Investment known by Vaccine per Type



Source: Table D, Graph 3.

101. Direct public investment was destined to the vaccines' R&D. There were two types of agreements made directly between governments and the pharmaceuticals. Some of them were awards¹³⁵ but governments mainly financed vaccine development by purchasing vaccines before their production (advance purchase mechanisms)¹³⁶.

102. Because of that investment, the contracts made between states and companies are profit-sharing agreements. Venture investment was established while there was a risk that the vaccines would not be authorized for use, and yet the states invested, which shifted the risk entirely to the governments and enabled a strategic risk allocation to the pharmaceuticals.

103. For example, the U.S. government awarded up to \$1.525 billion for the manufacturing and 100 million doses¹³⁷ of the mRNA-1273 vaccine while still performing phase 3 trials.

104. The R&D applications of the investments included early development through clinical trials, development of studies, the establishment of infrastructure, scale-up of manufacturing capacity as part of the company's global development and supply strategy, and development of a manufacturing prototype.

¹³⁵ The awards are a type of agreement between the States and the pharmaceuticals that does not have the guarantee of doses of the vaccine in return. It is a pure investment that entails the risk of the vaccine ending up not being approved, almost like a bet. It reflects the heightened government interest in the race to develop a vaccine and other treatments in order to stop the pandemic. The awards provide financial assistance for pharmaceutical companies to research and development. Of all the investments analyzed, only two presented public-private partnership.

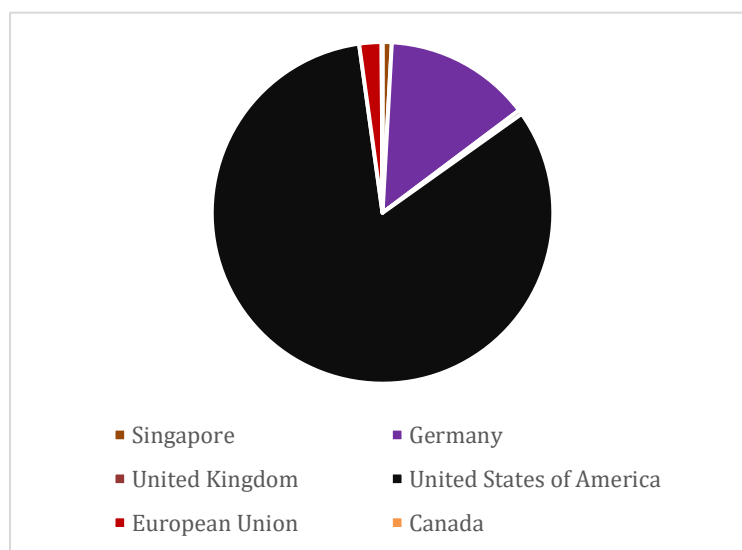
¹³⁶ They, in majority, also have the option granted to governments to purchase up to an additional of million doses. Although we know which vaccines received public investment from the governments because there were public reports on the pharmaceuticals and governments' official websites, few information about the quantity were available. Due to this lack of transparency, our analyses are based on the known public investment we were able to find.

¹³⁷/An option was granted to U.S. government to purchase up to an additional 400 million doses.

2.3.1.1 Assessing the origin and impact of public investments for vaccine development

105. As mentioned, data also shows that larger public investments meant that vaccines could go further in their clinical development. Vaccines that received low sums of governmental investment are to this day in phases 1 and 2 of trial registers. These are: PTX-COVID19-B from Providence Therapeutics that received USD 4.7M¹³⁸ from Canada; LNP-nCoVsaRNA from Imperial College London that received USD 22M¹³⁹ from the United Kingdom; and LUNAR-COV19-ARCT-021 from Arcturus Therapeutics that received USD 46.6M¹⁴⁰ from Singapore.

Image 13. Public Investment (USD) in millions per Investing Country



Source: Table “Summary Board on mRNA Vaccines”, Graph 3.

¹³⁸ <https://www.providencetherapeutics.com/providence-therapeutics-confirms-government-of-canada-will-support-its-phase-1-clinical-trials-for-a-covid-19-vaccine>

¹³⁹ <https://www.imperial.ac.uk/news/197573/covid-19-vaccine-secures-government-investment/>

¹⁴⁰ <https://ir.arcturusrx.com/node/10501/html>

106. Larger public investments were responsible for ensuring the necessary sums of investment for R&D to de-risk innovation and achieve positive outcomes. In coordination with streamlined regulatory procedures by different respective agencies and the WHO, the R&D process was able to be drastically shortened by allowing two phases to be conducted at once, compressing results into phases named “phase 1/2” and “phase 3/4”. Nevertheless, this was only possible due to decades of prior investments in basic research such as those for the mRNA technology in the first place.

107. The most significant example of this scenario is the Pfizer / BioNTech vaccine, which received USD 2.7B from the USA, EU, and Germany alone. Its clinical evaluation was composed of phases 1, 1/2, 2, 2/3, 3, and 4, as described above. It was also directly reliant on decades of previous research agreements that allowed the development of mRNA for a Covid-19 vaccine after prior attempts in other fields.

108. The U.S. government invested a total of USD 1.95B in return for 100 million doses¹⁴¹. It was part of Operation Warp Speed, an effort to drastically shorten the time it would take to manufacture and distribute the vaccine.

109. From Germany, Pfizer and BioNTech received USD 445M¹⁴² from an initiative led by the German Federal Ministry of Education and Research to support the accelerated development of COVID-19 vaccines. Also, the companies received USD 113M¹⁴³ from the European Union to expand their manufacturing capacity.

¹⁴¹ Available at <<https://www.nytimes.com/2020/07/22/us/politics/pfizer-coronavirus-vaccine.html>>.

¹⁴² Available at <<https://investors.biontech.de/news-releases/news-release-details/biontech-receive-eu375m-funding-german-federal-ministry/>>.

¹⁴³ Available at <<https://www.keionline.org/misc-docs/EuropeanInvestmentBank-BioNTech-Finance-Contract-10June2020.pdf>>.



110. There was a French public investment, but the amount was not publicized.¹⁴⁴ From Singapore, public investment accounted for USD 250M.¹⁴⁵ At last, COVAX¹⁴⁶, a public-private partnership, as mentioned, agreed to advance the purchase of up to 40 million doses of Pfizer / BioNTech vaccines in 2021¹⁴⁷.

111. The second vaccine to receive the most public investment is the Moderna vaccine, which received USD 2.5B from the USA. Its clinical evaluation was also composed of phases 1, 1/2, 2, 2/3, 3, and 4.

112. Moderna and NIAID both received from BARDA, a US Federal Agency, USD 955M¹⁴⁸ million in federal funding to accelerate the vaccine's development. From DARPA, a research and development agency of the US, the companies received USD 56M.¹⁴⁹ From the U.S. government, a contract of USD 1.525B¹⁵⁰ was made as a big support to its vaccine platform and the purchase of initial 100 million doses.

¹⁴⁴ Available at <<https://www.biopharma-reporter.com/Article/2021/02/10/France-ramps-up-COVID-19-vaccine-manufacturing#:~:text=French%20CDMO%20Delpharm%20will%20follow,the%20site%20to%20support%20production>>.

¹⁴⁵ Available at <<https://www.reuters.com/article/us-biontech-placement/temasek-led-investor-group-in-250-million-vaccine-bet-on-germanys-biontech-idUSKBN2400PS>>.

¹⁴⁶ COVAX is the vaccines pillar accelerator of the Access to COVID-19 Tools (ACT) and is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi and the World Health Organization (WHO), alongside UNICEF. It brings together governments, global health organizations, manufacturers, scientists, private sector, civil society and philanthropy. Its objective is providing innovative and equitable access to COVID-19 diagnostics, treatments and vaccines, according to the Institution. The Facility also use its collective purchasing power that comes from having so many countries participate in order to negotiate highly competitive prices from manufacturers that are then passed on to participants. 30 countries have signed commitment agreements to the COVAX Facility as well as the European Union. Available at: <https://www.gavi.org>.

¹⁴⁷ Available at <<https://www.businesswire.com/news/home/20210122005366/en/>>.

¹⁴⁸ Available at <<https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-award-us-government-agency-barda-483-million>> and <<https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-expansion-barda-agreement-support-larger-phase>>.

¹⁴⁹ Available at <<https://investors.modernatx.com/news-releases/news-release-details/darpa-awards-moderna-56-million-enable-small-scale-rapid-mobile>>.

¹⁵⁰ Available at <<https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-supply-agreement-us-government-initial-100>>.



113. A French public investment was also made, but the amount was not publicized¹⁵¹. At last, CEPI also invested, but the figures were not publicized as well¹⁵².

114. Contrary to the Pfizer / BioNTech vaccine, the E.U. pays 20 percent more than the U.S. per dose of mRNA-1273 vaccine. However, no information about the purchase price per dose was available for Japan and the United Kingdom.

115. The third to receive the highest sum of public investment is the CVnCoV Vaccine. It received USD 760M from Germany and UE, and its clinical evaluation was composed of phases 1, 2, 2/3, 3, and 4 and is about to be submitted for authorization.

116. CureVac received USD 299M directly from the German government¹⁵³, which has also purchased shares from CureVac for USD 340M.¹⁵⁴ The European Investment Bank has invested in developing CureVac's vaccine in an amount of USD 85M.¹⁵⁵ The CEPI, a public partnership in the majority, invested USD 34M¹⁵⁶ in CureVac, and all further data about public investments from France was not publicized.

117. Its technology is from a Chimpanzee adenovirus-vectored vaccine (ChAdOx) that the University of Oxford developed. It received massive public funding for R&D, mainly comprised of the USD 66M invested by the United Kingdom¹⁵⁷, USD 117M by Japan¹⁵⁸, and USD 111M from Switzerland.¹⁵⁹

¹⁵¹ Available at <<https://www.biopharma-reporter.com/Article/2021/02/10/France-ramps-up-COVID-19-vaccine-manufacturing#:~:text=French%20CDMO%20Delpharm%20will%20follow,the%20site%20to%20support%20production>>.

¹⁵² Available at <<https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-funding-award-cepi-accelerate-development>>.

¹⁵³ Available at <<https://www.curevac.com/en/2020/06/15/bundesregierung-beteiligt-sich-mit-300-millionen-euro-an-curevac/>>.

¹⁵⁴ Available at <https://www.kfw.de/KfW-Group/Newsroom/Latest-News/News-Details_600640.html>

¹⁵⁵ Available at <<https://www.keionline.org/misc-docs/EuropeanInvestmentBank-Curevac-Finance-Contract-27June2020.pdf>>.

¹⁵⁶ Available at <https://cepi.net/news_cepi/curevac-and-cepi-extend-their-cooperation-to-develop-a-vaccine-against-coronavirus-ncov-2019/>.

¹⁵⁷ Available at <<https://www.gov.uk/government/news/extra-476-million-for-vaccines-manufacturing-and-innovation-centre>>.

¹⁵⁸ Exchange Japanese Yen to US dollars: 1 Japanese Yen = 0.009 USD (03/24/2021). Available at <<https://the-japan-news.com/news/article/0007248481>>.

¹⁵⁹ Available at <https://www.swissinfo.ch/eng/swiss-stump-up-more-cash-to-buy-a-covid-19-vaccine/46155560>.

118. From the Global South, further examples of public funding relate, among other things, to the Oxford/Astrazeneca vaccine (also known as Covishield in India), which received R&D investments from COVAX and participation of the government of India in quantity unknown for increasing the manufacturing capacity¹⁶⁰ and allocation of doses.¹⁶¹ Fundação Oswaldo Cruz, related to Brazil's Ministry of Health, invested USD \$330M on AstraZeneca.¹⁶² In its turn, South Africa by a purchase of 1.5M doses.

2.3.2 Contractual transparency

119. Although there were public declarations about the destination of the money invested, the lack of transparency was glaring as information on how much governments and public-private partnerships invested is scarce. Most of the contracts between the pharmaceuticals and governments/public-private partnerships were not available. No contracts of awards were accessible, and direct purchase contracts were partially censored. The censored information included deadlines, expected dates for deliveries, testing data, number of doses in each delivery, and performance-based payments.

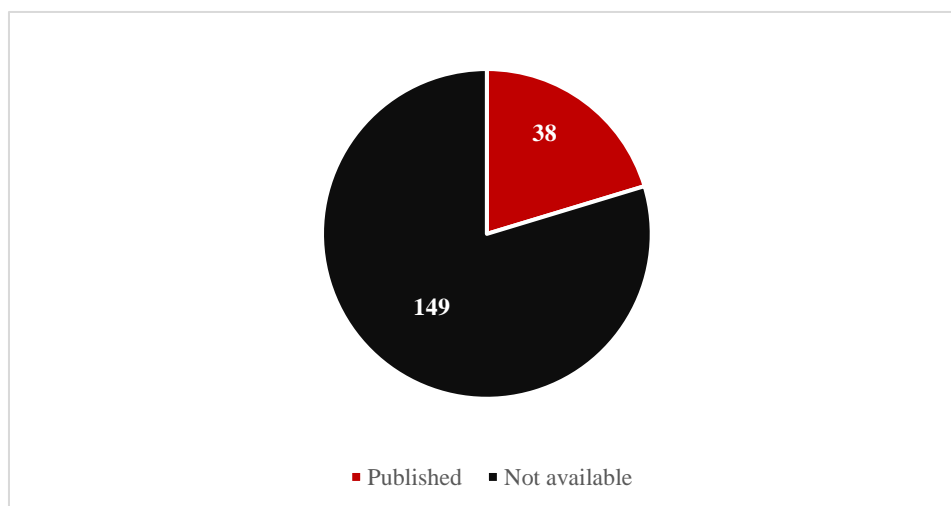
120. Considering it, the few contracts found had almost no information available. Another information that could not be found in its completeness was the total confirmed doses of all vaccines purchased from the governments. Therefore, the total confirmed doses and the value per dose, and the total purchase price were not available.

¹⁶⁰ Available at <[https://www.who.int/news/item/25-03-2021-covax-updates-participants-on-delivery-delays-for-vaccines-from-serum-institute-of-india-\(sii\)-and-astrazeneca](https://www.who.int/news/item/25-03-2021-covax-updates-participants-on-delivery-delays-for-vaccines-from-serum-institute-of-india-(sii)-and-astrazeneca)>.

¹⁶¹ Exchange Brazilian Real to US Dollars: 1 USD = 5.2 Brazilian Real (12/24/2020). Available at <https://www.gavi.org/covax-vaccine-roll-out/argentina>.

¹⁶² Available at <https://www.in.gov.br/web/dou/-/extrato-de-convenio-296273527>.

Image 14. Number of contracts with open prices per purchase



Source: Table “Purchases’ Analysis”, Graph 1.

121. The graph above gathers information from the transparency of total purchases of Moderna, AstraZeneca, Janssen, CureVac, Pfizer / BioNTech, and Sputnik vaccine doses made by governments all around the world.

122. As for the mRNA vaccines, the most transparent is Moderna, which informed the price per purchase in five (5) of the seventeen (17) available contracts, resulting in a 29,41% of transparency, followed by CureVac’s transparency level of 20,00%, barely topping Pfizer’s 19,15%, representing only nine (9) out of forty-seven (47).

123. The second highest transparency level among all is AstraZeneca, with 28,33%. In third, there is Johnson and Johnson with 23,08%. At last, there is Sputnik with only 6,67% of data published.¹⁶³

124. Among the available information was the purchase price from the European Commission (“EC”) and the U.S. of the Moderna and Pfizer / BioNTech vaccines. The transparency in the pricing of the purchase from EC was only possible because of a data leak.¹⁶⁴

¹⁶³ Available at <https://www.knowledgeportalia.org/covid19-vaccine-arrangements>.

¹⁶⁴ Available at https://www.washingtonpost.com/world/eu-coronavirus-vaccines-cheaper-than-united-states/2020/12/18/06677e34-4139-11eb-b58b-1623f6267960_story.html.

