



Position of the Brazilian Society of Bioethics (SBB), the Brazilian Association of Collective Health (ABRASCO), the Brazilian Center for Health Studies (CEBES) and the United Network (Rede Unida) for the not patenting of products developed to confront COVID-19

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SBB, ABRASCO, CEBES and Rede Unida, with a seat on the National Health Commission (CNS), have been working together with other public entities in the defense of health and for access to vaccines and other products against COVID-19 to all, through the Unified Health System (SUS).

With such objectives, these entities participate in *movements* such as the *Frente pela Vida* (Ahead for Life), *Vacinas para todas e todos* (Vaccines for all) and *O Brasil precisa do SUS* (Brazil needs SUS [Brazilian Unified Health System]).

The current situation of the COVID-19 pandemic is serious in almost all countries, especially in Brazil. Here, a year after the confirmation of the first death, on February 25, 2021, the unacceptable number of 250,000 people who died due to infection with SARS-CoV-2 was reached. This corresponds to 10% of deaths in the world, with Brazil having less than 3% of the world population.

Up to this moment, there is no specific scientifically proven treatment to prevent infection or to prevent the progression of the disease, with the exception of the use of dexamethasone for hospitalized patients with severe symptoms. On the other hand, science was able, in record time, to develop, test, prove the efficacy and safety, and to guarantee the authorization (for emergency or final use) of 12 vaccines against COVID-19.¹ In Brazil, two vaccines have already been authorized by the National Health Surveillance Agency (ANVISA) for emergency use, and a third has been just authorized for full use.^{2 3}

It is worth mentioning the Director General of the World Health Organization (WHO), Tedros Adhanom Ghebreyesus, at the opening of the 148th Session of the WHO Executive Council,

¹ Coronavirus Vaccine Tracker- New York Times (25/02/2021) -

<https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>

² Anvisa concede registro definitivo para a vacina da Pfizer (23/01/2021) - <https://agenciabrasil.ebc.com.br/saude/noticia/2021-02/anvisa-concede-registro-definitivo-para-vacina-da-pfizer>

³ A vacina da PFIZER já foi liberada (24/02/2021) - <https://noticias.uol.com.br/saude/ultimas-noticias/redacao/2021/02/24/registro-da-pfizer-pode-alavancar-compra-de-doses-diz-presidente-da-anvisa.htm>

on January 18, 2021,⁴ when he spoke about the ethical imperative of equal access to vaccines against COVID -19:

"I need to be blunt: the world is on the brink of a catastrophic moral failure – and the price of this failure will be paid with lives and livelihoods in the world's poorest countries."

However, the availability and effective use of vaccines so far authorized has been not only slow, but they are not equally accessible to all countries. This is confirmed by the fact that only 3% of the world population has received at least one dose,⁵ that 75% of vaccines have been administered in only 10 countries, and that 130 countries have not yet received any dose.

The COVID-19 pandemic will not be controlled without immunizing the majority of the world's population and this is clear in the WHO motto: "Nobody is safe until everyone is safe", which means that only when safe and effective vaccines are made available, at affordable prices and widely distributed, it will be possible to really confront and mitigate the unacceptable social, health and economic crises, which were accentuated by COVID-19.

Thus, equal access to vaccines worldwide will be essential and urgent. This access presupposes government leadership, social participation, quality public health, with serious and transparent funding of public health and science, under the management of each of the countries involved. On the other hand, the vaccines so far developed had a significant input of science and public funding, but are mostly produced by private pharmaceutical industry, are patented, which makes it even more difficult to effectively distribute them to all who need them.

To mitigate this situation of global inequity, WHO, CEPI (*Coalition for Epidemic Preparedness Innovations*) and GAVI (*Vaccine Alliance*) have established the *COVAX Initiative*,⁶ which can be considered the first step on the path of protecting human rights and health, with the objective of deploying vaccines to all countries. This Initiative, already with the participation of 190 countries, about 90 of them low- and middle-income countries (LMIC), aims to acquire a substantive number of vaccines for immediate distribution to at least 20% of the population of all countries. To this end, developed countries and other donors will pay for vaccines, while LMIC would receive them free of charge. The proposal has already managed to raise 6 billion dollars, but still need another 2 billion dollars to reach the planned goals for 2021.⁷

Thus,

Considering that, despite this important initial effort by the COVAX Initiative, this will not be sufficient to guarantee the necessary immunization for the remaining 80% of the population;

Considering that the cost to acquire these vaccines protected by patents will be unfeasible for most countries, since the financial value for the purchase is defined by the industry itself, and with patenting there is no possibility of producing generics at this moment;

