



## Position Statement of 5 July 2022 on the Decision of the WTO Ministerial Conference on the TRIPS Agreement adopted on 17 June 2022

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### 1. Introduction

After nearly one and a half years of heated debate concerning the proposal to waive IP protection ‘in relation to prevention, containment or treatment of COVID-19’<sup>1</sup> which was submitted to the Council for Trade-Related Aspects of Intellectual Property Rights of the WTO, the WTO Ministerial Conference has issued its decision.<sup>2</sup> The Decision neither mentions the original or amended<sup>3</sup> Proposal; nor has it adopted any of the proposed provisions. While the Decision refers to ‘clarifications and waiver’, it does not in fact waive any intellectual property (IP) rights as such under the TRIPS Agreement.<sup>4</sup> Instead, the Decision for the most part **clarifies the application of the existing TRIPS flexibilities** that inhibit the exclusive effect of patent rights.

This Position Statement, which is a follow-up on the Institute’s Position Statement of 7 May 2021,<sup>5</sup> reflects on the scope of the Decision and its legal and practical implications in view of the ultimate goal of overcoming the COVID-19 pandemic. Overall, it is argued that, to the

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<sup>1</sup> Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19. Communication from India and South Africa (2 October 2020) IP/C/W/669 (hereinafter the Proposal).

<sup>2</sup> 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).

<sup>3</sup> Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19. Revised decision text (25 May 2021) IP/C/W/669/Rev.1.

<sup>4</sup> 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 Agreement).

<sup>5</sup> Reto M. Hilty et al., Covid-19 and the Role of Intellectual Property. Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021, [https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021\\_05\\_25\\_Position\\_statement\\_Covid\\_IP\\_waiver.pdf](https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_25_Position_statement_Covid_IP_waiver.pdf), accessed 5 July 2022 (hereinafter MPI Position Statement).



extent that the Decision can make the application of TRIPS flexibilities more expedient, it is to be welcomed. At the same time, the effect of the clarifications and waiver introduced by the Decision **should not be limited to, or justified by, ‘the exceptional circumstances of the COVID-19 pandemic’**<sup>6</sup> – instead, they should be viewed as part of a general effort to improve and facilitate the national implementation of TRIPS flexibilities in the public interest, especially public health protection.<sup>7</sup>

## 2. The scope of the Decision

The application of the Decision is limited in several aspects.

### a) The focus on patents

Unlike the initial Proposal for an IP waiver, the Decision focuses on the scope and exercise of rights under Article 28(1) TRIPS. As far as patent protection is concerned, the Decision addresses instances where the exercise of patent rights may be limited, i.e. where the protected subject matter may be used without the authorisation of the right holder. The subject matter potentially falling within the scope of the Decision is defined to ‘include [...] ingredients and processes necessary for the manufacture of the COVID-19 vaccine’.<sup>8</sup> The reference to ‘ingredients’ and the ‘necessity’ factor raise further questions. A vaccine comprises active and non-active ingredients, but the vaccine manufacturing process involves other components such as purification filters and cell culture media. If the intention was to limit the scope to vaccine ingredients, the non-exhaustive list introduced by the term ‘including’ contradicts this intention. In case of doubt, the wording should not be interpreted narrowly, i.e. as limiting the eligible subject matter to vaccine ingredients as such. In principle, it would be reasonable for the Decision to **cover any product or process** required for the production and supply of Covid-19 vaccines, given that the safeguards of the economic interests of patent holders, including the compensation requirement, are still preserved (see below at 2(d) and (e)).

The ‘necessity’ clause is potentially problematic as it raises the question of how ‘necessity’ should be assessed or proved. Whereas there is no established ‘necessity test’ adopted specifically in relation to the TRIPS Agreement (in particular, regarding Article 8(1) TRIPS), the WTO Appellate Body has previously held that the assessment of necessity ‘involves in every case a process of weighing and balancing a series of factors’.<sup>9</sup> While the Decision does not provide guidance on how necessity should be established, the principle of proportionality and the urgency of circumstances should be guiding principles for the national authorities when defining the burden and standard of proof to be assumed by an applicant for a compulsory licence.

