

# Intellectual Property Law For Covid-19 Treatments: State Of The Art And Patentometry

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## Abstract:

The present study aims to provide a situational overview of pharmacological patents for Covid-19. To this end, it uses the methodology called patentometry and bibliographic survey. The data was collected from the Espacenet databases and the Industrial Property Institute (INPI). Searches will not be filtered by period, as Covid-19 emerged in 2019. The results show a rapid mobilization of the pharmaceutical industry to produce preparations to be used in the prevention and treatment of Covid-19 as well as reduced time for evaluation of patents and concession.

**Key Word:** Patents; Covid-19; Patentometry.

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## I. Introduction

This is a study that addresses the topic of pharmacological patents for Covid-19. This topic has great relevance in the context of public health, since the world was caught off guard by the pandemic with the fatality rate varying between more vulnerable countries, and it is fair to say that it was an impactful event in the recent history of Health public. Through situational urgency, there was a rapid increase in research into the creation of vaccines and medicines that could circumvent the disease's progression.

The problem of the topic lies in the fact that it has a situational overview of pharmacological patents for Covid-19, with this, we seek to offer an answer to the following problem: State of the art of Covid-19 Treatments and Preventions. Thus, the object of the study is limited to drawing an overview of the situation of pharmacological patents.

To this end, the methodology used is patentometry and systematic bibliographical research, as it is a recognized and valid method to achieve the established objective. This method provides elements to extract information from patents. This is research with a basic purpose in nature and a quantitative approach. The data was collected from the Espacenet databases and the Industrial Property Institute (INPI). Searches will not be filtered by period, as Covid-19 emerged in 2019.

The theoretical foundations show that Covid-19, the disease caused by SARS-CoV-2, is a highly contagious disease and marked the beginning of this decade as one of the most impactful events in the recent history of public health (Werneck, 2022). Through situational urgency, there was a rapid increase in research into the creation of vaccines and medicines that could circumvent the disease's progression. In March 2020, a study published by Quintella (2020) and collaborators identified 991 patents, 126 articles and 119 clinical studies, two of which mention vaccines, demonstrating a rapid emergence in the creation of pre-clinical and clinical patents.

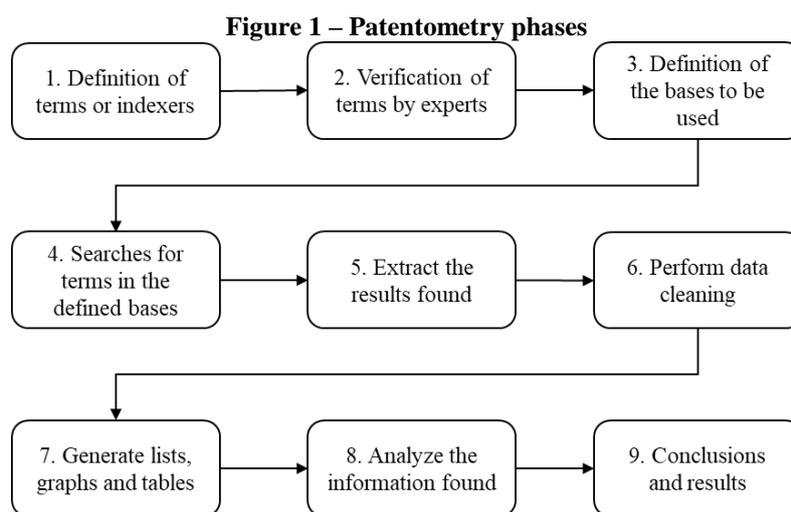
The global effort became more effective after the genetic mapping of the virus, as well as the recognition of viral proteins, initially resulting in the creation of 30 vaccine patents, and 4787 related to therapeutics against Covid-19 between 2020 and 2021. In addition to the 8,050 patent applications published since the beginning of 2020, around 597,057 scientific literature articles, including in journals, books and meeting proceedings, have been published by the end of September 2022, based on the CAS Content Collection (WIPO, 2023).

As main results, the INPI has a total of 379 patents filed and 16 patents granted. At Espacenet, the result was 416 patents filed. The present study is composed, in addition to this introduction, of the theoretical framework, methodology, final considerations and references used.