2.3.3 Public investments, private profits

125. The massive amount of public money invested in vaccine development by pharmaceuticals resulted in increased profit and stock price. It is crucial to analyze the available data about Moderna, Pfizer, and CureVac's stock prices and revenues since the investment of public money.

126. Pfizer forecasts a 43% growth in revenues for the year 2021¹⁶⁵, amount to around USD 60B. This predicted profit margin is led by the expected USD 15B¹⁶⁶ in sales of their vaccine this year, 25% of their total expected revenue¹⁶⁷. Such profits are solely achievable because of public investment in R&D.

127. Moderna's shareholders have been experiencing a different kind of great financial return: as the pandemic escalated, the stock price soared. In January 2020, its shares' value was around USD 20.00¹⁶⁸ per share. The company first began to recognize revenue from sales of its COVID-19 vaccine in December 2020, when mRNA-1273 was authorized for use. Ever since, stock prices have been increasing, representing total growth of 757.3%¹⁶⁹ over the past 12 months. The company's economic boom was only possible due to the public money investment in vaccines.

128. Thus, as seen, vaccines that did not receive any sort of public investment never went past the pre-clinical trials. All public investment in RNA-based vaccines was directed to its R&D. Such high public investment creates duty both moral and legal for the pharmaceuticals to meet the world's demand on vaccines as global public goods. We currently face the opposite scenario.

¹⁶⁵ Available at <https://investors.pfizer.com/investor-news/press-release-details/2021/PFIZER-REPORTS-FOURTH-QUARTER-AND-FULL-YEAR-2020-RESULTS-AND-RELEASES-5-YEAR-PIPELINE-METRICS/default.aspx>.

¹⁶⁶ Available at <https://www.bloomberg.com/news/articles/2021-02-02/pfizer-forecasts-15-billion-in-covid-vaccine-sales-for-2021>.

¹⁶⁷ Available at <https://www.bloomberg.com/news/articles/2021-02-02/pfizer-forecasts-15-billion-in-covid-vaccine-sales-for-2021>.

¹⁶⁸ Available at <https://www.investopedia.com/moderna-q4-2020-earnings-5113673>.

¹⁶⁹ Available at <https://www.investopedia.com/moderna-q4-2020-earnings-5113673>.



2.4. The Global South's Productive Capacity

129. The analysis below will consider aspects of the pharmaceutical market of the Global South.¹⁷⁰

130. The Global South pharmaceutical sector is a pungent one. It features large-scale production of generic drugs, high-tech medicines, and vaccines. It is important to say that this production is dedicated both for national supplies and exports, as it will be demonstrated, and there is a substantial public investment to develop production and research in this sector.

131. China is the second-largest pharmaceutical industry globally.¹⁷¹ Brazil is the largest pharmaceutical industry in Latin America,¹⁷² while Mexico is the second.¹⁷³ In Africa, there is significant vaccine manufacture in Senegal, Egypt, South Africa, and Tunisia¹⁷⁴. Egypt is the largest manufacturer of pharmaceuticals in the Middle East and Africa, too.¹⁷⁵ Also, Indian pharmaceuticals supply over 50% of the global demand for various vaccines,¹⁷⁶ Bangladeshi manufacturers meet 97% of national demand for pharmaceutical products¹⁷⁷, and national companies in Argentina account for over 50% of production and sales.¹⁷⁸

¹⁷⁰ To give an example for some analysis, we have selected some countries with production capacity in Global South and that stand out in pharmaceutical market.

¹⁷¹ "Growth Insights on China's Pharmaceutical Industry, Forecast to 2025", Jan 2020, [https://www.researchandmarkets.com/reports/4968410/growth-insights-on-chinas-pharmaceutical?utm_source=dynamic&utm_medium=BW&utm_code=3tk4mv&utm_campaign=1348829+-+Growth+Insights+on+China%27s+Pharmaceutical+Industry+\(2020+to+2025\)+-+Key+Market+Trends+Supporting+the+Expansion+of+the+Chinese+Pharmaceutical+Industry&utm_exec=jamu273bwd](https://www.researchandmarkets.com/reports/4968410/growth-insights-on-chinas-pharmaceutical?utm_source=dynamic&utm_medium=BW&utm_code=3tk4mv&utm_campaign=1348829+-+Growth+Insights+on+China%27s+Pharmaceutical+Industry+(2020+to+2025)+-+Key+Market+Trends+Supporting+the+Expansion+of+the+Chinese+Pharmaceutical+Industry&utm_exec=jamu273bwd).

¹⁷² "Latin America Pharmaceutical Market", published on Mar 09, 2018, <https://pharmaboardroom.com/facts/brazil-facts-figures-snapshot/>.

¹⁷³ "La industria farmacéutica en México", published on April 1, 2020, <https://ameifac.com/blog/f/la-industria-farmac%C3%A9utica-en-m%C3%A9xico#:~:text=M%C3%A9xico%20es%20el%20segundo%20mercado,contra%20el%20c%C3%A1ncer%2C%20entre%20otros>.

¹⁷⁴ VMPA study, "Vaccine manufacturing and procurement in Africa", published in 2017, page 44.

¹⁷⁵ NGAGE Consulting, "A Egypt's Pharmaceutical Sector Following Bold Economic Reforms: challenges and opportunities", page 4.

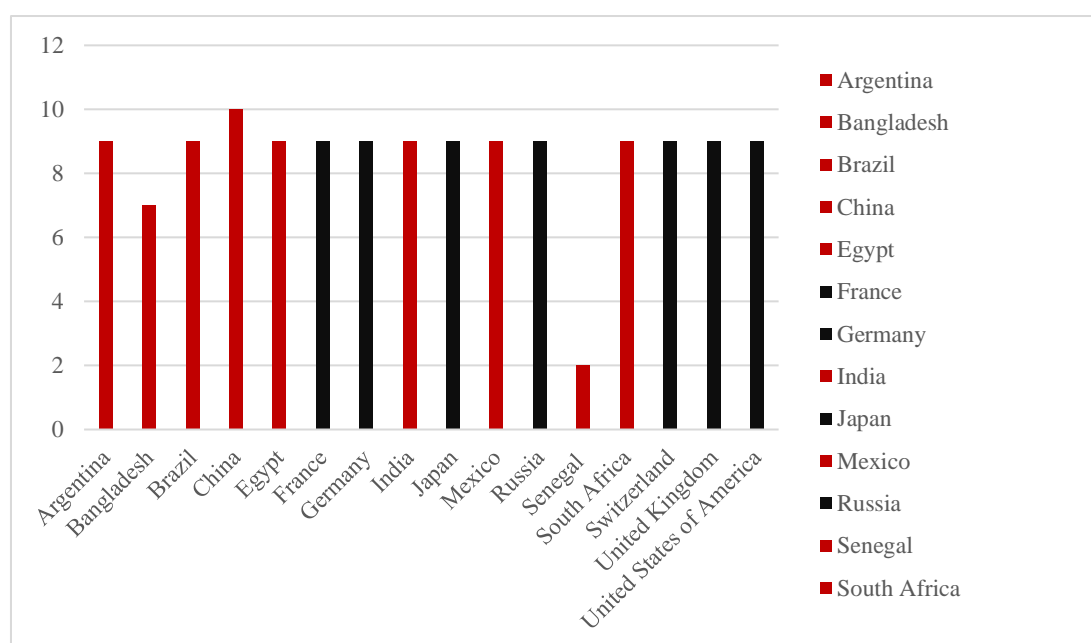
¹⁷⁶ IBEF, "Indian Pharmaceuticals Industry Analysis", last updated on Mar 19, 2021, <https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation>.

¹⁷⁷ DATABD, "Pharmaceuticals Overview", last updated on May 30, 2019, <https://databd.co/profiles/industries/profile-pharmaceuticals>.

¹⁷⁸ Embassy of India in Argentina, "Pharmaceutical Industry in Argentina", Aug 2018, page 28.

132. Furthermore, all of the ten biggest pharmaceutical companies by revenue in the world 2020¹⁷⁹ take part in the pharmaceutical market in the Global South. As shown below, the main pharmaceutical companies have branches in the Global South, revealing the appeal of their markets.

Image 15. Number of Pharmaceutical Companies with the Ten Highest Revenues in the World per Country



Source: Table A, Graph 1.

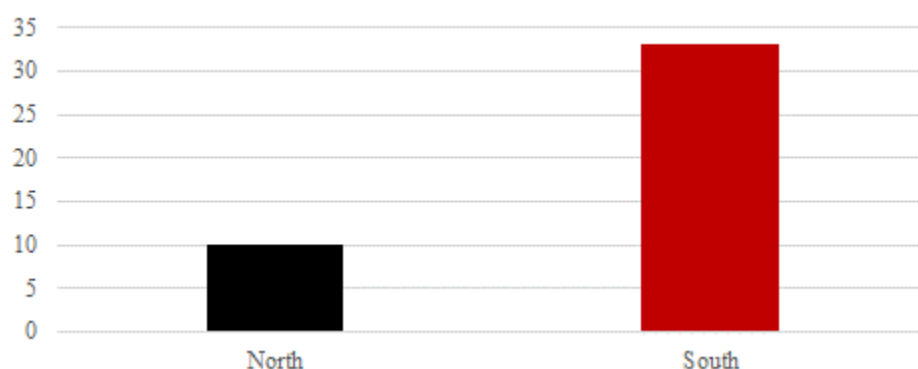
133. Regarding exports from the Global South, despite the large share destined to the U.S., the main destinations are in the Global South itself. This shows the potential of the pharmaceutical sector in these countries to supply all these exports and the possibility of the Global South to supply itself with pharmaceutical products.

¹⁷⁹ MCGRAIL, Samantha, “10 of the Largest Pharmaceutical Companies by Revenue”, Oct 16, 2020, <https://pharmanewsintel.com/news/10-of-the-largest-pharmaceutical-companies-by-revenue>

134. Although Argentina focuses on national supply¹⁸⁰, it is also an important supplier of pharmaceutical products for Latin America, such as Brazil and Mexico. This is also true for African countries, some of the main destinations for India, Bangladesh, South Africa and Egypt exports. China exports pharmaceuticals to over 160 countries and areas¹⁸¹.

135. This scenario reveals the importance of the pharmaceutical sector of these countries for global supply, as show in the graph bellow, that represents the number of Countries that are the main Export Destination of Pharmaceutical Products from Productor Global South for each Group.

Image 16. Main destinations of Global South Producers' Exports per Region



Source: Table O, Exports Graph.

136. When it comes to APIs, no country is self-sufficient. It is possible to see that all of them, to some extent, import it. These usually come from Asia, especially from India and China, who, in their turn, also import API, if less than other countries, as we show in the graph below. India has become a major exporter to all key markets, including China.¹⁸² In that context, in 2019, China exported API to 189 countries and regions, mainly concentrated in the major markets of Asia, Europe, and North America.¹⁸³

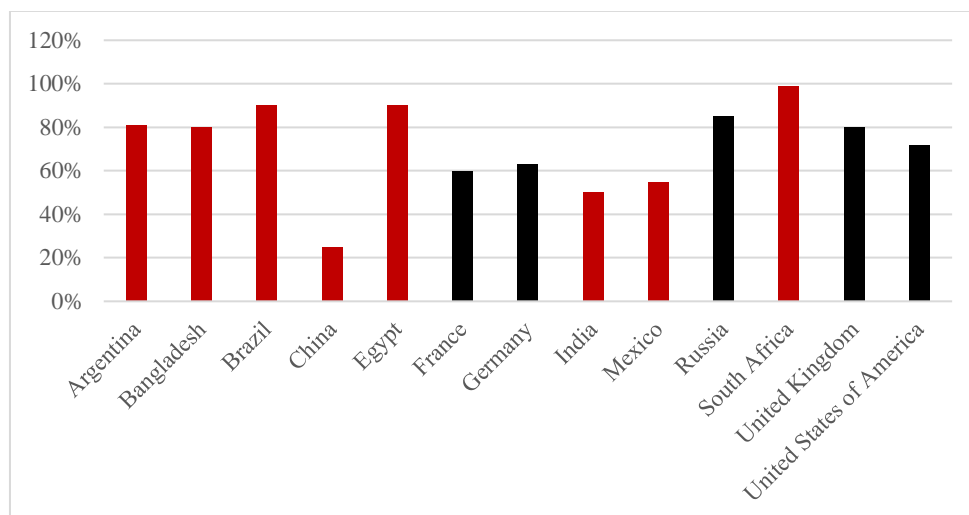
¹⁸⁰ Embassy of India in Argentina. "Pharmaceutical Industry in Argentina", Aug 2018, page 39

¹⁸¹ "China's Pharmaceutical Industry will be the world's largest in under 10 years", Feb 9, 2021, <https://daxueconsulting.com/pharmaceutical-industry-china/>

¹⁸² GBR, "India's API Industry: Exporting to the World", Mar 17, 2020, <https://www.gbreports.com/article/indias-api-industry-exporting-to-the-world>

¹⁸³ Echemi, "2019 China API import and export situation & analysis", Apr 26, 2020, <https://m.echemi.com/cms/101335.html>

Image 17. Percentage of API imports



Source: Table N, API Graph.

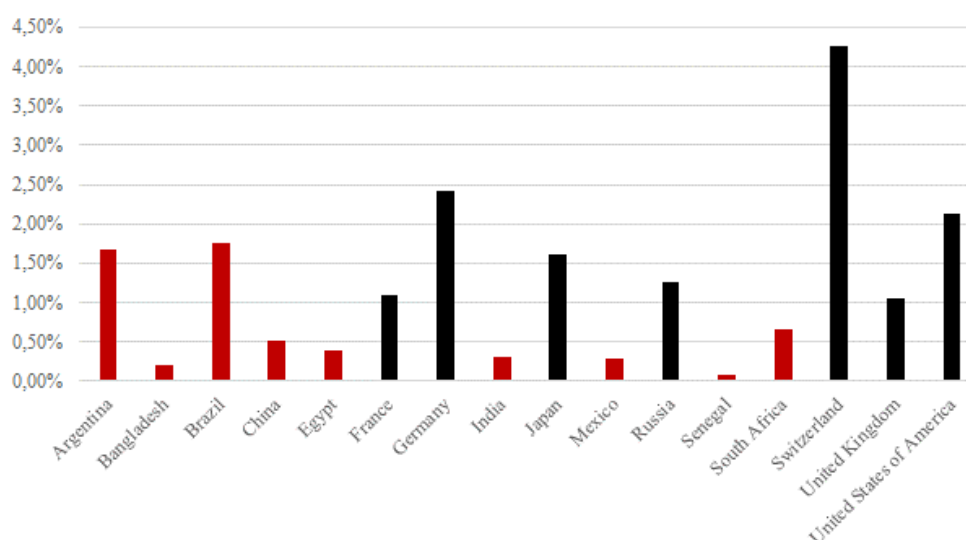
137. The same can be said of raw materials used for the production of vaccines, no country is self-sufficient and independent in the Global North nor South, as shown in the graph bellow

184-185

¹⁸⁴ As raw materials we mean the products defined as under value of 3002 imports as found at the UM Comtrade system: Data available from UN Comtrade Harmonized System, focused on commodity code 3002 - Pharmaceutical products - Human blood, animal blood for therapeutic, prophylactic or diagnostic uses, antisera, Other blood fractions, immunological products, modified or obtained by biotechnological processes, vaccines, toxins, cultures of micro-organisms (excluding yeasts) etc. and TrendEconomy, <https://comtrade.un.org/data/>

¹⁸⁵ This percentage is about the total imports of the country and depends on the total imports of each country. So, it is a variable measure but reveals that all countries depend on pharmaceutical raw materials imports.