### b) The limitation to Covid-19 vaccines

The application of the Decision is restricted to the production and supply of Covid-19 vaccines. It is envisaged that, within six months from the date of this Decision, ‘Members will decide on

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<sup>6</sup> Decision (n 2) preamble (emphasis added).

<sup>7</sup> Declaration on Patent Protection. Regulatory Sovereignty under TRIPS (15 April 2014), <https://www.ip.mpg.de/de/forschung/meldungen-aus-der-forschung/declaration-on-patent-protection.html>, accessed 6 July 2022.

<sup>8</sup> Decision (n 2) footnote 2.

<sup>9</sup> *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef (Korea – Beef)*, Appellate Body Report (11 December 2000) WT/DS161/AB/R, para 164.



its extension to cover the production and supply of COVID-19 diagnostics and therapeutics'.<sup>10</sup> The motivation behind this limitation and postponement is unclear – it is currently more critical to ensure access to therapeutics and diagnostics than to vaccines.<sup>11</sup> If the overall goal is to overcome the pandemic and its effects on people's health and, towards that end, to facilitate the operation of TRIPS flexibilities, there is no reason why the same measures should not apply to other medicinal products with indications related to COVID-19. Understandably, patent holders might be concerned that the Decision's provisions might be misused, given that many treatments used for COVID-19 also have other therapeutic indications. However, mitigating such concerns is a matter of enforcing the purpose limitation – as such, these concerns cannot justify a decision not to apply **the same level of TRIPS flexibilities** to COVID-19 therapeutics and diagnostics. At the same time, it should be noted that nothing prevents countries from using the compulsory licensing mechanism provided under Articles 31 and 31*bis* TRIPS for the production and export of therapeutics and diagnostics. The Decision affirms that it is 'without prejudice to the flexibilities that Members have under the TRIPS Agreement, including flexibilities affirmed in the Doha Declaration on the TRIPS Agreement and Public Health' and their interpretation.<sup>12</sup>

#### c) The eligible WTO Members

The eligibility to make use of the Decision is restricted to **developing countries**. This applies to the exportation of vaccines manufactured in accordance with the Decision,<sup>13</sup> which is nevertheless a notable extension compared to Article 31(f) TRIPS (see below at 2(c)). At the same time, developing countries with the 'capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision'.<sup>14</sup> As specified, '[s]uch binding commitments include statements made by eligible Members to the General Council, such as those made at the General Council meeting on 10 May 2022, and will be recorded by the Council for TRIPS and will be compiled and published publicly on the WTO website'.<sup>15</sup> Reportedly, this limitation targeted China, as the only country that accounts for more than ten per cent of global export of COVID-19 vaccine doses, while the rationale for such 'encouragement' was to protect domestic manufacturing of vaccines in other developing countries.<sup>16</sup> Such a voluntary but binding commitment appears questionable. First, it restricts the options that developing countries with limited or no manufacturing capacity might otherwise have. Second, it is doubtful whether the urgent circumstances of the pandemic are the right time for this kind of protectionism. In a situation of a public health crisis, it would be **unreasonable** for a country with low production capacity to pursue the development of a

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<sup>10</sup> Decision (n 2) para 8.

<sup>11</sup> Philip C. Robinson et al., COVID-19 Therapeutics: Challenges and directions for the future (6 April 2022) 119(5) PNAS, doi: 10.1073/pnas.2119893111; Unmet Need for COVID-19 Therapies in Community Settings (2021) 21(11) Lancet Infect Dis., doi: 10.1016/S1473-3099(21)00633-2.

<sup>12</sup> Decision (n 2) para 9.

<sup>13</sup> *ibid* para 3(b).

