IMPLEMENTATION OF THE WTO MINISTERIAL DECISION ON PATENTS RELATED TO COVID-19 VACCINES IN LATIN AMERICAN COUNTRIES

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Smart IP for Latin America is an initiative of the Max Planck Institute for Innovation and Competition, a research institute of the Max Planck Society for the Advancement of Science located in Munich, Germany. The Initiative provides a neutral forum for academic and policy debate on intellectual property and competition law in Latin America.

The Initiative aims to raise awareness of the importance of effective and balanced intellectual property protection. It promotes academic and institutional cooperation within Latin America and provides support for the enforcement of intellectual property and competition law as instruments for sustainable development and economic growth. Collaboration between academia and the legislature, the judiciary, intellectual property offices, competition authorities, the private sector, and other stakeholders is essential to ensure that Latin America can reach its full social, cultural and economic potential.

1. Introduction

On 17 June 2022, the WTO General Council adopted a Decision on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[1] in the context of the COVID-19 pandemic (the Decision).[2] This Decision opens the possibility for local research and development of vaccines against COVID-19. After more than a year and a half of debate, the resulting document is a far cry from the original proposal submitted by India and South Africa for an intellectual property rights exemption.[3] The Decision introduces clarifications on the current flexibilities available regarding compulsory licensing. In addition, it presents an exemption to TRIPS Article 31(f) and the obligation to supply "predominantly" the local market from compulsory licensing. Paragraphs 2 to 6 of the Decision deal mainly with the conditions for the grant and exercise of a compulsory license for a patent.

This document is a follow-up to the *Position Statement* of 5 July 2022 of the Max Planck Institute,[4] but with a particular focus on implementation given the goal of overcoming the

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) 1869 U.N.T.S. 299, 33 I.L.M. 1197 (hereinafter TRIPS).
[2] Ministerial Conference of the World Trade Organization, Ministerial Decision on the TRIPS Agreement adopted on 17 June 2022 (22 June 2022) WT/MIN(22)/30, WT/L/1141 (hereinafter the Decision).
[3] *Waiver* from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19 virus. Communication from India and South Africa (2 October 2020) IP/C/W/669.
[4] Reto Hilty et al., Position Statement of 5 July 2022 on the Decision of the WTO Ministerial Conference on the TRIPS Agreement adopted on 17 June 2022, https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2022-07-05__2._Position_Statement_Covid_IP_Waiver.pdf.

Covid-19 pandemic in Latin America. Overall, while the Decision does not exempt intellectual property rights, it may be a mechanism to accelerate the issuance of compulsory licenses for technologies related to vaccine production that may be needed to overcome the pandemic. Also, the effect of the *clarifications* introduced by the Decision should not be limited or justified by "the exceptional circumstances of the COVID-19 pandemic".[5]

It is noteworthy that, to date, WTO Members' Decisions on the TRIPS Agreement have fallen on public health issues (Doha Declaration on TRIPS and Public Health,[6] the pharmaceutical export waiver[7] and the TRIPS amendment[8]), highlighting the tension between intellectual property rights and other public interests such as health.

2. Outreach [9]

The WTO Members' Decision is limited in scope, as it confines the possibility of use without the patent holder's authorisation to ingredients and processes necessary for manufacturing COVID-19 vaccines. In other words, treatments and diagnostics are outside the scope of the Decision. However, footnote 2 should be understood broadly to include any product or process necessary for producing and supplying finished Covid-19 vaccines.[10] The reference to "necessary" in the footnote should not be interpreted restrictively but broadly, as it refers to those products or processes that constitute the vaccine, even if substitutes exist, and are not subject to a "necessity test". [11]

It should be noted that, as far as treatments and diagnostics are concerned, WTO member countries are not limited in any way by the Decision in terms of compulsory licensing under the requirements of TRIPS Articles 31 and 31bis[12] , in addition to the exceptions available in

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[5] Ibid. 1.

[6] WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001, WT/MIN(01)/DEC/2, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm accessed 21 July 2022 accessed 21 July 2022.

