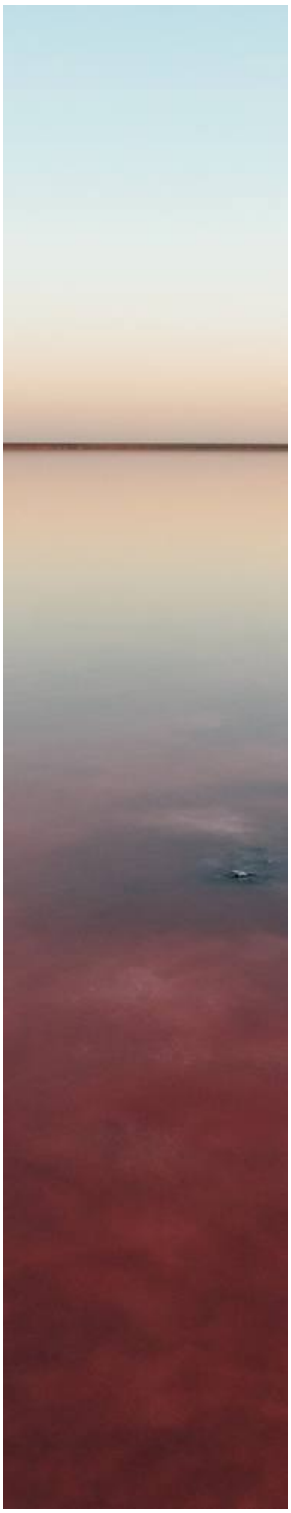


# ARTICLE

## THE WTO DECISION ON THE "LIFTING" OF PATENTS ON COVID VACCINES, IN 6 QUESTIONS

Intellectual Property, Media, and Art Law Patent Law | 08/07/22 | François Pochart Océane Millon de La Verteville

A decisive step has just been taken in the process of "lifting" the patents on vaccines against COVID-19, on which we have been publishing regularly since 2021 [1]. At the end of its twelfth session, held from 12 to 17 June 2022, the Ministerial Conference of the World Trade Organisation ("WTO") issued a decision which, in essence, authorises certain WTO members to practice a kind of "waiver" of patents as long as they are necessary for the production and supply of vaccines against COVID-19 [2].

This decision, a true world premiere in industrial property, is explained below in 6 questions and answers.

**What genesis?**

At the beginning was the communication from India and South Africa [3], tabled in October 2020 and subsequently sponsored by 60 WTO Members [4], calling for the lifting of all intellectual property rights (including patents) on all "*health products and technologies*" (including vaccines, diagnostics, treatment and medical devices) to address the Covid-19 pandemic, particularly in less affluent countries.

In December 2020, the TRIPS Council issued a report stating that the common objective of all WTO Members is to ensure access to quality, safe, effective and affordable vaccines and medicines for all [5].

In June 2021 the EU presented its own proposal which, essentially , favoured the use of compulsory licensing rather than patent lifting [6].

Discussions ensued, notably between South Africa, India, the United States and the European Union in the 'quad' restricted group [7]. It is in line with these discussions that the decision commented on here was issued by the WTO Ministerial Conference, the supreme decision-making body of the WTO which meets once every two years and brings together all WTO Members.

**A licence to use what?**

Under the decision, some WTO Members will be able to limit the rights conferred by a patent [8] by allowing the subject-matter of that patent, where it is necessary for the production and supply of COVID-19 vaccines, to be used without the consent of the patent holder. The decision specifies that the "subject-matter of a patent" includes the "ingredients and processes necessary for the manufacture of the COVID-19 vaccine" [9], but also provides that, by December 2022 at the latest, the scope of the patent may be extended "to the production and supply of diagnostic tools and treatments for COVID-19" [10].

At present, the patented elements that could be affected by this authorisation are not precisely identified in the decision, but the States concerned could rely on the "list of essential inputs for vaccines against COVID-19" published on 7 June by the WTO [11].