<sup>14</sup> *ibid* para 1, footnote 1.

<sup>15</sup> *ibid*.

<sup>16</sup> Bryan Mercurio, Sharpening the Tools in the Pandemic-Ending Toolbox (*Think Global Health*, 23 June 2022), <https://www.thinkglobalhealth.org/article/sharpening-tools-pandemic-ending-toolbox>, accessed 29 June 2022. See also Ministerial Conference of the World Trade Organization, Draft Ministerial Decision. Communication from the Chair of the Council for TRIPS (10 June 2022) WT/MIN(22)/W/15, footnote 1 (stating in brackets: 'For the purpose of this Decision, developing country Members who exported more than 10 percent of world exports of COVID-19 vaccine doses in 2021 are not eligible Members').



vaccine, instead of importing it directly, immediately and at a lower cost.

d) The term of application

The period during which the eligible WTO Members can avail themselves of the Decision's provisions is limited to five years.<sup>17</sup> The question might arise whether the applicability of the Decision's provisions might terminate earlier than that. The object clause and the purpose limitation under paragraph 1 of the Decision suggest that the Decision applies 'to the extent necessary to address the COVID-19 pandemic'. Should such need dissipate, it would arguably not be lawful to continue relying on the Decision. Yet, the question arises as to how the threshold for such 'necessity' should be defined, given that it is unlikely that the virus will go away in the foreseeable future.<sup>18</sup> Arguably, this remains for the General Council to decide based on the annual review of the operation of the Decision.

A more critical issue is whether the term limitation applies to the Decision's provisions, which are framed as 'clarifications'. Notably, the Decision often invokes its particular circumstances, such as the necessity to address the COVID-19 pandemic in the chapeau (para 1), the references to 'the purpose of this Decision' (para 2) and 'the importance of the timely availability of and access to COVID-19 vaccines' (para 4). Such references might be interpreted as restrictive clauses. In principle, however, clarifications of the TRIPS provisions **should not be bound to the specific circumstances of COVID-19** and, therefore, limited in duration.

### 3. The legal consequences of the Decision

**None** of the provisions of the Decision – including the one formulated as a 'waiver'<sup>19</sup> – has a **binding effect**. While most of the provisions are framed as 'clarifications' of Article 31 TRIPS, they do nevertheless have significance as a guidance to interpretation which should not be downplayed.

a) Any instrument would do

Importantly, Paragraph 2 of the Decision addresses the issue that surfaced following the COVID-19 outbreak: Many countries did not have in place a streamlined procedure for granting a compulsory licence or allowing government use for public health protection. It is welcome that the Ministerial Conference addresses the underlying concerns by stating that no special law is required to make use of the limitations envisaged under Article 31 TRIPS. Notably, the Decision emphasises that the provision is introduced 'for greater clarity', as if it was not clear enough. Paragraph 2 of the Decision suggests a variety of instruments that can undoubtedly make the exercise of patent limitations **more expedient**. These instruments, which go beyond legislative acts, address concerns regarding procedural cumbersomeness associated with the implementation of Articles 31 and 31*bis* TRIPS. Thus, even where the national law of the

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<sup>17</sup> Decision (n 2) para 6.

<sup>18</sup> Iqbal Pittalwala, *Are We Stuck with COVID-19 Forever?* (*University of California*, 25 February 2021), <https://www.universityofcalifornia.edu/news/are-we-stuck-covid-19-forever>, accessed 29 June 2022; Michael Greshko, *COVID-19 Will Likely Be With Us Forever. Here's How We'll Live With It* (*National Geographic*, 22 January 2021), <https://www.nationalgeographic.com/science/article/covid-19-will-likely-be-with-us-forever-heres-how-well-live-with-it>, accessed 29 June 2022.

<sup>19</sup> That is, para 3(b) of the Decision, the only provision in which the verb 'waive' is used.



eligible Members already provides for compulsory licensing and government use, the Decision can further relax procedural hurdles by adopting a more flexible instrument.