Image 18. Percentage of raw pharmaceutical materials' imports



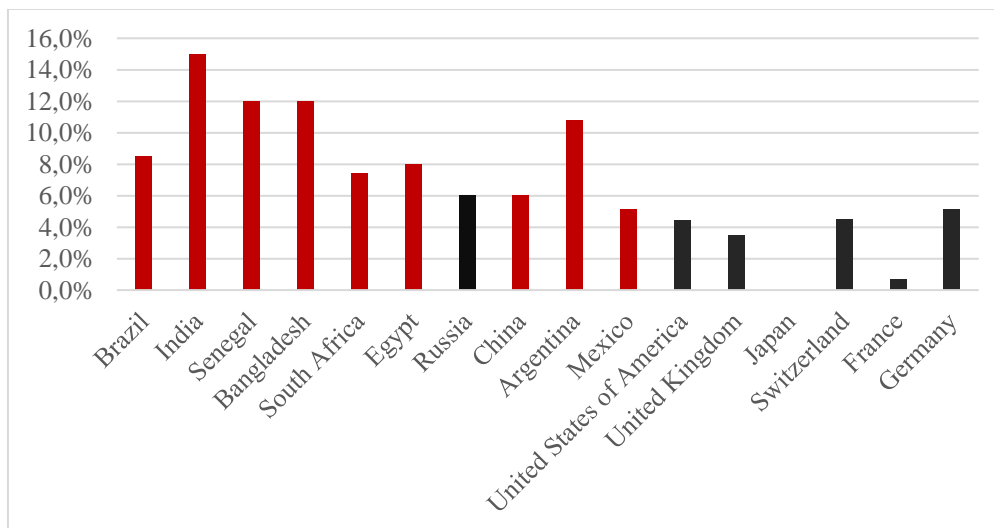
Source: Table N, Raw Materials Graph.

138. In conclusion, all countries depend on these inputs and Global North have *per se* no advantage in relation to Global South, since all of them import APIs and raw materials (although insourcing of production has been reported in multiple countries, such as the United States, in an attempt to achieve technological independence for the manufacturing of Covid-19 vaccines) . Moreover, in respect to APIs, the advantage comes from the South, as the main producers are India and China. These two countries have well-established manufacturing facilities and an abundant talent pool serving the pharmaceutical industry¹⁸⁶.

139. It is also important to highlight the continuous growth forecasts for the pharmaceutical market in the Global South. Comparing the growth forecast of Global North and Global South, the expected growth is bigger for Global South. It also demonstrates the size of the pharmaceutical market and its potential for technological and productive development.

¹⁸⁶ Daxue Consulting, "The API industry in China: Producing and exporting to the global market", Jul 01, 2020, <https://daxueconsulting.com/api-industry-in-china/>

Image 19. Growth Rate Indicated



Source: Table A.2, Graph X. Japans growth rate indicated is zero. In the absence of similar calculation periods, the rate was considered by the fact that all countries consider the year 2020. Thus, the comparison year in question is 2020.



2.4.1. Covid-19 vaccine production capacity

140. The Global South features several institutions producing COVID-19 vaccines, producing already approved vaccines, such as: mAbxience,¹⁸⁷ in Argentina, Bio-Manguinhos/Fiocruz¹⁸⁸ in Brazil, Shenzhen Kangtai Biological Products,¹⁸⁹ based in China, Serum Institute in India,¹⁹⁰ Liomont Laboratorio,¹⁹¹ established in Mexico, are producing the AstraZeneca vaccine. Instituto Butantan,¹⁹² in Brazil, and Sinovac Biotech Ltd,¹⁹³ in China, are producing Coronavac, an Inactivated virus vaccine.

¹⁸⁷ mAbxience, “mAbxience enters into an agreement with AstraZeneca to produce covid-19 vaccine”, Aug 17, 2020, <https://www.mabxience.com/mabxience-enters-into-an-agreement-with-astrazeneca-to-produce-covid-19-vaccine/>.

¹⁸⁸ G1 Globo, “Instituto da Fiocruz começa a produção da vacina Oxford/AstraZeneca”, Feb 09, 2021, <https://g1.globo.com/jornal-nacional/noticia/2021/02/09/instituto-da-fiocruz-comeca-a-producao-da-vacina-oxfordastrazeneca.ghtml>.

¹⁸⁹ Reuters, “AstraZeneca's China partner expects to be able to make 400 million COVID-19 vaccine doses a year”, Feb 2, 2021, <https://www.reuters.com/article/us-health-coronavirus-kangtai-astrazenec-idUSKBN2A20VB>.

¹⁹⁰ CNBC, “India’s Covid vaccine maker told to meet domestic demand first, urges ‘rest of the world’ to be patient”, Feb 21, 2021, <https://www.cnbc.com/2021/02/22/covid-19-vaccine-serum-institute-of-india-told-to-prioritize-domestic-demand.html>.

¹⁹¹ Reuters, “México dice laboratorio local está casi listo para envasar vacuna AstraZeneca contra COVID-19”, Feb 16, 2021, <https://www.reuters.com/article/salud-mexico-vacunas-idLTAKBN2AG2J8>.

¹⁹² Butantan, “SP inicia produção brasileira de vacina do Butantan”, Dec 11, 2020, <https://butantan.gov.br/noticias/sp-inicia-producao-brasileira-de-vacina-do-butantan#:~:text=A%20capacidade%20de%20envase%20di%C3%A1rio,dever%C3%A3o%20ser%20produzido%20no%20local>.

¹⁹³ Business Wire, “Sinovac Announced Buildup of Two Billion Annual Capacity of Its COVID-19 Vaccine”, Apr 01, 2021, <https://www.businesswire.com/news/home/20210401005993/en/Sinovac%C2%A0Announced-Buildup-of-Two-Billion-Annual-Capacity-of-Its-COVID-19-Vaccine>.

141. Furthermore, other institutions have declared production capacity for other COVID-19 vaccines, such as União Química,¹⁹⁴ established in Brazil, is producing Sputnik V. Also, Virchow Biotech Private Limited,¹⁹⁵ Stelis Biopharma,¹⁹⁶ Gland Pharma,¹⁹⁷ Hetero Biopharma,¹⁹⁸ Panacea Biotec¹⁹⁹, all established in India, and Richmond Laboratorio established in Argentina, already signed a deal to produce Sputnik V.²⁰⁰ Biological E.,²⁰¹ an Indian institute, and Aspen in South Africa signed a deal to produce the Jansen vaccine.²⁰²

142. Cuba has developed a series of national vaccines, and two are reaching the final stages of clinical trials²⁰³. The unilateral economic embargoes against the country render its manufacturing with other countries more difficult.

¹⁹⁴ União Química, “Parceria para produção da Sputnik”, <https://www.uniaoquimica.com.br/novidades/pareceria-vacina-sputnik-uniao-quimica/>

¹⁹⁵ Business Today, “Russia's Sputnik V vaccine to be rolled out soon? Dr Reddy's files application again”, Mar 24, 2021, <https://www.besnesstoday.in/current/economy-politics/russia-sputnik-v-vaccine-to-be-rolled-out-soon-dr-reddy-files-application-again/story/434738.html>

¹⁹⁶ Business Today, “Russia's Sputnik V vaccine to be rolled out soon? Dr Reddy's files application again”, Mar 24, 2021, <https://www.besnesstoday.in/current/economy-politics/russia-sputnik-v-vaccine-to-be-rolled-out-soon-dr-reddy-files-application-again/story/434738.html>

¹⁹⁷ Business Today, “Russia's Sputnik V vaccine to be rolled out soon? Dr Reddy's files application again”, Mar 24, 2021, <https://www.besnesstoday.in/current/economy-politics/russia-sputnik-v-vaccine-to-be-rolled-out-soon-dr-reddy-files-application-again/story/434738.html>

¹⁹⁸ Business Today, “Russia's Sputnik V vaccine to be rolled out soon? Dr Reddy's files application again”, Mar 24, 2021, <https://www.besnesstoday.in/current/economy-politics/russia-sputnik-v-vaccine-to-be-rolled-out-soon-dr-reddy-files-application-again/story/434738.html>

¹⁹⁹ The New Indian Express, “COVID-19: RDIF collabs with Panacea Biotec to produce 100 million doses of Sputnik V vaccine in India”, Apr 07, 2021, <https://www.newindianexpress.com/world/2021/apr/07/covid-19-rdif-collabs-with-panacea-biotec-to-produce-100-million-doses-of-sputnik-v-vaccine-in-indi-2286992.html>

²⁰⁰ Reuters, “Argentine lab strikes deal to produce Russia's Sputnik V vaccine”, Feb 26, 2021, <https://www.reuters.com/article/us-health-coronavirus-argentina-vaccine-idUSKBN2AQ27D>

²⁰¹ LEROY, Leo, “Biological E: The mass producer of Johnson & Johnson vaccine”, Mar 20, 2021, <https://www.livemint.com/companies/news/biological-e-the-mass-producer-of-johnson-johnson-vaccine-11616235431098.html>

²⁰² The Conversation, “Vaccine production in South Africa: how an industry in its infancy can be developed”, Jan 20, 2021, <https://theconversation.com/vaccine-production-in-south-africa-how-an-industry-in-its-infancy-can-be-developed-153204#:~:text=Vaccine%20production%20capacity,-The%20Biovac%20Institute%20is%20scheduled%20to%20start,bulk%20outside%20of%20South%20Africa.>

²⁰³ <https://brasil.elpais.com/sociedade/2021-04-13/cuba-esta-a-um-passo-de-obter-a-primeira-vacina-latino-americana-contra-a-covid-19.html>

143. Finally, Sinopharm (China National Pharmaceutical Group) is producing its own vaccine BBIBP-CorV, an inactivated virus vaccine.²⁰⁴ Drugmex Laboratories in Querétaro, Mexico²⁰⁵, and CanSino Biologics Inc are producing the CanSino's developed vaccine, Ad5-nCoV²⁰⁶. Anhui Zhifei Longcom Biopharmaceutical established in China is producing its own developed and approved ZF2001, a recombinant adenovirus vaccine²⁰⁷. Bharat Biotech in India is producing its own vaccine BBV152²⁰⁸.

Table 5. Institutions available for bulk manufacturing and fill and finish in vaccine manufacturing.

Country	Institution	Vaccine	Observations about productive process
Argentina	mAbxience	AZD1222	-
Brazil	Bio-Manguinhos/Fiocruz	AZD1222	Only fill and finish
China	Shenzhen Kangtai Biological Products	AZD1222	-
India	Serum Institute	AZD1222	-
Mexico	Liomont Laboratorio	AZD1222	Only fill and finish
Brazil	Instituto Butantan	Coronavac	Only fill and finish
China	Sinovac Biotech Ltd	Coronavac	-
Brazil	União Química	Sputnik V	-
India	Virchow Biotech Private Limited	Sputnik V	-
India	Stelis Biopharma	Sputnik V	-
India	Gland Pharma	Sputnik V	-
India	Hetero Biopharma	Sputnik V	-
India	Panacea Biotec	Sputnik V	-
Argentina	Richmond	Sputnik V	Only fill and finish
India	Biological E.	JNJ-78436735	-
South Africa	Aspen	JNJ-78436735	Only fill and finish
China	China National Pharmaceutical Group (Sinopharm)	BBIBP-CorV	-

²⁰⁴ SHUMEI, Leng, YUWEI, Hu, "China's Sinopharm to raise vaccine production to 3 billion per year", Mar 04, 2021, <https://www.globaltimes.cn/page/202103/1217366.shtml>

²⁰⁵ Gobierno de Mexico, "Mexico continues its strategy of securing purchase agreements for COVID-19 vaccines", Feb 16, 2021, <https://www.gob.mx/sre/en/articulos/mexico-continues-its-strategy-of-securing-purchase-agreements-for-covid-19-vaccines-264425?idiom=en>

²⁰⁶ JIAXIN, Zang, "China ready for mass production of COVID-19 vaccines" Dec 10, 2020, http://www.stdaily.com/English/ChinaNews/2020-12/10/content_1058956.shtml

²⁰⁷ PINGHUI Zhuang, CHIK Holly, "China's production bottleneck 'could be eased with latest Covid-19 vaccine'", Mar 17, 2021, <https://www.scmp.com/news/china/science/article/3125809/chinas-production-bottleneck-could-be-eased-latest-covid-19>

²⁰⁸ BISWAS, Soutik, "Covaxin: What was the rush to approve India's homegrown vaccine?", Jan 05, 2021, <https://www.bbc.com/news/world-asia-india-55534902#:~:text=On%20Sunday%2C%20India's%20drug%20regulator,and%20exports%20to%20123%20countries.>

Country	Institution	Vaccine	Observations about productive process
Mexico	Drugmex Laboratories	Ad5-nCoV	Only fill and finish
China	CanSino Biologics Inc	Ad5-nCoV	-
India	Bharat Biotech	BBV152	-
China	Anhui Zhifei Longcom Biopharmaceutical Co. Ltd	ZF2001	-

Source: Table J, Graph 1.

144. There are also at least seven institutions that have declared to be developing vaccines. Other five institutions have published that they already had productive capacity to develop and produce COVID-19 vaccines.

145. In Brazil, two institutions are developing its own Covid-19 vaccines that are not yet approved: Versamune from Faculdade de Medicina de Ribeirão Preto da USP²⁰⁹ and ButanVac from Instituto Butantan.²¹⁰ Globe Biotech Ltd is developing Bongavax in Bangladesh.²¹¹ In Egypt, Egypt's National Research Center is developing CoviVax.²¹² In India, Zydus Cadila is developing Zy-CoV-D,²¹³ Mynvax is developing a homegrown vaccine to prevent Covid-19 infections too²¹⁴ and India Immunologicals started a research with an Australian University to develop a vaccine.²¹⁵

²⁰⁹ SANTOS, Maria Tereza, "Butanvac e Versamune: diferenças entre as vacinas brasileiras da Covid-19", Apr 01, 2021, [https://saude.abril.com.br/medicina/butanvac-e-versamune-diferencas-entre-as-vacinas-brasileiras-da-covid-19/#:~:text=Estamos%20falando%20da%20Butanvac%2C%20produzida,Paulo%20\(FMRP%2DUSP\).](https://saude.abril.com.br/medicina/butanvac-e-versamune-diferencas-entre-as-vacinas-brasileiras-da-covid-19/#:~:text=Estamos%20falando%20da%20Butanvac%2C%20produzida,Paulo%20(FMRP%2DUSP).)

²¹⁰ SANTOS, Maria Tereza, "Butanvac e Versamune: diferenças entre as vacinas brasileiras da Covid-19", Apr 01, 2021, [https://saude.abril.com.br/medicina/butanvac-e-versamune-diferencas-entre-as-vacinas-brasileiras-da-covid-19/#:~:text=Estamos%20falando%20da%20Butanvac%2C%20produzida,Paulo%20\(FMRP%2DUSP\).](https://saude.abril.com.br/medicina/butanvac-e-versamune-diferencas-entre-as-vacinas-brasileiras-da-covid-19/#:~:text=Estamos%20falando%20da%20Butanvac%2C%20produzida,Paulo%20(FMRP%2DUSP).)

²¹¹ SUMON, Shehab, "Bangladesh joins global COVID-19 vaccine race with Bongavax set for clinical trial", Jan 08, 2021, <https://www.arabnews.com/node/1789016/world>

²¹² ZAID, Mohammed Abu, "Egyptian coronavirus vaccine to undergo clinical trials", Mar 20, 2021, <https://www.arabnews.com/node/1828876/middle-east>

²¹³ OZA, Nandini, "ZyCoV-D will hit markets in May-June", Mar 28, 2021, <https://www.theweek.in/theweek/specials/2021/03/18/zycov-d-will-hit-markets-in-may-june.html>

²¹⁴ GANGULY, Shreya, "Mynvax's "warm COVID-19 vaccine" is ready for safety tests and human clinical trials", Nov 18, 2020, <https://yourstory.com/2020/11/mynvax-covid-19-vaccine-ready-safety-test-clinical-trial>

²¹⁵ The Week, "India developing seven more COVID vaccines, says health minister", Feb 07, 2021, <https://www.theweek.in/news/health/2021/02/07/india-developing-seven-more-covid-vaccines-says-health-minister.html>

146. In addition, Biovac Institute, established in South Africa, declared a collaboration with US-based ImmunityBio to manufacture a second-generation Covid-19 vaccine.²¹⁶ Egypt declared that it would sign an agreement between its Holding Company for Biological Products & Vaccines (VACSERA) and Sinovac Biotech to manufacture Coronavac.²¹⁷ Advaccine Biopharmaceuticals Suzhou Co Ltd partnered with Inovio Pharmaceuticals Inc to manufacture and commercialize INO-4800 in China.²¹⁸

147. Also, in Senegal, Institut Pasteur in Dakar declared its production capacity to produce Covid-19 vaccines and Incepta Pharmaceuticals located in Bangladesh²¹⁹ since these institutes already produced other vaccines. Table 6 below presents a list of players in the Global South that have declared that they are manufacturing COVID-19 vaccines or, at least, may manufacture those soon. It should be emphasized that the list contains only players that have declared their production or capability, but there could be several more.

