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CONSTRAINTS FACED BY DEVELOPING COUNTRIES AND LEAST DEVELOPED COUNTRIES (LDCS) IN MAKING FULL USE OF PATENT FLEXIBILITIES AND THEIR IMPACTS ON ACCESS TO AFFORDABLE ESPECIALLY ESSENTIAL MEDICINES FOR PUBLIC HEALTH PURPOSES IN THOSE COUNTRIES (UPDATE OF DOCUMENT SCP/26/5)

Document prepared by the Secretariat

INTRODUCTION

1. At its thirty-fifth session, held in Geneva from October 16 to 20, 2023, the Standing Committee on the Law of Patents (SCP) agreed that the Secretariat would update document SCP/26/5 (Constraints Faced by Developing Countries and LDCs in Making Full Use of Patent Flexibilities and their Impact on the Access to Affordable Especially Essential Medicines for Public Health Purposes in those Countries), based on the information received from Member States, in view of their experiences relating to the COVID-19 pandemic (see document SCP/35/10, paragraph 30, second bullet point under “Patents and Health”).

2. Accordingly, the Secretariat invited Member States to submit relevant inputs to the International Bureau, through Circular Note C. 9199, dated December 7, 2023. Given the limited number of submissions received in response to this Circular from the Member States,[1] the Secretariat utilized information made available from various SCP activities and consulted publicly available literature to obtain supplementary material on the topic.[2] Based on those sources, the Secretariat prepared this updated document for discussion at the thirty-sixth session of the SCP.

1 The submissions are published at: https://www.wipo.int/scp/en/meetings/session_36/comments_received.html.
2 However, this document is not intended to provide an exhaustive literature survey on the topic.

3. Regarding the existing literature on flexibilities, numerous publications discuss their meaning, scope, and offer general recommendations for effective utilization. These works often emphasize the importance of flexibilities in promoting access to medicines, including COVID-19-related technologies, particularly in developing countries and least developed countries (LDCs). However, they often do not specifically address the constraints to making full use of them, and the consequent impact of such constraints on access to medicines.

4. In line with the agreed scope of this study, this updated document does not engage in such general discussions on the importance of the flexibilities. Instead, it primarily focuses on the constraints to their use and their impacts on access to affordable, essential medicines for public health purposes in developing countries and LDCs. It is also important to note that, given this scope, the document does not aim to discuss solutions or measures to overcome these challenges. In the same line, the paper does not provide an analysis of legal obligations created by the international agreements regarding patents; nor does it enumerate the specific options available for national/regional implementation of these international agreements, or examine how each specific option impacts access to affordable medicines. However, the thorough analysis of these issues can be found elsewhere.[3]

TERMINOLOGIES

Patent flexibilities

5. International treaties provide various options for governments to implement them through an appropriate method of implementation under their applicable laws, responding to distinct domestic needs and evolving national policy priorities. Therefore, regarding intellectual property international treaties, Member States of WIPO have enjoyed a considerable degree of flexibility in the national implementation of those treaties.[4]

6. While this fundamental concept of the implementation of multilateral treaties has been accepted for some time, the term “flexibility” has been more commonly used since the adoption of the TRIPS Agreement. That term is expressly contained in paragraph 6 of the Preamble and Article 66.1 of the TRIPS Agreement, in the context of the needs of the LDC Members to implement the Agreement and to create a viable technological base, but the underlying concept is apparent in other TRIPS provisions that provide policy space to WTO Members to implement and apply the Agreement in a manner that is responsive to domestic policy needs.[5] It was through the negotiations leading to the Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) that the expression “flexibilities” had gained widespread use in the broader sense, and following the conclusion of the negotiations, that term became part of the glossary of the IP community.[6]

7. The Doha Declaration in paragraph 4 confirmed that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” and that it “can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all”. It further states that the Members reaffirmed their “right to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”. The choice of the word “reaffirm” in the

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3 See, e.g., Andrew D. Mitchell et al., ‘Intellectual Property and Vaccine Manufacturing: Utilizing Existing TRIPS Agreement Flexibilities for COVID-19 and Other Public Health Crises’, Tulane Journal of Technology and Intellectual Property, V.25, 2023; Andrew D Mitchell and Antony Taubman ‘Practical means of applying the TRIPS Agreement’s flexibilities to spur vaccine production’, Asia-Pacific Research and Training Network on Trade, ARTNeT Working Paper Series, No.225. 2023.

4 http://www.wipo.int/ip-development/en/agenda/flexibilities/meaning_of_flexibilities.html.

5 For instance, Articles 1.1 and 8.1 of the TRIPS Agreement.

6 Carolyn Deere, *The Implementation Game*, Oxford University Press, 2009, p. 27.

Declaration clarifies that this right was not a concept that has been newly introduced by the Doha Declaration in 2001, but was already integral to the TRIPS Agreement.

8. The Doha Declaration, in paragraph 5, clarifies that these flexibilities include:

> "a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
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> b. Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
>
> c. Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
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> d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4."

9. Despite repeated references to "flexibilities" in the policy debate after the adoption of the Doha Declaration, no instrument has formally defined the exact meaning of this term.[7]

10. However, guided by paragraphs 4 and 5 of the Doha Declaration, it may be possible to arrive to the understanding that:

> (i) the TRIPS flexibility refers to the right of WTO Members to exploit various options and legal tools when implementing the TRIPS Agreement at the national level, so that both national interests, including protection of public health, are accommodated and TRIPS provisions are also complied with;[8]
>
> (ii) each WTO Member, whether it is a developed, developing or LDC, has such right;
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> (iii) the right of the WTO Members to "use, to the full, the provisions of the TRIPS Agreement" covers the TRIPS Agreement as a whole, as paragraph 5(a) of the Doha Declaration refers to the interpretation of "each provision" of the TRIPS Agreement, in the light of the object and purpose of the Agreement;
>
> (iv) the flexibilities enumerated in paragraph 5 of the Doha Declaration are non-exhaustive.

11. On the basis of the above understanding, and particularly of the examples set out in paragraph 5 of the Doha Declaration, the TRIPS flexibilities may be grouped as follows:

> (i) the application of the customary rules of interpretation of public international law, in particular, reading each provision of the TRIPS Agreement in the light of its objective and purpose (for example, interpretation of Article 30 with respect to exceptions to patent rights etc.);

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7 For the discussion on the concept of flexibilities, see the second edition of WHO, WIPO, and WTO Study, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, (hereafter 'the Trilateral Study') 2020, pp. 90 and 94, available at: https://www.wipo.int/edocs/pubdocs/en/wipo_pub_628_2020.pdf.

8 Document CDIP/5/4 Rev.; Carolyn Deere, *The Implementation Game*, Oxford University Press, 2009, p. 68.

(ii) each Member's discretion in interpreting and applying explicit but undefined terms in the TRIPS Agreement in line with the general rules of treaty interpretation as applied in WTO dispute settlement practice (for example, interpretation of the terms, such as "national emergency or other circumstances of extreme urgency", "inventions", "novelty", "inventive step" etc.);

(iii) each Member's freedom to decide whether and how to implement explicit options (permissive provisions) in the TRIPS Agreement (for example, rules for the grant of compulsory licenses, establishment of exhaustion regime, inclusion/non-inclusion of the best mode requirement, excluding/not excluding plants from patentable subject matter etc.); and

(iv) each Member's freedom to determine matters on which the TRIPS Agreement is silent, for example, the grounds for compulsory licenses or procedural aspects related to patent prosecution which are not included in the TRIPS Agreement. They may include patent examination procedures, opposition procedures beyond what is explicitly required under Article 62 of the TRIPS Agreement, the structure of the office, the distribution of competences among the staff and mandatory representation.

12. The term "patent flexibilities", in contrast to the term "TRIPS flexibilities", is used in this study to relate to the right of Member States to use options and legal tools made available in various international agreements when implementing their patent-related provisions at the national level. However, generally speaking, flexibilities in international agreements are not limited to those in the TRIPS Agreement and WIPO-administered treaties, but also include flexibilities with respect to patents provided under bilateral, regional and plurilateral agreements.[9]

13. In some instances, the term "flexibilities" has been utilized in the literature and in statements made by various delegations during WIPO meetings to convey a different concept from the one discussed above. From that point of view, the term "flexibilities" not only refers to the right and freedom of Member States to implement, within their national laws, certain options available in international agreements, but also to the actual use of a specific provision or requirement established within national patent law, such as compulsory licenses, exhaustion, the regulatory review exception (so-called Bolar exception), etc. For example, a statement "no flexibility has been used in country X" could actually mean, "no compulsory license has been issued in country X" or "no third party has used a patented invention for the purposes of obtaining regulatory approval before the expiration of the patent", despite these options being available under country X's patent law. Thus, it should be highlighted that the way this term is utilized affects the understanding of the term "full use of flexibilities".

Full use of patent flexibilities[10]

14. As stated in the Doha Declaration, Member States exercise their right to choose options made available in international treaties to meet their domestic policy objectives. First, a government makes choices from the various options and second, implements those choices under the national legislation, i.e., generally the national law which may be supplemented by

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9 Document SCP/20/13, paragraph 104.

10 While the Doha Declaration and some Recommendations adopted by Member States of the UN organizations (for example, A/HRC/32/6 and A/RES/65/1) refer to the "*use* to the full *of the TRIPS provisions*" providing flexibilities, some other internationally agreed texts (for example, WHA/56/27, WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, Element 5.2(a) and A/RES/65/277) refer to the "*use* to the full *of flexibilities*" contained in the TRIPS Agreement (emphasis in *italics* added). Since those texts and recommendations were adopted by largely the same group of countries in the same context of protecting public health, it is presumed that they are interchangeable expressions.

other legal instruments, such as Regulations, Ministerial Decrees, Instructions, Guidelines, etc. At the operational level, public administration fulfils the legal obligations under the national law: for example, patent offices conduct examination on formality and/or substantive examination, decide on patent grant or refusal and publish patent applications and/or patents, while the judiciary interprets the enacted law provisions and reviews the administrative decisions. Public authorities also support stakeholders as well as the general public through, for example, provision of information and public awareness raising, so that the operation of national law would meet the intended public policy objectives. Such use of patent flexibilities from the government's perspective is also referred to in the Resolutions adopted by the Human Rights Council[11], by the World Health Assembly (WHA)[12] and by the UN General Assembly[13] as well as the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. Furthermore, the United Nations Sustainable Development Goals (SDGs), the 2030 Agenda for Sustainable Development refers to the right of developing countries to use to the full the provisions in the TRIPS Agreement regarding flexibilities.[14] More recently, WTO Ministerial Declaration on the WTO Response to the Covid-19 Pandemic and Preparedness for Future Pandemics also reaffirms that Members have the right to use, to the full, the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health including in future pandemics.[15]

15. Once the government transposes options in the international agreements to the national level, various individual stakeholders use the national legal framework. At this stage, there is public expectation that adequate use of the national legal framework by each stakeholder would lead to the attainment of the public policy goals, such as public health and access to medicines.

16. In general, government policy pursues various public policy goals and chooses policy options. For example, in the area of public health, as stated in the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, the use of flexibilities that would permit improved access to health products needs to be considered in conjunction with its impact on innovation.[16] Furthermore, any flexibility in international treaties needs to be considered for action by national authorities in the light of the circumstances in their countries.[17] In that respect, there is no one-size-fits-all in the use of flexibilities by each government.