Paragraphs 2 to 6 of the Decision mainly clarify the conditions for granting and exercising a compulsory licence for a patent.

b) Prior negotiations with the patent holder

The Decision states that eligible Members ‘need not require the proposed user of the subject matter of a patent to make efforts to obtain an authorization from the right holder as set out in Article 31(b) [TRIPS]’.<sup>20</sup> It is worth emphasising that under the said Article it was already possible to forego this requirement ‘in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use’. Paragraph 3(a) of the Decision thus can be read as recognition that the COVID-19 pandemic **qualifies for such a case**.<sup>21</sup>

c) No limitation on the production quantity for export

The Decision provides for the possibility to waive the requirement under Article 31(f) TRIPS according to which the exercise of a patent compulsory licence for a patent shall be limited ‘predominantly’ to the supply of the domestic market.<sup>22</sup> Departing from this limitation, paragraph 3(b) of the Decision allows countries to export **the entirety of vaccines** manufactured under the authorisation in accordance with the Decision. This is the only substantive difference that the Decision makes relative to what the TRIPS Agreement already provides. Furthermore, the Decision does not prevent the simultaneous export through international initiatives such as COVAX. Nor does the Decision limit exportation to the eligible Members with no or insufficient manufacturing capacity, unlike Article 31*bis* TRIPS.<sup>23</sup> As a side note, it is worth highlighting that Article 31*bis* TRIPS has not worked in practice, in part due to procedural challenges and the lack of economic incentives.

d) Safeguards regarding vaccine re-exportation

Paragraph 3(c) of the Decision aims to prevent the re-exportation of vaccines manufactured and imported under the Decision. It imposes a double obligation: on the one hand, the eligible Members are required to ‘undertake all reasonable efforts’ to prevent such re-exportation; on the other hand, all WTO Members are required to ‘ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products manufactured under the authorization in accordance with this Decision, and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement’. In other words, non-eligible Members are not intended to benefit from the Decision. The provision reads as a **safeguard for patent holders’ interests** and draws on the elements of 31*bis* TRIPS concerning re-exportation of products manufactured under a compulsory licence, as also clarified under the Annex to the TRIPS Agreement.<sup>24</sup>

An exception is envisaged for exceptional circumstances where an eligible Member may re-export COVID-19 vaccines to another eligible Member ‘for humanitarian and not-for-profit purposes’, subject to the duty to communicate this to the Council according to paragraph 5 of

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<sup>20</sup> Decision (n 2) para 3(a).

<sup>21</sup> For this argument, see MPI Position Statement (n 5) 4.

<sup>22</sup> Decision (n 2) para 3(b).

<sup>23</sup> As stipulated under para 2(a)(ii) of the Annex to the TRIPS Agreement.

<sup>24</sup> In particular, paras 3-4 of the Annex to the TRIPS Agreement.



the Decision.<sup>25</sup> Such exception might be motivated by recent experiences of unused vaccine doses being discarded.<sup>26</sup>

Lastly, it should be noted that the relation of the Decision to parallel importation is not addressed by the Decision and remains subject to interpretation and implementation by eligible Members.

e) Determination of ‘adequate remuneration’

The Decision does not provide for a possibility to waive the remuneration requirement<sup>27</sup> but refers to ‘the **humanitarian and not-for-profit purpose** of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines’ as factors to be taken into account when determining the ‘adequate remuneration’ to patent holders. The benchmark of ‘the humanitarian and not-for-profit purpose’ appears to be more suitable and specific compared to the criterion of ‘the economic value to the importing state’ under Articles 31(h) and 31*bis*(2) TRIPS. In this regard, one could argue that the Decision should go beyond ‘may take into account’ and require that such considerations ‘shall be taken into account’. However, as one of the guidance documents referenced in footnote 4 of the Decision points out, ‘the humanitarian and non-commercial reasons’ that prompted the 2003 waiver of Article 31(f) TRIPS have already played a role in royalty calculation for exporting medicinal products Article 31*bis* TRIPS.<sup>28</sup>