Table 6. Declaration of COVID-19 vaccines production

Country	Institution	Declaration
Brazil	Faculdade de Medicina de Ribeirão Preto da USP	Developing Covid-19 vaccine: Versamune
Brazil	Instituto Butantan	Developing Covid-19 vaccine: ButanVac
India	Zydus Cadila	Developing Covid-19 vaccine: Zy-CoV-D
India	Mynvax	Developing Covid-19 vaccine
India	India Immunologicals	Developing Covid-19 vaccine
Bangladesh	Globe Biotech Ltd	Developing Covid-19 vaccine: Bongavax
Egypt	Egypt's National Research Center	Developing Covid-19 vaccine: Covi Vax
Senegal	Institut Pasteur in Dakar	Production capacity
Bangladesh	Incepta Pharmaceuticals	Production capacity
South Africa	Biovac Institute	Collaboration for manufacturing hAd5
Egypt	Holding Company for Biological Products & Vaccines - VACSERA	Collaboration for manufacturing Coronavac
China	Advaccine Biopharmaceuticals Suzhou Co Ltd	Collaboration for manufacturing INO-4800

²¹⁶ ASH, Paul, “Cape Town company to manufacture Covid-19 vaccine”, Mar 18, 2021, <https://www.timeslive.co.za/news/south-africa/2021-03-18-cape-town-company-to-manufacture-covid-19-vaccine/>

²¹⁷ North Africa Post, “Egypt eyes production, exportation of Chinese Covid-19 vaccine”, Mar 24, 2021, <https://northafricapost.com/48494-egypt-eyes-production-exportation-of-chinese-covid-19-vaccine.html>

²¹⁸ Reuters, “Inovio partners with Advaccine to commercialize COVID-19 vaccine in China”, Jan 04, 2021, <https://www.reuters.com/article/health-coronavirus-inovio-pharma/inovio-partners-with-advaccine-to-commercialize-covid-19-vaccine-in-china-idUSL4N2JF2RT>

²¹⁹ PATNAIK, Priti, “Views from a vaccine manufacturer: Q&A – Abdul Muktedir, Incepta Pharmaceuticals”, Apr 01, 2021, <https://healthpolicy-watch.news/views-from-a-vaccine-manufacturer-qa-abdul-muktadir-incepta-pharmaceuticals/>

Source: Table J, Graph 2.

2.4.2. Productive adaptation

148. As shown, there is an untapped productive capacity in the Global South for the production of COVID-19 vaccines. We will now show that the specific production of mRNA vaccine production is less complex and risky than inactivated virus vaccine, and that there is a similarity between the equipment required for the production of both vaccines, showing how such productive capacity could be used for the COVID-19 vaccine production, such as Pfizer / BioNTech and CureVac vaccines.

149. The innovation in mRNA COVID-19 vaccine production is related to the volume produced in less time and to the flexibility in production. Studies show that it is possible to transfer technology for the production of mRNA vaccines and build up production in smaller and more accessible spaces.

150. The new technology for the mRNA vaccines has been developed very quickly. While conventional vaccines take an average of eight to fourteen years to develop, Moderna, the company that produced the first mRNA vaccine, started clinical trials only two months after the virus's genetic sequence identification²²⁰.

151. As for the productive process, for bulk manufacturing mRNA vaccines, there are three phases: (i) plasmid production; (ii) in vitro transcription; (iii) purification from chromatography, tangential flow filtration and enzymatic capping²²¹⁻²²². Phases (i) and (ii) are considered upstream phases and (iii) is downstream phase. For plasmid production, manufacturing equipment required are bioreactors and plasmid manufacturing.

²²⁰ “The COVID-19 vaccine development landscape.” Nature, Apr 09, 2020, <https://www.nature.com/articles/d41573-020-00073-5>.

²²¹ Merck, “Manufacturing Strategies for mRNA Vaccines and Therapeutics”, <https://www.sigmaaldrich.com/technical-documents/articles/white-papers/manufacturing-strategies-for-mrna-vaccines.html>

²²² KIS, Zoltán. KONTORAVDI, Cleo. DEY, Antu K. SHATTOCK, Robin. SHAH, Nilay. “Rapid development and deployment of high-volume vaccines for pandemic response.” Journal of Advanced Manufacturing and Processing, Volume 2, Issue 3, e10060, Jun 29, 2020, <https://aiche.onlinelibrary.wiley.com/doi/full/10.1002/amp2.10060>.

152. In addition, vessels system is another equipment used not only in mRNA vaccines production, to convert DNA in RNA through biological reactions with enzymes and chemicals but also in adenovirus and inactivated virus vaccine production²²³.

153. Another similarity between manufacturing equipment for all vaccines is the equipment to phases of chromatography, filtration, that are part of downstream both in mRNA, inactivated virus²²⁴ and viral vector vaccines²²⁵, frozen and thaw system.

154. The manufacturing equipment for fill and finish, the next stage, is even more accessible and possible because every platform, mRNA, inactivated virus and viral vector, encompass the formulation step to add ingredients or adjuvants²²⁶. Independently of the ingredient that is added, all vaccines share the same equipment to finish the formulation step.

155. After that, fill and finish takes place using equipment to inspect and fill glass vials, such as washing machine, rubber cleaning, vial and ampoule filling, capping and inspection machine and freezer dryer to maintain the temperature to preserve vaccines in labs.

156. It is necessary to say that it is possible to change some equipment titled as “single-use technologies” for cheaper and more accessible options as bioreactors that can be replaced by large plastic bags for cell culture in fill and finish.²²⁷ Therefore, the equipment used in fill and finish is similar.

157. No equipment differs totally in fill and finish process of mRNA, viral vector and inactivated virus.

²²³ WEISE, Elizabeth, WEINTRAUB, Karen, “A COVID-19 vaccine life cycle: from DNA to doses”, Feb 7, 2021, <https://www.usatoday.com/in-depth/news/health/2021/02/07/how-covid-vaccine-made-step-step-journey-pfizer-dose/4371693001/>

²²⁴ “Towards Vaccinating the World Landscape of Current COVID-19 Supply Chain and Manufacturing Capacity, Potential Challenges, Initial Responses, and Possible “Solution Space”: A Discussion Document Appendix.”, pages 3 and 4

²²⁵ CYTIVA, “Cell-based flavivirus production”, <https://www.cytivalifesciences.com/en/us/solutions/bioprocessing/products-and-solutions/vaccine-platforms>

²²⁶ HATCHETT, Richard. Towards Vaccinating “The World, Landscape of Current COVID-19 Supply Chain and Manufacturing Capacity, Potential Challenges, Initial Responses, and Possible “Solution Space” - a Discussion Document.” Mar 09, 2021, https://www.dcvmn.org/IMG/pdf/landscape_of_current_c19_supply_chain_manufacturing_capacity_embargo_9_march_2021.pdf, page 5

²²⁷ UCL, “Manufacturing new vaccines for pandemics – BioIndustry. Future vaccine manufacturing research hub”, Oct 2020, page 7.

158. At last, we could not identify the exact index biosafety level²²⁸ of each vaccine's laboratories, but we can compare the necessity or lack of high-level of biosafety. For inactivated virus vaccines, it is required a high-level of biosafety, minimum 3. Meanwhile, for mRNA and viral vector vaccines, it is not required a high-level of biosafety, which also reveals the lower complexity and risks for mRNA vaccines production and the possibility to technology transfer and know-how.²²⁹

159. In short, all aspects considered, despite being innovative, mRNA COVID-19 vaccines could be produced by all institutions already producing approved COVID-19 vaccines or that have declared their productive capacity could produce the mRNA COVID-19 vaccine if only technology would be transferred to them.

2.5. Why the Pfizer / BioNTech and / or CureVac vaccines?

160. For more than a year, the world faces a pandemic that has already resulted in more than two million and eight hundred thousand deaths.²³⁰ Many countries are in a state of calamity, and many more faces overburdened health systems. In this scenario, the pharmaceutical industry's response was the development of vaccines in record time.

161. Never before have mRNA vaccines been approved for use in any disease, and now they have the highest reported efficacy rates of all Covid-19 vaccines, especially for new variants. While viral vector vaccines have overall efficacy between 60.3% and 66.9%, the effectiveness of mRNA vaccines is between 94.1% and 95%.²³¹ Also, the effectiveness against the South African variant 501Y.V2 is 6.5 times to 8.6 times lower in mRNA vaccines, while in the Oxford-AstraZeneca vaccine, it is up to 86 times lower.²³²

²²⁸ A set of bio-containment precautions to isolate dangerous biological agents in a closed laboratory and it is important to measure contamination risk and protection equipment required for individual protection and other ways of protection. There are four biosafety levels, 4 being the highest. Science Safety Security, "Biosafety Levels", <https://www.phe.gov/s3/BioriskManagement/biosafety/Pages/Biosafety-Levels.aspx#:~:text=The%20four%20biosafety%20levels%20are,and%20other%20types%20of%20research.>

²²⁹ SMEATON, John, HARRISS, Lydia, "Manufacturing COVID-19 vaccines", Jan 14, 2021, <https://post.parliament.uk/manufacturing-covid-19-vaccines/#inactivated>

²³⁰ "WHO Coronavirus (COVID-19) Dashboard", Updated 09 Apr. 2021, <https://covid19.who.int/>.

²³¹ "Comparing vaccines: efficacy, safety and side effects", Updated 11 Mar. 2021, <https://healthydebate.ca/2021/03/topic/comparing-vaccines/>.

²³² "New SARS-CoV-2 Variants — Clinical, Public Health, and Vaccine Implications", Updated 25 Mar. 2021, <https://www.nejm.org/doi/full/10.1056/NEJMc2100362>.

162. Although all vaccines are safe and benefits outweigh potential negative consequences, mRNA vaccines have not reported any strong side effects. Because of reports of unusual blood clots with low platelets by people who got the AstraZeneca vaccine, countries in the EU suspended the injection, and 18 of the cases were fatal.²³³ EMA included these symptoms as rare side effects of the vaccine.²³⁴ Based on the FDA's recommendation, South Africa has also suspended the launch of the Johnson & Johnson vaccine because of the same side effects.²³⁵

163. Moreover, the mRNA vaccines have easier and faster repurposing of manufacturing facilities for new vaccines, as compared to other technological platforms. According to Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, modifying mRNA vaccines to target new COVID-19 variants is not difficult because the codes can be changed through computer programs.²³⁶ Also, the production of these vaccines needs less space than the others, lower biosafety levels, no cell lines, and a simpler procedure for manufacturing.²³⁷

164. BioNTech and Pfizer have developed a vaccine technology with 95% effectiveness rate, the highest among approved vaccines²³⁸. Because of the easy handling of the antigen, the production speed, and the high production yield, the Pfizer vaccine is ideal for large-scale production in record time.

²³³ "More EU nations suspend AstraZeneca shot as regulator says benefits still outweigh the risks", Updated 15 Mar. 2021, <https://www.cnn.com/2021/03/16/more-eu-countries-halt-astrazeneca-shot-as-ema-reviews-side-effects-.html>.

²³⁴ "AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets", Updated 07 Apr. 2021, <https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood>.

²³⁵ "South Africa suspends rollout of Johnson & Johnson Covid vaccine", Updated 13 Apr. 2021, <https://businesstech.co.za/news/trending/482897/south-africa-suspends-rollout-of-johnson-johnson-covid-vaccine/>.

²³⁶ "COVID-19 Vaccines vs Variants—Determining How Much Immunity Is Enough", Updated 17 Mar. 2021, <https://jamanetwork.com/journals/jama/fullarticle/2777785>.

²³⁷ "How COVID unlocked the power of RNA vaccines", Updated 12 Jan. 2021, <https://www.nature.com/articles/d41586-021-00019-w>.

²³⁸ "What does 95% COVID-19 vaccine efficacy really mean?", Updated 17 Feb. 2021, [https://doi.org/10.1016/S1473-3099\(21\)00075-X](https://doi.org/10.1016/S1473-3099(21)00075-X)

165. Moreover, once validated, the mRNA vaccine has the potential to produce ten times faster than conventional technologies, as this platform does not require productive processes involving cell cultures or high biosafety containment level²³⁹⁻²⁴⁰. In traditional vaccine production, cell cultures make the API yield unpredictable and make manufacturing more complex and time-consuming. MRNA vaccines, on the other hand, are chemical, not biological, so the production does not require manipulation of infectious cells, so the mRNA transcription step can be done in vitro, guaranteeing safety during the manufacture of the vaccine²⁴¹⁻²⁴²⁻²⁴³.

166. Also, mRNA vaccine production efficiency is better than the other platforms because mRNA vaccines require fewer antigens per dose. Therefore, it is possible to consume fewer supplies in the production of the same number of doses as traditional vaccines. Pfizer / BioNTech vaccine has the highest yield among the mRNA vaccines that are in use. The Moderna vaccine has 100 µg of mRNA per dose, and Pfizer / BioNTech's vaccine has 30 µg of mRNA per dose.²⁴⁴ Therefore, the productive potential of the Pfizer / BioNTech vaccine is best suited of the two for large-scale production.

167. The CureVac vaccine platform composition includes a natural self-amplifying mRNA (saRNA), the RNA replicates itself within human cells. Consequently, less RNA is needed, just 12 µg per dose, providing greater productivity, lower material costs, and faster production.²⁴⁵

²³⁹ "Rapid development and deployment of high-volume vaccines for pandemic response." Journal of Advanced Manufacturing and Processing, Volume 2, Issue 3, e10060, Jun 29, 2020, <https://aiche.onlinelibrary.wiley.com/doi/full/10.1002/amp2.10060>.

²⁴⁰ "Manufacturing COVID-19 vaccines." UK Parliament, Jan 14, 2021. Available: <https://post.parliament.uk/manufacturing-covid-19-vaccines/#inactivated>.

²⁴¹ HATCHETT, Richard. Towards Vaccinating "The World, Landscape of Current COVID-19 Supply Chain and Manufacturing Capacity, Potential Challenges, Initial Responses, and Possible "Solution Space" - a Discussion Document." Mar 09, 2021, https://www.dcvmn.org/IMG/pdf/landscape_of_current_c19_supply_chain_manufacturing_capacity_embargo_9_march_2021.pdf.

²⁴² "COVID-19 vaccine development and a potential nanomaterial path forward." Nature, Jul 15, 2020, <https://www.nature.com/articles/s41565-020-0737-y?elqTrackId=5debe8a10e41435b86d1608376c3e89a#Sec11>

²⁴³ "mRNA vaccines — a new era in vaccinology." Nature, Jan 12, 2018, <https://www.nature.com/articles/nrd.2017.243>.

²⁴⁴ "Resources, Production Scales and Time Required for Producing RNA Vaccines for the Global Pandemic Demand". MDPI, Vaccines 2021, 9, 3. Dec 23, 2020, <https://www.mdpi.com/2076-393X/9/1/3>.

²⁴⁵ "Resources, Production Scales and Time Required for Producing RNA Vaccines for the Global Pandemic Demand" 23 Dec. 2020, <https://doi.org/10.3390/vaccines9010003>.