## II. Methodological procedures

This is research with a basic purpose in nature and a quantitative approach (Creswell, 2007; Günther, 2006). Regarding the objectives, the research is characterized as exploratory (Lakatos; Marconi, 2019) with technical procedures of bibliographical surveys (Gil, 2018) and patentometry. On Espacenet, the criteria are defined by the following search formula: (*nftxt* = "Orthocoronavirinae" AND (*nftxt* = "covid-9" OR *nftxt* = "SARS-CoV-2")) AND (*nftxt* = "medicine\*" OR *nftxt* = "pharmaceutical\*" OR *nftxt* = "drug\*" OR *nftxt* = "vaccine\*"). At INPI, the following two indexers were used in the summary, namely: Covid-19 or SARS-CoV-2. The searches will not be filtered by period, as Covid-19 appeared in 2019. From these searches, there is a population returning from searches on INPI and Espacenet. The analyzes will be carried out using Espacenet searches.

There are several tools that are being used by organizations to analyze patents, including patentometrics (Abbas; Zhang; Khan, 2014). It provides knowledge about patents that can be transformed into technical information that assists commercial agents in strategic decisions, therefore being a science that analyzes patent information (Nagaoka; Motohashi; Goto, 2010; Nascimento, 2020). The patentometry of this work is composed of nine phases (Figure 1).



Source: Mendes and Melo (2017)

The first and third stages were described in this methodology, stages that were carried out based on teachings in the classroom by the subject teacher, the fourth, fifth, sixth, seventh and eighth were carried out in the analysis and discussion of the results and the ninth in final considerations.

## III. Theoretical Reference

Covid-19, the disease caused by SARS-CoV-2, is a highly contagious disease that marked the beginning of this decade as one of the most impactful events in the recent history of public health (Werneck, 2022). Although Covid-19 was initially detected in December 2019, in the Chinese city of Wuhan, it was only officially detected in January 2020. The evolution of the number of cases occurred so significantly that in the first 30 days, they were recorded 11,821 cases and 259 deaths, until in March 2020, the Covid-19 pandemic status was declared, by the World Health Organization (WHO) (Marco et al., 2020).

As described by Benvenuto and collaborators (2019), SARS-CoV-2 is a ribonucleic acid (RNA) virus, with genetic material represented by a single positive RNA molecule (RNA+), where after the introduction of viral genetic material in the host cell, the virus is retained and multiplied through endocytosis or membrane fusion. Coronaviruses are made up of four structural proteins, namely the spike (S), membrane (M), envelope (E) and nucleocapsid (N) proteins. Inside the body, SARS-Cov-2 binds to the ACE-2 receptor, highly expressed in lung epithelial cells, which explains the wide range of symptoms, and the high transmissibility of the virus through aerosols and droplets (Parasher, 2021).

The disease caused by SARS-CoV-2 is mainly characterized by respiratory tract infection, but symptoms can vary drastically for each individual and organic system, such as: fever, chills, sputum production, fatigue, lethargy, arthralgia, myalgias, headache, dyspnea, nausea, vomiting, anosmia, and diarrhea (Liu et al., 2022). Despite the similarity with other previous outbreaks through severe acute respiratory syndrome (SARS), the one caused by SARS-Cov-2 achieved a worldwide catastrophic effect mainly through the high level of

contagion, general lack of knowledge about the virus, unpreparedness of health and socioeconomic vulnerability (Werneck, 2022).

In this way, the world was caught off guard by the pandemic, with the fatality rate varying between more vulnerable countries, public health, population aging and socioeconomic issues. Brazil was also hit hard by the pandemic, through the direct and indirect and disruptive effects on health and the economy, through an ineffective initial management of the pandemic, which culminated in the exhaustion of resources and waiting lists in the Unified Health System (SUS), resulting in around 705,775 accumulated deaths (Cavalcante, 2020).

A patent, as described by the National Institute of Intellectual Production (INPI), is a temporary property title over an invention or utility model, granted by the State to inventors or authors or other natural or legal persons holding rights to the creation. Thus, a patent is considered an intangible asset that grants market exclusivity to an inventor for an invention. There is also a strong positive relationship between the quality of science and patents for the control of diseases and pandemics, with innovation being a strong ally in both health and economic issues (Liu et al., 2021)

Another factor that contributes to the development of patents is competitiveness, in which several companies internationally, for example, competed to develop a high-tech and efficient vaccine against the disease, spread and symptoms of COVID-19 (Nie; Wen; Chan, 2023). Despite this, due to competitiveness and health urgency, there was a concentration on the creation and distribution of patents only in countries with greater technology and greater economic income (Forchette et al., 2021), even given the global nature of the pandemic.