17. Consequently, the full use of patent flexibilities could be looked at in the light of the optimal choice from the national implementation options available to the government concerned to pursue its policy goals. Therefore, presumably, Member States fully use the flexibilities in different ways - each taking into account its own circumstances, assessing and applying the available options in diverse ways, resulting indifferent outcomes in national patent laws.[18]

CONSTRAINTS TO THE FULL USE OF PATENT FLEXIBILITIES BY DEVELOPING COUNTRIES AND LDCs

General observations

18. Based on the above outlined understanding of the full use of flexibilities, constraints to the full use of flexibilities by developing countries and LDCs would mean the difficulties for their

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11 For example, A/HRC/RES/12/24, A/HRC/RES/15/12 and A/HRC/RES/17/14.

12 For example, WHA/56.27, WHA/57.14, WHA/59.26 and WHA/60.30.

13 A/RES/65/1 and A/RES/65/277. See also A/RES/78/3 (paragraph 37).

14 A/RES/70/1, SDG 3.

15 WTO Ministerial Declaration can be found at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/31.pdf&Open=True.

16 WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, Element 6, paragraph 36.

17 *Ibid.*

18 See, for example, responses to the SCP Questionnaire on Exceptions and Limitations to Patent Rights: http://www.wipo.int/scp/en/exceptions/.

governments to exercise their right to choose an optimal national implementation option that would support their policy objectives and at the same time, being in compliance with international agreements to which they are party. These difficulties may also include legal and administrative challenges that governments face in their national implementation.

19. At the national level, each individual stakeholder might face constraints in using the national legal framework, resulting from the government's implementation of international agreements. These challenges have been highlighted by some SCP participants during some sessions of the SCP. As the constraints faced by stakeholders are of a different character than those faced by the governments in implementing international agreements, this study will examine them separately.

20. The current international legal framework on patents is a web of multilateral treaties and bilateral/plurilateral/regional agreements containing provisions on patents. All WTO Members are parties to at least one trade agreement.[19] Many of them include intellectual property provisions, ranging in character from general and broad to precise and detailed. Furthermore, many countries are members of a regional agreement establishing a regional patent system that provides regional patent standards and granting procedures. With such multiple layers of bilateral/regional/plurilateral/multilateral agreements in place today, transposition of international agreements into domestic law has become far more complex than at the time when the Paris Convention was the only international treaty covering industrial property.

21. On the one hand, since countries are free to provide more extensive protection than the minimum standards set by the TRIPS Agreement, provided that such protection does not contravene the TRIPS provisions, making a decision to conclude a trade or regional agreement that goes beyond the TRIPS minimum standard could be considered as a mere exercise of their sovereign right to choose an option as they deem fit. On the other hand, as in any negotiation, parties negotiating trade agreements might have asymmetrical negotiation power[20] which may result in, for example, reducing the scope of available flexibilities. During the SCP, one non-governmental organization reiterated its concern on free trade agreements (FTAs), which include obligatory provisions that are not found in the TRIPS Agreement and in its view, are against the public interest.[21] In relation to public health, the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property suggests that governments take into account the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the TRIPS Agreement (Element 5.2(b)), as well as in trade agreements the flexibilities contained in the TRIPS Agreement, including those recognized by the Doha Declaration and the WTO decision of August 30, 2003 (Element 5.2(c)). To address concerns that FTA standards could negatively affect public health by limiting the flexibilities available under the TRIPS Agreement and other instruments, many FTAs contain a reaffirmation of the Doha Declaration on TRIPS and Public Health in their IP chapter.[22] In general, assessing the impact of specific chapters of FTAs in an isolated manner might disregard the overall architecture of the FTAs. In practice, governments'

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19 https://www.wto.org/english/tratop_e/region_e/region_e.htm.

20 While the study does not examine the reasons for power asymmetries, according to Drahos, the bargaining power in the context of trade negotiations has four basic sources: (i) state's market power; (ii) state's commercial intelligence networks (networks that gather, distribute and analyze information relating to a state's trade, economic and business performance as well as similar information about other states; (iii) enrolment power (capacity of state to enroll other actors in a coalition) and (iv) state's domestic institutions. See Drahos, P*. When the Weak Bargain with the Strong: Negotiations in the World Trade Organization, International Negotiation, 2003, 8 (1), 79–109.* Available at: http://ssrn.com/abstract=418480.

21 Statements made by the Third World Network (TWN) at the 13th, 14th and 22nd sessions of the SCP (see documents SCP/13/8, paragraph 115, SCP/14/10, paragraph 108 and SCP/22/7, paragraphs 67 and 123, respectively). The similar views are found in: South Centre http://www.unsgaccessmeds.org/inbox/2016/2/26/south-centre?rq=flexibilit; and Sisule F. Musungu and Cecila Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?,* Commission on Intellectual Property Rights, Innovation and Public Health, WHO, August 2005.

22 The Trilateral Study, 2020, p. 259.

motives to enter into FTA negotiations and to accept at times controversial trade-offs are complex and multifaceted. Therefore, it appears important that the discussion on this issue involves assessment of the given FTA as a whole in terms of wealth creation and improved living standards.[23, 24]

Constraints encountered by governments at the stage of national implementation of flexibilities

Constructive ambiguity of international treaties

22. In practice, international treaties are often built on so-called "constructive ambiguity" – terms and provisions that may, in the eyes of the negotiators, lend themselves to different interpretations, with effect, in turn, on the perceived scope of available flexibilities. Against this background, for instance, with respect to the TRIPS Agreement, in articulating the general role of the TRIPS Agreement in promoting access to medicines, and in clarifying specific options to that end, the Doha Declaration provided a clearer context for specific operational choices for the use of policy options under the TRIPS Agreement.[25] However, the ways in which texts of international treaties are drafted, and the possibility of interpreting them in more than one way, often lead to different understandings about the full range of options available for their implementation.[26]

Complexity of practical implementation

23. The practical implementation of any patent flexibility may have its own complexity. For example, Article 31 of the TRIPS Agreement allows, under certain conditions, compulsory licensing and government use of a patent without the authorization of its owner. While all WTO Members may grant such licenses for various health technologies, including medicines and vaccines, needed to address the COVID-19 pandemic, it has been noted that the conditions imposed under this provision could create coordination issues in a global pandemic due to the potential need to initiate compulsory licensing proceedings in multiple jurisdictions.[27]

24. Furthermore, in general, the Special Compulsory Licensing System provided under Article 31*bis* of the TRIPS Agreement,[28] given the broad scope of products covered, was noted

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23 The Trilateral Study, 2020, p. 261.

24 One study notes that, while these countries accept that they are losing TRIPS flexibilities, they seem to consider that overall there is a net gain and the concessions in IP affecting medicines are justified. However, the study states that it is difficult to estimate whether increased earnings in the agricultural sectors may lead to better earnings for workers and therefore better ability to afford higher cost medicines. See Sisule F. Musungu and Cecila Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?*, Commission on Intellectual Property Rights, Innovation and Public Health, WHO, August 2005, p.54.

25 The Trilateral Study, 2020, p. 93.

26 See, for example, Wise, Jacqui, Bulletin of the WHO, *Access to AID Medicines Stumbles on Trade Rules*, 2006, available at: https://iris.who.int/handle/10665/269649; Anand Grover, *Promotion and Protection of all Human Rights, Civil, Political, Economic. Social and Cultural Rights. Including the Right to Developmen*t, Report of the Special Rapporteur on the Rights of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, 2009; Monirul Azam, *Intellectual Property and Public Health in the Developing World*, 2016, p.16; Sisule F. Musungu and Cecila Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?*, Commission on Intellectual Property Rights, Innovation and Public Health, WHO, August 2005; and Mohammed El Said and Amy Kapczynski, *Access to Medicines: The Role of Intellectual Property Law and Policy,* 2012.

27 Médecins Sans Frontières (MSF) briefing document 'Compulsory Licenses, the TRIPS Waiver and Access to Covid-19 Medical Technologies', May 2021, p. 7.

28 The "Special Compulsory Licensing System" (sometimes called the "Paragraph 6 System") a mechanism to enable compulsory licensing expressly for exports of medicines to countries confronted with no or insufficient manufacturing capacity in the pharmaceutical sector, is a public health flexibility directly stemming from the Doha Declaration, which was made operational by the 30 August 2003 WTO decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. The Special Compulsory Licensing System initially took the form of a waiver of the obligations of an exporting Member under Article

[Footnote continued on next page]

to have potential to serve as one tool among others in ensuring equitable access to COVID-19-related health technologies.[29] However, the limited use of the System[30] has drawn considerable criticism from WTO Members and other stakeholders - a critique that has intensified during the pandemic. In particular, questions have been raised as to whether the System can provide an effective and expeditious response to the COVID-19 pandemic, and concerning the choice of developed country WTO Members to exclude themselves from using the System as importers.[31]

25. Much of the criticism is related to its procedural requirements under the System. In particular, some WTO Members have expressed the view that the System is overly complex and have questioned its practical applicability.[32, 33] For example, during recent discussions on a proposal for a temporary waiver of certain provisions of the TRIPS Agreement in relation to the "prevention, containment or treatment" of COVID-19 ("TRIPS waiver"), which was submitted to the TRIPS Council on October 2, 2020,[34] the proponents argued that many countries, particularly developing countries, may encounter institutional and legal challenges when utilizing TRIPS flexibilities. They specifically cited the System provided under Article 31*bis* as a cumbersome process for the import and export of pharmaceutical products.[35] The South Centre also notes that the lack of effective use of the System was not due to a lack of need but to the cumbersome conditions imposed.[36]

31(f) and 31(h) of the TRIPS Agreement regarding compulsory licenses under certain conditions. In 2005, WTO Members unanimously agreed to adopt the Protocol Amending the TRIPS Agreement. The Protocol Amending the TRIPS Agreement entered into force on January 23, 2017. The amendment inserted a new Article 31*bis* into the Agreement as well as an Annex and Appendix. Decision of the General Council of 6 December 2005, available at: ttps://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm. Dedicated webpage on the WTO decision of 30 August 2003: https://www.wto.org/english/tratop_e/trips_e/public_health_e.htm.

29 Information Note on 'The TRIPS Agreement and COVID-19', WTO, October 15, 2020, available at: https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf.p.10.

30 Despite Bolivia notifying its need for COVID-19 vaccines under the System, and Antigua and Barbuda notifying its intention to use it, the System has been used only once to date. See Trilateral Study, second edition, 'Updated extract: integrated health, trade and IP approach to respond to the COVID-19 pandemic, 30 August 2021', p. 9. See Notifications to TRIPS Council at: https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm.

31 See Trilateral Study, second edition, 'Updated extract: integrated health, trade and IP approach to respond to the COVID-19 pandemic, 30 August 2021', p. 9.

32 See, e.g., The Trilateral Study, 2020, p. 243; TRIPS Council, Minutes of the Meeting, IP/C/M/84/Add.1, paragraph 64 and IP/C/M/83 Add.1, paragraphs 152, 154 and 169. As regards the views of some commentators, see UNDP, *Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement*, 2010, p. 35-36; and Patrick L. Osewe et al., *Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities*, The International Bank for Reconstruction and Development (IBRD), The World Bank, 2008.

33 The submission of Costa Rica to SCP/36 generally notes "complexity of practical implementation" as one of the difficulties that country faces "in taking full advantage of the flexibilities under the TRIPS Agreement".

34 The proposal was initially submitted by South Africa and India on 2 October 2020 and subsequently co-sponsored by 63 additional Members. As revised (WTO Doc. IP/C/W/669/Rev.1), it proposed waiving Members' obligations to implement, apply, or enforce TRIPS provisions on copyright, industrial designs, patents, and undisclosed information for a period of at least three years, and until terminated by the General Council, for health products and technologies for the prevention, treatment or containment of COVID-19. See https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm.

35 Other WTO Members opposed to the waiver proposal, noting that there is no concrete indication that intellectual property rights have been a genuine barrier to accessing COVID-19 related medicines and technologies, and that IP was only one aspect of many that affected the manufacture and distribution of the new vaccines. See: https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm.