[7] WTO General Council, 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' Decision adopted on 30 August 2003, https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm accessed 21 July 2022 accessed 21 July 2022.

[8] WTO General Council, 'Amendment to the TRIPS Agreement' (WT/L/641), entered into force 23 January 2017, https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm accessed 21 July 2022.

[9] For further information, see (n 4).

[10] Ibid (section 2.a))

[11] The necessity test establishes the WTO consistency of a measure on the basis of whether the measure is "necessary" to achieve certain policy objectives. These tests reflect the balance in WTO agreements between two important objectives: preserving Members' freedom to set and achieve policy objectives through measures of their own choosing, and deterring Members from adopting or maintaining measures that unduly restrict trade. Necessity tests typically strike this balance by requiring that measures that restrict trade in some way (including in violation of an agreement's obligations) are only permissible if they are "necessary" to achieve the Member's policy objective. Thus, the purpose of the "necessity test" is clear, which is why the use of one or the other component for this type of test is not included. The literal meaning of the word "necessary" is used in this context, implying a product or process critical to the production of the vaccine. See WTO Secretariat "'NECESSITY TESTS' IN THE WTO" S/WPDR/W/27, 2 December 2003, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/S/WPDR/W27.pdf&Open=True accessed on 2 August 2022.

[12] Bolivia recently tried to make use of this mechanism for the importation of COVID-19 vaccines from Canada, but was unsuccessful. See Bolivia's notification to the TRIPS Council (IP/N/9/BOL/1)

national legislation, such as experimental use and Bolar exceptions. On these technologies, the Decision indicates that Members shall decide on their inclusion within a period not exceeding six months.[13] Currently, under national legislation, Member States have the power to grant compulsory licences for therapeutics and diagnostics mainly to supply the internal market.[14]

Based on the authorisation provided for in the Decision, the competent authority and third parties interested in developing and commercialising COVID-19 vaccines may grant or apply for such a licence to the technology, including all patents relating to the products or processes that constitute them.[15]

3. Domestic implementation

The variety of instruments suggested in paragraph 2 of the Decision goes beyond legislative acts and can certainly make the use of patent flexibilities more streamlined and, in that sense, address concerns regarding national procedural complexity for the implementation of TRIPS Articles 31 and 31bis. Even in cases where the national legislation of eligible Members[16] already provides for compulsory licensing and public non-commercial use, the Decision can further reduce procedural obstacles and lack of legal certainty by adopting a more flexible instrument.

A. Uses without authorisation of the owner.

The Decision focuses on patent law, the compulsory licensing, and the public non-commercial use regime of Art. 31 of TRIPS. It should be noted that this mechanism is already available in Latin American countries under their national rules. However, in many cases, it will be necessary to establish the administrative or judicial procedures by which such uses will be granted without the right holder's authorisation.[17]

Furthermore, it must be borne in mind that an overly restrictive application of the procedural modalities set out in Art. 31(a) to (l) of TRIPS may induce the patentee to exploit his bargaining position in voluntary licensing negotiations that may harm the public interest.

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https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=s:/IP/N/9BOL1.pdf&Open=True, accessed 21 July 2022.

[13] Decision (n 2) paragraph 8.

[14] Article 31 (f) of TRIPS indicates that a Member State may not export more than 49% of the product manufactured under a compulsory licence.

[15] See United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development and UNCTAD-ICTSD Project on IPRs and Sustainable Development pp. 468;; Carlos María Correa and Abdulqawi Yusuf (eds), Intellectual Property and International Trade: The TRIPS Agreement (3rd Ed. , Wolters Kluwer 2016) p. 310.

[16] According to footnote 1 of the Decision, "all developing country members are eligible members". See (n 2)

[17] Juan Correa & Matthias Lamping, 'Implementation of the Flexibilities of the Patent System in Selected Latin American Countries', https://sipla.ip.mpg.de/en/publications/details/implementacion-de-las-flexibilidades-del-sistema-de-patentes-en-paises-seleccionados-de-latinoamerica.html. 2021. Pp. 87-137.