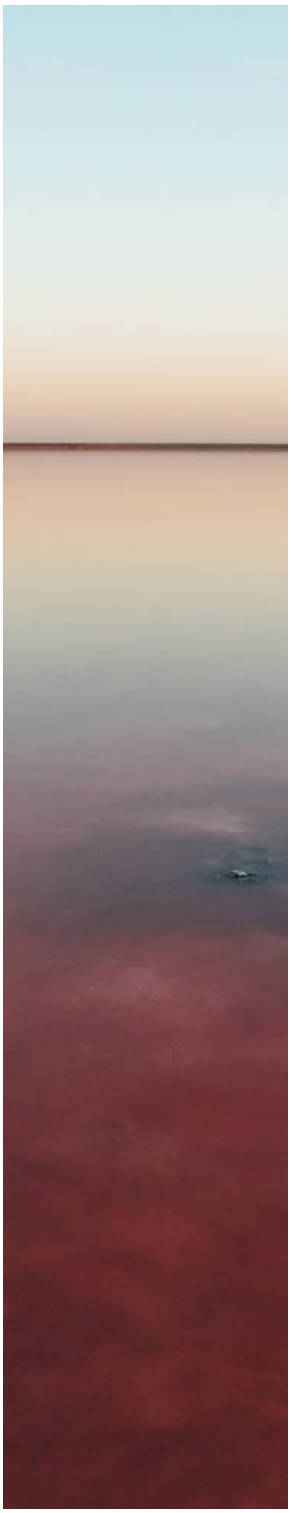
**What form of authorisation is given?**

The authorisation of use will be done through "any instrument available in the Member's legislation", an extremely broad notion which includes "executive decrees, emergency decrees and judicial or administrative decisions", regardless of whether the Member has a compulsory licensing regime in place [12].

**An authorisation given by or for whom?**

The authorisation of use can be given by an "eligible Member", an expression that designates "all developing countries Members", knowing that there is no definition of "developing countries": it refers to the Members that announce that they are part of the "developing" countries in order to benefit from the preferences in favour of these countries, the other Members being able to contest this decision [13]. More than ¾ of WTO Members declare themselves to be "developing countries " [14] among them: China, India, South Africa [15].

A small footnote strongly limites, if not negates, the eligibility of developing Members to grant such a use authorisation. The footnote states that developing countries that have, at the time of the Decision, the capacity to manufacture vaccines are encouraged to make a binding commitment not to avail themselves of the Decision [16]. This includes China, which has already formalised this commitment in May 2022 [17].



Other Members that make such a commitment will have to register with the WTO [18]. We will be watching in the coming weeks to see whether India will also make such a commitment.

**An autorisation given on what legal basis and under what conditions?**

This authorisation will be "under Article 31 of the TRIPS Agreement " [19]. The conditions set out in this article therefore apply, except those for which the WTO decision provides for derogations.

In particular, eligible Members shall not need to require that the prospective user of the subject-matter of a patent make prior efforts to obtain authorisation from the right holder as provided for in Article 31(b).

In addition, the requirement in Article 31(f) that the authorised use be primarily for the supply of the domestic market of the authorising Member may be waived: export of the vaccines produced in this way to eligible Members is thus permitted, except for those Members that, like China, would waive their right to avail themselves of the Decision. All the more reason to wonder what India's position will be on this decision.

It is further clarified that the protection of undisclosed data, including clinical trial data, provided for in Article 39.3 of the TRIPS Agreement shall not prevent an eligible Member from allowing early approval of a vaccine produced under the Decision. [20] In practice this seems to mean that the applicant for marketing authorisation for such a vaccine will not be able to invoke the *data exclusivity* protecting the reference medicinal product marketing authorisation data and will therefore have access to these data to apply for marketing authorisation in the territory of the eligible Member in question. It remains to be seen whether this will actually allow that Member to issue a rapid approval or whether other regulatory hurdles will have to be overcome, in particular on biosimilar status (assuming that local legislation contains such provisions) which will in any case have to be established. Furthermore, in any case, the mechanism does not allow access to the know-how of the development of these vaccines, let alone to the production capacity, which makes the measure ineffective.