36 The statement by the South Center further notes that "in the context of the Covid-19 pandemic, the value of the system has been further put into question, as it has not worked to support countries with no domestic manufacturing capacity in dire need for access to vaccines. There is a need to undertake a profound assessment of the special compulsory licensing system under Article 31*bis*. An effective solution to the problem identified in Paragraph 6 of the Doha Declaration must still be found". See the statement by the South Centre on the WTO Doha Ministerial Declaration on TRIPS And Public Health on its Twentieth Anniversary, 14 November 2021, available at: https://www.southcentre.int/statement-on-the-doha-declaration-on-trips-and-public-health-on-its-20th-anniversary-14-november-2021/. MSF also notes that "Article 31*bis* of

[Footnote continued on next page]

26. Various views have been presented as to whether constraints on its use were built into the System itself, or whether it was a consequence of how individual countries chose to implement the System.[37] A recent publication focusing on practical means of applying the TRIPS flexibilities to spur vaccine production has broadly categorized the actual and potential problems relating to the use of the System in the following four categories:

> "1. Constraints specifically embedded within the system itself: examples commonly cited include the need for prior notification and the requirement for special labelling.
>
> 2. Constraints resulting from specific choices made at the domestic level in implementing the system, which are more restrictive than is required under TRIPS: a commonly cited example is a requirement for eligible medicines to be specifically scheduled under domestic legislation before an application for a license can be made.
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> 3. Constraints that are inherent in the use of compulsory licensing more generally: examples include the need for specific authorisation for use, as opposed to an entitlement to produce generic medicines without government authorization […].
>
> 4. Constraints that are not directly related to the IP system or patent rights as such, but rather relate to other aspects of production and supply: these include regulatory approval in either exporting or importing countries or both, the viability of production of small runs of medicines, and procurement policies and procedures."[38]

27. Among other recommendations for removal of the above listed obstacles, the authors of the paper suggest that Members should ensure that the domestic procedures adopted for implementing both Articles 31 and 31*bis* are as simple, efficient and transparent as possible. This can be achieved in part by ensuring that additional requirements are not imposed as part of the compulsory license process. Members should also reduce the number of administrative, legislative and judicial authorities involved in the compulsory licensing process, clearly defining their respective roles and ensuring that they pursue their policy goals harmoniously, particularly where a license is issued in circumstances of urgency. Judicial bodies should be reserved for the role designated to them by Articles 31(i) and (j) and other applicable TRIPS provisions, subject to the requirements of an individual Member's system of government.[39]

28. The WTO Secretariat, with respect to the System, notes that "because of the plurality of development pipelines and the wide range of national needs and circumstances, it is very difficult to speculate in advance whether or when this specific problem identified in the Doha Declaration[40] would arise in relation to COVID-19 medical treatments and vaccines which are currently under development." It further emphasizes that, as indicated in the Doha Declaration, the System's primary purpose is to enable vulnerable countries to make 'effective use' of

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the TRIPS Agreement, fails to provide an expeditious solution to the challenges identified. Instead, Article 31*bis* introduces unnecessary and burdensome procedures for using compulsory license for exportation that are not appropriate to address health emergencies". MSF briefing document 'Compulsory Licenses, the TRIPS Waiver and Access to Covid-19 Medical Technologies', May 2021, p.8.

37 The views expressed by WTO Members on the operation of the System can be found in the Trilateral Study, 2020, p.243.

38 The authors of the paper, *inter alia*, not only categorize the obstacles and challenges associated with the System but also analyze its specific requirements and offer recommendations for its practical operation and the removal of obstacles to its effective use. See: Andrew D Mitchell and Antony Taubman 'Practical means of applying the TRIPS Agreement's flexibilities to spur vaccine production', Asia-Pacific Research and Training Network on Trade, ARTNeT Working Paper Series, No.225. 2023, pp. 55 and 56.

39 *Ibid*, p.66.

40 A WTO Member (importing Member) lacks a specific patented pharmaceutical product, which cannot be produced locally, and hence has to be imported from a generic producer in another Member (exporting Member); the product is subject to patent protection in the exporting Member; and thus there is a need to issue a compulsory license in the exporting Member enabling generic producers to manufacture the product exclusively for export to the importing Member.

compulsory licensing, and that the mere identification of the potential for the System's use may be helpful in facilitating access, whether a compulsory license is ultimately issued or exercised in any particular procurement scenario or not. It further notes that, as with conventional compulsory licensing, the System serves as a reminder that patent rights are not absolute and that public interest considerations could prevail – thus, even the prospect of using it can play a role, including in negotiations on access conditions.[41]

29. The WTO Secretariat also suggest that one way for a Member to use this System would be for it to send a simple, brief notification to the WTO Secretariat of its expected requirements at a very early stage in its procurement of a COVID-19 vaccine or treatment; this would open up the widest possible range of potential suppliers, including through the System, if that is the avenue that yields the preferred access to affordable and sustainable supply of the vaccine or treatment.[42]

30. In addition, it is noted that, setting aside the broader policy debate, compulsory licensing cannot function as a practical stand-alone tool for medicines procurement in the absence of other factors such as, production capacity, regulation for safety, quality and efficacy, economies of scale, and procurement policies.[43, 44]

Operation of law and administrative framework

31. National implementation of international treaties includes not only the passing of legislation, but also execution and operation of the law by administrative bodies and courts. Some have stated that one of the constraints in making effective use of the flexibilities depends, to a large extent, on providing clarity in scope.[45] For the operation of law, sufficient details are required in order to ensure legal certainty and predictability.

32. In addition, the successful operation of the law is most likely underpinned by simple, straightforward, inexpensive and transparent administrative and judicial procedures, which are available to those who need them to make use of the system, enforce their rights or, as third parties, defend their interests.[46, 47] Where more than one administrative body is involved, the

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41 See Information Note on 'The TRIPS Agreement and COVID-19', October 15, 2020, p.10, available at: https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf. See also Staff Working Paper ERSD-2020-12 of October 21, 2020 'Patent-Related Actions Taken in WTO Members in Response to the Covid-19 Pandemic' by Xiaoping Wu and Bassam Peter Khazin, available at: https://www.wto.org/english/res_e/reser_e/ersd202012_e.pdf.

42 *Ibid*, Information Note on 'The TRIPS Agreement and COVID-19', October 15, 2020, p.10.

43 Background note prepared by the Secretariat of the WTO to the UN Secretary-General's High-Level Panel on Access to Medicines: http://www.unsgaccessmeds.org/reports-documents/. Reviewing this question, the Trilateral Study observed: "The special export licence [under the TRIPS amendment] is one legal pathway that can be followed when it represents the optimal route to effective procurement, but, as for any compulsory licence, it does not in itself make the production of a medicine economically viable. Sufficient scale and predictability of demand are prerequisites for making it practically and commercially viable for companies to undertake the regulatory, industrial and commercial steps required to produce and export a medicine under such a licence. Regional approaches to procurement and joint notifications by countries with similar needs for accessible medicines may offer pathways to aggregating demand under the System, thus enabling an effective response to the needs identified." The Trilateral Study, 2020, p.244.

44 Capacity building workshops organized by the WTO have also been focusing on how to make effective use of the System in practice. The summary of findings can be found at: https://www.wto.org/english/news_e/news16_e/trip_28oct16_e.htm.

45 See, for example, the statement made by the Delegation of Indonesia which noted that "the lack of clarity *on the* scope made the implementation [of exceptions and limitations] difficult […]" (document SCP/25/6/Prov., paragraph 58). See also the submission by UNCTAD in document SCP/25/3: "It may be stated that patent exceptions and limitations, while available in domestic law, are often unclear in scope and therefore difficult to make operational."

46 See also Articles 41.2 and 62 of the TRIPS Agreement.

47 In this respect, the submission of Costa Rica to SCP/36 notes the absence of administrative and judicial procedures for proper implementation of the law as one of the difficulties that country faces "in taking full advantage of the flexibilities under the TRIPS Agreement".

clarity of their responsibilities and mandates might be also important for a clear decision-making process.

Institutional challenges, including institutional capacity

33. In close relation to clarity in the scope of existing flexibilities and the operation of national law, during the SCP sessions, some WIPO Member States stated that the insufficient local legal and technical expertise to incorporate and implement the TRIPS flexibilities into the national law and policy was one of the major problems in making full use of patent flexibilities. For example, the Delegation of Algeria on behalf of the African Group stated that "[…] the majority of developing countries did not have the technical capacity to make use of those flexibilities, for example, compulsory licensing".[48] Similarly, the Delegation of Nigeria also noted that "[…] the lack of capacity to fully comprehend the full range of the flexibilities that could be implemented raised concerns about costly violations of existing agreements".[49] Similar views were also expressed more recently with respect to the implementation of the Special Compulsory Licensing System. Specifically, the submission of Costa Rica to the thirty-sixth session of the SCP noted a lack of knowledge and expertise of local authorities for its implementation.[50] In the context of COVID-19, the submission of South Africa also notes that many developing countries face, *inter alia*, technical and institutional challenges in using TRIPS flexibilities.[51] Furthermore, as stated above, during recent WTO discussions on a proposal for a so-called "temporary IP waiver" in response to COVID-19, Members supporting the waiver also highlighted difficulties related to institutional challenges when using TRIPS flexibilities.[52]

34. Moreover, a number of publications highlight that lack of capacity is one of the challenges in the use of flexibilities, and stress the need to invest in national capacity building and technical expertise through various training programs, targeting various stakeholders in developing countries and LDCs.[53] For example, one of the studies state that the existence of well-trained individuals with high levels of knowledge and expertise is important for any country to be able to use the flexibilities available internationally having due regard to their international commitments and obligations.

35. At the sixteenth and twenty-fourth sessions of the SCP, the African Group proposed a work program for the SCP under the agenda item, Patent and Health, which sought to enhance the capacity of developing countries and LDCs to adapt their patent regimes and make full use of flexibilities in the international patent system to address public policy priorities related to public health. The proposed work program consists of three elements, i.e., the elaboration of studies on various topics, information exchange among Member States and from leading

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48 Document SCP/19/8, paragraph 91.

49 Document SCP/25/6/Prov., paragraph 165.

50 The submissions of Member States to SCP/36 can be found at: https://www.wipo.int/scp/en/meetings/session_36/comments_received.html.

51 South Africa's intervention at the informal open-ended meeting of the TRIPS Council, 19 June 2020, available at: https://www.keionline.org/33388.

