

“Fair and Equitable Sharing of Benefits” – also in Vaccine Development?

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Introduction

When the search for a vaccine against SARS-CoV-2 began in 2020, Latin America stood out as a central testing area for the newly developed vaccines. The reasons for this are obvious: Due to poor hygienic conditions, tight housing, and the economic impossibility of going into quarantine, there was a massive increase in the number of infections.^[i] It was exactly these infections that were needed to conduct meaningful studies.^[ii]

While the pharmaceutical companies could assume that Latin Americans would continue to become infected and thus test the efficiency of their vaccines against SARS-CoV-2, these same Latin Americans were hoping to receive a piece of the pie when they were successful. But while the companies' expectations were fulfilled, those of the people in Latin America were disappointed. Today, we are faced with the peculiar situation that a third injection of the vaccine is already being discussed in the European Union and the United States,^[iii] while in the countries that have tested the vaccine, not even 20% of the people enjoy full protection.^[iv] Even these vaccinations do not credit their European or American partners to a large extent. Most of the vaccines against SARS-CoV-2 used in Latin America instead come from Russia or China.^[v]

These developments give rise to the question of whether and in which manner preferential access to new pharmaceutical products for people in testing regions is, or at least should be, enshrined in international law. Thereby it is not about the general question of access to vaccines, since availability and accessibility of scientific progress is already guaranteed by Art. 12 (1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR).^[vi] Instead, it is a question of international distribution that arises most acutely in the phase of a pandemic when the demand for vaccines still far exceeds the supply. This issue was only very sporadically addressed prior to the SARS-CoV-2 pandemic.^[vii] However, it could gain new momentum since the countries, whose high infection rates made the development of safe vaccines against SARS-CoV-2 possible, ended up being left behind in the distribution of those same vaccines.

This article aims to shed light on two questions and to stimulate their discussion: Firstly, the question on which legal basis a preferential access for the countries concerned could be established. And secondly, the ensuing problem of who is the direct addressee of a possible obligation under international law and what could be the concrete legal consequences resulting from such an obligation.

A legal basis for preferential or equal access?

As a legal basis, human rights, especially those from the ICESCR, would first come to mind. This is in line with the idea of the Office of the United Nations High Commissioner for Human Rights (OHCHR), which published a paper entitled „Human Rights and Access to Covid-19 Vaccines“^[viii] shortly before the first vaccines against SARS-CoV-2 were approved in the EU.^[ix] The publication mainly emphasizes the responsibility of countries and companies in the context of the pandemic and presents the legal bases, such as Art. 12 ICESCR, under which all people worldwide must have access to the vaccines. The OHCHR recognizes that there is a massive distribution problem with vaccines and condemns the hoarding of them as a violation of international law. Nevertheless, not a word is said about the timeframe over which the vaccines are to be distributed.

Developed countries are asked to provide support. However, the question of the extent to which the worst-affected countries, which have contributed to the development of the vaccines, should be given preferential or at least equal access is left out. If an answer to this question cannot be found in the ICESCR, it should be examined whether general principles of international law or customary law can provide a satisfactory solution. The focus of this paper is thereby on the concept of fair and equitable sharing of benefits.^[x]

The concept of benefit-sharing is familiar to most lawyers from the field of international environmental law. There it forms one of the three pillars of the Convention on Biological Diversity (CBD),^[xi] concretized in the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.^[xii] However, the basic idea behind this concept is much older: Art. 27 (1) of the 1948 Universal Declaration of Human Rights (UDHR)^[xiii] already refers to everyone’s right to share in the benefits of scientific advancement, and Art. 2 (3) of the 1986 UN Declaration on the Right to Development stresses the States’ duty to ensure the “active, free and meaningful participation in development and in the fair distribution of the benefits resulting therefrom”.^[xiv] Furthermore, a number of international documents also make use of this as an instrument.^[xv] A prominent example is the deep-seabed mining regime of the 1982 UN Convention on the Law of the Sea (UNCLOS).^[xvi] The dissemination of this formula has led to individual academic attempts to derive a general principle according to which participation rights could be established in certain situations that are characterized especially by an imbalance of power between the parties.^[xvii] The following will focus on how this principle can be justified and whether it is applicable to vaccine distribution.

Indeed, it is not easy to construct a legally binding effect from the concept of fair and equitable sharing of benefits. While it has already been recognized as customary law in some sectors,^[xviii] the question of whether this also applies across sectors still requires further legal research.^[xix] Such work cannot be done within the scope of this brief article. However, attention should be drawn to one argument in particular: On several occasions, the UN General Assembly has given special emphasis to the concept of fair and equitable sharing of benefits.^[xx] Legal scholars have drawn from this a core of elements that are reflected also in other areas of international law.^[xxi] Therefore, at least the essence of benefit-sharing should be considered a general principle of international law.^[xxii] This could be formulated as follows: If the people of a country make a special contribution to

the development of knowledge by making their natural resources available or in some other way, they should be enabled to participate fairly and equitably in the progress if they have not been able to achieve this on their own for socio-economic reasons.