168. Based on studies by researchers at Imperial College London and the International AIDS Vaccine Initiative (IAVI), mRNA platforms can produce more than 1 billion doses of RNA drug substance per year in a 5-liter range of bioreactor work in a small installation area²⁴⁶.

169. Thereby, once the antigen is known, mRNA vaccines are easier to produce. There is great flexibility in handling genetic material, vaccines can be produced by synthetic processes, and the production is simplified by having fewer steps²⁴⁷⁻²⁴⁸⁻²⁴⁹. Besides, the installation scale required to produce mRNA vaccines can be two to three times smaller than conventional vaccine facilities, and the automation of vaccine manufacturing procedures facilitates technology transfer.²⁵⁰²⁵¹ This information indicates that there may be an easy adaptation of factories that do not have access to mRNA vaccine technology.

170. Given the potential of this vaccine, both Pfizer and BioNTech received public investments from the USA, Germany, France, Singapore, and the EU, totaling US\$ 2.7 billion destined to pharmaceutical companies for the fast development of the vaccine and the expansion of productive capacity. As mentioned, vaccine development was largely funded by public money, and the Pfizer vaccine is the one that received the most public incentives.

²⁴⁶ "Rapid development and deployment of high-volume vaccines for pandemic response", 29 Jun. 2020, <https://doi.org/10.1002/amp2.10060>.

²⁴⁷ LE, Tung Thanh. ADREADAKIS, Zacharias. KUMAR, Arun. ROMÁN, Raúl Gómez. TOLLEFSEN, Stig. SAVILLE, Melanie. MAYHEW, Stephen. "The COVID-19 vaccine development landscape." *Nature*, Apr 09, 2020, <https://www.nature.com/articles/d41573-020-00073-5>.

²⁴⁸ MICHELETTI, Martina. "Part 2: Manufacturing new vaccines for pandemics." Department of Biochemical Engineering, UCL, Oct 2020, https://www.ucl.ac.uk/steapp/sites/steapp/files/vax-hub_vaccine_explainer_part_2_manufacturing_new_vaccines_for_pandemics_oct_2020.pdf.

²⁴⁹ HATCHETT, Richard. "Towards Vaccinating the World, Landscape of Current COVID-19 Supply Chain and Manufacturing Capacity, Potential Challenges, Initial Responses, and Possible "Solution Space" - a Discussion Document." Mar 09, 2021, https://www.dcvmn.org/IMG/pdf/landscape_of_current_c19_supply_chain_manufacturing_capacity_embargo_9_march_2021.pdf.

²⁵⁰ "Rapid development and deployment of high-volume vaccines for pandemic response." *Journal of Advanced Manufacturing and Processing*, Volume 2, Issue 3, e10060, Jun 29, 2020, <https://aiche.onlinelibrary.wiley.com/doi/full/10.1002/amp2.10060>.

²⁵¹ "mRNA Vaccine Production and Facility Design", Updated 21 Jan. 2021, <https://cellculturedish.com/mrna-vaccine-production-and-facility-design/>.

171. Because of that, today the Pfizer / BioNTech vaccine is the COVID-19 vaccine with the second largest production projection in the world. Nonetheless, the companies opt for a production concentration strategy with few partnerships and concentrating manufacturing in a few regions. The supply of their vaccine prioritizes the Global North countries and more than 70% of the production is destined for high-income countries.²⁵²

172. The CureVac vaccine, still pending WHO approval, is also a promising candidate to respond to the pandemic. The self-amplifying RNA vaccine platform has a higher yield potential than the Pfizer vaccine, in terms of doses per liter of bioreaction.

173. Nevertheless, CureVac announced at the end of March a very small production capacity for 2021 (300 million doses of coronavirus vaccines), far from making up for receiving the third-largest sum of public investment among the vaccine candidates, totaling US \$ 760M, from Germany and EU.²⁵³

174. Besides, the CureVac vaccine has a more stable mRNA, so it can be stored in a standard 5 ° C refrigerator for at least three months, and up to 24 hours at room temperature.²⁵⁴ It may be favorable for vaccine distribution in countries that do not have a cold chain for ultra-cold storage, such as low-income and middle-income countries. However, according to the “Covid-19 Vaccine Market Dashboard” by UNICEF Supply Division, 87% of advance sales of doses were acquired by the EC.²⁵⁵

²⁵² "Total Purchases by Country Income Level Classification and Manufacturing Projection (2021)", Updated 02 Apr. 2021,

<https://public.tableau.com/profile/duke.global.health.innovation.center#!/vizhome/TotalPurchasesbyCountryIncomeLevelClassificationandManufacturingProjection2021/Dashboard1>.

²⁵³ "CureVac Confirms Capabilities to Produce 300 Million COVID-19 Vaccines", Updated 31 Mar., 2021, <https://www.precisionvaccinations.com/2021/03/31/curevac-confirms-capabilities-produce-300-million-covid-19-vaccines>.

²⁵⁴ "CVnCoV - CureVac's mRNA-based vaccine candidate against COVID-19", Updated 23 Mar. 2021, <https://www.curevac.com/en/covid-19/>.

²⁵⁵ "COVID-19 Vaccine Market Dashboard", Updated 13 Apr., 2021, <https://app.powerbi.com/view?r=eyJrIjoiNmE0YjZiNzUtZjk2OS00ZTg4LTlhMzMtNTRhNzE0NzA4YmZlIiwidCI6Ijc3NDEwMTk1LTE0ZTEtNGZiOC05MDRiLWFiMTg5MjAyMzY2NyIsImMiOiJh9&pageName=ReportSectiona329b3eafd86059a947b&pageName=ReportSectione677ee4fb12a74d09f80>.



175. The inequality in the distribution of vaccines between regions is a way of prolonging this crisis, which, at its turn, enhances the risk of mutations that may harm rich and low-income nations alike. For this reason, the only efficient way to face the pandemic is to expand production to the Global South and therefore promote equitable vaccination.²⁵⁶

176. The Pfizer / BioNTech and CureVac vaccines have the potential to be a powerful global weapon against the Coronavirus pandemic. However, Pfizer, BioNTech and CureVac are not able to meet the global demand or to contribute to equitable access to this technology. Patent, technology and know-how licensing are therefore of the utmost importance.

²⁵⁶ "Vaccine nationalism will leave everyone more at risk of coronavirus", Updated 03 Feb. 2021, <https://www.newscientist.com/article/mg24933201-800-vaccine-nationalism-will-leave-everyone-more-at-risk-of-coronavirus/#ixzz6rXfAZk00>.

III. Legal arguments in litigations for equitable access to Covid-19 vaccines

177. In a preliminary stage, the present chapter aims to assess some of the legal arguments for providing global access to Vaccines. At first, we will turn to IP remedies, focusing on patent licensing and know-how transfer. The second part will be devoted to analyzing how the human rights violations originated from the vaccine supply debacle legitimates the proposed claim, including subsidiary/additional arguments on corporate responsibility and transparency.

3.1. Compulsory License

178. The compulsory license is a mechanism that allows “*third parties and/or government, under certain circumstances and conditions, to use a patented invention without the authorization of the right holder*”.²⁵⁷ It is an exception of the owner’s exclusive IP rights, granted by a competent national authority. Ruled by the country’s domestic law, compulsory license provisions also have to attend the TRIPS and, specifically on health issues, the WTO Doha Declaration on TRIPS and Public Health.

179. As for compulsory license objectives, we can refer to them as (i) safeguarding the general public interest; (ii) ensuring the balance between public and private interests; (iii) preventing abuse of rights and anticompetitive behavior; and, in some cases, (iv) promoting public health.²⁵⁸

180. Taking this legal background into account, the main goal of this topic is to (i) understand the COVID-19 vaccine as a global public good, to emphasize its relationship with the public interest; (ii) show the antitrust concerns regarding this matter; and (iii) present the intellectual property solutions for it, that is, the compulsory license of the patents to the Pfizer vaccine.

²⁵⁷ WIPO. *Draft Reference Document on the Exception Regarding Compulsory Licensing*. May 2019. p. 3. Available at: < https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=437425>.

²⁵⁸ Ibidem. pp. 4-6.

3.1.1. Global Public Goods

181. In the context of the global pandemic, the necessary know-how and technology to produce COVID-19 vaccines emerge as “global public goods”.

182. According to KAUL et al., there are two definitions of *public* goods. They can be characterized by (i) their potential for being public if they have non-excludable benefits, nonrival benefits, or both, (ii) or by their *de facto* non-exclusivity and availability all to consume²⁵⁹.

183. In this sense, considering the potential non-rivalrous benefits of the know-how and technology to produce vaccines - the possibility of vaccines being produced by all countries that present the minimum infrastructure required - if the know-how and the technology used to manufacture COVID-19 vaccines is distributed around the world, we can call it a public good.

184. The Nobel Prize winner Elinor Ostrom outlined another classification of goods. Ostrom expands on the private/public divide and includes two other categories according to the subtractability of use and difficulty of excluding potential beneficiaries.²⁶⁰

185. In that regard, the know-how and the technology to produce COVID-19 vaccines can be grouped within the “common-pool resources”, characterized by their serious difficulty of excluding potential beneficiaries and their high subtractability of use.

186. Although the category “common-pool resource” seems more accurate to describe the current status of vaccine know-how and technology in the context of the pandemic and the shortage of public health resources, we will adopt the terms “global public good” and “global common good” interchangeably.

²⁵⁹ KAUL, Inge et al. How to Improve the Provision of Global Public Goods. In: KAUL, Inge et al (ed.). *Providing Global Public Goods: Managing Globalization*. Oxford: Oxford University Press, 2003, p. 22-23.

²⁶⁰ OSTROM, Elinor. *Beyond Markets and States: Polycentric Governance of Complex Economic Systems (Prize Lecture)*. Stockholm University, 2009, p. 408- 436, p. 412-413.

187. Having explained the public aspect, we now turn to the global one. Public goods become *global* public goods when humanity in its entirety can be considered its beneficiary – in the sense that most everyone benefits from its use, regardless of countries, population groups, or generation.²⁶¹

188. The global aspect of the pandemic has already been recognized by international organizations such as the WHO, who urged all the countries for cooperation in the form of a proposal for a new treaty on pandemics as recently as March 30th, 2021, and insisted on joint work between “*governments globally and all stakeholders, including civil society and the private sector*” to face the present pandemic and future ones.²⁶²

189. UNESCO has also emphasized the need for cooperation, recognizing the need to share intellectual property to ensure global access to COVID-19 vaccines:²⁶³

“Ultimately the goal should be to make vaccines available to all at a reasonable cost. It is important to share intellectual property, so that manufacturers in other countries can also upscale the delivery of vaccines to all. Vaccines should be considered global common goods²⁶⁴. For real equity in the global access to vaccines, a shared ethical recognition of health as a global common good with no territorial limit is needed, as well as new global legal instruments for economic and political agreements and treaties.”

190. In this sense, how can global public goods be available to all, especially considering that there is a strong inequality between the Global North and the Global South in the COVID-19 vaccine production²⁶⁵.

²⁶¹ KAUL, Inge et al. How to Improve the Provision of Global Public Goods. In: KAUL, Inge et al (ed.). Providing Global Public Goods: Managing Globalization. Oxford: Oxford University Press, 2003, p. 22-23.

²⁶² World Health Organization, “COVID-19 shows why united action is needed for more robust international health architecture”, 30 March 2021. Available at: <<https://www.who.int/news-room/commentaries/detail/op-ed--covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture>>. Access: 09/04/2021.

²⁶³ UNESCO. UNESCO’s Ethics Commissions’ Call for Global Vaccines Equity and Solidarity: Joint Statement by the UNESCO International Bioethics Committee (IBC) and the UNESCO World Commission on the Ethics of Scientific Knowledge and Technology (COMEST). 24 February 2021. Available at: <<https://unesdoc.unesco.org/ark:/48223/pf0000375608>>. Access: 09/04/2021.

²⁶⁴ Although different organizations adopt different terminologies, it is the know-how and technology to produce COVID-19 vaccines (including the necessary technology and know-how, which are protected by patents and trade secrets) that should be given the technical status of global public good – not “immunization” or “vaccines” itself – and therefore released for global use.

²⁶⁵ KATZ, Ingrid T. et al. From Vaccine Nationalism to Vaccine Equity – Finding a Path Forward. The New England Journal of Medicine, vol. 384, p. 1281-1283, 2021.

191. Anoteworthy example is the open science model implemented to mitigate Influenza pandemics, which is guided by the “*rule that scientific results are the common property of all scientists*”.²⁶⁶ In this model, “*those making new discoveries freely share them rather than excluding others. In exchange, they earn reputational credit, which in turn can lead to increased funding and salary*”.²⁶⁷

192. Other successful initiatives that encourage the absence of patent rights and the sharing of information include the Drugs for Neglected Disease (DNDi) and the Structural Genomics Consortium (SGC), both of which create an open network between scientists around the world that have immensely contributed to public health without being bound by borders.²⁶⁸

193. Framing COVID-19 as global public goods, associated directly with the notion of common-pool resources (which is not equivalent to lack of regulation or free appropriation), can be an important step towards achieving equitable vaccine manufacturing and allocation. A legal demand to recognize vaccines as such and how this runs contrary to the exclusivities-based model that currently characterizes the discussion is relevant.

194. It is vital at this point to repeat that the granting of the “public good status” through the Courts that allow for an expanded production is positive and necessary to all countries in the world, since as already stated previously, widespread and fast vaccination is important to prevent the multiplication of new and more dangerous mutations of the virus.

3.1.2. Structural problem: oligopoly framework and abuse of dominance in the pharmaceutical sector

195. The present chapter aims to describe the oligopoly structure traditionally found in pharmaceutical markets, which may be accentuated in the recent COVID-19 vaccine market. Also, we emphasize that, without the license of the vaccine technology and know-how, this perverse structure will remain.

²⁶⁶ KAPCZYNSKI, Amy. Order Without Intellectual Property Law: Open Science in Influenza. *Cornell Law Review*, vol. 102, n. 6, p. 1539-1648, 2017, p. 1591.

²⁶⁷ *Id.*, p. 1548.

²⁶⁸ The purposes and achievements of both initiatives can be checked on their official websites: <<https://dndi.org>>; SGC <<https://www.thesgc.org>>.

196. First, we will discuss how this market is structurally organized. One may consider the sector's economic concentration as a key element to its understanding, including a brief analysis of recent merger control involving Big Pharma²⁶⁹ companies and how competition authorities have addressed its concerns on the matter.

197. As it is known, the sheer existence of market power is not, in itself, a competition law violation, neither does it imply the existence of a violation. However, there is a close relationship between the two, and the high number of investigations due to exploitative abuses, especially under the pandemic, is alarming.

198. Thereby, a brief scenario will also be presented to reinforce the potential abuse of dominance in the context of a global pandemic and its anticompetitive consequences. In that regard, at last, we will try to show the potential harm that this framework can cause in primary and secondary markets of COVID-19 vaccines, such as its potential network and lock-in effects for consumers and governments.

199. The structural problem is related to the market power possessed by a handful of pharmaceutical companies. Pharmaceuticals constantly try to impose entry barriers in the sector to exclude competition and make the market susceptible to their antitrust violations, including patent settlements.²⁷⁰

²⁶⁹ "Big Pharma is used as a term to denote large multinational pharmaceutical companies that constitute together a business group with powerful economic, political and social influence.² Smaller biotech companies play a crucial role in developing new health technologies. Often, Big Pharma does not itself engage in the lengthy and sometimes risky investments in developing such technologies, but simply buys smaller companies or their technologies, including the intellectual property rights, when they are ready to be manufactured and marketed at large and profitable scale.³ This pattern has also been observed in the current pandemic, although more in the form of manufacturing partnerships in which Big Pharma has imposed its intellectual property policies". Big Pharma takes it all: How pharmaceutical corporations profiteer from their privileges – even in a global health crisis like COVID-19. A Public Eye Report, March 2021, p. 5.