52 See: https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm.

53 See the Report of the United National Secretary-General's High-Level Panel on Access to Medicines, *Promoting Innovation and Access to Health Technologies*, 2016, p.24; Bulletin of the WHO, *Access to AID Medicines Stumbles on Trade Rules*, available at: https://iris.who.int/handle/10665/269649; Monirul Azam, *Intellectual Property and Public Health in the Developing World*, 2016, p.16; and Sisule F. Musungu and Cecila Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?*, Commission on Intellectual Property Rights, Innovation and Public Health, WHO, August 2005; Management Science for Health, *Managing Access to Medicines and Health Technologies*, 2012, p.3.11, available at: https://msh.org/wp-content/uploads/2013/04/mds3-fm-revised-nov2012.pdf; Mohammed El Said and Amy Kapczynski, *Access to Medicines: The Role of Intellectual Property Law and Policy,* 2012, p. 10; and Carlos M. Correa, *The Use of Compulsory Licenses in Latin America*, The South Centre, 2013, available at: https://www.southcentre.int/question/the-use-of-compulsory-licenses-in-latin-america/.

experts, and the provision of targeted technical assistance to Member States, particularly to developing countries and LDCs.[54]

36. The need to provide technical assistance and capacity building, tailored to a specific country's context, for using TRIPS flexibilities has been stressed in other international fora, including the WHO and WTO. The need to reinforce technical assistance and capacity building to Members of the WTO was raised by some Members*, inter alia*, during the WTO TRIPS Council extraordinary session on January 30, 2017, which was held on the occasion of the entry into force of Article 31*bis* of the TRIPS Agreement. Some Members referred to the WHO-WIPO-WTO Trilateral Cooperation as part of the increasing international efforts to improve the ability of developing countries and LDCs to have access to medicines and a source of technical assistance provided by international organizations and individual countries.[55]

37. Recommendation 14 of the Development Agenda states that "[w]ithin the framework of the agreement between WIPO and the WTO, WIPO shall make available advice to developing countries and LDCs, on the implementation and operation of the rights and obligations and the understanding and use of flexibilities contained in the TRIPS Agreement." Accordingly, WIPO often in close collaboration with the Secretariats of WHO and WTO, has been actively assisting countries on the implementation of their intellectual property legal system and the understanding and use of TRIPS flexibilities, taking into account specific country's circumstances and needs.[56] In addition, WIPO's technical assistance and capacity building activities cover not only assistance in drafting national legislations, but also aim at supporting judiciary and governmental agencies for their execution and operation of national law. They include staff of IP offices and health authorities as well as officials involved in IP discussions in various bilateral, regional and multilateral fora.[57,58]

38. In June 2021, the Directors-General of the WHO, WIPO, and WTO issued a joint statement in which they agreed to intensify their cooperation to tackle the COVID-19 pandemic. They emphasized their joint commitment to universal and equitable access to COVID-19 vaccines, therapeutics, diagnostics, and other health technologies.[59] In line with this commitment, a series of capacity-building workshops have been conducted and a joint platform

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54 See documents SCP/16/7, SCP/16/7 Corr. and SCP/24/4. Although the Committee has not approved these proposals, since the submission of the proposal contained in document SCP/24/4, working documents on WIPO's experiences regarding capacity building activities relating to negotiating licensing agreements (SCP/30/6) and a report on WIPO's technical assistance activities in respect of enhancing patent examiners capacity (SCP/28/6) were prepared. In addition, a number of sharing session on the related topics were held. They include sharing sessions on: (I) practices involving licensing of medical technologies for the diagnoses, prevention and treatment of COVID-19, including examples of compulsory and voluntary licensing (2023); (ii) challenges and opportunities in relation to types of patent licensing provisions in the healthcare technologies (2020); (iii) capacity building activities relating to negotiating licensing agreements (2019); (iv) negotiating licensing agreements (2018); (v) enhancing examiners capacity, particularly in small and medium-sized offices (2018); and (vi) national experiences relating to use of health-related patent flexibilities for promoting public health objectives or the challenges thereof (2016).

55 TRIPS Council Minutes of Meeting, IP/C/M/84/Add.1.

56 See document SCP/18/5.

57 From January 2020 to December 2023, , legal advice, comments and draft laws were provided in response to requests from the authorities of 64 countries. During the same period, advisory and outreach missions on IP laws were primarily conducted through written and online channels to ensure expediency and sustainability. Field missions were undertaken where the nature of activities required in-person engagement., mainly to discuss with the government authorities new or revised legislation, or to consult on specific topics of IP law. A number of national/regional seminars and workshops regarding flexibilities and public policies in the patent field have been organized during this period.

58 Under the lead of WTO, the WHO, WTO and WIPO have been providing an annual training workshop in Geneva on Trade and Public Health to government officials from developing countries and LDCs, bringing together officials from the trade, health or IPR sectors. An important component of the workshop is the implementation and use of TRIPS flexibilities. See: https://www.wto.org/english/news_e/news16_e/trip_28oct16_e.htm.

59 See: https://www.wto.org/english/news_e/news21_e/igo_23jun21_e.htm.

for technical assistance have been launched to address countries' needs for COVID-19 health technologies.[60]

39. The WIPO Program of Work and Budget 2022/23 approved a number of specific activities including the WIPO COVID-19 Response Package aiming to answer to Member States' evolving needs with respect to technical assistance in the areas of COVID-19 response, recovery and future pandemic resilience.[61]

National governance and internal coordination

40. The incorporation of the TRIPS flexibilities into the national law generally requires the involvement of various government departments and ministries, such as patent offices, ministries of health and trade, and drug regulatory authorities. In some countries, reportedly, their activities are not necessarily coordinated in order to pursue common policy goals, creating tensions between ministries responsible for the promotion of trade, protection and enforcement of intellectual property and public health, respectively.[62, 63] Various publications have stressed the need to take a nationwide collaborative approach, involving all stakeholders for effective implementation of the TRIPS flexibilities into national laws.[64] In this regard, joint capacity building activities by the WHO, WTO and WIPO, involving government officials from health, trade and IPR sectors have been carried out with a view to facilitating interdepartmental coordination. Additionally, one study concluded that policy approaches utilizing TRIPS flexibilities within low-income countries depend upon functioning governance, which requires the necessary administrative resources and authority to implement health policies and regulations. The authors found that developing countries often lack these basic capacities, making it difficult for them to meet basic public health needs.[65]

Extrinsic influences

41. During the SCP sessions, some Member States and non-governmental organizations reported on cases of political and economic pressure from some industrialized countries and/or pharmaceutical industries which had intervened to the governments' decision making process to issue compulsory licenses.[66] Some publications also cite those cases, most of which are the cases of Brazil, India, South Africa, Thailand and Colombia.[67] At the same time, while noting

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60 See: https://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm.

61 See: https://www.wipo.int/export/sites/www/about-wipo/en/budget/pdf/budget-2022-2023.pdf

62 The Report of the United National Secretary-General's High-Level Panel on Access to Medicines, *Promoting Innovation and Access to Health Technologies*, p.24. See also a paper by Patrick L. Osewe et al., which reports that in most developing countries in Africa, national coordination systems on IP issues are generally weak or nonexistent. Patrick L. Osewe et al., *Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities*, International Bank for Reconstruction and Development and World Bank 2008.

63 With respect to the difficulties that countries face "in taking full advantage of the flexibilities under the TRIPS Agreement", the submission of Costa Rica to SCP/36 also notes a "need to optimize inter-institutional coordination".

64 I*bid*.

65 Cindy Bors *et al*., *Improving Access to Medicines in Low-Income Countries: A review of Mechanisms*, the Journal of World Intellectual Property (2015) Vol. 18, no. 1-2.

66 See, e.g., the statements made by the Delegation of South Africa at the 20th session of the SCP (document SCP/20/13), the Representatives of Knowledge Ecology International (KEI) at the 24th session of the SCP (document SCP/24/6) and the Representatives of Médecins Sans Frontières (MSF), KEI and Third World Network (TWN) at the 25th session (SCP/25/6 Prov., paragraphs 28, 52 and 53).

67 Anand Grover, *Promotion and Protection of all Human Rights, Civil, Political, Economic. Social and Cultural Rights. Including the Right to Developmen*t, Report of the Special Rapporteur on the Rights of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, 2009; Monirul Azam, *Intellectual Property and Public Health in the Developing World*, 2016, p.17; Mohammed El Said and Amy Kapczynski, *Access to Medicines: The Role of Intellectual Property Law and Policy,* 2012, p. 11; and Civil Society submissions to the United States Trade Representative (USTR) Special 301 hearing, available at:

[Footnote continued on next page]

the concerns about possible negative reactions to grant of compulsory licenses from developed countries' governments and their implications for trade or political relations, one publication questions the generalization of the negative effect and the scale of such extrinsic influences.[68]

42. Concerns about political and industry pressure have recently been voiced by some governments at the WTO during the Council for TRIPS in conjunction with the discussions on the "TRIPS waiver" proposal. For example, South Africa noted that while Members often point out that the TRIPS flexibilities are available and should be used, "this is not a reality for many developing countries [since] whenever such flexibilities are invoked, political and other sanctions are used to counter such efforts." The Delegation also referred to the Pharmaceutical Research and Manufacturers of America (PhRMA) submission for the 2021 Special 301 Report in which "countries have been criticized simply because they have either used TRIPS flexibilities, or adapted emergency rules to facilitate the use of TRIPS flexibilities in the pandemic […]."[69] Pakistan has also cited reports "surfacing that the same pharmaceutical companies are lobbying with their governments to impose sanctions to countries that adopt compulsory license".[70, 71]

43. It was observed that addressing such pressures, where they exist, was inherently a broader political matter beyond the formal scope of agreed international legal standards and the formal means for resolving differences.[72] Nonetheless, following the confirmation made by the Doha Declaration and the experience of COVID-19, there is a clear consensus at both international and national levels that the use of flexibilities is a legitimate and necessary measure for countries to address public health challenges from an intellectual property perspective.[73, 74]

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http://keionline.org/node/2735. See also a paper by Laurence R. Helfer et al., which reported on three cases where countries members of the Andean Community have faced pressure from the United States of America and pharmaceutical companies in the use of TRIPS flexibilities. Laurence R. Helfer et al., The *Influence of the Andean Intellectual Property Regime on Access to Medicines in Latin America***,** in Balancing Wealth and Health: Global Administrative Law and the Battle over Intellectual Property and Access to Medicines in Latin America (Rochelle Dreyfuss & César Rodríguez-Garavito, eds. 2013).

68 Carlos M. Correa, *The Use of Compulsory Licenses in Latin America*, The South Centre, 2013, available at: https://www.southcentre.int/question/the-use-of-compulsory-licenses-in-latin-america/.

69 WTO, TRIPS Council, Minutes of Meeting held on 10-11 March 2021, WTO Doc IP/C/M/98/Add.1, 287 and 289.

70 WTO, TRIPS Council, Minutes of Meeting held on 10-11 March 2021, WTO Doc IP/C/M/98/Add.1, 251.

71 2021 publication also notes that "despite a [compulsory license] being a flexibility allowed for by TRIPS, some states have traditionally been [...] reluctant to invoke the process for issuing a CL, including due to fears of challenge and/or of trade sanctions being imposed on them". See Siva Thambisetty et al., 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID- 19 Pandemic' (LSE Law, Society and Economy Working Papers 06/2021), p. 27. In a 2021 briefing of MSF it is also noted that: "[h]istorically developing countries have been systematically discouraged from using compulsory licensing for access to medicines due to pressures from their trading partners and pharmaceutical corporations. In the COVID-19 pandemic, pharmaceutical corporations continue to pressure countries over the use of compulsory licensing.". MSF briefing document 'Compulsory Licenses, the TRIPS Waiver and Access to Covid-19 Medical Technologies', May 2021, p.6.

72 Andrew D Mitchell and Antony Taubman 'Practical means of applying the TRIPS Agreement's flexibilities to spur vaccine production', Asia-Pacific Research and Training Network on Trade, ARTNeT Working Paper Series, No.225. 2023, p.36.

73 MSF welcomed the 2021 Special 301 Report from the U.S. Trade Representative, which acknowledged the right of all countries to grant compulsory licenses. However, MSF emphasized that "to remove political and trade pressures completely, this needs to lead to an actual end to pressuring countries for issuing compulsory licenses to support access to generic medicines, vaccines and other medical products and not just be an exception because of COVID-19.". See MSF briefing document 'Compulsory Licenses, the TRIPS Waiver and Access to Covid-19 Medical Technologies', May 2021, p.6.

74 In this line, one paper states that "[d]eveloping countries are unlikely to be met with litigious threats for issuing compulsory licenses to deal with a global pandemic. To the contrary, developing countries are likely to receive support from the international community. Domestic-level IP enforcement in developing countries may also be unattractive to patent holders due to the physical, procedural, and legal complexities associated with such

[Footnote continued on next page]

Constraints faced by various stakeholders in using a national legal framework that has implemented policy options

44. In addition to the constraints described above, some Member States and academic publications point to constraints faced by various stakeholders in using a national legal framework once the government has implemented the policy options provided in the international agreements. Most of such debates relate to the constraints for stakeholders to obtain and use compulsory licenses for manufacturing or importing a generic version of medicines, aiming at increased access to such medicines.