**An authorisation given in return for what remuneration for the patent holder?**

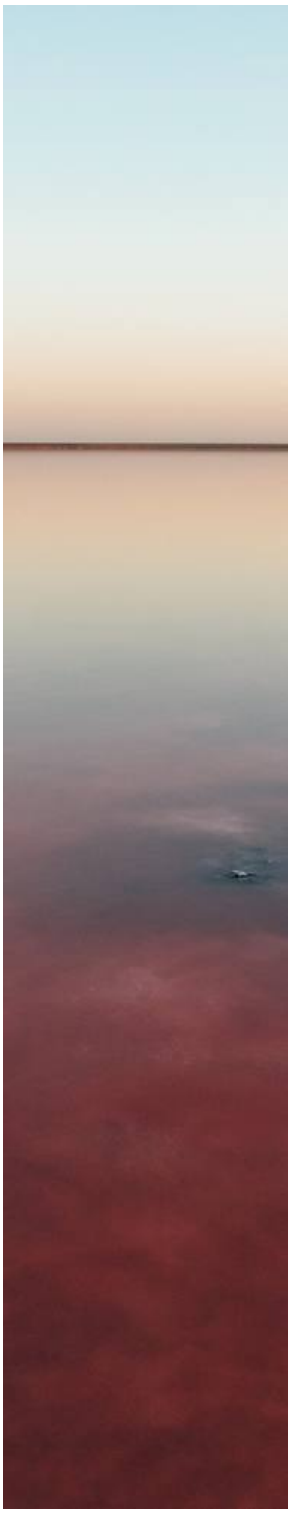
The WTO decision specifies [21] that the determination of the "adequate remuneration" of the right holder - in this case essentially pharmaceutical laboratories - may take into account the "humanitarian and non-profit purpose of specific vaccine distribution programmes". In this case, the "economic value" provided for in Article 31(h) of the TRIPS Agreement will no longer be taken into account. The determination of adequate remuneration may take into account existing good practices such as those set out in the WHO-WIPO-WTO study entitled "Promoting Access to Medical Technologies and Innovation " [22] and in the guidelines published by the WHO entitled "*Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies* " [23]. By way of comparison, the mechanism provided for at European level by Regulation 816/2006, refers to a maximum remuneration per holder equal to 4% of the total price paid by the importing country [24].

This WTO decision is far from being unanimously accepted [25]: too prejudicial to the rights of patentees for some [26], too timid for others [27]. It is a real first in industrial property law, but footnote 1 should not be forgotten. If all eligible Members with existing manufacturing capacity decide, as they are strongly urged to do, not to avail themselves of this decision, this so-called "waiver" of patents is very likely to have little impact.

After two years of negotiations, one may wonders whether it would not have been more effective to consider ways of directly providing vaccines to developing countries, for example the unused doses among the 4 billion that have been set aside by the EU [28].

[1] See in particular the interviews with F. Pochart on Radio Classique on 20/06/2022 https://www.youtube.com/watch?v=d6fwWp3Ukpk (French), in Le Point on 09/02/2021 https://www.lepoint.fr/editos-du-point/laurence-neuer/covid-19-il-n-y-a-pas-que-le-brevet-dans-la-production-de-vaccins-09-02-2021-2413123_56.php (French), on LCI on 11/03/2021 https://www.youtube.com/watch?v=3IccUSBMdfU (French) and with M. Rauline in l'Express on 05/02/2021 https://www.lexpress.fr/actualite/societe/faut-il-liberer-les-brevets-des-vaccins-anti-covid_2144207.html (French) ; see also the article by F. Pochart and L. Millot in Dalloz Actualité on 12/04/2021 "L'ineptie du débat sur les licences d'office et la levée des brevets ", https://www.dalloz-actualite.fr/node/l-ineptie-du-debat-sur-licences-d-office-et-levee-des-brevets#.YrsQ9XZBxD9 (French).

[2] decision available on the WTO website: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True



[3] communication IP/C/W/669 available here https://ipaccessmeds.southcentre.int/wp-content/uploads/2020/11/IPCW669.pdf which has been the subject of a revised version IP/C/W/669/Rev.1, available here https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True

[4] As stated on the WTO website: https://www.wto.org/english/news_e/news21_e/gc_05may21_e.htm

[5] see the commentary on this agreement on the WTO website: https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm

[6] proposal IP/C/W/681 commented in particular by the EEJC here: https://www.ceje.ch/fr/actualites/action-exterieure/2021/06/propositions-de-lue-lomc-relatives-des-mesures-commerciales-pour-faire-face-la-crise-de-la-covid-19/ (French); see also this article from Le Figaro: https://www.lefigaro.fr/conjoncture/vaccins-l-ue-ne-soutiendra-pas-une-levee-des-brevets-20210604 (French)

[7] On 3 May 2022, WTO Director General Ngozi Okonjo-Iweala presented the final document of the informal process with the Quadrilateral (South Africa, the United States, India and the European Union) to respond to COVID-19 in the area of intellectual property: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W688.pdf&Open=True commented on in https://www.francesoir.fr/societe-sante/brevets-vaccins-omc (French)

[8] Rights under Article 28:1 of the TRIPS Agreement: https://www.wto.org/english/docs_e/legal_e/trips_e.htm#part2

