

Original Paper

Barking at the Wrong Tree: Articles 31-31bis TRIPs Revisited in Light of COVID-19 Lessons

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Abstract

The COVID-19 reality challenged the assumption underlying Articles 31-31bis of the TRIPS agreement. It illustrated that the major obstacle to access of developing countries and LDCs to medicines and/or vaccines in cases of broad-scale, global pandemics is global production capacity and distribution priorities, namely: availability, rather than price. This article examines the future implications of this understanding.

Keywords

patents, pandemics, vaccines, trade-related intellectual property rights, developing countries

1. Introduction

Patent rights ensure exclusive developers' rights for royalties on new medicines and/or vaccines. These rights encourage further research and development by helping developers reimburse their high investments. Thus, the price of new, patent-protected medicines and vaccines is high, turning them particularly inaccessible for patients in developing and least developed countries (LDCs). (Note 1)

An ethical dilemma arises when such populations encounter pandemics to which there are available but expensive, patent-protected medicines and/or vaccines.

Unfortunately, the global interest in this issue is highly motivated by the fact that globalization reinforces the risk for quick spillover of such pandemics from poor countries to the rest of the world, rather than by pure ethical and moral considerations. This risk was well illustrated during the 1990s with HIV/AIDS and during the swine flu in 2010 (Dziuba, 2010). The broad and quick global spillover of COVID-19 fully reflects the broad-scale potential of such a risk.

Article 31 of the TRIPs agreement, concluded in 1995, was drafted to balance patent developers' interests with the public right to health in such scenarios. It implies a commonly agreed understanding,

giving governments the powers to adopt measures necessary to protect public health. It is commonly understood as granting governments the authority to temporarily waive patent rights, to allow for compulsory licensing and parallel imports of medicines and/or vaccines necessary to cure global or regional pandemics (Noam, 2005).

Its short and vague drafting reflects a compromise achieved, balancing the two conflicting sets of interests (Helfer, 2003) after tough and long negotiations. It leaves open, *inter alia*, the following questions:

- Which circumstances justify the waiving of patent rights? (What should be the due balance of interests)?
- Who should have the final say regarding this decision: the state under risk or the global community?
- What are the legal and economic risks such a decision involves? Might they deter decision-makers from effectuating the waiver?
- Can medicine developers quantify the waiver's risk in advance and include it in the medicine's price?

Due to these dilemmas and others which emanated from the wording of TRIPs Article 31, in the WTO Doha Round this issue was revisited, for fine-tuning. The Doha Declaration (2001) interpreted Article 31 TRIPs, reflecting the WTO members' understanding of this issue in more detail. Consequently, Article 31bis was added to the TRIPs agreement. However, it does not deviate from the basic concept of Article 31, assuming that in the case of a broad-scale pandemic the price of medicines or vaccines would be the major obstacle to their accessibility by poor populations. It was criticized for presenting an insufficient solution for developing countries and LDCs even in that respect. (E.g., Sykes, 2002).

The COVID-19 reality challenges this assumption. It illustrates that the major drawback to accessible vaccines for developing countries and LDCs is the combination of global production capacity and distribution priorities, namely: quantity shortage, rather than price.

In the COVID-19 pandemic, governments were ready to contribute money to help developing and least developed countries. However, no government was ready to give up its priority in terms of access to the available vaccines in favor of the latter. This position was held not only for the first dose of vaccines but also for the second and third doses, persisting despite the global realization that any unvaccinated population on the globe potentially risks the entire world population, due to the spillover effect enhanced by globalization.

This reality illustrates the limits of the mechanism set forth by Articles 31-31bis TRIPs in such scenarios. It further illuminates the lack of any other global instrument to deal with this challenge in future cases of global pandemics. The article examines the implications of this fact. Section 2 briefly describes the mechanism set forth by Articles 31-31bis TRIPs. Section 3 illustrates its shortcomings, exposed by the COVID-19 pandemic, and their global implications. Section 4 examines alternative ways to overcome this lacuna. Section 5 concludes.