Ambiguity and operationability of national law

45. Clarity of law, sufficient depth of implementing regulations, simplified and transparent administrative and judicial procedures, and a clear decision-making process positively affect the use of national legal framework by various stakeholders. Several publications refer to these factors with respect to the use of compulsory licenses.[75,76]

46. For instance, while provisions on compulsory licensing are found in a great number of countries, it was observed that in many countries, the procedural aspects relating to such licenses are not spelled out in detail under the national legal frameworks or are difficult to find. This issue was, for example, also highlighted in a recent communication of Costa Rica which stated that the challenge for the Industrial Property Registry was to establish the procedure to review the conditions under which the license may be granted, limitation of the scope of the license, its duration and the economic remuneration to be received by the right holder.[77] South Africa also notes that "many developing country Member States may also face legal, technical and institutional challenges in using TRIPS flexibilities. National patent laws may not even have the necessary provisions to issue compulsory licenses in the public interest or government use licenses or where such a possibility exists. Sometimes, provisions on compulsory licensing in national legislation are subject to specific processes and as such, the issuance of compulsory license may involve lengthy processes that are time-consuming."[78] Similarly, with respect to France, it has been opined that "the deterrent effect of the mechanism of compulsory licensing in the interest of public health is primarily due to the complexity and length of the consultation

processes. See Andrew D. Mitchell et al., 'Intellectual Property and Vaccine Manufacturing: Utilizing Existing TRIPS Agreement Flexibilities for COVID-19 and Other Public Health Crises', Tulane Journal of Technology and Intellectual Property, V.25, 2023, p.61.

75 Mohammed El Said and Amy Kapczynski, *Access to Medicines: The Role of Intellectual Property Law and Policy,* 2012, p. 9; Patrick L. Osewe et al., *Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities*, The International Bank for Reconstruction and Development (IBRD), The World Bank, 2008; and Sisule F. Musungu and Cecila Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?,* Commission on Intellectual Property Rights, Innovation and Public Health, WHO, August 2005. .

76 In this respect, 2021 South Centre publication notes that "[t]he lack of Andean regulation on non-commercial public use is possibly the reason why Colombia has not considered the possibility of issuing a compulsory license". See Guillermo E. Vidaurreta, *Uso público no comercial y licencias obligatorias en América Latina. Estado de situación*. South Centre, 2021, p.44. However, the Superintendency of Industry and Commerce of Colombia, by means of Resolution No. 20049 of 2024, granted a compulsory license on 'non-commercial public use' ground for two patents related to dolutegravir. The Superintendency referred to prejudicial interpretation by the Court of Justice of the Andean Community (IP-144-2019), which defined "public interest" as a generic category of reasons that can trigger the granting of a compulsory license. This includes "other reasons that also qualify as public interest", such as non-commercial public use and the need to access specific products at a given time, including medications. Resolution No. 20049 can be found at: https://www.statnews.com/wp-content/uploads/2024/04/NC_534_Licencia_obligatoria_aceptada.pdf.

77 See the submission of Costa Rica to SCP/30.

78 South Africa's intervention at the informal open-ended meeting of the TRIPS Council, 19 June 2020, available at: https://www.keionline.org/33388.

and decision-making process".[79] As regards the compulsory licensing provisions in the laws of LDCs, one paper notes that, in some cases, conditions for the grant of such licenses as well as related procedural requirements are restrictive and burdensome.[80]

47. While COVID-19 has prompted some countries, among other measures, to modify compulsory licensing laws or adopt or engage in discussion on specific 'emergency laws' to facilitate their use at the national level during the pandemic or in broader public health context,[81] according to some authors, domestic procedures for implementing legitimate pro-access policy measures in some countries appear to remain overly restrictive, inefficient and bureaucratic.[82, 83] For example, in implementing pro-access policy measures and addressing the limited applicability of compulsory licensing mechanisms to patents,[84] there has been advocacy for amending national IP laws to allow compulsory licensing of patent applications, especially since some COVID-19 pandemic-related technologies are still in the patent application stage.[85, 86]

48. Ambiguity and uncertainty in the scope of national law provisions are not confined to compulsory licensing alone. For instance, in respect of exhaustion of rights, it has been reported that some countries apply different exhaustion policies across various IP categories. For example, a pharmaceutical product might have its chemical formula protected by patents, its brand name by trademarks, and its instructions by copyright law. Although these different categories of IP cover various features of the product with different scopes and durations of protection, during the period when all these IP rights on the same product are effective, the application of different exhaustion policies on different categories of IP can impact the legality of parallel importation of the product and create legal uncertainty for parties who wish to engage in parallel trade. While the distinct policy justifications and rationales for each IP category may

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79 See Francois Pochart, Mathilde Rauline, Océane de La Verteville. Compulsory licenses granted by public authorities: an application in the Covid-19 crisis in France? Part 1, (August Debouzy), April 23, 2020, available at: https://patentblog.kluweriplaw.com/2020/04/23/compulsory-licenses-granted-by-public-authorities-an-application-in-the-covid-19-crisis-in-france-part-1/.

80 LDC Watch submission to the High- Level Panel on Access to Medicines, February 2016, available at: http://www.unsgaccessmeds.org/inbox/2016/2/28/prerna-mingma-bomzan?rq=OAPI.

81 Countries such as Canada, Germany, Hungary and France either amended their national laws or issued additional regulations to clear the way for government authorities to issue government use, compulsory licenses or other measures. In other countries, such as Chile and Ecuador, legislative bodies issued resolutions expressing their respective views on the need to take initiatives to facilitate access to COVID-19 related technologies, including the issuance of compulsory licenses. WTO, 'Report of the Trade Policy Review Body from the Director-General on Trade-Related Developments from mid-October 2019 to mid-May 2020' (10 July 2020) WT/TPR/OV/W/14, para 5.8. See also Sven Bostyn, 'IP and access to publicly funded research results in health emergencies. Policy, law and practice in Europe', 2024, available at: https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_ge_24/wipo_ip_ge_24_a_discussion.pdf.

82 Andrew D Mitchell and Antony Taubman 'Practical means of applying the TRIPS Agreement's flexibilities to spur vaccine production', Asia-Pacific Research and Training Network on Trade, ARTNeT Working Paper Series, No.225. 2023, p.3.

83 In the context of the TRIPS waiver discussion, another paper also claims that the procedures for obtaining a compulsory license at the national level can often be bureaucratic, uncertain and/or time consuming. See Thambisetty at al., 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID- 19 Pandemic' (LSE Law, Society and Economy Working Papers 06/2021), p. 27.

84 Art. 31 of the TRIPS Agreement 'Other Use Without Authorization of the Right Holder' states: "Where the law of a Member allows for other use [...] of *the subject matter of a patent* without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: […]" (emphasis is added).

85 Olga Gurgula and John Hull, 'Compulsory licensing of trade secrets' (2021) 16(11) Journal of Intellectual Property Law & Practice, p. 1248.

86 In Europe, the European Commission, in April 2023, proposed a draft regulation covering compulsory licensing for crisis management. The envisaged law would empower the Commission to grant EU-wide licenses with respect to patent applications, patents, utility models and supplementary protection certificates. See Art. 2 of the Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006. COM/2023/2024 final.

account for these differences, policymakers may need to analyze IP exhaustion holistically to avoid unintended consequences.

49. Another flexibility relating to health, the scope of which has been reported to be unclear in some national laws, is the regulatory review exception. For example, in Türkiye and Portugal, courts have reportedly issued conflicting opinions regarding the scope of the exception in the respective applicable laws.[87, 88] In the submission of the Netherlands (Kingdom of the), it was observed that during the implementation of Article 10(6) of Directive 2004/27/EC, the precise scope of certain terms, such as 'trials and studies' and 'consequential practical requirements', remained unclear due to the lack of jurisprudence from the European Court of Justice.[89]

Technical IP capacity

50. The use of various provisions in the national/regional laws by various stakeholders at the practical level requires not only a supportive and coherent legal framework, but also technical resources and expertise of users. While not all stakeholders can be IP experts, their general knowledge of the legal norm concerned is important for its effective use. For example, UNCTAD, in relation to the regulatory review exception, reported that even in countries that have enacted that exception, it is not necessarily used by generic companies due to lack of awareness of patent issues, among others.[90]

51. Local stakeholders need IP specialists, the so-called patent agents or patent attorneys, whom they can consult on the use of exceptions and limitations, challenging the validity of patents or obtaining patent protection on local improvement made on existing medicines, among others. Their expertise in searching patent documents, analyzing patent claims and providing legal advice may be also relevant for the local business to make use of the patent system for their benefit.

Identifying relevant patents and their status

52. In order to determine whether a patent license is necessary to legally manufacture or import a pharmaceutical product in a particular country, first, relevant patents covering that product and granted in that country should be identified, and then, the legal status of such patents should be determined. This process is essential for transfer of technology under patent protection, i.e., determining the need for obtaining licenses, whether they are voluntary or compulsory. However, particularly in developing countries and LDCs, such information about valid patents in those countries may be not easily accessible. In addition, even if legal status information is made accessible to the public by the respective national/regional patent office, the varied format of such information makes it difficult for the users to access the data seamlessly.[91]

53. In practice, although making the patent data easily available to the public is the fundamental first step, a good knowledge of pre- and post-grant patent procedures in a given country is often necessary to fully analyze the data and comprehend the legal status of the patent concerned for the intended purposes. The difficulty faced by those who do not have both

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87 See submission of Türkiye to the SCP/27 to be found at: http://www.wipo.int/scp/en/meetings/session_27/comments_received.html.

88 See a response from Portugal to the Questionnaire and document SCP/21/3, p.9.

89 See the response to the Questionnaire from the Netherlands. See also response from Spain which referred to the amendment of the relevant provision of its national law implementing Directive 2004/27/EC and introducing the exception, questioned whether it had a retroactive effect or not. See document SCP/21/3.

90 See document SCP/25/3, paragraph 6.

91 In August 2017, the Committee on WIPO Standards adopted Standard ST.27: "Recommendation for the exchange of patent legal status data". The Standard is intended to promote efficient exchange of patent legal status data in a harmonized manner between IP offices in order to facilitate access to the data by the offices themselves, IP information users, IP data providers and the general public.

sufficient technical and IP expertise in unequivocally identifying patents covering a specific pharmaceutical product or process and understanding their legal status has been fairly known.

54. Some examples demonstrate how both the availability of patent data and the IP expertise may affect effective use of regulatory review exception by generic companies. For instance, information on the expiration date of a pharmaceutical patent would assist generic companies in their planning when to start studies and testing on the patented invention to generate information necessary for obtaining a marketing approval of the generic medicine from a regulatory authority.[92] Many national laws stipulate, in principle, the term of patent protection is 20 years from the filing date. A patent may lapse or may be surrendered, withdrawn, revoked or invalidated before the expiration of 20 year-term due to non-payment of fees, unilateral action of the patentee, or decisions made by administrative bodies or courts. However, some countries' laws may also provide, under certain conditions, an extension of the patent term, a restoration of rights or a grace period for non-payment of a maintenance fee. It shows that seemingly a simple calculation of an expiry date of a patent requires a thorough understanding of the patent procedures in the given country.