Therefore, procedural requirements must be calibrated to avoid undue burden on the licence applicant.[18]

B. *Remuneration to the incumbent.*

While the Decision does not provide for an exemption of the remuneration requirement, it refers to *the humanitarian and non-profit purpose of specific vaccine distribution programmes aimed at providing equitable access to COVID-19 vaccines* as factors to be considered in determining the *appropriate remuneration* to patent holders. The *humanitarian and non-profit purpose* criterion appears to be more appropriate and specific than the *economic value to the importing State* under Articles 31(h) and 31*bis* (2) of TRIPS.

The Decision cements the possibility for WTO member states to consider this factor when calculating the form and amount of the royalty. However, the document directly references in footnote 4 two studies to estimate the royalty[19].

In particular, the tiered royalty method (TRM) proposed by the World Health Organisation (WHO) determines a global base royalty adjusted for different countries. This method does not take the generic price as a basis but the price of the patented product in the high-income country. The percentage used as a base is 4% of the price in the high-income country, and adjustments can be made for variables such as relative per capita income, relative income per person with the disease, or the disease burden of the country, especially for countries with high disease burdens[20]. This calculation method has already been used in compulsory licensing in Ecuador[21].

In the case of remuneration to the rightsholder for use of the Decision, the royalty calculation must consider the humanitarian and non-profit purpose which may lead to a reduction in the remuneration initially envisaged.

C. *Effect of the decision on WTO Members*

The clarifications and the waiver of the Decision affect all WTO members. Although their application is not mandatory, no Member can take action against a country that chooses to use the Decision. In this sense, the possibility, and the admissibility, of variations in the application of the TRIPS provisions are expressly recognised in Article 1.1 of the Agreement: "*Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their legal system and practice*".[22] However, they remain subject to limits, as this provision

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[18] Declaration on Patent Protection. Regulatory Sovereignty under TRIPS (15 April 2014), para. 33. https://www.ip.mpg.de/de/forschung/meldungen-aus-der-forschung/declaration-on-patent-protection.html, accessed 6 July 2022.

[19] Decision (n 2) footnote 4.

[20] World Health Organization. Remuneration Guidelines for non-voluntary use of a Patent on Medical Technologies. Health Economics and drugs TCM Series N18. James Love. (World Health Organization, 2015). <https://apps.who.int/iris/bitstream/handle/10665/69199/WHO_TCM_2005.1_eng.pdf?sequence=1&isAllowed=y> accessed 30 September 2022.

[21] Salud y Fármacos, *Ecuador issues its first compulsory licence for HIV/AIDS,* 2011. < https://www.saludyfarmacos.org/boletin-farmacos/boletines/feb2011/ecuador-emite-su-primera-licencia/> accessed 30 September 2022.

[22] (n 1)

only allows for options regarding the "method of implementation", but not the substantive or enforcement standard.

In conjunction with Art. 1.1, Member States may implement the TRIPS Agreement in a balanced manner between the public interest and the exclusive rights of right holders (as reaffirmed in Art. 7 and 8 of the Agreement). This was clarified by the WTO Panel in *Canada - Patent Protection of Pharmaceutical Products*[23] and in *Australia - Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*,[24] which confirmed Members' space to implement their public health policies and the interpretative value of the Doha Declaration.

The freedom for different interpretations derives from general expressions or ambiguities in the Agreement's text resulting from compromises reached in the negotiation. The scope for different variations can also derive from the absence of definitions.

However, the implementation may violate a WTO rule that may affect or threaten the legally protected interests of one or more - but not all - Members. As a general rule, the WTO dispute settlement system is open to Members whose trade has been adversely affected, in actual or potential terms, by violation of their obligations. Article 3(8) of the Dispute Settlement Understanding introduces a presumption that violations of WTO obligations cause nullification or impairment of Members' benefits. The defendant can challenge this presumption and if the challenge is successful, adjudication is prevented.[25] Given that some flexibilities are controversial in academic and international fora, it is advisable that as many Latin American countries as possible implement the flexibilities provided for in the Decision in their national legislation as a matter of public policy. This would contribute to strengthening the interpretation in favour of the flexibilities. Consequently, it would reduce the likelihood of certain WTO members being exposed to complaints - and eventually trade retaliation - by other members for having implemented them.