This fact generated the debate regarding the "breaking of patents", so that underdeveloped countries could also have access to medicines and vaccines (Bustamante et al., 2023), despite the counter-argument that the protection of intellectual property rights is important and particularly relevant for inventions that result from rigorous research and development (Musyuni et al., 2020).

Patentometry is a type of bibliometric study that aims to measure the number of scientific articles, patents and citations on a given subject, as well as other possible sub-analyses based on this research. Patentometrics uses quantitative methods to provide an objective assessment of scientific production, with Figueiredo (1977) highlighting that "bibliometrics since its origins has been marked by a double concern: the analysis of scientific production and the search for immediate practical benefits for libraries". It was proposed by Nicolás and collaborators (2018), for example, the assessment of technological maturity, which consists of collecting data relating to technology in three categories of bibliometric sources, whether emerging, growing, and mature (Watts and Porter, 1997), to technological scenario recipient of a specific technology or patent under development can be identified.

Therefore, through patentometry, obtaining information about a technological field can be deepened, evaluating the patents found and carrying out a complete analysis of the cycle inserted by the technology (Speziali; Nascimento, 2020). Analysis over time can also demonstrate trends, dispersion, and scientific obsolescence, as well as the scientific productivity of certain authors, organizations, and countries (Gicovate et al., 2020), helping the scientific community to understand the system in which it operates (Tizotte et al., 2021). In the context of public health, patentometric analysis assists in the epidemiology, prevention, diagnosis, control, and treatment of the disease, also including data regarding the time, location, and source of publication (Gicovate et al., 2020)

For example, given the context of Covid-19, in which there was a jump in the number of scientific productions and patents, it is possible to analyze all the issues previously mentioned for this topic, helping to elucidate how the process of creating new technologies, which were excluded, and the trend of natural evolution currently predominant (Nie; Wen; Chan., 2023). Finally, the global coronavirus patent landscape is essential not only to encourage research and policy given the current pandemic crisis, but also to anticipate important possible future developments (Pereira et al., 2022).

Through situational urgency, there was a rapid increase in research into the creation of vaccines and medicines that could circumvent the disease's progression. Despite the global calamity situation, the scientific process for development requires phases with specific prerequisites until a patent can be commercialized. As described by Pich (2011), trials are divided into four phases: Phase I tests a new medicine or treatment in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people; and Phase IV occurs after the drug or treatment has been licensed and marketed.

In March 2020, a study published by Quintella (2020) identified 991 patents, 126 articles and 119 clinical studies, two of which mention vaccines, demonstrating a rapid emergence in the creation of pre-clinical and clinical patents. The global effort became more effective after the genetic mapping of the virus, as well as the recognition of viral proteins, initially resulting in the creation of 30 vaccine patents, and 4787 related to therapeutics against Covid-19 between 2020 and 2021. In addition to the 8,050 patent applications published since the beginning of 2020, around 597,057 articles of scientific literature, including in journals, books, and meeting proceedings, were published until the end of September 2022 (WIPO, 2023).

Currently, the main treatments studied for Covid-19 are diverse, highlighting antiviral drugs, biological immunomodulators, neutralizing antibodies, anti-inflammatories and cell and gene therapies (Yuan et al., 2023). Initially, the main antiviral drugs tested for the treatment of Covid-19 were remdesivir, hydroxychloroquine and lopinavir-ritonavir, with the latter two having controversial results following cardiovascular complications, lack of reduction in mortality and questioned efficacy (Panahi et al., 2023).

In view of the Covid-19 cycle, it was observed that the effectiveness of the drugs developed may vary depending on the stage of the disease, with gaps in treatment being generally admitted, and the advantage of a combined therapy compared to a single therapy, which infers the importance of prevention and vaccination as essential to interfere with viral spread (Yuan et al., 2023). There are mainly three common types of vaccines against the SARS-CoV-2 virus: mRNA, adenovirus vector, and inactivated vaccines (Forchette et al., 2021).

The first vaccines to be approved and produced on a large scale were those developed by Pfizer-BioNTech, Inc. (USA) and Moderna, Inc. (USA), being mRNA vaccines, approved in December 2020, having the advantage of being typed to be modified against new viral strains. As an example of an adenovirus vaccine, there was the Johnson & Johnson vaccine, approved in February, and as for vaccines with inactivated viruses, such as the AstraZeneca and Coronavac vaccines (Forchette et al., 2021).