²⁷⁰ "On 8 July 2009 the European Commission adopted the Final Report on its competition inquiry into the pharmaceutical sector, pursuant to Article 17 of Regulation 1/2003 EC. Since then, the Commission has been monitoring patent settlements between originator and generic companies and publishes annual Reports. The main objectives of the monitoring exercises are to better understand the use of this type of agreement in the European Economic Area and to identify those settlements that delay generic market entry to the detriment of the European consumer." Available at: <<https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/>>.

200. The sector is highly concentrated and points to an oligopolistic structure. Competition authorities have signaled that the pharmaceutical market is a source of great concern regarding merger controls. The US Federal Trade Commission also seems to adopt a new approach when analyzing how drug-company deals affect competition.²⁷¹

201. The same can be said about the COVID-19 vaccine market. As seen, only a few companies currently produce and distribute vaccines. The small offer of different types of vaccines induces an unavoidable concentration of the market.

202. Another specific feature of the pharmaceutical sector is the high R&D expenses, including in the COVID-19 vaccine market. It constitutes the most important part of the drug or vaccine development process, imposing a large scale of fixed and sunk cost for the pharmaceutical company that develops new technology. Big Pharma justifies its exorbitant profits by saying that the innovator has to generate as much profit as possible in order to compensate expenditures for R&D²⁷².

203. According to the 2020 EU Industrial R & R&D Investment Scoreboard, pharmaceuticals & biotechnology sector received the most investment on R&D in the EU in 2019, a total of € 166.8 billion. It also experienced the third-highest increase in investment among the listed sectors (10%), only behind software & computer services (20.6%) and construction & materials (20.3%).

²⁷¹ KENDALL, Brent. HOPKINS, Jared S. March 2021. 'FTC Prepares to Take Tougher Stance on Pharmaceutical Mergers'. *The Wall Street Journal*. Available at: <https://www.wsj.com/articles/federal-trade-commission-to-consider-tougher-line-on-pharmaceutical-mergers-11615905000>.

²⁷² BURANYI, Stephen. 2021. 'Big Pharma did not save the day'. *Prospect*. Available at: <https://www.prospectmagazine.co.uk/politics/big-pharma-covid-19-vaccine-uk-revenue-stephen-buranyi>.

Table A3.1 – Main statistics for the 2020 Scoreboard sample of 2500 world companies aggregated by industrial sectors (top 15 sectors, ICB 3-digits).

Rank	Sector	R&D in 2019, € bn	1-year change, %	Net Sales, € bn	1-year change, %	R&D intensity, %	Operating profits, € bn	1-year change, %	Profitability, %	Employees, million	1-year change, %
1	Pharmaceuticals & Biotechnology	166.8	10.0	1043.9	7.5	15.4	143.1	12.8	14.7	2.7	2.0
2	Software & Computer Services	142.7	20.6	1212.6	11.2	11.8	186.7	-0.9	15.4	3.4	6.7
3	Technology Hardware & Equipment	139.6	8.9	1557.1	0.3	9.0	195.0	-17.8	12.6	3.8	8.5
4	Automobiles & Parts	132.7	1.9	2749.4	-1.0	4.8	115.4	-22.5	4.3	7.5	-3.0
5	Electronic & Electrical Equipment	68.9	6.3	1352.1	1.8	5.1	113.9	-19.8	8.5	5.5	1.4
6	Industrial Engineering	32.5	6.4	996.4	3.9	3.3	89.5	-3.8	9.1	3.6	1.4
7	Chemicals	23.1	-3.2	964.9	-4.3	2.4	86.0	-23.7	9.0	1.8	-2.6
8	Aerospace & Defence	20.6	4.3	518.4	6.4	4.0	46.6	-7.5	9.1	1.6	3.2
9	General Industrials	20.4	0.5	672.1	0.1	3.0	48.7	34.6	7.4	2.2	3.5
10	Construction & Materials	19.2	20.3	1048.9	9.8	1.8	70.4	5.6	6.7	3.1	2.2
11	Health Care Equipment & Services	18.9	9.3	495.1	8.1	3.8	43.3	14.5	8.8	1.6	4.6
12	Leisure Goods	16.5	3.5	269.6	-1.1	6.1	25.3	-0.5	9.4	0.7	1.4
13	Banks	11.4	5.6	351.7	0.4	3.2	90.3	-14.9	25.7	1.6	-0.7
14	Oil & Gas Producers	9.9	5.2	2725.5	-3.3	0.4	304.2	-23.8	11.2	1.8	-2.2
15	Household Goods & Home Construction	9.0	3.5	360.6	4.6	2.5	35.3	34.9	9.8	1.2	0.4
Total 38 industries		904.7	8.9	21039.9	1.9	4.3	2060.1	-10.2	9.9	55.8	1.3

Source: The 2020 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG R&I.

204. Due to this background of high expenses on R&D, Big Pharma companies make use of the so-called “legitimate business” defense to thwart antitrust liability. It consists in the argument that exploitative consequences of companies’ acts are simply related to the maximization of its profits, a rational and legitimate business purpose.

205. This justification is particularly found in Risk Evaluation & Mitigation Strategies (REMS) and “product hopping” cases, mostly related to *“hinder generic market entry and, as a result, prevent any savings from trickling down to consumers”*²⁷³.

²⁷³ Levy, Mark. (2016). Big Pharma Monopoly: Why Consumers Keep Landing on "Park Place" and How the Game is Rigged. The American University law review. 66. 247-303. p. 255.

206. According to that defense, if executives chose a different way, they would be rising up against the companies' interests. Although this argument has already been rejected by courts in recent cases, such as *FTC v. Actavis*, from 2013,²⁷⁴ firms continue to use it to avoid competition law scrutiny, reinforcing the market susceptibility to abuse.²⁷⁵

207. Also, as mentioned above, vaccines received mostly public investments in R&D, which was essential for their success. For that reason, the "legitimate business" defense gets even weaker once the public investments have largely dwarfed the sum of private investments on R&D. Therefore, Big Pharma cannot rely on its exorbitant profits to commit anticompetitive abuse and freeriding on taxpayers' money²⁷⁶.

208. Other types of exploitative abuses committed by the pharmaceutical sector can be found in the literature. Besides REMs manipulation and product hopping, we can also mention excessive prices and price gouging abuses, including in the COVID-19 outbreak²⁷⁷.

²⁷⁴ In this case, "the United States Supreme Court alleviated consumer coercion by holding that, under some circumstances, antitrust law can apply to pharmaceutical patent holders. Despite the Court's momentary effectiveness in tempering abuse, brand-name firms are utilizing other strategies to delay or prevent generic drugs from entering their markets, consequently allowing them to enjoy market exclusivity long past their patents' expiration dates and thereby harming consumers". Levy, Mark. Big pharma monopoly: why consumers keep landing on "park place" and how the game is rigged (2016). *Op. Cit.* p. 254.

²⁷⁵ "At this point, defendants often proffer a 'legitimate business purpose' defense, highlighting economic efforts to maximize profits. In other words, defendants may proffer a market-related excuse for their conduct, contending that the anticompetitive effects are merely incidental to an underlying business decision that benefits the company. Pharmaceutical patent holders often claim that their anticompetitive conduct serves a legitimate business purpose to immunize themselves from antitrust liability; for instance, they argue that reverse payment settlements reflect a purely economic desire to avoid excessive litigation costs" Ibidem. p. 268.

²⁷⁶ Big Pharma takes it all: How pharmaceutical corporations profiteer from their privileges – even in a global health crisis like COVID-19. A Public Eye Report, March 2021, p. 22.

²⁷⁷ See: Gabriella Muscolo, Amalia Luzzati, Pharma & COVID-19: An overview of EU and national case law, 10 March 2021, *e-Competitions Pharma & COVID-19*, Art. N° 99409; George S. Cary, Maurits J. F. M. Dolmans, Bruce Hoffman, Thomas Graf, Leah Brannon, Richard Pepper, Henry Mostyn, Alexis R. B. Lazda, Savannah Haynes, Kristi Georgieva, Jan Przerwa, Exploitative abuses, price gouging & COVID-19: The cases pursued by EU and national competition authorities, 30 April 2020, *e-Competitions Competition Law & Covid-19*, Art. N° 94392; and Behrang Kianzad, Excessive pricing during the COVID-19 crisis in the EU: An empirical inquiry, February 2021, *Concurrences N° 1-2021*, Art. N° 98670, pp. 250-259.

209. The competitive issues in the traditional pharma sector mentioned above can already be noticed in the COVID-19 vaccine market. Considering the high probability that the virus becomes endemic, the secondary market of vaccines for COVID-19 variants will be susceptible to those violations. Pfizer representatives, for example, have already declared that a third Covid vaccine dose is likely needed within 12 months²⁷⁸, while, at the same time, the company has raised the cost of future orders of its coronavirus vaccine placed by the European Commission more than 60 percent, as already mentioned²⁷⁹.

210. The evidence of exploitative abuses and high concentration levels threatens the possibility of a healthy competitive environment in this secondary market. Accordingly, there are potential network and lock-in effects on that secondary market, both from the perspective of the population and the governments.

211. As for the population already skeptical over vaccines, the trust would not likely be extended to vaccines other than the one received for the first dose. Accordingly, over time, this limits the capacity of governments to buy different types of vaccines.

212. Currently, vaccines are not interchangeable with each other when speaking of first and second doses application. Governments are also tied up to a specific pharma company after administering the first shot because of the lack of studies that prove otherwise.

213. Recent studies investigate whether we can mix and match different types of vaccines when applying the first and second doses. In the UK, the National Health Service (NHS) conducts pioneer research called Com-COV to find answers to this question, considering the combination are AstraZeneca and Pfizer / BioNTech vaccines.²⁸⁰

²⁷⁸ Access: <https://www.cnn.com/2021/04/15/pfizer-ceo-says-third-covid-vaccine-dose-likely-needed-within-12-months.html>

²⁷⁹ Available at: <https://www.cityam.com/pfizer-hikes-cost-of-covid-vaccine-for-eu-by-60-per-cent/>

²⁸⁰ Even this study was publicly funded, around £7 million, 'World-first COVID-19 alternating dose vaccine study launches in UK'. February 2021. Available at: <https://www.gov.uk/government/news/world-first-covid-19-alternating-dose-vaccine-study-launches-in-uk>.

214. This is strongly related to the realistic possibility of a sudden lack of doses in a country while immunization policies are still in the way. In that case of absolute scarcity, there will be no other option than to mix the shots. In January, UK authorities faced that exact scenario, leading them to affirm that *“this option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again”*²⁸¹.

215. This is the precise reason of the aforesaid study, to find scientific confirmation that mixing vaccines is a safe and efficient policy. However, we still do not have enough evidence of that hypothesis. Scientists cautioned that *“there was no guarantee that clinical trials would reveal a benefit to mixing vaccines. In the search for an H.I.V. vaccine, researchers tried combining viral vectors and protein boost without success”*²⁸². There are similar trials being conducted on China²⁸³, India and Russia, but with no scientific data available until now.²⁸⁴

216. According to the UK researchers, the study is expected to be concluded as late as March 2022. Meanwhile, pharmaceutical companies can still use their leverage. That is, the oligopolistic structure here described can, during a whole year or may be more, induce or foreclose sales in another market (for supplementary doses) and thereby monopolize both. In other words: chances of market power abuse are on their way.

217. Furthermore, even if mixing of different vaccines is proven more efficacious and turn into new standards for vaccination programs around the world, the dependency towards the specific combinations and the likely impossibility to meet them readily (given the scarcity of vaccines) will also bear negative consequences.

²⁸¹ WU, Katherine J. January 2021. ‘Britain Opens Door to Mix-and-Match Vaccinations, Worrying Experts’. *The New York Times*. Available at: <<https://www.nytimes.com/2021/01/01/health/coronavirus-vaccines-britain.html?>>.

²⁸² ZIMMER, Carl. March 2021. ‘Getting One Vaccine Is Good. How About Mix-and-Match?’. *The New York Times*. Available at: <<https://www.nytimes.com/2021/03/30/health/coronavirus-vaccine-astrazeneca-pfizer.html>>.

²⁸³ <https://g1.globo.com/bemestar/vacina/noticia/2021/04/11/china-considera-misturar-vacinas-para-aumentar-eficacia.ghtml>.

²⁸⁴ BELAGERE, Chetana. April 2021. ‘Mixing COVID-19 vaccination shots: Too Much, too soon, doctors say’. *The new Indian Express*. Available at: <<https://www.newindianexpress.com/cities/bengaluru/2021/apr/05/mixing-covid-19vaccinationshots-too-much-too-soon-doctorssay-2285876.html>>.

218. The leveraging power of companies already in the market, and for those expected to enter soon, is also enhanced in such a scenario. In reality, this means that countries cannot truly seek the best efficacious vaccination strategies and are primarily constrained by the less risky mixes (or absence of mixes), which is furthered by the first vaccines available in the country if any.

219. On the other hand, we can also see potential tie-up effects on the manufacturer side. When a pharmaceutical company produces a specific kind of vaccine, contracts with third parties are celebrated, and a lot of money and effort is put into producing this vaccine in particular. Therefore, even though the adaptation of vaccine production is perfectly feasible from a technical standpoint, commercially, it is not such a seamless transition.

220. Often, there are also contractual exclusivity obligations preventing such shifts. Changing to a new platform also requires divesting and perhaps stopping ongoing production altogether in order to repurpose the facilities to the new vaccine platform, which would also create subsequent manufacturing reduction.

221. It must also be said that, once governments have already made great investments in the development and production of specific vaccines and have entered into long-term contractual relations with specific pharmaceuticals, incentives for shifting vaccine providers are very low.

222. All these characteristics point to the fact that the logic of “winner-takes-it-all” is perfectly applicable to the Coronavirus pandemic. If Pfizer, BioNTech, and CureVac get a head start in a secondary vaccine manufacturing market, as the current situation points to, other competitors will face high entry barriers when trying to achieve it.

223. The dependence is also technological. Once the domestic factory gets a voluntary license of the vaccine know-how, the change to another technology is rare and not economically viable due to the costs of adaptation. The tendency, therefore, is that even fewer companies get access to the secondary market, which corroborates the oligopoly structure mentioned above.

224. The transparency issue already mentioned above also relates to this oligopolistic structure. Contracts entered into with pharmaceutical companies are either completely or partially unavailable. Thus, access to what has been agreed upon between companies and governments is very limited.

225. Furthermore, governments of different countries do not have basic information about what has been agreed upon in contracts with third parties. This situation greatly favors pharmaceutical companies under less pressure to lower prices, harming especially the impoverished regions.

226. Informational asymmetry, a situation in which one party to a transaction has more information than the other regarding a transaction, is one of the four main market failures identified by antitrust. Therefore, the concentration of enormous amounts of relevant information by pharmaceuticals is a real threat to creating and maintaining competitive markets.

227. Reducing informational asymmetry is central to the ability of governments, organizations, and the population to make informed, public, and democratic decisions on strategies to tackle the pandemic. Also, the public availability of information increases market competition, resulting in lower prices and bigger pressure to boost production. It can also foster public debates about the adequacy of the role of pharmaceutical companies and the importance of rethinking the production and distribution of vaccines.

228. At the market in question, high entry barriers and consequent reduction of competitiveness can be predicted by its low contestability. In this COVID-19 vaccine market, just as the pharmaceutical market, eventual abuses can't be quickly solved by a tempestuous, probable and sufficient new agents' entry due to the oligopoly structure verified in both of them. Hence, the chance of market power abuse only grows.

229. In recent antitrust history, we watched the same thing happening to big tech companies. Due to its innovative and unknown developments, authorities from all over the world were too afraid to police that market, causing its massive expansion without proper regulation. Lately, we are witnessing an attempt to review and reverse this situation, since

recent concerns about big tech mergers clarify it²⁸⁵. When it comes to public health, we cannot take that risk. We cannot refrain from properly regulating such a sensitive market just because of its innovative attributes.