D. Relationship with free trade and investment agreements

The Decision only prevents another Member State from taking action in the multilateral framework. To avoid legal action by individuals, national implementation through mechanisms to ensure the regulation's legality is necessary. At the same time, consideration should be given to speeding up regulatory processes to ensure that manufacturers and potential investors have as much time as possible to research and develop COVID-19 vaccines. A law seeking to implement the Decision may take too long to produce and distribute these products. That said, paragraph 2 of the Decision[26] allows for the use of any mechanism for national implementation according to the law of WTO members.

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[23] Canada - Patent Protection of Pharmaceutical Products - Complaint by the European Communities and their Member States - Report of the Panel WT /DS114/R para 7.92 <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm#> accessed 1 November 2021.
[24] WTO Panel Decision *Australia - Tobacco Plain Packaging*, paras. 7.2404 and 7.2411.
[25] See *EC - Regime for the Importation, Sale and Distribution of Bananas*, WTO Appellate Body, WT/DS27/AB/R.
[26] Decision (n 2) paragraph 2.

Another point of tension is the relationship between the implementation of the Decision and the Free Trade Agreements (FTAs) or Bilateral Investment Treaties signed by Latin American countries.

In their intellectual property chapters, several FTAs signed by Latin American countries introduce provisions that seek to admit the possibility for a state to make use of legal mechanisms to safeguard public health. In some cases, specific provisions on exemptions were introduced in the texts of these agreements.[27] Thus, third parties and member states have no legal claim to be recognised in the dispute settlement mechanisms established in these agreements in case of adopting these flexibilities.[28]

For any claims under international treaties, in addition to the safeguards already discussed (such as Articles 7 and 8 of TRIPS and the public health clauses of Free Trade Agreements), Member States may also apply ordinary international law concerning state responsibility.[29] These defences should be raised to exclude the unlawfulness of their domestic measures implementing the Decision concerning their international intellectual property and investment commitments. In particular, it would be possible to argue that acceptance of the Decision by WTO Members would be sufficient to provide consent that excludes the wrongfulness of any acts introduced by legislative amendments to national patent law.[30]

4. Exhaustion of rights

If the invention within the scope of the Decision is the subject of a patent in an Eligible Member wishing to import it, the grant of a compulsory licence under Article 31 of TRIPS combined with paragraphs 2 and 3 of the WTO Ministerial Decision at the national level may be appropriate. In this case, this licence should cover importation as a permitted use of the invention.

However, it is questionable whether the importation of products containing this invention is possible even without issuing a compulsory licence in the importing country.

This may be possible if the patent holder's rights are exhausted in this country. Although exhaustion of rights is not defined in the TRIPS Agreement, this term usually refers to the loss of rights of the patent holder on the use of a product containing the patented invention

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[27] See United States Trade Representative (USTR), US-Colombia FTA, Ch (16), Art. 16.10, https://ustr.gov/sites/default/files/col-ipr.pdf, accessed 21 July 2022; USTR, Trade Agreement between the US and Peru, Ch (16), Art. 16.10, https://ustr.gov/sites/default/files/uploads/Countries%20Regions/africa/agreements/pdfs/FTAs/peru/16%20IPR%20Legal.June%2007.pdf accessed 21 July 2022.

[28] See FTA between the European Union, Colombia and Peru, Arts. 196-197 https://trade.ec.europa.eu/doclib/docs/2011/march/tradoc_147704.pdf accessed 21 July 2022; FTA between the European Community and Chile, Art. 91 https://eur-lex.europa.eu/resource.html?uri=cellar:f83a503c-fa20-4b3a-9535-f1074175eaf0.0004.02/DOC_2&format=PDF accessed 21 July 2022.

[29] See South Centre, Grosse Ruse-Khan, Henning and Paddeu, Federica, A TRIPS-COVID Waiver and Overlapping Commitments to Protect Intellectual Property Rights Under International IP and Investment Agreements (January 27, 2022), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4082915.