As future perspectives, vaccines with other mechanisms of action are being studied, such as DNA, mRNA and viral vectors. A study carried out by YADAV and colleagues (2023), a total of 242 vaccines against COVID-19 are in clinical studies, among which 46 are in phase 3 clinical trials, while 46 are in phase 4, which have been approved in several countries on December 30, 2022. It is expected that the new generation of vaccines will bring updates regarding new strains of the disease, maintenance, and greater immunological response, in addition to lower health risks and mild to moderate local and systemic adverse effects (Zhang et al., 2023).

#### IV. Result and Discussions

Considering the objectives proposed by this study, the analyzes carried out on pharmacological production for Covid-19 are presented. Initially, the research carried out using the INPI and Espacenet databases is shown, using the indexers: (*nftxt = "Orthocoronavirinae" AND (nftxt = "covid-9" OR nftxt = "SARS-CoV-2")*) AND (*nftxt = "medicine\*" OR nftxt = "pharmaceutical\*" OR nftxt = "drug\*" OR nftxt = "vaccine\*"*). At INPI, the following two indexers were used: Covid-19 or SARS-CoV-2.

The research carried out at the INPI database resulted in a total of 379 patents filed, and up to the date of this study, 16 patents had been granted, as shown in table 1, which is equivalent to 4.2% of patents granted in the period analyzed.

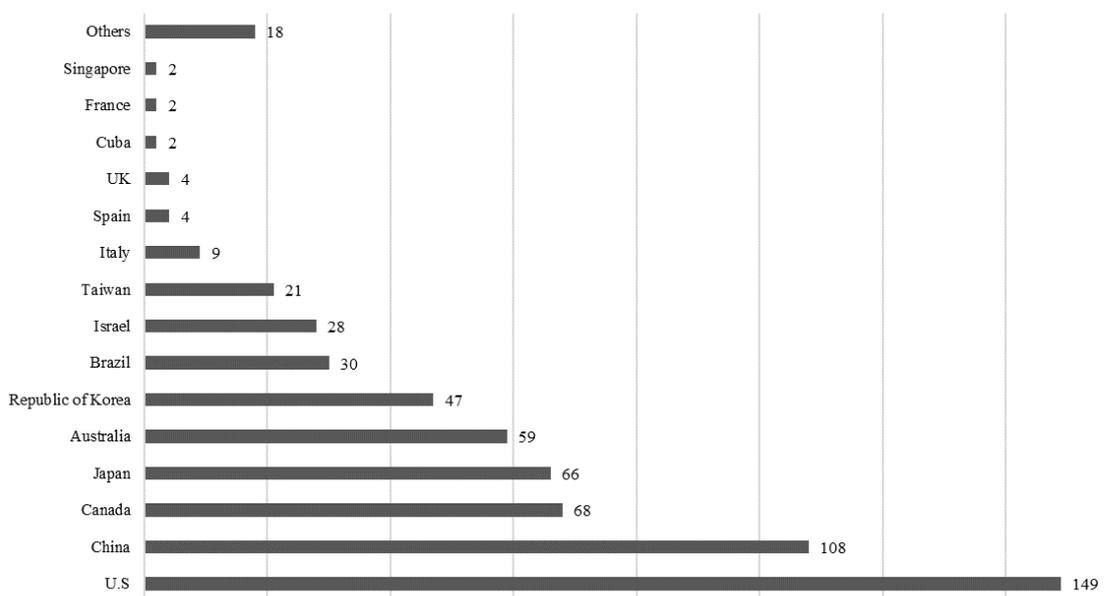
**Table 1** – Searches at INPI

Year	Deposited	Granted
2019	0	0
2020	96	12
2021	266	4
2022	17	0
<b>Total</b>	<b>379</b>	<b>16</b>

Source: INPI (2023)

The Espacenet-based search resulted in 416 patents, with 307 filed at the World Intellectual Property Organization (WIPO) under the acronym WO and 137 at the European Patent Organization (OEP) under the acronym EP. The patents were published in several countries, notably the United States with 149 patents, which corresponds to 35.8% of all published patents; Japan with 108 published patents, corresponding to 25.9%; Canada with 68 patents which corresponds to 16.3% of the total number of published patents and Australia with 59 patents which corresponds to 14.1% of all published patents as shown in figure 2.