If we use this definition as a benchmark, we can see a parallel to the problem outlined at the beginning: The people of Latin America have made it possible to develop safe vaccines against SARS-CoV-2 because of their high infection rates. While European and American pharmaceutical companies brought the scientific know-how, the countries of Latin America made themselves available as a testing area. Both contributions were essential in the fight against the SARS-CoV-2. Therefore, all parties involved should benefit equally from the outcome. The way in which this could be ensured will be analyzed in the final section

Possible ways to implement the right to equitable participation

The easiest way to enforce the participation rights of local people would be to grant them an enforceable right directly against the pharmaceutical companies concerned. However, this would require recognition that companies can be direct addressees of obligations under international law. Such a legal obligation for private companies is indeed being discussed, especially in human rights protection. The prevailing view, however, still rejects this.^[xxiii] Another question worth considering is whether the massive state subsidies for vaccine development^[xxiv] might not result in companies being bound by international law. However, state support can at most lead to the attribution of the behavior of private parties to the state,^[xxv] but not to an attribution of the state's status to private parties.

The remaining option, therefore, is to hold those states responsible from which the corporations operate and which support their research. In this context, it is certainly not possible to derive concrete obligations under international law from the vague concept of "benefit-sharing", for example, to agree to the much-discussed waiver of intellectual property rights under the World Trade Organization (WTO) Agreement on Trade-related Intellectual Property Rights (TRIPS).^[xxvi] Nevertheless, it must be excluded that states block the export of vaccines against SARS-CoV-2 or hoard them to an extent that exceeds what is necessary for their population. In its application, the concept of "fair and equitable sharing of benefits" can therefore only oblige states to meet a minimum of requirements due to its vagueness. Unfortunately, we have seen that even this minimum standard was not always met during the SARS-CoV-2 pandemic.^[xxvii]

Conclusion

This paper has attempted to show that there is a generalizable principle that fair participation in jointly-created scientific progress is required under international law. This principle can be deduced from various sources of international law and applied to the distribution of vaccines against SARS-CoV-2. However, it has also been shown that, as things are standing right now, companies are not directly bound by this principle. Even states have only the obligation to observe and implement a minimum standard. These results may be unsatisfactory and it is the public debate about global vaccine distribution

that seems to call for a more concrete framework than the voluntary commitments in the Covid-19 Vaccines Global Access (COVAX) program. However, the results can also be seen as an opportunity to establish a more solid legal framework in vaccine distribution and to strengthen international collaboration in the field of health policy. Because whether we like it or not, the SARS-CoV-2 pandemic is unlikely to be the last of its

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[i] *Gurk*, Vom Hotspot zum Hoffnungsträger – Wie die Pharmaindustrie Lateinamerika zum Experimentierfeld gegen Sars-CoV-2 macht, *Süddeutsche Zeitung*, 3 August 2020, p. 2.

[ii] *Brühwiller*, Das Corona-Labor, *Frankfurter Allgemeine Zeitung*, 17 September 2020, p. 7.

[iii] While this article was being written, the so-called „booster vaccinations“ have already started in Germany, see *Geinitz/Stahnke*, Runde Drei, *Frankfurter Allgemeine Zeitung*, 21 August 2021, p. 6.

[iv] A good and updated overview is available at https://ourworldindata.org/covid-vaccinations?country=OWID_WRL (last visited 29 August 2021).

[v] *Gurk*, Profiteure der Armut, *Süddeutsche Zeitung*, 11 May 2021, p. 2.

[vi] Committee on Economic Social and Cultural Rights (CESCR), General Comment No. 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights), para. 70.

[vii] *Mira Chang*, for instance, proposed a legal standard under which people would have preferential access to pharmaceutical products tested in their country, quoted from *Beyerle*, Erst kommt der Test, dann die Moral, *MaxPlanckForschung* 1/2011, p. 34–41, 39.

[viii] OHCHR, Human Rights and Access to Covid-19 Vaccines, 17 December 2020, available at https://www.ohchr.org/Documents/Events/COVID-19_AccessVaccines_Guidance.pdf (last visited 29 August 2021).