2. TRIPs Mechanism Securing Public Health

Noam (2005, pp. 191-192) identifies three groups of interests concerning intellectual property rights: the *first group* consists of the developed, industrialized countries, such as the United States and the European Union. The *second group* consists of the Newly Industrialized Countries-NICs, including some East Asian and Latin American countries, that do not engage in intensive research and development of new products but have technological capacities to produce products developed in countries belonging to the first group, in relatively cheap prices. Some of the *second group* countries engage in unlawful copying and distribution of patent-protected products, including medical products. These phenomena are enhanced by globalization. Such practices made first group countries accuse the former of free riding, demanding the initiation of preventive global regulation. The *third group* includes Least Developed Countries (LDCs), lacking the technological capacities to copy patent-protected products, including medical products. They thus depend on the import of such products from the first group countries, but at the same time lack the money to pay for them.

In the TRIPs negotiations, patent-protected medicines formed a major source of conflicting interests, particularly between the first group and second group countries. The agreement reflects a compromise between the first group countries, wanting to strengthen the global protection (Note 2) of their industries' patented rights, namely on their vested economic interests and investments, and the interests of the other two groups, aiming to ensure themselves access to medical products in emergency cases.

Since the latter failed to exclude medicines from the broad definition of "patentable subject matter" (TRIPs Article 27(1)), they focused their efforts on ensuring flexibility of application and patents' handling (Noam, 2005, p. 199).

The balance between the economic rights of patent owners and other public rights is reflected by the general principles in the TRIPs preamble, used for the interpretation of its operative provisions (according to the interpretative principles set forth by the Vienna Convention on the Law of Treaties, 1969, article 31(2)). As a result of developing countries' pressure, these principles explicitly acknowledge public policy considerations as underlining Intellectual Property rights policy (Gathii, 2002). Article 7 TRIPs, specifying its objectives, stresses "the balance of rights and obligations" while Article 8(1), specifying its underlining principles explicitly allows WTO member states to "adopt measures necessary to protect public health" (a demand made by the developing countries in the negotiations) "provided that such measures are consistent with the provisions of this Agreement" (a restraining demand made by the developed countries in the negotiations). In the operative part, Article 31 TRIPs authorizes the WTO member states to temporarily waive patent rights, "in the case of a national emergency or other circumstances of extreme urgency or cases of public non-commercial use." This provision has been perceived as the major instrument that would enable developing and least-developed countries' governments to obtain access to patented medicines and vaccines at affordable prices (Abbott, 2002) in cases of broad-scale pandemics, by introducing compulsory licensing and parallel imports of vaccines/medicines. The Doha Declaration reinforced this provision

by giving it a broad interpretation, later embodied in Article 31bis, allowing governments to issue compulsory licenses to obtain this purpose. (Bartelt, 2003).

3. The Shortcomings of TRIPs Arrangement COVID-19 Exposed

COVID-19, which started at the end of 2019 in China and burst on a global scale in early 2020 caused, by mid-November 2021 254,744,256 illness cases and 5,125,935 deaths globally (Worldometer, 2021). Except for these severe human life and health consequences, the pandemic implies severe economic consequences.

At the beginning of 2020, the WTO (World Trade Organization, 2020) (Note 3) assessed that the pandemic caused the severest economic crisis in the last hundred years.

After almost two years since the beginning of the pandemic, the OECD depicts signs of global economic recovery. However, its overall positive growth projection for 2021-2022 is not clean of challenges still emanating from the pandemic, such as growing inflation (Note 4) in certain countries, high unemployment rates (Note 5), and negative growth in other countries. (OECD, 2021). Handling economies in COVID times implies additional national costs to finance COVID-related measures, burdening national budgets. (International Monetary Fund, 2021).

The World Bank (Gerzon et al., 2021) assessed that during 2020 the pandemic added some 97 million extremely poor people globally. This assessment implies substantial regression in handling extreme poverty, obtained during recent decades. (Brown, 2021). (Note 6)

These data illustrate the vicious circle created by the pandemic: the escalation in their social and economic status decreases the chances of those added to the extremely poor population to obtain vaccines or medicines to avoid or recover from it. This is not only their problem: the spillover effect, enhanced by globalization, turns it into a global challenge since ill populations anywhere risk further global contamination and the development of new, more violent mutations to the virus, that might be resistible to the available vaccines, thus risking the development of new global pandemic waves.

The richer economies were willing to contribute money, directly and via international organizations, to help to pull the poor countries out of the economic crisis. Thus, for example, the IMF suggests financial assistance to members in need (International Monetary Fund, 2021a). The World Bank suggests, among other things, help in debt suspension, multilateral investment guarantee, and fast-track financial support to help sustain economies and preserve jobs during the pandemic (World Bank, 2021).