[30] See articles on Responsibility of States for Internationally Wrongful Acts, annexed to UNGA Res 56/83. "For the commentary of the UN International Law Commission (ILC), see Commentary to the Articles on Responsibility of States for Internationally Wrongful Acts, (2001) Yearbook of the ILC, vol II(2), UN Doc A/CN.4/SER.A/2001/Add.1.

when this product is legitimately introduced on the market for the first time.[31] From that moment on, those who acquired the specific product can, in principle, market it freely.

If a country adopts the *international* level of exhaustion of patent rights, this loss of rights will occur upon the introduction of the product in any market in the world. In this case, importation of the product (so-called parallel importation[32]) will be allowed. Therefore, it would not be necessary to apply the mechanism of the Decision to allow the importation of COVID-19 vaccines.

However, this alternative to compulsory licensing could be undermined in two different cases.

Firstly, the legislation of the importing country may dictate that exhaustion only occurs at the *national* or *regional* level.[33] In such cases, only the introduction of the product on the domestic market of a country or the market of a particular region is relevant for the exhaustion of rights. Placing the product in another country would not give rise to such exhaustion. Consequently, importation without the consent of the patent holder would not be possible without a legal amendment.

Secondly, even if the international level of exhaustion is chosen, national law may dictate that parallel importation is only possible after the product is introduced on the international market by the patent holder or *with his consent.*[34] Thus, the introduction of a product on the foreign market by third parties through a compulsory licence - and thus without the consent of the patent holder - could prevent such importation.

In fact, it is true that the TRIPS Agreement expressly refrains from any regulation regarding the exhaustion of rights.[35] Although the issue is controversial,[36] much of the specialised doctrine recognises that the consent of any person authorised to introduce the product on the international market - such as the beneficiary of a voluntary or compulsory licence - may be sufficient to exhaust the respective patent rights.[37]

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[31] Keßler, Florian, Article 6 - Exhaustion, in: Stoll, Peter-Tobias/Busche, Jan/Arend, Katrin (eds.), WTO - The Trade-Related Aspects of Intellectual Property Rights, Leiden/Boston 2009, p. 170; Correa, Carlos M./Correa, Juan I., Parallel imports and the principle of exhaustion of rights in Latin America, in: Calboli, Irene/Lee, Edward (eds.), Intellectual Property Exhaustion and Parallel Imports, Cheltenham 2016, p. 198.

[32] This term implies that the right holder himself can import the product into the country in question at the same time as a third party does so. However, it is also used in the case where there is no importation by the duty holder. In this case, importation by a third party is sufficient to characterise parallel importation.

[33] Correa, Carlos M., Trade-Related Aspects of Intellectual Property Rights - A Commentary on the TRIPS Agreement, 2nd Ed., Oxford 2020, p. 71 f.

[34] See Correa/Correa, op. cit., p. 201 f. and 215 f., who gives examples of regulations in Latin American countries.

[35] Art. 6 TRIPS. "(...) no use shall be made of any provision of this Agreement in respect of with the issue of exhaustion of intellectual property rights". See also paragraph 5 (d) of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health of 20.11.2001. WT/MIN(01)/DEC/2.

[36] For a different view, see e.g. Kessler, op.cit., p. 176 f.; Höhne, Focke, Artikel 6 - Erschöpfung, in: Busche, Jan/Stoll, Peter-Tobias/Wiebe, Andreas (eds.),TRIPs - Internationales und europäisches Recht des geistigen Eigentums, 2nd Ed., Cologne 2013, Art. 6 Recital 2.

[37] See Hilty, Reto M./Lamping, Matthias, Declaration on Patent Protection - Regulatory Sovereignty under TRIPS, Max Planck Institute for Innovation and Competition, Munich 2016, Recital 18; Gervais, Daniel. The TRIPS Agreement - Drafting History and Analysis, 4th Ed, UK 2012. Art. 6 Recital 2.101; Correa, op. cit., p. 77 f.