55. Similarly, with respect to compulsory licenses, it was reported that a request for a compulsory license had been filed in Zambia, because a requester was not certain about the existence of the relevant patents or patent applications in that country.[93] Argentina, in 2005, announced plans to issue compulsory licenses for oseltamivir to allow local production of the product. However, it was reported that the patent for that particular medicine was never granted in Argentina.[94] In 2021, Bolivia notified the TRIPS Council of the need to import COVID-19 related vaccine under the special compulsory licensing system. Responding to a question on a patent status of the product protected in its territory, the government noted "to be determined".[95,96] These anecdotal examples seem to suggest that both access to data and IP literacy to analyze the data are important for effective use of a compulsory license mechanism by stakeholders.

56. The COVID-19 pandemic heightened the urgency of accessing patent documents with technical IP expertise, as they are crucial for studying the virus, developing technologies to combat it, and supporting procurement efforts. It was reported that these technologies are covered by a complex web of patents owned by various patentees and sublicensed to multiple companies.[97]

57. In such intricate patent landscape, the importance of the availability of the patent status information for facilitating voluntary licenses can be found in the example of the Technology Access Pool (C-TAP) database. The WHO launched the C-TAP database in 2023 to provide wide-ranging information on selected COVID-19 therapeutics, diagnostics, vaccines and other health products, which includes information on patent and licensing status, clinical trial status, regulatory status, and suppliers of selected COVID-19 health products, as well as other relevant data.[98] The complex patent landscape was also seen as a challenge for a government intending to effectively use a compulsory license mechanism for a COVID-19-related medical

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92 See SCP/28/3, Annex, paragraph 77.

93 The statement made by the Representative of KEI (document SCP/25/6/Prov., paragraph 52).

94 See Ellen F.M 't Hoen, *Private Patents and Public Health, Changing Intellectual Property Rules for Access to Medicines*, 2016, p.72.

95 See: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=s:/IP/N/9BOL1.pdf&Open=True.

96 One paper notes in this respect: "Bolivia's WTO filing demonstrates poignantly that such a lack of transparency around applicable patents makes it difficult to determine which patents and patent applications are relevant for a [compulsory licensing] process in the first place". Siva Thambisetty *et al*., 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic' (LSE Law, Society and Economy Working Papers 06/2021), p. 28.

97 Mario Gaviria and Burcu Kilic, 'A network analysis of COVID-19 mRNA vaccine patents', Nature Biotechnology, vol. 39 (12 May 2021), p. 546; Cecilia Martin and Drew Lowery, 'mRNA vaccines: intellectual property landscape', Nature Reviews Drug Discovery, vol. 19 (September 2020), p. 578.

98 See: https://www.who.int/initiatives/covid-19-technology-access-pool.

product, as the government would need to verify the patent status, a process which is often found to be burdensome and costly.[99]

58. The importance of establishing and maintaining publicly accessible databases with patent status information on medicines and vaccines has been universally recognized,[100] leading to various initiatives at national, regional and international levels. Within the work of the SCP, the Delegations of Argentina, Brazil, Chile and Switzerland proposed that a regular update on publicly accessible databases of patent status information concerning medicines and vaccines to be carried out in WIPO. Highly supported by the Member States, since the thirty-first session of the SCP in 2019, representatives of a number of initiatives that provide such information have presented the latest information on their databases.[101, 102]

59. To improve accessibility and availability of patent legal status information in general, a number of other activities have also been carried out at WIPO. For example, a modification to Rule 95.1 of the Regulations under the PCT was introduced with a view to facilitating access to timely and accurate information about national phase entry and other national phase events relating to the PCT international applications. Accordingly, the designated Offices are required to notify certain national phase processing events to the International Bureau within two months, or as soon as reasonably possible. The collected data is made available to the general public on the PATENTSCOPE website.[103] Relatedly, in countries where patents may be granted by a national patent office as well as by a regional patent office, synchronizing the national and regional patent status information would facilitate the provision of a complete picture of the patent status in a given country.[104]

60. Regarding the patents on COVID-19-related technologies, in 2020, a COVID-19 search functionality within the PATENTSCOPE database has been established to help to identify patent documents relevant to the detection, prevention and treatment of COVID-19 pandemic.[105] The European Patent Office[106] and a number of national patent authorities have developed similar tools, as well as databases of COVID-19-related patents. [107] In addition, the

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99 Olga Gurgula, 'Compulsory licensing vs. the IP waiver: what is the best way to end the COVID-19 pandemic?', South Centre, Policy Brief, No. 104, October 2021, p.3.

100 World Health Assembly resolution WHA72.8 on "Improving the transparency of markets for medicines, vaccines, and other health products", adopted in 2019, urges WHO member states and the WHO Director General to take a number of actions toward improving transparency, including toward improving public reporting of patent status information and the marketing approval status of health products.

101 See document SCP/35/9. The Committee will receive further updates on such databases during the thirty-sixth and thirty-seventh sessions of the SCP.

102 MSF 2024 report 'Transparency and Access to Medical Products' recommends Member States of WIPO to address the lack of transparency in key patent information concerning medicines, vaccines and diagnostics, and establish disclosure requirements for the International Nonproprietary Names (INNs) in patent applications in their national laws. It also recommends to national patent offices to create free-to-access, publicly available and searchable databases that contain all relevant patent information associated with medical products, including information on what patents are filed, where and when, their expiration date, INN and API information, as well as any existing licensing agreements, changes in legal status of patents or patent applications, including rejections, nullifications or revocations. The report is available at: https://www.msfaccess.org/secrets-cost-lives-transparency-and-access-medical-products, pp. 27 and 31. PATENTSCOPE provide a patent search function by a chemical compound structure and by a various types of names attributed to such a compound, e.g., a trivial name, commercial name, IUPAC name, CAS name and INNs.

103 See: https://www.wipo.int/patentscope/en/data/national_phase/procedures.html.

104 Patrick L. Osewe et al., *Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities*, 2008 The International Bank for Reconstruction and Development , The World Bank, p. 23.

105 See: https://patentscope.wipo.int/search/en/covid19.jsf.

106 See: https://www.epo.org/en/searching-for-patents/technology-platforms/fighting-coronavirus.

107 E.g., in the Republic of Korea, the Korean Intellectual Property Office has made patent information related to COVID-19 diagnosis and treatment technologies publicly available, including patent analysis and trend reports. In Chile, as part of the effort to contain the spread of COVID-19, the National Institute of Industrial Property

[Footnote continued on next page]

WIPO Pearl terminology database has added 1,500 COVID-related terms in 10 languages with the aim of fostering international collaboration and promoting access to information in patent documents and other public resources.[108] Furthermore, to offer valuable insights into the patent landscape of COVID-19-related vaccines and therapeutics, WIPO published a Patent Landscape Report in March 2022, titled 'COVID-19-related Vaccines and Therapeutics: Preliminary Insights on related Patenting Activity during the Pandemic'.[109] Building on the findings of this initial report, WIPO released a second report on the same subject in 2023.[110]

Other challenges where use of patent flexibilities alone may not achieve intended policy outcomes

61. In some cases, use of flexibilities implemented under national patent laws alone does not guarantee that it would achieve the intended outcome of improving access to medicines. In reality, various factors other than patents *stricto sensu* may affect the intended policy goals. The following paragraphs describe such other factors.

Manufacturing and distribution capacity

62. Patent flexibilities may be insufficient on their own to ensure or facilitate access to the product. As reported by several Member States, the lack of technological or manufacturing capacity in developing countries was one of the major issues that was relevant to the use of technology in general.[111] Some commentators note that not many developing countries have domestic technological and commercialization capacity as well as regulatory capacity to reverse engineer and manufacture pharmaceutical products without the assistance of the patent owner.[112]

63. Focusing on the COVID-19 pandemic, an UNCTAD publication notes that "with discussions focused on the issue of patents and profits, a fundamental issue is being overlooked: the lack of productive capacity in developing countries".[113] The statement of South

(INAPI) prepared special editions of its reports on public domain technologies focused on elements for personal protection (such as face masks, safety goggles and gloves) to reduce contagion. In addition, ember countries of the Forum for the Progress and Development of South America (PROSUR) published reports of certain health technologies related to COVID-19. In addition, some PROSUR member countries, such as Argentina, Brazil, Colombia and Ecuador, have published patent landscapes with respect to COVID19-related technologies, such as diagnostics and ventilators. See: Information Note on 'The TRIPS Agreement and COVID-19', WTO, October 15, 2020, pp.12 and 13.

108 See: https://www.wipo.int/pressroom/en/articles/2020/article_0021.html.

109 See: https://www.wipo.int/edocs/pubdocs/en/wipo-pub-1075-en-covid-19-related-vaccines-and-therapeutics.pdf.

110 https://www.wipo.int/web/patent-analytics/covid-19-vaccines-and-therapeutics.

111 As part of the SCP activities, a questionnaire was sent to Member States to study, *inter alia*, whether any challenges had been encountered in relation to the implementation of various exceptions and limitations in respective countries. In relation to the use of compulsory license and/or government use, responses from Uganda, the United Republic of Tanzania and Zambia indicated that in their respective countries, they encountered the challenge of insufficient or lack of technological capacity on the part of local industries to produce generic pharmaceutical products (see document SCP/21/4, paragraph 66). With respect to compulsory licensing, the submission of Costa Rica to the thirty sixth session of the SCP also noted a lack of specialized infrastructure for manufacturing complex medicines such as biological and biotechnological medicines. The lack of technological capacities was also raised by TWN with respect to use of exceptions and limitations in general (see document SCP/25/3, paragraph 6).

112 A paper by Beatrice Stirner and Harry Thangaraj notes in this regard that, Brazil which issued a compulsory license is a relatively affluent developing country, which has private and public sector reverse engineering capacities to manufacture antiretrovirals and other medicines. Not many developing countries can act under comparable conditions such as a domestic technological, productive and regulatory capacity to reverse engineer and manufacture the pharmaceutical product without the assistance of the patent owner. See Beatrice Stirner and Harry Thangaraj, Learning from practice: compulsory licensing cases and access to medicines, Pharm. Pat. Analyst (2013) 2(2), 195–213.

113 See: COVID-19 heightens need for pharmaceutical production in poor countries | UNCTAD: https://unctad.org/news/covid-19-heightens-need-pharmaceutical-production-poor-countries.

Africa in the WTO also highlights that the limited domestic manufacturing capacity for producing COVID-19-related pharmaceutical products, diagnostics, and personal protective equipment in most countries worldwide has left them reliant on imports to meet their medical needs.[114] Another publication also notes that, according to the available data, while a patentee sometimes sets high prices for patented product in the absence of market competition, the vaccine inequity in the COVID-19 context is caused primarily by insufficient manufacturing levels that fail to meet demand, procurement and stockpiling initiatives, and the high concentration of production facilities, rather than the price of vaccines alone.[115]

64. The issue is rather complex, since oftentimes, the technological ability to make and use the patented invention is one thing, and the capacity to produce a marketable product on a commercial scale in a sustainable manner is another.[116, 117] Developing and bringing a generic product to market also requires substantial investment, even if generic producers do not need to incur R&D costs. Economies of scale and associated marketing costs are just a few examples of economic factors that might affect return on investment and consequently, business decisions of generic producers.[118] Taking those risk factors into consideration, governments could take certain policy measures, for example, the introduction of the regional mechanism in the Special Compulsory Licensing System under the TRIPS Agreement[119] or the government's commitment to procure a certain quantity of medicines. These issues, however, are outside the scope of this study.

65. One study notes that in addition to the issue of local capacity to manufacture or distribute AIDS medicines, more serious health policy problems exist in relation to the access to such medicines: even non-patented drugs have not been easily accessible; or they have expired in the central storage facilities; or they have been misappropriated.[120] Similarly, the WTO Members opposing a "TRIPS waiver" proposal have pointed out that lack of manufacturing capacity is the most notable obstacle, but have also highlighted other obstacles that a waiver alone is unlikely to resolve, such as underfunded health care and procurement systems and spiking demand.[121, 122]

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114 South Africa's intervention at the informal open-ended meeting of the TRIPS Council, 19 June 2020, available at: https://www.keionline.org/33388.