f) The communication requirement

Motivated by transparency considerations, the Decision requires eligible Members to ‘communicate to the Council for TRIPS any measure related to the implementation of this Decision, including the granting of an authorization’.<sup>29</sup> The duty applies flexibly and can be fulfilled ex-post – thus, the implementation of a measure by the eligible Member is **not conditioned** on whether the measure is communicated ex-ante. It is also welcome that the communication requirement does not presuppose the assessment of the legitimacy of a measure, which is in line with the notification duty under 31*bis* TRIPS.<sup>30</sup>

#### 4. The reference to Article 39(3) TRIPS

Paragraph 4 of the Decision states that given ‘the importance of the timely availability of and access to COVID-19 vaccines, it is understood that Article 39.3 of the [TRIPS] Agreement does not prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccine produced under this Decision’. This clarification<sup>31</sup> seems to address the often raised concerns that the protection obligation under Article 39(3) TRIPS can render a compulsory licence or government use of patents futile if it is implemented in a way that can prevent the expedited regulatory authorisation of the respective medicinal products. In this regard, it is

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<sup>25</sup> Decision (n 2) footnote 3.

<sup>26</sup> Below (n 35) and the accompanying text.

<sup>27</sup> Decision (n 2) para 3(d).

<sup>28</sup> James Love, Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies (2005) WHO/TCM/2005.1, 36-37 (referring to the Canadian legislation).

<sup>29</sup> Decision (n 2) para 5.

<sup>30</sup> Annex to the TRIPS Agreement, para 2(c), footnote 8 (stating that ‘this notification does not need to be approved by a WTO body in order to use the system’).

<sup>31</sup> That the provision is a clarification follows from its wording. See also above (n 19) and the accompanying text.



rather unfortunate that the provision is framed by references to ‘the importance of the timely availability of and access to COVID-19 vaccines’ and, in particular, to COVID-19 vaccines ‘produced under this Decision’. Such references might be interpreted as restrictive clauses and suggest that, in other circumstances, Article 39(3) TRIPS ought to be interpreted and applied otherwise.

It should be emphasised that the TRIPS Agreement does not prohibit the WTO Member States from implementing public health flexibilities with regard to Article 39(3) TRIPS. In principle, the implementation of the protection obligation under Article 39(3) TRIPS – irrespective of whether it is implemented at the national level in the form of market or data exclusivity or unfair competition – should be aligned with the limitations on patent rights where such limitations concern medicinal products and pursue the objective of public health protection. The Ministerial Conference could have used the opportunity to confirm this **general principle** and should not have limited the clarification in paragraph 4 to COVID-19 vaccines.

The legal and practical effects of paragraph 4 of the Decision will depend on the regulatory framework for the marketing authorisation of medicinal products of the eligible Member concerned. In jurisdictions where Article 39(3) TRIPS was implemented in the form of data exclusivity, there are reasons why it might not be advisable or even possible to completely rely on test data submitted to regulatory authorities by vaccine originators. In contrast to small-molecule drugs, biological molecules are more complex and, hence, prone to variations. Biosimilar medicinal products need to undergo certain testing before the risk-benefit balance can be demonstrated with certainty.<sup>32</sup>

## 5. Potential impact on overcoming Covid-19 and the legislative outlook

The reference to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the WTO suggests that the Decision was ‘arrived at by consensus’. However, the document is silent on the purpose it aims to achieve and, in particular, on the reasons for not accepting the original Proposal for an IP waiver. From the beginning of COVID-19, factual problems related to the availability of raw materials, manufacturing capacity and supply chains constituted the main hurdles for vaccine manufacturing and distribution.<sup>33</sup> With time, it has become even more evident that factors not related to IP, including the lack of political commitment and vaccine hesitancy,<sup>34</sup> have been slowing down the attainment of vaccine herd immunity. Staying silent on the reasons underlying the Decision, as the outcome of the closed-door negotiations, exposes the WTO to criticism for promoting the interests of IP holders at the expense of broader public interests.