230. Besides, this report bears enough evidence of the vaccine shortage. A global pandemic takes a global solution by using the legal tools that assemble remedies suited to its magnitude.

3.1.3. Compulsory license in EU and Germany

231. As already mentioned, Section 24(1) and (2)²⁸⁶ of the PatG rules the compulsory license in Germany.²⁸⁷ The competent authority to do so is the *Bundespatentgericht*, whose decisions can be revised by the BGH.

²⁸⁵ Recently, the UK's antitrust enforcer (Competition and Markets Authority) carried out an investigation of Facebook acquisition of Giphy, due to the company's refusal to address remedies to the competitive concerns that the authority pointed out. See: ARANZE, Janith. 'CMA opens Phase II investigation into Facebook/Giphy'. April 2021. *Global Competition Review*. Available at: <<https://globalcompetitionreview.com/digital-markets/cma-opens-phase-ii-investigation-facebookgiphy>>.

286 "(1) The non-exclusive authorization to commercially use an invention shall be granted by the Federal Patent Court in an individual case in accordance with the following provisions (compulsory license) were

1. a license seeker has, within a reasonable period of time, unsuccessfully attempted to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions, and
2. the public interest calls for the grant of a compulsory license.

(2) Where a license seeker cannot exploit an invention for which he holds protection under a patent with a later filing or priority date without infringing a patent with an earlier filing or priority date, he shall be entitled, in respect of the proprietor of the patent with the earlier filing or priority date, to the grant of a compulsory license from the proprietor of the patent if

1. the condition under subsection (1) no. 1 is fulfilled, and
2. his own invention demonstrates an important technological advance of substantial economic significance compared to that of the patent with the earlier filing or priority date.

The proprietor of the patent can require the license seeker to grant him a cross-license on reasonable terms and conditions for the use of the patented invention with the later filing or priority date".

²⁸⁷ There is also a provision in Section 13 of a compulsory license required *ex officio* by the Federal Republic of Germany, which we won't take long on explaining due to the object of this research.

232. To be granted, it is necessary that the requirement in matter (i) attends a public interest and (ii) has been object of previous negotiations between its owner and the license seeker. The patent owner shall be entitled to remuneration, and it can also be limited to a specific period of time and a certain territorial scope, according to Section 24(6).²⁸⁸

233. At last, *PatG*, Section 85(1), points out to an exceptional provision, which sets that *“the claimant may, at his request, be permitted to use the invention on the basis of an injunction if he substantiates that the requirements under section 24 (1) to (6) are fulfilled and that there is an urgent need, in the public interest, for the immediate grant of the permission”*.

234. As mentioned, few precedents on compulsory license exist in Germany.²⁸⁹ Although the number seems small, the country is a pioneer in granting compulsory license through Court decisions in comparison to other nations, being an example for most countries, whose Courts rarely granted compulsory licenses. The decisions established solid criteria for the question under consideration, involving the limits for interpreting the concepts of *“public interest”* and *“previous negotiations within reasonable period of time”*.

²⁸⁸ *“(6) The grant of a compulsory license in respect of a patent shall be admissible only after the patent has been granted. The compulsory license may be granted subject to limitations and made dependent on conditions. The extent and the duration of use shall be limited to the purpose for which the compulsory license was granted. The proprietor of the patent shall be entitled to remuneration from the proprietor of the compulsory license, such remuneration being equitable in the circumstances of the case and taking into account the economic value of the compulsory license. Where, in relation to recurrent remuneration payments due in the future, there is a substantial change in the circumstances which governed the fixing of the amount of remuneration, each party shall be entitled to require a corresponding adjustment. Where the circumstances upon which the grant of a compulsory license was based no longer apply and if their recurrence is improbable, the proprietor of the patent can require withdrawal of the compulsory license”*.

²⁸⁹ We can find three: *Polyferon* case (BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190), *Raltegravir* or *Merck v. Shionongi* case (BGH, judgement of 11 July 2017, ref: X ZB 2/17, GRUR 2017, 1017) and *Alirocumab* or *Sanofi v. Amgen* case (BGH, judgement of 4 June 2019, ref: X ZB 2/19, GRUR 2019, 1038).

235. Compulsory license can also be result of competition law provisions. In the *Standard-Spundfass* case, the BGH ruled that abuse of market power, an unfair restraint, or discrimination of market players, can be understood as a legitimate reason to grant a compulsory license²⁹⁰. In that matter, it is important to clarify that the exercise of an exclusive intellectual property right may involve abusive conduct meaning that the scope for objective justification of unequal treatment of would-be licensees must also be fundamentally broad²⁹¹.

236. Regarding the undetermined legal concept of public interest, German Courts prescribed that its definition must be filled by the concrete meaning of the case law. For that matter, by using the reasonableness principle, authorities must weigh in all beneficial and adverse circumstances that are relevant in the individual case and the interests involved²⁹²⁻²⁹³.

237. In the *Raltegravir* case, the BGH ruled for licensing a patent justifying that, in case that medicament ran out of the market, the patients that were treated with it would be subjected to the administration of other therapeutic medicines. In doing so, they would be exposed to especially high risk if their body did not seamlessly adapt to other medications. The Court then recognized that, although there might be alternative options in the market, extreme vulnerability justified the public interest in licensing the patent.

238. Nevertheless, in the recent *Alirocumab* case, the BGH pointed out that:

A public interest requiring the grant of a compulsory license for a medicinal product may be affirmed where significant results of a clinical trial, based on recognized bio-statistical principles, demonstrate that the active substance of the medicinal product in the treatment of serious diseases possesses therapeutic properties which are not, or not to the same extent, established for other products available on the market, in particular where the treatment reduces the patient's risk of dying as a result of the disease, or where such superior properties are otherwise demonstrated.

²⁹⁰ BGH, judgement of 13 July 2004, ref: KZR 40/02, GRUR 2004, 966.

²⁹¹ WIPO Circular C.8828 – *Contribution to the preparation of a draft reference document on the exception of compulsory licence*. p. 7. Available at: https://www.wipo.int/export/sites/www/scp/en/meetings/session_30/comments_received/germany.pdf>. Access: 09/04/2021.

²⁹² See *Polyferon* and *Raltegravir* cases.

²⁹³ WIPO Circular C.8828. *Op. Cit.* p.4.

239. This point is particularly important in COVID-19 vaccine conundrum. As mentioned, the scientific data provided until now shows no evidence of the possibility of mixing different vaccines. In a scenario of a vaccine shortage crisis, specific groups of people can be subject to high risk if they do not receive the corresponding second dose.

240. Conversely, this risk may also be felt if they are actually required to take specific combinations that will not be readily available. Either way, the consequences are negative. That situation is on the brink of happening in multiple places of Europe, as well as in the Global South. The compulsory license of COVID-19 vaccines, therefore, is urgent.

241. Meanwhile, on the requirement of preceding negotiations, the German case law fixed that they must occur within a “*reasonable period of time*”. This means the license seeker does not have to file the requirement for negotiation simultaneously to the compulsory license action; it can be done until the close of the oral hearing phase. However, it is not acceptable that the seeker starts the license negotiation while the proceedings are already in progress. Again, it will always depend on the circumstances of the individual case²⁹⁴.

242. We must recognize that this might be a problem in the context of an eventual COVID-19 vaccine compulsory license since there are no current direct and unsuccessful negotiations known at the moment. In that context, we understand that the recent WHO initiative of organizing a technology access pool of IP rights related to COVID-19 under C-TAP has enough legal value to be considered a previous negotiation since it was announced globally and for all COVID-19 patent owners.

243. The April 2021 call for expression of interest by the WHO on the creation of a Technology Transfer Hub, as already noted, also furthers this understanding. For that reason, and considering the unprecedented global pandemic, the requirement in question may be deemed already completed.²⁹⁵

²⁹⁴ See *Raltegravir* case.

²⁹⁵ “C-TAP is intended to provide a means to accelerate the development of products needed to fight COVID-19 as well as to accelerate the scale-up of manufacturing and the removal of barriers to access in order to make products available globally. Sharing information, knowledge, data and other resources is a powerful way to accelerate product development and avoid unnecessary duplication of efforts arising from the absence of such sharing.” Available at: <<https://www.who.int/initiatives/covid-19-technology-access-pool>>.

244. Still, as mentioned, compulsory license under German law does not allow the license seeker to obtain access to the know-how and technology essential to the production of the Vaccine.

245. However, there is one regulatory possibility that can be found in EU provisions, rarely explored by potential license seekers, and that might apply to the concrete case. EU Regulation (EC) N° 816/2006 was created to implement the Paragraph 6 of the Doha Declaration on TRIPS and Public Health.²⁹⁶ It aims to regulate compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.²⁹⁷ The PatG has already incorporated that provision²⁹⁸.

²⁹⁶ “6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.” Available at: < <https://www.who.int/medicines/areas/policy/tripshealth.pdf> >.

²⁹⁷ Regulation (EC) N° 816/2006 of the European Parliament and of the Council, of 17 May 2006. Available at: <<https://www.legislation.gov.uk/eur/2006/816/data.pdf>>.

²⁹⁸ 85a. (1) The procedure in accordance with Article 5-point (c), Article 6, Article 10 (8) and Article 16 (1) and (4) of Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157 p. 1) shall be initiated by an action in accordance with section 81 (1), first sentence. (2) Sections 81 to 85 shall apply *mutatis mutandis* in so far as the proceedings are not determined by Regulation (EC) No 816/2006.

246. The main aspects of that regulation are: (i) it applies to any pharmaceutical product, according to Article 2 (1);²⁹⁹ (ii) it recognizes the relevance of transferring know-how and technology of pharmaceutical sector manufactures to the least developed countries and other developing countries;³⁰⁰ and (iii) in situations of national emergency or other circumstances of extreme urgency, there will not be required the previous negotiations with the patent owner within a reasonable period of time, according to Article 9 (2).³⁰¹⁻³⁰²

247. For that matter, at first sight, Regulation (EC) N° 816/2006 seems to be adequate for the vaccine supply debacle. However, it has not been used so far. The only notice of a similar provision that happened to be effective was found in Canada. The Canadian authority granted a compulsory license to the domestic manufacturer Apotex for the purpose of producing and exporting an antiretroviral drug to Rwanda, that was facing a national epidemic. It was a one-time-only intervention related to Paragraph 6 of the Doha Declaration.³⁰³

248. Also, this Regulation has already been considered inefficient, because of its strict and inapplicable criteria.³⁰⁴ For that reason, we consider that the solid German jurisprudence related to domestic grant of the compulsory license makes it the preferable legal tool to be used on the case in question. Again, although there are only two cases of licenses granted by the German courts, the country is a pioneer in court granting of compulsory license in comparison to other nations.

²⁹⁹ For the purposes of this Regulation, the following definitions shall apply:

(1) 'pharmaceutical product' means any product of the pharmaceutical sector, including medicinal products as defined in Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (4), active ingredients and diagnostic kits *ex vivo*". Ibidem.

³⁰⁰ "The Community recognizes the utmost desirability of promoting the transfer of technology and capacity-building to countries with insufficient or no manufacturing capacity in the pharmaceutical sector, in order to facilitate and increase the production of pharmaceutical products by those countries". Ibidem.

³⁰¹ "1 The applicant shall provide evidence to satisfy the competent authority that he has made efforts to obtain authorization from the rights-holder and that such efforts have not been successful within a period of thirty days before submitting the application.

2 The requirement in paragraph 1 shall not apply in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement". Ibidem.

³⁰² "Furthermore, the obligation to enter into negotiations with the patent-holder before a compulsory licence may be granted (which can be waived for situations of national emergency, extreme urgency and public non-commercial use), set out in Article 31 TRIPS, is waived neither in the Waiver Decision nor in Regulation 816/2006". FIGUEROA, Pablo. GUERRERO, Alejandro (Eds.). *EU Law of Competition and Trade in the Pharmaceutical Sector*. 2019. p. 402.

³⁰³ Ibidem. p. 403.

³⁰⁴ Idem. Ibidem.

3.2 Human rights and vaccine distribution

249. The present section is devoted to analyzing the human rights foundations to the proposed claim for licensing of technology and know-how related to The Vaccines.

3.2.1 International fundamental human rights to life and health

250. Human rights enforcement involves an extensive set of rights, including the right to life and the right to health, as stated in the Universal Declaration of Human Rights (“**UDHR**”), the primary document on human rights.³⁰⁵ It can be stressed that these two are probably the primary rights that should be enforced as they are related to the very human existence in its essence and human well-being.

251. The right to life is widely guaranteed in human rights legislation around the world³⁰⁶. In its turn, the right to health is a logical extension of the right to life, as life depends on good health to be sustained. Even if the right to health is an “emergent right” in the human rights enforcement agenda,³⁰⁷ there is a powerful intersection between them, as they mutually enrich one another by combining and enriching research and field experiences³⁰⁸.

252. A state has the primary responsibility for securing the realization of the right to health for individuals in their specific jurisdiction, but it can only be achieved with international cooperation.³⁰⁹ There is an explicit legal commitment in international law obliging states to cooperate to guarantee the right to health: The International Covenant on Economic, Social and Cultural Rights (“**ICESCR**”).

³⁰⁵ See articles 3 and 25 of the UDHR. Available at: <https://www.un.org/en/about-us/universal-declaration-of-human-rights>.

³⁰⁶ For instance, Inter-American Convention of Human Rights (article 4, “Right to life”) and European Convention of Human Rights (article 2, “Right to Life”).

³⁰⁷ Audrey R. Chapman, *Global Health, Human Rights, and the Challenge of Neoliberal Policies*. Cambridge: Cambridge University Press, 2016, 2-4.

³⁰⁸ See: Jonathan M. Mann et al. Health and Human Rights. In: Michael A. Grodin et al. *Health and Human Rights in a Changing World*. New York: Routledge, 2013, 25.

³⁰⁹ John Tobin. *The Right to Health in International Law*. Oxford: Oxford University Press, 2012, 325.

253. ICESCR provides that each signatory state take steps, individually and through international cooperation, to fully realize the rights recognized in the Covenant, including the right to health.³¹⁰ This obligation is also confirmed in articles 3 and 4 of the Convention on the Rights of the Child (“**CRC**”).³¹¹ To fully secure the right to health’s enforcement in the international arena, developing countries’ needs should be considered, as provided in article 24(4) of the CRC.

254. The right to health includes the following axis: (i) Availability; (ii) Accessibility; (iii) Acceptability; and (iv) Quality. In a pandemic context, the enforcement of this right is directly linked to the guarantee of mass vaccination to all world populations. Thus, it is impossible to discuss it without addressing the availability of vaccines.

255. As this access shall be only guaranteed by the compulsory license previously mentioned, there is a need to address the question also bearing in mind the link between business and human rights, which will be discussed in detail below.

3.2.2. Business and Human Rights

256. Companies have duties beyond their shareholder's interests and are required not to engage in violations of human rights and refrain from impeding governments from ensuring human rights. Therefore, blocking and impeding access to Covid-19 vaccines can be framed along the lines of failure to respect human rights obligations.

257. It may also be understood as a failure towards corporate duties and a misrepresentation of their own corporate social responsibility policies (which stress their commitment to ensuring the promotion of health and well-being). That is especially the case when a select group of pharmaceutical companies holds the knowledge to produce the COVID-19 vaccines, the biggest guarantor of the right to health and life:

³¹⁰ International Covenant on Economic, Social and Cultural Rights (ICESCR) (New York, 16 December 1966 entered into force on January 3, 1976, 993 UNTS 3), articles 2 and 12. Available at: <https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx>.

³¹¹ Convention on the Rights of the Child (CRC) (New York, 20 November 1989, entered into force on September 2, 1990, 1577 UNSTS 3). Available at: <https://www.ohchr.org/en/professionalinterest/pages/crc.aspx>.