115 Andrew D Mitchell and Antony Taubman 'Practical means of applying the TRIPS Agreement's flexibilities to spur vaccine production', Asia-Pacific Research and Training Network on Trade, Working Paper, No.225. 2023, p.11.

116 Submission of the OAPI to the 22nd session of the SCP "the description only needs to present the means necessary for carrying out the invention: there is no requirement for the description to reveal those indications for the practical execution of the invention, i.e., execution know-how. There must be no confusion between the invention, pertaining to the patent, and its execution, pertaining to industrial know-how".

117 The statements made by the Delegation of Brazil in documents SCP/21/12, paragraph 58 and SCP/25/6 Prov., paragraph 48. See also Eric Bond and Kamal Saggi, Compulsory licensing, price controls, and access to patented foreign products, Department of Economics Vanderbilt University, April 2012, page 5, available at: http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_4_12/wipo_ip_econ_ge_4_12_ref_saggi.pdf .

118 One paper notes that "issuing a successful CL depends on a willing licensee who is able to develop the product, register it, and bring it to market. Companies might be willing to do this in larger and richer countries, but the economic incentives are weak in smaller and poorer countries. Single-country licenses are ineffective to incentivize robust generic competition by multiple licensee/entrants competing at efficient economies of scale producing sustainable cost savings". See a submission of the Health Global Access Project to the UN High-Level Panel on Access to Medicines.

119 Article 31*bis*.3 of the TRIPS Agreement.

120 Ben Sihanya, *Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya,* available at: https://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm.

121 Andrew D Mitchell and Antony Taubman, *Ibid*, p.21. Authors continue that: "[i]mplicit in these claims is that manufacturing capacity is a broader issue in respect of which IP rights can only play a limited role. Manufacturing capacity requires, amongst other things, adequate levels of investment, strong physical infrastructure systems, and suitable systems of labour."

122 The WTO General Council, the TRIPS Council and the Working Group on Trade and Technology Transfer are considering Member proposals to facilitate, *inter alia*, geographical diversification of manufacturing capacity,

[Footnote continued on next page]

66. Another related issue that affects production and availability of medicines is the lack of raw materials. Thus, in India, the Central government in an affidavit filed before the Supreme Court in the matter "Distribution of Essential Supplies and Services During Pandemic" dated May 9, 2021, with respect to compulsory license stated, *inter alia*: "[t]he main constraint is in availability of raw materials and essential inputs. Therefore, any additional permissions and licenses may not result in increased production immediately".[123]

Trade secrets

67. Article 29.1 of the TRIPS Agreement requires that an applicant for a patent discloses the claimed invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. If the disclosure of a know-how relating to, for example, optimal manufacturing of the claimed invention is not necessary to meet that requirement,[124] such know-how information may be protected under trade secret protection regime.[125] One study focusing on access to COVID-19 vaccines and trade secrets notes that vaccines are protected by a range of IP rights, most prominent being patents and trade secrets. Specifically, while vaccine formula may be protected by a patent, the complex processes involved in production of such complex biologics, the specialist knowledge on the use of equipment and the experience of the engineers controlling the production process – particularly for newer technology platforms like mRNA vaccines – are more likely to be protected as trade secrets.[126]

68. Thus, even if there is no patent in force in a particular jurisdiction, or a compulsory license is obtained to make the patented invention, further technological knowledge and substantial amount of experimentation may be required to manufacture the product.[127] Experts have stated that, in the context of COVID-19 related technologies, which are difficult to replicate or reverse engineer, obtaining access to confidential information is critical to technology transfer and generic vaccine production.[128, 129, 130]

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particularly in developing and LDC Members. See: Written Submission by the WTO Secretariat to the WHO INB on a Pandemic Instrument, 10 November 2023, available at: https://www.wto.org/english/tratop_e/trips_e/03_written_submissions_e.pdf.

123 In explaining how it plans to ensure that accessibility to medicines improve, the Indian government stated that: "[w]hen there is a surge in cases and in demand of patented medicines/drugs/vaccines from all over the world the solution needs to be found out essentially at an executive level engaging at diplomatic levels. Any exercise of statutory powers either under the patents act 1970 read with TRIP Agreement and Doha Declaration or in any other way can only prove to be counter-productive at this stage, The central government is very actively engaging itself with global organizations at a diplomatic level to find out a solution in the best possible interest of India. It is earnestly urged that any discussion or a mention of exercise of statutory powers either for essential drugs or vaccines having patent issued would have serious, severe and unintended adverse consequences in the countries efforts being made on global platform using all its resources, good-will and good-offices through diplomatic and other channels." See: https://www.livelaw.in/pdf_upload/uoi-affidavit-9052021-final-with-annexures-1-91-393168.pdf, paragraphs 44 and 47.

124 The Representative of OAPI explains: "the description only needs to present the means necessary for carrying out the invention; there is no requirement for the description to reveal those indications for the practical execution of the invention, i.e., execution know-how." See submission of the OAPI to SCP/22.

125 See Art. 39.1 and 39.2 of the TRIPS Agreement.

126 Olga Gurgula and John Hull, 'Compulsory licensing of trade secrets' (2021) 16(11) Journal of Intellectual Property Law & Practice, pp. 1242, 1244 and 1246.

127 See the statements made by the Delegation of Brazil in documents SCP/21/12, paragraph 58 and SCP/25/6, paragraph 48.

128 Andrew D Mitchell and Antony Taubman 'Practical means of applying the TRIPS Agreement's flexibilities to spur vaccine production', Asia-Pacific Research and Training Network on Trade, ARTNeT Working Paper Series, No.225. 2023, p.15.

129 In this connection, a call was made for introducing a mechanism for the compulsory licensing of trade secrets. See, e.g., Olga Gurgula and John Hull, 'Compulsory licensing of trade secrets' (2021) 16(11) Journal of Intellectual Property Law & Practice.

130 The proposal on TRIPS Waiver discussed recently in WTO contained obligations in four Sections of the TRIPS Agreement, including on Section 7 of the Agreement: 'Protection of undisclosed information'. See WTO Doc. IP/C/W/669/Rev.1.

69. The TRIPS Agreement requires Members to protect undisclosed information as defined in Article 39.1 of the Agreement. Consequently, trade secrets are protected by various legal instruments under the national laws. While these are diverse in character, they typically allow for exceptions to protect the public interest and national security.[131]

Quality standards

70. Furthermore, since the production and sale of medicines is highly regulated to ensure their safety and efficacy, manufacturing medicines without meeting the quality standards would fail to achieve the intended goal of improving access to those medicines. For example, a couple of cases were reported from Kenya and Zimbabwe where, although a compulsory license had been issued, local production of medicines was not successful because of the difficulties in meeting the WHO prequalification quality standards.[132, 133]

Test data protection

71. Article 39.3 of the TRIPS Agreement requires WTO Members to protect clinical trial data against unfair commercial use and disclosure, subject to certain conditions. It also provides for an exception to the obligation to protect such data against disclosure when this is necessary to protect the public interest or unless steps are taken to ensure that the data are protected against unfair commercial use. Chile, Colombia and Malaysia, for example, waive data exclusivity where necessary to protect public health.[134]

72. In general, countries have adopted different regimes of test data protection, ranging from data exclusivity to keeping the data secret while allowing the competent authorities to rely on the data.[135] Divergent regulatory mechanisms and cumbersome regulatory procedures have in themselves been identified as an obstacle to the timely production and distribution of COVID-19 related vaccines.[136]

73. With respect to compulsory licensing and test data protection specifically, in countries where test data is protected in the form of data exclusivity or market exclusivity, the implementation of the compulsory license may be impeded.[137, 138] In particular, unless the

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131 See Part III of the WIPO Guide to Trade Secrets and Innovation, 2024, available at: https://www.wipo.int/web-publications/wipo-guide-to-trade-secrets-and-innovation/en/part-iii-basics-of-trade-secret-protection.html.

132 The statements made by the Delegations of Kenya and Zimbabwe during the sharing session on countries' use of health-related patent flexibilities, paragraphs 104 and 108 of document SCP/20/13, respectively.

133 One publication reported: "With respect to local production of HIV/AIDS medicines, country experiences in Ghana, Kenya and Zimbabwe reveal major challenges: the high cost of bioequivalence tests for each product, required for prequalification by the WHO; the high cost of active pharmaceutical ingredients (APIs) when purchased in small quantities; and the inadequate market share and lack of economies of scale. The latter, in turn, are related to an inability to supply under the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) when manufacturers lack WHO prequalification for their products. These factors have rendered local production unsustainable in the medium to long term." See Patrick L. Osewe et al., *Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities*, 2008, The International Bank for Reconstruction and Development, The World Bank.

134 Trilateral Study, 2020, p. 61.

135 For the discussions on regulatory exclusivities in general, see the Trilateral Study, 2020, pp. 59 to 62 and 80 to 83.

136 Andrew D Mitchell and Antony Taubman 'Practical means of applying the TRIPS Agreement's flexibilities to spur vaccine production', Asia-Pacific Research and Training Network on Trade, ARTNeT Working Paper Series, No.225. 2023, p.16.

137 Data exclusivity provisions prevent regulatory authorities from relying on the reference product test data for approval of a generic medicine for a given period of time. Market exclusivity provisions prevent a regulatory authority from granting market approval for a certain period of time. Market exclusivity is distinct from data exclusivity because it prevents a competing firm from obtaining regulatory approval whether or not it is referring to the originator's data.

138 See, e.g., Ellen F. M. 't Hoen et al., Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation, Journal of Pharmaceutical Policy and Practice, June 2017.

national law specifies that data exclusivity may not be invoked when a compulsory license is granted, the needed products would not be practically authorized for commercialization.[139] This also applies to the situation where a country requires regulatory review of products destined for export under the Special Compulsory Licensing System.[140] Therefore, some countries provide for such explicit data exclusivity waiver in their laws, with a view to facilitating registration of generic medicines. For example, Chile and Malaysia do not provide data exclusivity if making, etc., of the product is allowed under a compulsory license.[141] In Canada and the European Union, a data protection waiver exists in relation to products produced under compulsory licenses for export under the Special Compulsory Licensing System.[142]

Availability of parallel imported medical products

74. Another issue that has been reported is that the enactment of the international exhaustion regime allowing parallel importation may not necessarily result in the anticipated level of availability of parallel imported pharmaceutical product in the country concerned.[143] In particular, noting that some countries allowing parallel importation of patented medicine lack guidelines for their regulatory agencies on authorizing these products, the submission of UNCTAD to the SCP highlighted the need for coherence between the areas of patent law and drug regulatory law in this respect.[144]

75. Similarly, the submission from Chile also reported that although parallel imports were permitted under the national law to acquire lower-priced goods from abroad, government bodies responsible for pharmaceutical procurement face practical obstacles.[145] These include difficulties in conducting public procurement abroad and negotiating with producers, who often refuse to sell directly and instead redirect them to local representatives or distributors, who do not offer the same prices available outside the country.

76. In summary, in the area of medical products, the regulatory approval regulations and public procurement processes abroad may also influence the availability of parallel imported products in the country concerned.

IMPACT OF CONSTRAINTS ON THE ACCESS TO AFFORDABLE ESPECIALLY ESSENTIAL MEDICINES FOR PUBLIC HEALTH PURPOSES IN DEVELOPING COUNTRIES AND LDCs

None of the Member States' submissions have provided information on impact of constraints on access to affordable especially essential medicines, including COVID-19 technologies, for public health purposes. Furthermore, a literature review has revealed a lack of meaningful empirical studies that would enable credible conclusions on this issue. Instead, numerous empirical studies have examined the relationship between patent protection and pharmaceutical product launch in developing countries, between patent systems and the pharmaceutical trade value, or between patent protection and general availability of medicines in developing countries and LDCs.[146] Leaving the impact of the constraints aside, even empirical studies providing a

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139 For example, in 2016, the issuing of a compulsory license was considered by the government of Romania for the hepatitis C medicine sofosbuvir, but the idea was reportedly not pursued because EU data exclusivity would expire only in 2024. See Ellen F. M. 't Hoen et al., ibid.