COVAX is a direct initiative held by the World Health Organization, CEPI, Gavi, and UNICEF aimed at financing vaccines for poor countries. Motivated by the understanding that ‘no one is safe unless everyone is safe’ it aims at ensuring fair and equitable access to vaccines to all countries. COVAX acts as an insurance policy: it encourages the rich countries to pool their buying power rather than compete against one another on vaccines. By accelerating the development and manufacture of COVID-19 vaccines they enable investment in factories, to enlarge the number of available doses as soon as the vaccine becomes available. Many countries contributed substantial amounts to this initiative. The

United States under President Biden changed the “America first” approach held by former President Trump, contributing 4 billion \$. The United Kingdom donated 730 million \$ and Germany-1 billion \$. Not only governments donate to COVAX, but also foundations, organizations, and corporations. Thus, for example, the Bill and Melinda Gates Foundation donated 150 million \$. (Statista, 2021). COVAX aims at using this money to obtain 2 billion vaccines by the end of 2021, to vaccinate those who are at the highest risk in poor countries. Money is thus not the problem, but rather the global shortage of vaccines. COVAX initiative illustrates the long time it takes to obtain this goal. Since no one is safe until everyone is safe, years of global health uncertainty imply severe economic consequences globally. Such initiatives also illustrate that due to the lack of a globally agreed, mandatory mechanism to meet this challenge, global initiatives rely on voluntary bases, which makes them weaker and less effective. The COVID-19 pandemic thus reflects the limits of Articles 31-31bis TRIPs, which does not suggest any solution where the major problem is the lack of enough vaccines for the entire global population, and the global capacity to produce them on short notice. This shortage causes demand gaps that in turn, may raise vaccines’ prices. Consequently, the richer countries gain priority in access to vaccines by being able to afford the price pharmaceutical companies ask for them. These companies act on pure business considerations, determined by the demand-supply ratio. To a certain extent, they may even have an incentive to keep the shortage of vaccines, to ensure that prices would not decrease, assuming that their competitors would act in the same way and that demand is stable and inflexible.

4. How to Overcome This Lacuna?

The prospect of future global pandemics necessitates drawing a lesson from the current experience, to improve the global arsenal of instruments to handle them.

This section examines several potential options.

4.1 Modification of TRIPs Articles 31-31bis?

Let alone the difficulty to make any change in the WTO agreements, emanating from the large number of its member states and their ongoing conflict of interests, stagnating the WTO (Pakpahan, N.D.), the TRIPs does not seem to be the right auspice for such provisions. The WTO agreements focus on removal of trade barriers. The TRIPs focuses on establishing minimum rules for the protection of IP rights, out of the realization that their infringement may deter players to engage in international trade. Articles 31-31bis form an exception to this rule, allowing for temporary waiving this protection in emergency cases. Extending these provisions to regulate the global allocation of vaccines would seem out of context. Thus, other solutions should be examined.

4.2 The EU Model: Equal Distribution

The European Union did not rush to conclude contracts with the pharmaceutical companies which developed COVID-19 vaccines. As a result, vaccination of its citizens started with some delay, since the vaccine producers were already committed by contracts to supply to other countries first. However, despite the public criticism on this delay (e.g., BBC, 2021), reinforced by the severe situation in some

of its member states, e.g., Italy, the EU insisted on handling and coordinating the vaccine procurement for all its members and on their equal access to the vaccines (European Union, 2021). While this model was criticized for its ineffectiveness in the short run, it seems to have ensured reasonable prices due to the strong bargaining power of all 27 members and equal distribution of the vaccine in the member states, which prevented hard feelings. This model was possible in the EU due to its unique supranational regime. It would be difficult to implement it in the global sphere without a suitable legal framework: if countries wish to engage in such an arrangement, they should build a legal mechanism that could be operated in cases of a global pandemic. Such a mechanism should refer, among other things, to the following questions: which body would be in charge of negotiations with the pharmaceutical companies for the mutual obtainment of medicines/vaccines and their equal distribution? How will it obtain competences to handle the situation for all countries involved in this arrangement? In which circumstances will it become operative? How and by whom will its action be financed?