This is because the patent owner, regardless of whether the product is marketed by himself, by a voluntary licensee or by a compulsory licensee, usually still receives due compensation for the invention's use.[38] In addition, the wording of Art. 31 (f) TRIPS ("predominantly") allows for the export of part of the products obtained under a compulsory license. Their full realisation can be achieved, inter alia, by parallel importation of these products into other countries.[39]

However, to be applicable, this flexibility must be implemented in national legislation.[40] If the exhaustion of rights arising from introducing a product on the market through a compulsory licence is not recognised, the importation of the product will not be possible without the patent holder's consent or a corresponding legal amendment.

Given these potential legal obstacles, it is questionable whether the WTO Ministerial Decision could be directly applicable to Eligible Members to allow the importation of products falling within its scope, even without compulsory licensing and irrespective of domestic duty exhaustion rules. This may be *prima facie* doubtful, as the text of the Decision does not oblige Eligible Members to use these flexibilities but grants them an option to do so. Further research, including on the background and objectives of the Declaration, as well as its relationship to other instruments of international law, is recommended to address this still open issue.

In any case, given the legal uncertainty of this alternative, developing countries would do well to make appropriate use of compulsory licensing and/or expressly apply the flexibilities in international law on parallel imports to import the products necessary for the production and supply of Covid-19 vaccines.

5. Undisclosed information for marketing approval of COVID-19 vaccines

According to the fourth paragraph of the Decision, it is understood that Article 39.3 of TRIPS does not prohibit Eligible Members from approving COVID-19 vaccines on an expedited basis.[41] It should be recalled that Article 39.3 provides that WTO Members, when commercially approving a pharmaceutical or agricultural product, shall protect undisclosed information against unfair competition, which does not create exclusive rights. The Agreement is complied with if unfair competition law is applied to protect such data.

This was also endorsed by the Doha Ministerial Conference, where it was affirmed that TRIPS Article 39.3 "does not require that 'exclusive rights' be granted to the owner of the data" and that "it does allow a competent national authority to rely on the data in its possession to assess a second and subsequent application for the same medicine, as this would not imply any 'unfair commercial use". In other words, nothing in the TRIPS Agreement can be interpreted as an exclusive right to data necessary for the commercial

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[38] See Govaere, Inge, The Use and Abuse of Intellectual Property Rights in E.C. Law, London 1996, p. 80. Law, London 1996, p. 80; Correa, op. cit., p. 77.
[39] See Gervais, op. cit., Art. 6 Recital 2.101; Malbon, Justin/Lawson, Charles/Davison, Mark, The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights - A Commentary, Art. 6 Recital 6.41; Correa, op. cit., p. 78.
[40] Malbon/Lawson/Davison, op. cit., Art. 6 Recital 6.13; Correa, op. cit., p. 79.
[41] See (n 2) Section 4.

approval of pharmaceutical or agricultural products.[42] It should be recalled that the relationship between the TRIPS Agreement and the Doha Declaration was analysed in *Australia - Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging* case, which concluded that the Doha Declaration "confirms the manner in which 'each provision' of the Agreement is to be interpreted and is therefore specific".[43]

Although the TRIPS Agreement does not require test data to be protected by exclusive rights, these were subsequently incorporated through FTAs. In Latin America, several countries have included data exclusivity through these treaties. In most cases, it is established that data protection will be for five years from the date of trade approval.

Under the Decision, the protection of test data through exclusive rights may hinder the immediate approval of COVID-19 vaccines. In legislation that protects such data merely against unfair competition, nothing prohibits the use of available data to approve new vaccines, provided that all aspects required by health authorities concerning the approval of products of biological origin are fulfilled.

In the case of Latin America, it is possible to discern three possible scenarios regarding the relationship between the Decision and test data protection. The first is where national rules protect test data through the unfair competition regime. The second, is where there is protection of test data through an exclusive right, but there are safeguards in the rules for its use by the state. Finally, the third, is where test data are protected through exclusive rights, but there are no safeguards.