Figure 2 – Countries of publications



Source: Espacenet (2023)

Brazil appears in seventh position with the number of 30 patents published, which corresponds to 7.2% of the total number of pharmacological patents for Covid-19 in the period from 2019 to 2023.

Furthermore, the global urgency in the face of the need to combat Covid-19, with the mobilization of the pharmaceutical industry to produce drugs to be used in combat and treatment, in 2020 there were 121 priority requests and 25 priority requests in the year 2021, which demonstrates a large concentration of applications shortly after the WHO classified the outbreak as a pandemic on March 11, 2020. It is immediately important to highlight that all patents granted were granted within a period of up to 2 years since the date of filing, which demonstrates the rapid analysis of patents given the situation given that the average time in the areas of pharmaceuticals and biopharmaceuticals is 5.8 years (Andrade, 2022). A parenthesis is opened here to highlight that despite the year 2019 being part of this study, it was considered prudent to ignore the data regarding the production of medicines and vaccines from the year in question considering that the identification of the cause of Covid-19 was only carried out in January 2020.

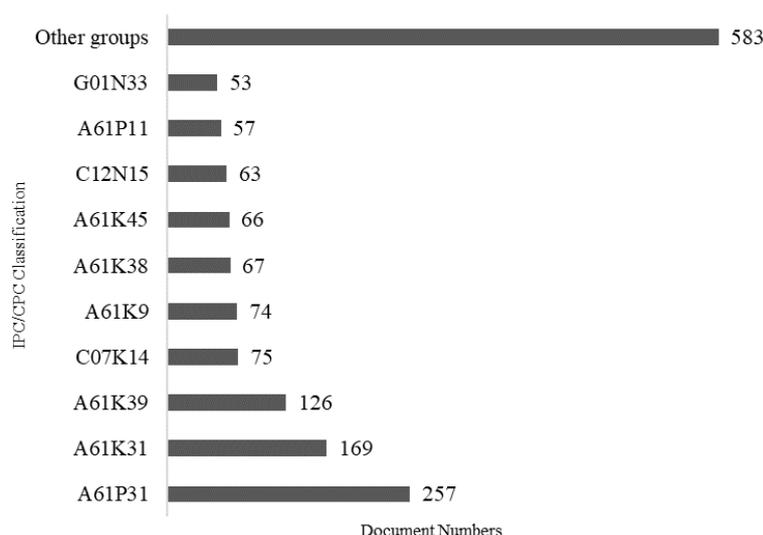
Table 2 – Year of publication and priority by patent family

Priority		Publishing	
Year	Quantity	Year	Quantity
2019	10	2016	1
2020	171	2018	3
2021	154	2019	263
2022	81	2020	121
		2021	25
		2022	3

Source: Espacenet (2023)

In figure 3 of the total number of patents, according to the IPC, 257 were classified by code A61P31 (Anti-infectives, antibiotics, antiseptics, chemotherapeutics) followed by 169 classified as A61K31 (Medicinal preparations containing organic active ingredients) and 126 patents were classified as A61K39 (Medicinal preparations containing antigens or antibodies).

Figure 3 – Patents by groups



Source: Espacenet (2023)

Regarding the classification subgroups used, table 3 shows a concentration on human needs and chemistry, which is consistent with the creation of preparations for medical purposes and therapeutic activity. Furthermore, the interaction of the main IPCs used with others related to genetic engineering and microorganisms takes place in the production of the main medicines currently used to combat Covid-19, namely: antivirals, biological immunomodulators, neutralizing antibodies, anti-inflammatories, and cell therapies. and genetics (Yuan et al., 2023).