4.3 International Regulation

International mandatory regulation, e.g., under the auspice of one of the international organizations, such as the WHO, could suggest a legal mechanism that would become operative in global emergency scenarios such as global pandemics. In such cases, the handling of negotiations with pharmaceutical companies, contracts conclusion, the decision on the vaccine/medicine price, and their equal distribution would be handled by this emergency mechanism. It could be headed by an executive body of experts, instructed by a board composed of representatives from all countries, or groups of countries with similar interests. However, such a mechanism requires a high level of cooperation and delegation of powers, characterizing a high level of market integration. Thus, it seems non-feasible in the current global reality, even in emergency cases.

4.4 International Sanctions

Imposition of international sanctions on countries that, in emergencies of global pandemics refuse to respect equitable access is another optional way to obtain this goal. It also necessitates a global legal framework that could be developed under the auspice of one of the international organizations, e.g., the WHO. This framework should define a mandatory obligation to respect the globally equal distribution of medicines/vaccines, accepted by a majority of the countries globally (otherwise, it would be ineffective). Then, it may define sanctions to be applied to countries that would not respect this rule. As an international initiative, such a legal framework would only bind countries that agree to be bound by it, unless acknowledged as customary law. Such an initiative also necessitates a high level of global cooperation and coordination, and the willingness of the strong and rich countries to engage in it, which currently seems non-feasible.

4.5 International Economic Incentives to Countries

A different, more positive approach may encourage the desirable behavior of strong and rich countries by suggesting global economic incentives to such behavior. This approach replaces the stick with a carrot. The question is what kind of economic incentive offered to countries respecting equal access to

vaccines would be strong enough to overcome the natural national tendency to protect the health of their citizens first, and national politicians' sensitivity to national pressure.

This way is particularly tricky since the countries expected to change their behavior are not the poorest, but rather the richest. These countries are not indifferent to economic incentives. However, their needs and expectations differ considerably, see e.g., the United States in comparison to China. This may imply the adoption of a different approach to each one of them, according to their economic needs. Moreover, the scale of necessary incentives may require multilateral or plurilateral cooperation.

4.6 Peer Pressure

Peer pressure is a strong soft law tool. It is successfully exercised in international organizations such as the WTO (Note 7) and the OECD. For example, at the beginning of the millennium the FATF (Doyle, 2002, Nance, 2017, Financial Action Task Force, 2021), acting under the auspice of the OECD, succeeded to motivate governments to stop allowing money laundering practices within their territories by initiating a 'black list' of states engaging in such practices. States included in this list fought hard to be excluded from it, thus changing their approach towards money launderers. Producing a black list of states which do not respect equal access to pandemic vaccines and/or medicines may change their behavior. However, this approach may work when a majority of states globally respect this principle and assume peer pressure on those which do not. It should also be reinforced by a global campaign, explaining the importance of equal access to pandemic vaccines/medicines to global health and the global economy. Such a campaign could shape a global public opinion which would affect governments' behavior. When most of the states – particularly the strong ones, dictating the global agenda - strive to get vaccines and/or medicines for their citizens first, and this national approach is globally acceptable, peer pressure will most probably not take place and even if it does – will prove ineffective.

4.7 International Ethical Code of Conduct

An alternative approach could focus on suppliers' behavior, namely the behavior of pharmaceutical companies. In recent years, consumers gain a growing power by dictating an ethical agenda in terms of the environment, labor rights, political values, etc., threatening multinationals to adhere to values of fairness in these respects or risk losing clients (Klein, 1999; Vogel, 2005; Shamir, 2007). This phenomenon has led multinationals to engage in voluntary codes of conduct which they draft (Munin, 2013). Global consumers' power could assume pressure on multinational pharmaceutical companies to stop concluding contracts for the sale of pandemic vaccines and/or medicines motivated purely by profit maximization considerations. It could require that they draft a relevant code of conduct and adhere to it. Such an initiative could either be supported by governments or not. However, it has to be broad-scaled and determined enough to change pharmaceutical companies' behavior.

Experience with other issues, such as child labor and equal employment terms for men and women shows that in many cases multinational companies draft voluntary codes of conduct and even adhere to it to a limited scale, to secure their global image, but effectively their profit consideration prevails

(Munin, 2013).