Even though the Decision does not explicitly state its goals, the object clause in paragraph 1 suggests that the non-binding provisions apply to the extent necessary to overcome the COVID-19 pandemic. Its ultimate impact on mitigating the pandemic, however, remains to be seen but can be expected to be minuscule. It is somewhat ironic that the long-awaited Decision of the WTO comes at a time when we are witnessing a global ‘massive oversupply’<sup>35</sup> of COVID-19

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<sup>32</sup> For this argument, see also MPI Position Statement (n 5) 2-3.

<sup>33</sup> *ibid* 1-2.

<sup>34</sup> World Health Organization, COVID-19 Vaccines, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines>, accessed 29 June 2022.

<sup>35</sup> Tom Braithwaite, We Are Drowning in Vaccine (*Financial Times*, 22 April 2022), <https://www.ft.com/content/dc35dfc0-94a2-440b-a880-91ba2e39c256>, accessed 29 June 2022 (reporting that



vaccines, with millions of doses being discarded. More pertinently, measures are needed to ensure sufficient supply and equitable distribution of **therapeutics and diagnostics**.

In sum, even though the Decision, by and large, preserves the legal status quo, it can be viewed as a step toward the improvement of the framework of patent flexibilities. In the EU, ‘the need to ensure that effective systems for issuing compulsory licenses are in place’<sup>36</sup> is addressed by an ongoing policy initiative.<sup>37</sup> A well-functioning compulsory licence regime would be a more balanced and organic approach than an IP waiver to address the risk of the blocking effects of patent rights.<sup>38</sup> In this regard, the effect of the Decision should not be limited specifically to ‘the exceptional circumstances of the COVID-19 pandemic’<sup>39</sup> – rather, the Decision should further facilitate the national implementation of TRIPS flexibilities to protect public interests.<sup>40</sup> This would allow the WTO and regional and national legislators to avoid the need to react to future challenges in an ad hoc manner.

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Moderna ‘has recently had to discard tens of millions of doses that had been earmarked for the African Union and the WHO-backed Covax programme but were then rejected’). See also Josh Wingrove, James Paton and Antony Sguazzin, Untapped Global Vaccine Stash Raises Risks of New Covid Variants (*Bloomberg*, 11 May 2022), <https://www.bloomberg.com/news/articles/2022-05-11/untapped-global-vaccine-stash-raises-risks-of-new-covid-variants>, accessed 30 June 2022 (‘The world finds itself awash in Covid-19 vaccines, but governments can’t get them into arms fast enough, as hesitancy and logistical hurdles threaten to indefinitely extend the pandemic.’).

<sup>36</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Making the most of the EU’s innovative potential – An intellectual property action plan to support the EU’s recovery and resilience COM/2020/760 final (25 November 2020), p. 12. See also European Parliament resolution of 11 November 2021 on an intellectual property action plan to support the EU’s recovery and resilience (2021/2007(INI)), para 50 (calling on the European Commission ‘to analyse and explore possible options for ensuring effectiveness and better coordination of compulsory licensing in the EU’).

<sup>37</sup> Intellectual Property – Revised Framework for Compulsory Licensing of Patents, [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13357-Intellectual-property-revised-framework-for-compulsory-licensing-of-patents\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13357-Intellectual-property-revised-framework-for-compulsory-licensing-of-patents_en), accessed 30 June 2022.

<sup>38</sup> MPI Position Statement (n 5) 4.

<sup>39</sup> Decision (n 2) preamble.

<sup>40</sup> Declaration on Patent Protection (n 7).