140 C. Correa, 'Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?', South Centre Policy Brief, No. 57, January 2019.

141 Section 5 of Malaysia 2011 Directive of Data Exclusivity, Article 91 of Law 19.996 of Chile, Article 4 of Decree 2085 of 2002 of Colombia.

142 Article 18 of EC Regulation No 816/2006 of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. See also the Trilateral Study, 2020, p.61.

143 See document SCP/34/3, paragraph 146.

144 See submission of UNCTAD in document SCP/25/3.

145 See submission from Chile to SCP/36.

146 For summary of such studies, see, e.g., documents SCP/21/8, SCP/31/5 and SCP/34/6.

systematic assessment of how patent flexibilities influence access to medicines in various countries are also scarce. Since the latter is beyond the scope of this paper, reference is made to SCP documents produced under the agenda item "exceptions and limitations to patent rights" where information on some countries' experiences regarding the impact of the use of certain patent law provisions on access to medicines can be found.[147]

PRELIMINARY CONCLUSIONS

77. This paper aimed to provide an update on constraints faced by developing countries and LDCs in making full use of patent flexibilities and their impact on the access to affordable especially essential medicines for public health purposes in those countries, in view of their experiences relating to the COVID-19 pandemic.

78. In general, when implementing the available flexibilities into the national patent laws with a view to access to medicines, governments seek to strike a right balance among conflicting interests of various stakeholders in order to optimize the public interest as a whole and to support access to both existing and future medicines. They adopt certain provisions in their national laws and set administrative procedures. Then, various stakeholders utilize those legal provisions to meet their needs.

79. As demonstrated in this paper, the debates related to the full use of patent flexibilities are twofold: national implementation through transposition of international law by governments and use of national provisions by individual stakeholders. As to the former, this study addressed the issues relating to international rules as well as national legal and administrative frameworks, national governance and internal coordination and relations with other governments. Regarding the latter, it addressed various factors that might influence the use of national law provisions by various stakeholders, such as clarity and certainty of law, technical and technological capacity, and identification of relevant patents and their status and other aspects that might affect the use of legal mechanisms implemented in the respective national law.

80. With respect to COVID-19-related experiences specifically, several governments stated that they faced constraints in implementing Articles 31 and 31*bis* of the TRIPS Agreement. Specifically, practical challenges in the implementation and utilization of these provisions were noted in some countries. Additionally, the absence of adequate administrative and judicial procedures for proper enforcement has been identified. Institutional challenges, including limited institutional capacity, remain a significant barrier for developing countries and LDCs in fully utilizing patent flexibilities. A lack of inter-institutional coordination and internal influences has also been reported.

81. Regarding constraints faced by various stakeholders in using a national legal frameworks that have implemented policy options, the following challenges have been noted, particularly in light of COVID-19-related experiences: ambiguity and uncertainty in the scope of national law provisions remain an issue in some countries. Specifically, procedural details related to compulsory licenses are reportedly unclear or not well-defined in national legal frameworks, making them difficult to navigate. Lack of local IP capacity, including IP specialists who can support local innovators, is another area of concern. Additionally, it is reported that

147 See section 'Results of national/regional implementation of the exception' in documents: SCP/35/4, SCP/34/3, SCP/32/3, SCP/30/3, SCP/29/3 and SCP/28/3. It is important to note that those experiences and findings may be valid within the specific context of the country/region, and no general conclusions about the impact of certain patent law provisions on access to medicines could be drawn from them. This is because: (i) patent law provisions are different from one country to another; (ii) the socio-economic environment and the legal framework in which the patent law provisions are used are different in each country; (iii) a patent law as a whole strikes a balance between technology holders and technology users. Focusing on the effect of one particular provision would not provide an overall assessment; and (iv) access to medicines and medical technologies is rarely due to a single isolated factor, but due to various factors which may, or may not, be inter-related.

stakeholders, particularly in developing countries and LDCs, continue to face practical challenges in identifying patents relevant to a specific product and determining the legal status of such patents, while various initiatives have been taken at the nation, regional and international level. Both the accessibility of data and the IP expertise to analyze and comprehend the data are relevant to these challenges. It is an important matter, since understanding the legal status of a patent is closely related to transfer of technology through patent licenses.

82. As discussed in this paper with respect to the use of compulsory licenses, the factors that determine the individual use of such licenses are very complex. Anecdotal examples cited in this paper suggest that the fact that a compulsory license has not been used does not necessarily mean that the policy objective has been compromised. Conversely, use of a compulsory license alone does not necessarily lead to improved access to medicines. It may also be noted that a low number of compulsory licenses granted on various countries, whether they are developed, developing or least developed countries, may not necessarily an indication of the existence of constraints on its use as such. It may be due to other reasons, such as no patent was granted on the invention concerned in a given country[148], or there was no need to resort to grant of a compulsory license to achieve the policy goal of access to medicines.[149, 150, 151] Thus, the effect of legal provisions/measures as a whole on the intended policy goal should be a central question for the evaluation of the full use of patent flexibilities.

83. At the same time, the patent system being just one building block in the innovation and public health ecosystems, the use of patent flexibilities alone may not achieve intended policy outcome of access to medicines. For example, though these are beyond the scope of patent law, the limited manufacturing capacity for producing COVID-19-related pharmaceutical products in developing countries and LDCs highlighted many countries continue to be a major general challenge in building capacities for using needed technology, producing final products according to the quality standards and delivering them to patients. Some Member States and

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148 One of the main reasons behind the low number of compulsory license grants in the East African Community was explained by the fact that all the pharmaceutical products produced and/or sold locally were generics, although the expert noted that the situation might change in future as they were moving to new treatment regimes. See Policy Coherence to Boost East Africa Pharmaceutical Industry, available at http://www.ip-watch.org/2015/10/02/policy-coherence-to-boost-east-africa-pharmaceutical-industry/. Similarly, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) states that, in reality, most pharmaceutical companies either do not patent in developing countries and LDCs or do not enforce their rights in those jurisdictions. See document SCP/27/6.

149 In some cases, the possibility of issuing compulsory licenses has led to price reductions for pharmaceuticals or making them otherwise available, for example, through the voluntary licensing (see the submission of Germany and Brazil to SCP/30). In that submission, Brazil states that, in most cases, public interest declaration of a drug in itself promotes the intensification of negotiations for price reduction. This measure represents a signal from the Government of the importance of the medicine to the Brazilian health system and the possibility of granting a compulsory license if the cost of treatment exceeds the budget. For similar effects of compulsory license provisions, see Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries (Kluwer Law International, 2001) 328; Hilary Wong, 'The case for compulsory licensing during COVID-19' (2020) 10(1):010358 Journal of Global Health 1, 2; Carlos Correa, The Use of Compulsory Licenses in Latin America, 2013, available at: https://www.southcentre.int/question/the-use-of-compulsory-licenses-in-latin-america/; and Ellen F.M 't Hoen, Private Patents and Public Health, Changing Intellectual Property Rules for Access to Medicines, 2016, p.71.

150 In Kenya, a local company applied for a compulsory license after taking measures to obtain voluntary licenses from the patentees. It led to the negotiations between the local company and the patentees and the conclusion of voluntary licenses, without having a need to issue a compulsory license. See document SCP/20/13, paragraph 104.

151 In some cases, the governments may not see the need to issue compulsory licenses, because national treatment programs were being sustained by health financing mechanisms, such as the Global Fund and The U.S. President's Emergency Plan for AIDS Relief (PEPFAR). See the Report of the United National Secretary-General's High-Level Panel on Access to Medicines, *Promoting Innovation and Access to Health Technologies*, September 2016. See also Patrick L. Osewe *et al.,* Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities, 2008 The International Bank for Reconstruction and Development , The World Bank, p. 14.

researchers have also pointed to trade secrets, regulatory rules and quality standards to be met by medical products, test data protection and availability of parallel imported medical products as other factors that may affect the policy goals.

84. No credible conclusion can be drawn on the impact of full use of patent flexibilities on access to medicines before or after the COVID-19 pandemic period, let alone the impact of constraints to such use, due to lack of data sufficient to permit empirical impact analysis. In terms of legal transposition of international agreements to national laws, information concerning use of flexibilities by Member States is widely accessible via, for example, WIPO Lex[152] and a Database on Flexibilities in the Intellectual Property System[153]. In addition, more detailed information on implementation of certain flexibilities has been collected through the activities of the SCP.[154] Furthermore, some sources provide insights into various policy options that some governments have deployed in response to the COVID-19 pandemic.[155]

85. However, systematic data that goes beyond such legal information is scarce. In certain cases, there are inherent difficulties in collecting information about the use of national provisions by individual stakeholders, since it is not always documented and/or publicly available or countable. For example, where those provisions relate to exceptions and limitations to patent rights, activities that benefit from the experimental use and research exception take place in research laboratories, and where international exhaustion doctrine is applied, importation of parallel goods are not necessarily documented separately. Furthermore, how to interpret the data may not always be straightforward. For instance, a high number of oppositions could be associated to the effectiveness of an external control mechanism, to the low quality of substantive examination or to any other incidental reason, such as a high level of potential threat to third parties due to the perceived high value of the patent concerned.

86. In addition, the complexity of the subject may be another reason why this area has not been explored. As discussed earlier, the mere introduction of a certain patent law provision implementing the flexibilities may not necessarily lead to the intended outcome, unless it is placed in the context and environment that facilitate the outcome. For example, introduction of international exhaustion alone might not be sufficient to induce parallel imports, unless it is supported by health regulations and trade rules. Securing access to medicines is of multi-disciplinary nature, and it may require a comprehensive understanding of how various factors could work together in the specific national setting.

87. Therefore, to better understand the impacts of flexibilities on access to medicines, and the constraints to their use, more data is needed to permit empirical analysis. In the previous version of the SCP document covering the same topic (document SCP/26/5), the Secretariat suggested that one way to help inform policy dialogue on these issues be through reporting by the Member States on the implementation and use of patent flexibilities in their territories. As some Member States continue to face challenges in making full use of patent flexibilities, that suggestion is retained in this updated document. In the context of the intersections between public health, intellectual property and trade, the innovation dimension and the access dimension of medical technologies are often highlighted. Neither dimension is static. Each evolves with time, as the socio-economic environment changes and technologies develop. Regular reporting might also assist the better understanding of the dynamic factors involved in

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152 http://www.wipo.int/wipolex/en/.

153 http://www.wipo.int/ip-development/en/agenda/flexibilities/database.html.

154 For example, the Questionnaire on exceptions and limitations (http://www.wipo.int/scp/en/exceptions/), opposition and administrative revocation mechanisms (http://www.wipo.int/scp/en/revocation_mechanisms/), certain aspects of national/regional patent laws (http://www.wipo.int/scp/en/annex_ii.html) and studies on inventive step (SCP/30/4, SCP/29/4, SCP/28/4, SCP/22/3) and sufficiency of disclosure (SCP/35/5, SCP/34/5, SCP/22/4).

155 See e.g., Staff Working Paper ERSD-2020-12 of October 21, 2020 ‘Patent-Related Actions Taken in WTO Members in Response to the Covid-19 Pandemic’ by Xiaoping Wu and Bassam Peter Khazin.

making full use of flexibilities, and provide insights into finding the optimal trajectory to meet national policy goals.

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