[9] Footnote 2 of the WTO decision

[10] §8 of the WTO decision

[11] Available here: https://www.wto.org/english/tratop_e/covid19_e/vaccine_inputs_report_jun22_e.pdf

[12] For a reminder of the compulsory licences provided for in French legislation, we refer you to our May 2020 flash available here: https://www.august-debouzy.com/en/blog/1538-compulsory-licenses-granted-by-public-authorities-an-application-in-the-covid-19-crisis-in-france and to the more detailed analysis published on Kluwer Patent Blog: http://patentblog.kluweriplaw.com/2020/04/23/compulsory-licenses-granted-by-public-authorities-an-application-in-the-covid-19-crisis-in-france-part-1/ and http://patentblog.kluweriplaw.com/2020/04/24/compulsory-licenses-granted-by-public-authorities-an-application-in-the-covid-19-crisis-in-france-part-2/

[13] See the explanations given on this subject by the WTO at https://www.wto.org/english/tratop_e/devel_e/d1who_e.htm

[14] "Least-developed countries" are designated according to a UN list.

[15] See the list of developing country groups that have formed coalitions at the WTO available here: https://www.wto.org/english/tratop_e/dda_e/negotiating_groups_e.htm#GRP002b

[16] Footnote 1 of the WTO decision

[17] See the WTO's explanation of this at https://www.wto.org/english/news_e/news22_e/gc_10may22_e.htm

[18] Footnote 1 of the decision

[19] The TRIPS Agreement is available here: https://www.wto.org/english/docs_e/legal_e/trips_e.htm#part2

[20] §4 of the WTO decision

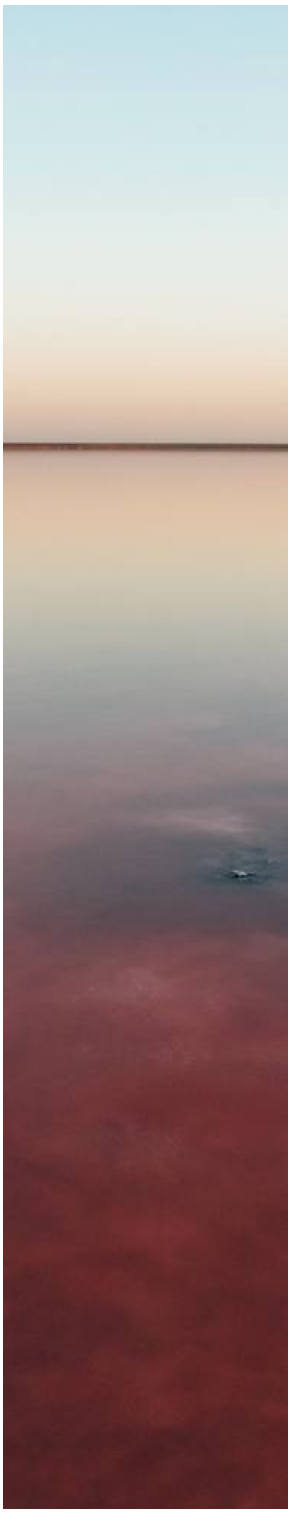
[21] §3d) of the WTO decision

[22] available here: https://www.wipo.int/publications/fr/details.jsp?id=305

[23] WHO/TCM/2005.1 available here: https://apps.who.int/iris/handle/10665/69199

[24] Regulation 816/2006/EC, Article 10§9a).

[25] See in this regard: https://www.lemonde.fr/planete/article/2022/06/17/covid-19-accord-timide-sur-la-levee-des-brevets-a-l-omc_6130857_3244.html



[26] See in this regard: https://www.lesechos.fr/industrie-services/pharmacie-sante/tolle-dans-lindustrie-pharmaceutique-apres-la-levee-des-brevets-sur-les-vaccins-covid-1414309 and https://www.ifpma.org/resource-centre/pharmaceutical-industry-expresses-deep-disappointment-with-decision-on-waiving-intellectual-property-rights-adopted-at-the-world-trade-organization-ministerial-conference/

27 https://www.amnesty.org/fr/latest/news/2022/06/covid-19-wto-ministerial-decision-on-trips-agreement-fails-to-set-rules-that-could-save-lives/; https://reliefweb.int/report/world/inability-agree-real-pandemic-intellectual-property-waiver-wto-devastating-global-failure-people-world-over

28 https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans_fr.