[ix] After the OHCHR paper was published on 17 December 2020, the European Medicines Agency (EMA) announced its recommendation for approval of the first vaccine on 21 December 2020, see <https://www.ema.europa.eu/en/news/ema-recommends-first-covid-19-vaccine-authorisation-eu> (last visited 29 August 2021).

[x] This approach is not entirely new. The World Health Organization (WHO) 2011 Pandemic Influenza Preparedness Framework (PIP Framework) embodies a multilateral system for sharing samples of pandemic influenza viruses and benefits arising from it, especially the sharing of vaccines produced from research on the virus, see World Health

Organization (WHO), Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits, WHO Doc. WHA64.5, 24 May 2011.

[xi] Convention on Biological Diversity (CBD), adopted on 5 June 1992.

[xii] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, adopted on 29 October 2010; a constantly updated overview of the states that have ratified the protocol can be found at <https://www.cbd.int/abs/nagoya-protocol/signatories/> (last visited 29 August 2021).

[xiii] Universal Declaration on Human Rights, UN Doc. A/810 (1948).

[xiv] UN Declaration on the Right to Development, GA Res 41/128, 4 December 1986.

[xv] A detailed overview is provided by *Morgera*, Fair and equitable benefit-sharing: history, normative content and status in international law, BENELEX Working Paper N. 12 (April 2017; REV June 2018), p. 2 et seqq.

[xvi] United Nations Convention on the Law of the Sea (UNCLOS), adopted on 10 December 1982.

[xvii] *Morgera*, Fair and equitable benefit-sharing: history, normative content and status in international law, BENELEX Working Paper N. 12 (April 2017; REV June 2018), p. 6; *Morgera*, The Need for an International Legal Concept of Fair and Equitable Benefit Sharing, EJIL Vol. 27 No. 2 (2016), p. 253–383.

[xviii] With regard to bioprospecting, see *Pavoni*, Biodiversity and Biotechnology: Consolidation and Strains in the Emerging International Legal Regimes, in Francioni/Scovazzi (eds.), *Biotechnology and International Law*, 2006, p. 29–58, 41 et seq; with regard to the deep-seabed mining regime *Harrison*, The Sustainable Development of Mineral Resources of the International Seabed Area: The Role of the Authority in Balancing Economic Development and Environmental Protection, 2014, p. 7 et seq; for a differentiated overview, see *Morgera*, Fair and equitable benefit-sharing: history, normative content and status in international law, BENELEX Working Paper N. 12 (April 2017; REV June 2018), p. 9 et seq.

[xix] *Morgera*, The Need for an International Legal Concept of Fair and Equitable Benefit Sharing, EJIL Vol. 27 No. 2 (2016), p. 253–383, 383.

[xx] UNGA Res. 63/230, 17 March 2009, Second United Nations Decade for the Eradication of Poverty (2008–2017), para. 12; UNGA Res. 29/3281, 12 December 1974, Charter of Economic Rights and Duties of States, Art. 10.

[xxi] *Morgera*, Fair and equitable benefit-sharing: history, normative content and status in international law, BENELEX Working Paper N. 12 (April 2017; REV June 2018), p. 6 et seqq.

[xxii] *Morgera*, Fair and equitable benefit-sharing: history, normative content and status in international law, BENELEX Working Paper N. 12 (April 2017; REV June 2018), p. 10; for the difference between customary law and general principles of international law, see *Lepard*, Customary International Law – A new Theory with Practical Applications, 2010, p. 162 et seqq.

[xxiii] *Von Arnould*, Völkerrecht, 4th ed. 2019, para. 632; a good overview of the state of discussion is provided by *Herdegen*, Völkerrecht, 20th ed. 2021, § 13.

[xxiv] According to „Tagesschau“, Germany and the USA have invested by far the most money in vaccine development, available at <https://www.tagesschau.de/wirtschaft/corona-impfstoffe-investoren-101.html> (last visited 29 August 2021); therefore, critical and advocating a waiver of the World Trade Organization (WTO) Agreement on Trade-related Intellectual Property Rights (TRIPS) *Arnold*, Was öffentlich finanziert wird, sollte auch öffentlich zugänglich sein, Cicero, 1 February 2021.

[xxv] On the attribution of conduct to a state, see Chapter Two of the Draft articles on Responsibility of States for Internationally Wrongful Acts, adopted by the International Law Commission at its fifty-third session, in 2001, and accepted by the UN General Assembly (Res. 56/83 of 12 December 2001).

[xxvi] See *Arnold*, Was öffentlich finanziert wird, sollte auch öffentlich zugänglich sein, Cicero, 1 February 2021.

[xxvii] On export restrictions and vaccine hoarding, see for example <https://www.tagesschau.de/ausland/usa-exportverbot-impfstoff-101.html> (last visited 29 August 2021).