Table 3 – Patents by subgroups

Section	Class	Subclass	Characterization	Quantity
A	61	K	Human needs and drug preparations	420
		P	Human needs, specific therapeutic action medicines	500
B	01	L	Chemistry or execution of operations, processing, or apparatus in general and laboratories	7
C	07	K	Organic chemistry and biomolecules	124
		D	Organic chemistry of heterocyclic compounds	11
	12	Q	Organic chemistry, biochemistry and handling or procedure technique	43
		N	Organic chemistry, biochemistry and handling or microorganisms and enzymes	76
G	01	N	Physical, measurements or tests for material analysis	70

\*\*Some patents have more than one CPC/IPC classification

Source: Espacenet (2023)

Considering the patents filed in Brazil, the Espacenet database returned thirty (30) patents. Given that Espacenet returns patents in the international context, when applying the filter of patents filed in Brazil, it resulted in thirty patents. Two patents in 2019, twenty-three in 2020 and five in 2021. Therefore, these patents will have their priority date based on the date of publication. In table 4 it is possible to see that among the 10 main depositors found, 50% correspond to private companies, 20% to Universities or educational institutions and 30% correspond to patents filed by independent inventors, which demonstrates the concentration of invention in environments sponsored by private capital. Regarding the IPC classification of the patents filed, these are mainly classified as human needs and preparations of medicines and human needs, medicine, specific therapeutic action.

Table 4 – Patents filed in Brazil

Year	Quantity	IPC/CPC Classification	Quantity	Depositors	Quantity	Depositors' countries	Quantity
2019	2	A61P31	25	ABIVAX	3	US	27
2020	23	A61K31	19	PHARMA MAR AS	3	CN	18
2021	5	A61K9	12	CENTRE NAT RECH	2	FR	15

		SCIENT					
	A61P11	10	CHIARA BRAMBATI	2	ES	14	
			DIASORIN ITALIA PA	2	AU	8	
			GIULIA MNNUCCI	2	DE	8	
			HARVARD COLLEGE	2	IT	8	
			INST CURIE	2	Outros	20	
			SIMONE BOCCHETTA	2			
			UNIV MONTPELLIER	2			

Fonte: *Espacenet* (2023)

Regarding the nationality of applicants in Brazil, this research identified that the United States of America leads with the filing of 27 patents, followed by Canada with 18 patents filed, France with 15 patents, Spain with 14 patents and Australia, Germany, and Italy with 8 patents each. Other countries have 20 patents filed. Inventors linked to the main institutions, the three main ones have published 3 patents each, they are Fernandez Sosa-Faro Jose Manuel, Alejandro Losada Gonzalez, Aviles Marin Pablo who each have 3 patents. There are no Brazilian inventors.

### V. Conclusion

The present study aimed to provide a situational overview of pharmacological patents for the SARS-CoV-2 virus that causes Covid-19, a highly contagious disease that in Brazil led to the death of around 705,775 people (Cavalcante, 2020). Using the data researched in the INPI and Espacenet database, it was possible to answer the research problem: What is the state of the Covid-19 Treatment and Prevention Technique?

Regarding technological activity and innovation, a considerably rapid temporal evolution of medicines and vaccines used to combat and treat Covid-19 has been observed, with the granting of 16 patents in the period from 2020 to 2021, that is, within 2 years 362 patents were filed and around 4.4% of these patents were granted. Despite the low grant percentage, the fact that all patents granted to date have had a grant period of up to 2 years stands out, which demonstrates that there is no major delay in granting considering that the average time for granting patents in pharmaceuticals area is 5.8 years.

The biotechnology protection market is dominated by North American holders who account for 52.1% of all published patents, followed by Asian holders who together obtain 39.9% of published patents. Together, they hold 92% of published patents, which demonstrates a concentration of biotechnological innovation in these regions. This concentration can also be observed in the languages used in patent documents, with English being the most used language followed by Chinese and Japanese.

Despite this, the European Office holds 57.8% of the deposits for the period researched while the American office holds 23.1% of patent deposits. In analysis of the data described above, it is understood that, despite the North American continent concentrating more than half of all published patents, its commercial interest is not limited to its own continent, with the European continent as its main market target.

In relation to the IPC, the most cited areas are areas related to human and chemical needs. The use of IPC A61P31, A61K31 and A61K39 demonstrates the concentration on the production of preparations for medical purposes and therapeutic activities, in addition to the use of genetic engineering and microorganisms. Therefore, it is understood that the focus on combating and treating Covid-19 is with the use of drugs that use the causative agent as a source in the production of medicines, namely: antivirals, biological immunomodulators, neutralizing antibodies, anti-inflammatories, and therapies cellular and genetic (Yuan et al., 2023).

Considering Brazilian patents, the database returned thirty patents. Given that Espacenet returns patents in the international context, when applying the filter of patents filed in Brazil, it resulted in thirty patents. Two patents in 2019, twenty-three in 2020 and five in 2021. Therefore, these patents will have their priority date based on the publication date.

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