In the first case, the Decision would apply directly without the need to amend or introduce new rules in domestic law, as the protection would be only against unfair competition and TRIPS Article 39.3 indicates that the disclosure would be for the safety of the public.

In the second case, the relevant FTA commitments could interfere with a WTO Member's ability to allow another person to obtain marketing approval for COVID-19 vaccines. However, domestic implementation of the bilateral commitment in Latin American countries has introduced exemptions to data exclusivity, which can be invoked to ensure that the regulatory authority can proceed with the registration of a generic product produced or imported under a compulsory licence.[44] In addition, safeguards available in some FTAs,

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[42] Article 39.1 of the TRIPS Agreement provides an essential contextual element and only requires protection against unfair trade practices, which does not imply exclusive rights. In WTO jurisprudence, the United States brought a case against Argentina: "in the event that Argentine law is inconsistent with Article 39.3.... Argentina agrees to submit to the National Congress an amendment to Argentine law within one year to conform to its obligations under Article 39.3". See *Argentina - Certain Measures on the Protection of Patents and Test Data.* WT/DS196. https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds171_e.htm accessed 25 July 2022.

[43] WTO Appellate Body. *Australia - Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging.* WT/DS435/AB/R WT/DS441/AB/R, para. 7.2410. https://www.wto.org/english/tratop_e/dispu_e/435_441abr_e.pdf accessed 25 July 2022.

[44] See Chile Law 19.039. Establishes rules applicable to industrial privileges and protection of industrial property rights, articles 89-91. < https://www.bcn.cl/leychile/navegar?idNorma=30406> accessed 21 July 2022; Colombia, Decreto 2085, *por el cual se reglamentan aspectos relacionados con la información suministrada. to obtain sanitary registration for new chemical entities in the area of medicines. < http://www.med-informatica.com/CIDMED-BIS-data/Decreto2085de2002.htm>*

which provide for cases where test data protection can be waived, can be used.[45] In these cases, the rules of both FTAs and domestic law do not interfere with the application of the Decision.

Finally, the third scenario is the most complex for the countries of the region, as the law resulting from FTAs or national rules directly interferes with the implementation of the Decision. In these cases, the introduction of a temporary clause in the legislation or the application of international law justifications should be considered,[46] in particular, the state of necessity.[47] This concept exempts the state from liability in cases where it is threatened by a grave and imminent peril and another subject of law has only minor interest, the infringement of which is the only way to protect the essential interest of the state.

6. *Conclusion*

The WTO General Council Decision is a step towards implementing the flexibilities available in TRIPS. The agreement reached by WTO members ensures that the production of vaccines to combat the COVID-19 pandemic will not be held back by international patent law. However, the mechanisms by which it will be implemented at the national level have yet to be developed.[48]

This paper has addressed some difficulties Latin American countries may face in implementing the Decision. These difficulties relate, for example, to how the Decision is implemented domestically, the possibility of parallel imports and the protection of test data. On this basis, possible policy and legal options for effective national implementation of the Decision were identified. It should be recalled that the Marrakesh Agreement provides that the adoption of a Decision providing for clarifications or exemptions to any of the WTO Agreements shall be by consensus, which implies acceptance by the parties. According to this argument, there should be no dispute in the implementation of the Decision by the Member States.[49]

As for the possibility of claims by private parties in member countries whose rights may be affected by the implementation of the Decision, the various national and multilateral safeguards provide sufficient support for the implementation of a national policy.

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[45] See FTA between the United States and Colombia, in force since 2012, Chapter 16 - Intellectual Property. <http://www.sice.oas.org/Trade/COL_USA_TPA_e/Index_e.asp> accessed 21 July 2022. FTA between the United States and Peru, in force since 2009, Chapter 16 - Intellectual Property. <http://www.sice.oas.org/trade/per_usa/per_usa_e/index_e.asp> accessed 21 July 2022.

[46] Fn (n 31) article 25.

[47] See Fn (n 30).

[48] See (n 4) Section 5

[49] Marrakesh Agreement Establishing the World Trade Organization, Art. IX - Adoption of Decisions, 15 April 1994, 1867 U.N.T.S. 154.