*“Launched, financed, and operated by nongovernmental actors, they are not public in the traditional sense. Yet they are not quite private, either: They owe their very existence to the grant of a state charter, and, due to their size and power, they may impact the lives of thousands or even millions of people.”*³¹²⁻³¹³

258. Various recent cases have sanctioned companies for human rights violations. While they are not exactly the present situation, they highlight that such possibility exists and is being increasingly explored in national courts. For example, the emblematic Shell Case^{314 - 315} in which the company was held liable for violating the human rights of Ogoni people of the Niger Delta in Nigeria. The case was settled before a trial could begin, and Shell was held to pay out \$15.5 million to the plaintiffs.

259. There also exists a specific duty in disaster situations based on the unique capacity of a specific enterprise to respond to a catastrophe³¹⁶, as Dunfee argues.³¹⁷ There are three main requirements for the positive accountability of companies in a disaster situation:

- i. The solution to the emergency must be contained in the corporate purpose of the company. In the present case, the main solution to the pandemic is vaccination, currently one of the main products of a pharmaceutical company that produces COVID vaccines.

³¹³ Lipton, Ann M. "Not Everything Is about Investors: The Case for Mandatory Stakeholder Disclosure." Yale Journal on Regulation, vol. 37, no. 2, Spring 2020.

³¹⁴ Okpabue and others v. Royal Dutch Shell Plc and another.

³¹⁵ An important case is also Nevsun Resources Ltd. v. Araya, that discusses alleged violations of human rights carried out by Nevsun in Eritrea. It is currently awaiting decision by the Supreme Court of Canada, that decided that it could go forward. Available at <https://www.scc-csc.ca/case-dossier/cb/2020/37919-eng.aspx>. Another fundamental jurisprudence is Lungowe v. Vedanta, in which the Supreme Court analyzed a claim brought by Zambian villagers against Vedanta, the parent company of Konkola, a mining company. It was claimed that toxic effluent discharge from the mine damaged local land and waterways used for irrigation and the use of polluted water for drinking, washing and bathing caused residents severe health problem. The company settled for the payment of compensation to the villagers. Available at <https://www.supremecourt.uk/cases/uksc-2017-0185.html>.

³¹⁶ The author defines catastrophe as: "(a) the harms must involve severe physical injury, deprivation or death, (b) hundreds of thousands of humans must be affected, (c) the harms must be immediate rather than projected."

³¹⁷ Thomas W. Dunfee "Do Firms with Unique Competencies for Rescuing Victims of Human Catastrophes Have Special Obligations? Corporate Responsibility and the Aids Catastrophe in Sub-Saharan Africa." (Business Ethics Quarterly, Cambridge, n. 2, v. 16, 2006). 185-210.

- ii. The company must be able to alleviate the disaster. As already proven, neither CureVac nor Pfizer and BioNTech present sufficient production capacity to face such challenges. However, they have the ability to provide the required technology and know-how for others.
- iii. Finally, comparative advantage is needed to justify that this company is held liable.

260. As better analyzed on item 2.5 of this Report, the Pfizer / BioNTech vaccine has a series of advantages such as its effectiveness, the security of the productive process, the possibility of massive production under shorter timeframes, the massive public investment, and the possibility of technology replication by other pharmaceutical companies around the world.

261. In addition, the Curevac also has advantages, such as the high yield potential, its more stable mRNA (so it can be stored in a standard 5 ° C refrigerator for at least three months, and up to 24 hours at room temperature), and the vast amount of public investment it received (the third-largest sum of public investment among the vaccine candidates).

262. All these arguments about the implications of corporate conduct may be pondered regarding their usefulness for the proposed litigation avenues.

3.2.3. Transparency

263. As already discussed, transparency and availability of information are central to the discussion about access to vaccines. The debate on transparency has also been at the forefront of global health discussions, particularly after the WHA 2019 resolution on Improving the Transparency of Markets for Medicines, Vaccines, and Other Medical Products.³¹⁸ Germany does not contain judicial mechanisms to ensure transparency-related obligations, but similarly to the previous sections, this topic may support the previous claims.

³¹⁸ https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_ACONF2Rev1-en.pdf.

264. The lack of access to information is a major problem for organizations, governments, civil society, and other companies, which have difficulties acting in the context of a pandemic. It is very hard to produce reliable knowledge without complete, abundant, and reliable information. This lack of transparency makes it challenging to draw firm conclusions about global access to COVID-19 vaccines and, therefore, to act.

265. The available studies, despite researchers' best efforts, are often based on the sparse information diffused by the media, organizations, governments, and companies, without adequate systematization and completeness, which compromises the reliability of the studies and therefore limits the global capacity to deal with the pandemic, considering the proven importance of science in the current scenario.

266. The availability of information, also addressed in Agenda 2030³¹⁹, especially of health, is fundamental for society to make decisions in an organized and democratic way. It is also central for civil society to be able to organize itself and make well-founded and adequate demands to pharmaceutical companies and governments, which, once again, hold enormous power over basic human rights. When governments and companies fail to publish health information proactively or to respond to requests for information, communities suffer adverse health impacts and cannot fully enjoy their right to health and life³²⁰.

267. Also, as companies, pharmaceutical companies owe a disclosure duty. One of the main fiduciary duties of companies is to publicize information to investors, who require a holistic overview of the company and its sector of activity in order to be able to invest in an informed and risk-aware basis. The availability of information is fundamental for a solid investment market³²¹.

³¹⁹ Sustainable Development Goal 16 "Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels" Target: Sustainable Development Goal 16.10 "Ensure public access to information and protect fundamental freedoms, in accordance with national legislation and international agreements" Indicator: SDG 16.10.2 "Number of countries that adopt and implement constitutional, statutory and/or policy guarantees for public access to information"

³²⁰ Concept Note for the Celebration of the International Day for Universal Access to Information (IDUAI) 2020 https://en.unesco.org/sites/default/files/unesco_ati_iduai2020_english_sep_24.pdf.

³²¹ PALMITER, Alan "When insufficient information is Available at securities markets, investors shy from investing – and the markets wither. Securities Regulation, ed. Nova York: Aspen Publisher, 2005, p. 69.

268. Besides the investors, the company has a disclosure duty to society since it is inserted therein and exercises great power over it. Public disclosures by corporations can expose antisocial practices, permit employees to compare working conditions and wages and allow competitors to identify monopoly rents and opportunities for innovation.³²²

269. Thus, a company has an intrinsic duty to reduce the informational asymmetry with its stakeholders by disclosing complete and timely information, which has not happened adequately over the Vaccines.

³²² Lipton, Ann M. "Not Everything Is about Investors: The Case for Mandatory Stakeholder Disclosure." *Yale Journal on Regulation*, vol. 37, no. 2, Spring 2020, pp. 501-502. The writer continues: "Outside of the United States, this principle is understood and incorporated into the regulatory framework. In Europe, for example, all limited liability companies must make annual disclosures about their operations and finances. A new European Union directive mandates that certain large companies regularly disclose information pertaining to their environmental impact, employee relationships, respect for human rights, and anticorruption measures, in order to 'meet the needs of investors and other stakeholders [and] to provide consumers with easy access to information on the impact of businesses on society.'"

IV. Conclusion

270. The research presented above demonstrates the necessity and urge to expand access to IP rights on COVID-19 vaccines and their compulsory licensing. Looking at the current uncontrollable number of cases and the possibility that the Pandemic will become endemic, taking immediate legal action emerges as necessary.

271. As projections demonstrated, until 2023 or even 2024, there will not be enough produced vaccines to cover the world's population. Vaccination is remarkably unequal at a global level and reproductive of several inequalities affecting disproportionately marginalized groups. Therefore, a choice is being made about who is going to live, which is a clear violation of human rights as well as an inefficient economic outcome, as the global economic downturn affects virtually all economic sectors in all countries

272. The Global North is the predominant destination of vaccine shots. The Global South is in a highly inferior position regarding the total vaccinated population when comparing both regions.

273. The preference for supply to high-income countries exists because the large pharmaceutical companies have already entered into contracts that can almost be considered exclusive agreements with such governments. Middle-low and low-income countries are lagging, sometimes even despite contracts having been signed.

274. As shown, the production of mRNA vaccines is highly concentrated. This productive approach demonstrates a lack of interest in expanding manufacturing and supplying regions with little or no access to COVID-19 vaccines by now. Meanwhile, mRNA-based vaccines could be produced by other companies already producing other types of vaccines, as technical adaptability is not an issue.

275. It is important to emphasize that the Global South pharmaceutical sector has enormous market opportunities and is very developed. The ten most prominent pharmaceutical companies by revenue in 2020 have activities in the Global South markets, with sites dedicated to national supplies and exports.

276. Therefore, not only the Global South pharmaceutical sector can supply pharmaceutical products, but it also has several institutions already developing COVID-19 vaccines. It produces already approved vaccines and presents institutions with declared production capacity for other COVID-19 vaccines.

277. Meanwhile, these institutions are not being used and are available to implement bulk manufacturing and fill and finish in vaccine production. If this were made available to mRNA-based vaccines, all institutions already producing COVID-19 vaccines or that have declared their productive capacity would produce these vaccines due to the easy to adapt manufacturing.

278. Pfizer / BioNTech and CureVac are not up to the task of supplying the global demand for vaccines to end the coronavirus pandemic. It is necessary to favor public interest and ensure access to their technologies to enhance manufacturing capacity and technology transfer drastically. These companies can impact the lives of billions of people and thus should have different and starker duties.

279. As demonstrated with the data presented above, the Global South has not begun to obtain manufacturing autonomy and has no prospect of addressing its populations' demands for vaccination for at least the next three years. Hence the public interest is severely being hindered.

280. Moreover, as demonstrated above, the tiny portion of the Global South that could buy doses of these companies or have associated with COVAX has been suffering from late deliveries and/or decreased the number of promised doses.

281. Thus, the direct result of manufacturing concentration in few pharmaceutical companies is the insufficiency of COVID-19 vaccine shots for the worldwide population and the default of vaccine supply contracts worldwide. Companies not expanding their production chain delays massive distribution and massive immunization.

282. Despite its exclusion of the manufacturing chain, the Global South would be a potential consumer market for vaccines produced by themselves. As most of them are out of stock or default, their inner demand is highly significant, as stated in the graphs presented above.

283. Image 5, “Saved lives daily if IP rights related to the Vaccines are available to developing countries” demonstrates how the social catastrophe the world is going through is an expected direct consequence of the destination of produced vaccine doses being mainly directed for the Global North. While South’s population approximately quadruples North’s, its countries’ vaccination rate represents a third of Global North countries’ registered average.

284. If the scenario remains the same and no supply or diffusion of production occurs, the number of deaths expected will become true. Therefore, the demand is urgent.

285. Mass vaccination is the only possible way to decrease the number of infections by COVID-19 and its deaths. As previously shown, the numbers of predicted deaths are incredibly high. Then, mass vaccination is crucial to guaranteeing fundamental rights to life and health, not only in the Global South but also globally. Since massive vaccination is fundamental to avoid the multiplication of virus mutations, the absence of vaccines will affect the whole world.

286. Vaccines must be seen as global public goods. Within this framework, compulsory licensing of the patents, accompanied by the transfer of technology and know-how to the effective production of Covid-19 vaccines, is needed.

287. Patents, know-how, and the necessary technology for manufacturing COVID-19 vaccines are “global public goods” in the sense that they present their serious difficulty of excluding potential beneficiaries and their high subtractability of use. Beyond being considered public goods, they also possess a global aspect because humanity in its entirety can be considered their beneficiary. As global public goods, they require a differentiated normative regulation based on knowledge sharing between scientists.

288. Regarding the compulsory license, an exception of the owner’s exclusive IP rights, we aimed at (i) exposing the antitrust concerns in the pharma market; (ii) demonstrating the inherent public interest in licensing COVID-19 vaccines; and (iii) providing an overview of the legal framework and the jurisprudential understanding of compulsory licensing in Germany.

289. The compulsory license of COVID-19 vaccines’ patents and the transfer of their know-how and technology are entirely indispensable. Only the sharing of intellectual property would break the abusive and oligopolistic structure that permeates the pharmaceutical sector.

290. Turning to antitrust issues, we have demonstrated the current abuse of dominant position in the pharma sector by the pharmaceuticals that concentrate the vaccines' production. Traditionally, the tendency towards oligopolization between pharmaceuticals and the creation of corporate dependence between consumer-pharmaceuticals and producer-pharmaceuticals is notorious.

291. Governments' massive public investment in vaccines does not support the "legitimate business" defense to thwart antitrust liability. The necessity of profit to supply R&D presented by pharmaceutical companies is an excuse. Pharmaceutical companies' profits do not need to be exorbitant because external investments supply research, clinical studies, and production infrastructure. Moreover, the public funding strengthens the public interest contained in the compulsory license.

292. Finally, we understand that the C-TAP public call for licensing has enough legal value to be understood as a negotiation with the major developers and producers of COVID-19 vaccines regarding the requirement of prior negotiation. Also, the most recent WHO Technology Transfer Hub furthers this understanding. Thus, this requirement is also met.

293. Although courts granted only two cases of compulsory licenses in Germany, it must be emphasized that is a lot if compared to other countries. In comparison with the rest of the world, Germany stands out as very progressive in granting this type of license through the Courts, and the great concern of German authorities with a legal interpretation aligned with reality is notorious.

294. In other respects, the lack of transparency regarding COVID-19 vaccines is glaring. Not much information on how much governments and public-private partnerships invest is available. Most of the contracts between the pharmaceuticals and governments/public-private partnerships were not available. No contracts of awards were accessible. On the direct purchase ones, only the total amount negotiated was not censored.

295. It is impossible to produce any sort of reliable knowledge without complete, abundant, and reliable information. The spread and known data collected are not systematized or complete. The price or number of doses each state-contracted are extremely difficult or even unattainable to find.

296. The right to know, especially on health matters, is crucial for sustaining democracy and, consequently, human rights. The ongoing discrepancy in knowledge information disables a competitive market structuring. A solid investment market cannot be set. Not only this reflects the company's disclosure duty to investors, but the governments' as well.

297. As there is no capability of identifying monopolies or antisocial practices, the concentration of production will be reinforced, with no room for other industries, especially from the Global South, to act in the pharma sector. The Global South must begin to produce as well, using its large idle capacity.

298. The right to life, clearly jeopardized by the Pandemic, is one of the most basic human rights. In its turn, the right to health, and especially during a pandemic, is a logical extension of the right to life. Human rights directly depend on a coalition of forces to be guaranteed. Not only governments but every social participant has a duty in this matter.

299. In the current scenario, the pharmaceutical sector, along with the states, has the power to change this big catastrophe (that has already sickened and killed many and will continue to do so) in their hands.

300. Since the supply for global demand requires unprecedented productivity, global purchasing patterns reflect the manufacturing approach. Contracts celebrated with manufacturers and states or national and international entities are the only available approach to hope to receive COVID-19 vaccine doses.

301. Pfizer, the biggest vaccine production centralizer, prioritizes the manufacturing sites for sales and deliveries on the countries that invested in their R&D – that is, most countries in the Global North.

302. The centralization contrasts the public interest coming from public investment. All mRNA vaccines on clinical development received public investment from the Global North directly through awards from governmental agencies or indirectly through the beforehand acquisition of doses intended for the R&D of the vaccines. Larger public investments meant that vaccines could go further on the clinical evaluation.

303. Based on all public interest demonstrated above, including the characterization of vaccines as global public goods, the need for a compulsory license, and the effects of the Pandemic on fundamental human rights, GDP concludes that it is necessary to share the intellectual property rights and all related rights needed to produce the Pfizer / BioNTech vaccine, and CVnCOV vaccine.

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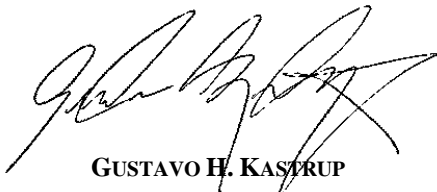
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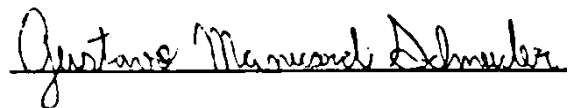
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