Considering that vaccines and products developed to cope with COVID-19 are a worldwide good and, therefore, must be accessible to all;

⁴ WHO Director-General's remarks at 148th Session of the Executive Board (18/01/2021) - <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-148th-session-of-the-executive-board>

⁵ New York Times Vaccine tracker (26/02/2021) - <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html>

⁶ COVAX Initiative - <https://www.who.int/initiatives/act-accelerator/covax>

⁷ <http://www.covid-scheme-covax-delivers-first-093114383.html>

Recognizing that the DOHA Declaration (2001)⁸ allows each country to exercise the right to establish a compulsory license, although the scientific, political and operational difficulties in making this decision prevent most countries from exercising it;⁹

Considering that the Brazilian Decree 4.830/2003,¹⁰ which deals with compulsory licensing, and which regulates Law 9.279/1996,¹¹ which deals with Industrial Property, establishes in its article 2nd: "A compulsory license may be conceded, ex officio, in cases of a national emergency or public interest; for the latter, only for non-commercial public use, provided that the Public Authority has verified that the patent holder, directly or through a licensee, have not met the public needs. "

Considering a proposal under discussion at the World Trade Organization (WTO), presented by South Africa and India,¹² together with more than 100 countries, but not supported by the Brazilian Government, to suspend intellectual property rights related to products to confront COVID -19, to ensure that all countries are able to access and purchase vaccines and other related products;

Considering that in Brazil, a draft Law I under evaluation in the Federal Senate (PL-12/2021)¹³ and another proposal in the House of Representatives (PL 1320/2020)¹⁴, both with similar objectives aiming at suspending patents of products developed for the control of the Pandemic;

And lastly, and just as important, *considering* the Universal Declaration on Bioethics and Human Rights (UDBHR)¹⁵ approved in 2005, by UNESCO's 191 member countries, including Brazil, which brings as principles guiding ethical coexistence, among others, Human Dignity and Human Rights; Respect for Human Vulnerability; Equality, Justice and Equity; Solidarity and Cooperation; Social Responsibility and Health; and Benefit Sharing.

SBB, ABRASCO, CEBES and Rede Unida are fully in line with the proposed suspension of intellectual property rights under discussion at the WTO, and with the draft bills under discussion (PL 12/2021 and PL 1320/2020), and urge other entities in the sectors of Health, Law, the social area and civil society to join to demand the approval of the WTO Resolution and of the aforementioned Draft Laws.

The suspension of the intellectual property rights of vaccines and medicines for COVID-19 will contribute to the access to safe and effective vaccines, widely distributed equally, being fundamental to overcoming these terrible social, health and economic crises, aggravated by the pandemic of the COVID-19. The proposed suspensions can facilitate the reversal of the extremely slow pace of vaccination worldwide, which poses risks for the emergence of other, more infectious viral mutants, which may even impair the effectiveness of current vaccines.

⁸ WTO Declaration on the TRIPS agreement and public health - Adopted on 14 November 2001 - https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

⁹ Kavanagh, M, Sunder, M. Opinion: Poor countries may not be vaccinated until 2024. Here's how to prevent that. Washington post 10/03/2021. Acessado em : <https://www.washingtonpost.com/opinions/2021/03/10/dont-let-intellectual-property-rights-get-way-global-vaccination/>

¹⁰ Decreto 4.830, 04 setembro de 2003 - http://www.planalto.gov.br/ccivil_03/decreto/2003/D4830.htm#art1

¹¹ Lei 9.279/1996 http://www.planalto.gov.br/ccivil_03/leis/l9279.htm#:~:text=LEI%20N%C2%BA%209.279%2C%20DE%2014,obriga%C3%A7%C3%B5es%20relativos%20C%C3%A0%20propriedade%20industrial.&text=Art.&text=6%C2%BA%20Ao%20autor%20de%20inven%C3%A7%C3%A3o,nas%20condi%C3%A7%C3%B5es%20estabelecidas%20nesta%20Lei

¹² South Africa and India push for COVID-19 patents ban. Lancet 2020; 396:1790-1.

¹³ PLS 12/2021 - <https://www12.senado.leg.br/noticias/materias/2021/02/05/projeto-permite-quebra-de-patente-de-vacinas-testes-e-remedios-para-covid-19>

¹⁴ PL 1340/2021 - <https://www.camara.leg.br/propostas-legislativas/2242509>

¹⁵ UNESCO Declaração Universal de Bioética e Direitos Humanos, 2005. <http://fs.unb.br/images/Pdfs/Bioetica/DUBDH.pdf>