4.8 Economic Incentives to Companies

Countries may join efforts by offering economic incentives to pharmaceutical companies that would be more attractive than their potential profit from the pure profit-motivated behavior regarding the sales of pandemic vaccines/medicines. Such incentives may involve tax reliefs, subsidies, or risk management schemes such as insurance (Climate adapt, 2021), or even attractive business opportunities. However, if countries already succeed to join efforts, they could simply assume joint pressure on these companies, affecting acquisition terms of the vaccines/medicines at stake. This tactic may save them a substantial amount of money in tough times of economic crises caused by the pandemic.

Additionally, the COVID-19 experience illustrates that when there is an available vaccine or medicine to a global pandemic, strong national public pressure is assumed on governments to act as fast as possible to obtain it. Public opinion would probably not tolerate long time pressure on the pharmaceutical companies for the sake of forcing them to adopt an equal access approach to the vaccine/medicine, while people continue to die in large masses.

5. Conclusion

The COVID-19 pandemic illuminated the conflict between the personal and national instinct of self-salvation and the global inter-dependence of the entire human race. It illustrated a fact that is often easy to ignore on daily basis: no one is safe unless everyone is safe, erasing the difference between strong and weak, poor and rich to that extent. In principle, this motto is true for any behavior having a global effect, e.g., on climate change, global pollution, child abuse, unjustified discrimination, trafficking. However, in the pandemic's context, deviation from it bears immediately measurable global health and economic consequences. Yet, despite the long time that has passed since the vaccines' introduction, equal access to vaccines has not been obtained. Eventually, the production capacity of pharmaceutical companies will meet the global demand for vaccines. Medicines may be developed to cure the pandemic and it will subside. However, in the meantime, the competition between countries to get quick access to vaccines takes its substantial economic toll, in terms of higher prices for the vaccine charged by their producers and the high global price of partly functioning economies.

The only international legal instrument which is available to ensure access of poor countries to patent-protected medicines and/or vaccines: TRIPs Articles 31-31bis, proved insufficient in the COVID-19 pandemic reality.

This article examined alternative, complementing approaches to meet this challenge. It reflects the fact that unless there is true and serious mutual global political determination to join forces to cure the pandemic globally, any of these potential instruments or mechanisms would not be effective. They could all be set and used as fig leaves, allegedly showing governments or multinationals care while effectively covering an ongoing selfish and competitive behavior. In times of severe crises like the COVID-19 pandemic, when death and severe illness hit broad populations, governments face enormous

political pressure to present quick solutions. They are expected to protect the national interest first and this is what they did in the COVID-19 pandemic. This behavior reflects short-term thinking, which is typical of politics. In times of such crises, it is highly fueled by panic and anxiety. Looking at things from a longer-term perspective, though, reflects the high economic price this policy choice implies, nationally and globally: as long as the pandemic is not globally cured, no one is safe. Thus, economies continue to function partly, people all over the world lose their jobs and businesses, (Note 8) inflation grows, growth decreases. (Note 9)

Development in advance of commonly agreed effective mechanisms to meet such challenges could prevent these consequences in the future.

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Notes

Note 1. These countries are defined by the United Nations and included in a list they publish (United Nations, 2021).

Note 2. E.g., by WIPO agreements to which not all WTO members are parties.

Note 3. This forecast was moderated later (World Trade Organization 2020a). See later data on the pandemic's global effect: Statistica (2021), Maital and Barzani (2020), Chudik et al., 2020.

Note 4. According to the OECD (2021b) inflation results from a surge in demand as a result of markets reopening and supply chain tensions.

Note 5. According to the OECD (2021a) unemployment hit particularly young employees, low educated employees and employees in low-paid occupations.

Note 6. Brown refers this result to the combination of COVID-19 with the climate change problem and the “crippling debt burdens.” Tourism, a sector severely hit by the pandemic, is a major source of income for many poor countries.

Note 7. E.g., in the Dispute Settlement Body, with regard to reviewing states' implementation of dispute settlement decisions and rulings. (WTO, 2021).

Note 8. See examples to the severe economic effect of the pandemic on tourism and the economy of Macau (Lim and To, 2021), on US firms (Blum, Fletcher and Yeh, 2021), on Chinese consumption (Haiqiang, Wenlan, & Quiang, 2021).

Note 9. This description refers to the overall economic effect of the pandemic, although the fact that certain businesses and/or industries could take advantage of the crisis to grow. (E.g., Verschuur, Koks, & Hall, 2021).