

Standing Committee on the Law of Patents

Twenty-Sixth Session
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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

Document prepared by the Secretariat

INTRODUCTION

1. At its twenty-fourth session, held in Geneva from June 27 to 30, 2016, the Standing Committee on the Law of Patents (SCP) agreed that the Secretariat would prepare a study to be submitted to its twenty-sixth session, consulting with independent experts, the World Health Organization (WHO) and the World Trade Organization (WTO), and that the study would examine the 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.
2. Pursuant to the decision, above, this document contains the said study for the Committee's discussions at its twenty-sixth session to be held in Geneva from July 3 to 6, 2017. As mandated by the Committee, in preparing the study, the Secretariat consulted with the WHO and WTO as well as the two independent experts, namely, Ms. Pamela Andanda, Professor of Law at the University of the Witwatersrand, Johannesburg, South Africa, and Mr. Andrew Christie, Professor of Law at the Melbourne Law School, University of Melbourne, Melbourne, Australia.
3. In order to set the scope of the study, the document first looks into the terminologies, "patent flexibilities" and "full use of flexibilities". It then examines the constraints faced by developing countries and LDCs in making full use of such patent flexibilities. Furthermore, the study examines the impact of such constraints on the access to affordable especially essential medicines for public health purposes in developing countries and LDCs.

4. The document is primarily based on the information collected through the SCP activities, including seminars and sharing sessions, supplemented by publically available literature. It is not a comprehensive literature survey on this topic.

5. In relation to existing literature on flexibilities, a number of academic authors focus on the meaning and scope of flexibilities and contain recommendations on how to effectively use those flexibilities in general.¹ While many of those studies underline the importance of flexibilities in the promotion of access to medicines in developing countries and LDCs in general, they do not necessarily pinpoint constraints in making their full use and how those constraints impact the access to medicines. Thus, in accordance with the agreed scope of the study, this document does not include such general issues on flexibilities, but primarily focuses on the constraints to their use and their impacts on the access to affordable especially essential medicines for public health purposes in developing countries and LDCs. Similarly, the paper does not provide an analysis of legal obligations created by the international agreements regarding patents; neither does it enumerate the specific options made available in those international agreements, nor does it thoroughly examine how each specific option impacts on access to affordable medicines.

TERMINOLOGIES

Patent flexibilities

6. 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.²

7. 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.³ 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.⁴

¹ See for example, Sisule F. Musungu and Cecilia 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; UNDP, *Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement*, 2010; 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; Tenu Avafia et al., *The TRIPS Agreement and Access to ARVs*, UNDP, 2006; Correa, C., *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective*, ICTSD / UNCTAD, 2007; and Ellen F. M’t Hoen, *Private Patents and Public Health, Changing Intellectual Property Rules for Access to Medicines*, 2016.

² http://www.wipo.int/ip-development/en/agenda/flexibilities/meaning_of_flexibilities.html.

³ For instance, Articles 1.1 and 8.1 of the TRIPS Agreement.

⁴ Carolyn Deere, *The Implementation Game*, Oxford University Press, 2009, p. 27.

8. 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 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.

9. 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.
- 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.
- 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.”

10. 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.⁵ 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;⁶
- (ii) each WTO Member, whether it is a developed, developing or least-developed country, has such right;
- (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.

⁵ For the discussion on the concept of flexibilities, see WHO, WIPO, and WTO Study, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, 2012, p. 71 and 72.

⁶ Document CDIP/5/4 Rev.; Carolyn Deere, *The Implementation Game*, Oxford University Press, 2009, p. 68.

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.);

(ii) each Member's range of options to interpret and apply explicit, non-defined expressions 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 choose whether and how it implements 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. 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.⁷

13. In some instances, the term "flexibilities" has been utilized in the literature and in statements made by various delegations during WIPO meetings to express a conception of flexibility different from that in the discussion above. From that point of view, the term "flexibilities" does not only address the right and freedom of Member States to implement certain options within their national laws as such, but rather refers 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, for example, "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 the presence of these options within the patent law of country X. Thus, it should be highlighted that the way this term is utilized affects the understanding of the term "full use of flexibilities".

⁷ Document SCP/20/13, paragraph 104.

Full use of patent flexibilities⁸

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 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 Council⁹, by the World Health Assembly (WHA)¹⁰ and by the UN General Assembly¹¹ 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.¹²

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 in view of an overarching policy. 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.¹³ Furthermore, any flexibility in international treaties needs to be considered for action by national authorities in the light of the circumstances in their countries.¹⁴ In that respect, there is no one-size-fits-all in the use of flexibilities by each government.

⁸ 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.

⁹ For example, A/HRC/RES/12/24, A/HRC/RES/15/12 and A/HRC/RES/17/14.

¹⁰ For example, WHA/56.27, WHA/57.14, WHA/59.26 and WHA/60.30.

¹¹ A/RES/65/1 and A/RES/65/277.

¹² A/RES/70/1, SDG 3.

¹³ WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, Element 6, paragraph 36.

¹⁴ *Ibid.*

17. Consequently, 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. The full use of flexibilities presumably results in Member States, each taking into account its own circumstances, assessing and applying the available options in diverse ways, resulting in different outcomes in national patent laws.¹⁵

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 governments to exercise their rights 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. Some SCP participants have raised such constraints by stakeholders during the previous 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 look into 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.¹⁶ 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 is 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 power¹⁷ which may result in reducing the ability of parties to those agreements to use flexibilities. During the SCP, one non-governmental organization reiterated its concern on free trade agreements (FTAs),

¹⁵ See, for example, responses to the SCP Questionnaire on Exceptions and Limitations to Patent Rights: <http://www.wipo.int/scp/en/exceptions/>.

¹⁶ https://www.wto.org/english/tratop_e/region_e/region_e.htm.

¹⁷ 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>.

which include obligatory provisions that are not found in the TRIPS Agreement and in its view, are against the public interest.¹⁸ 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)). Assessing the impact of specific chapters of FTAs in an isolated manner, however, might disregard the overall architecture of the FTAs. In practice, governments' motives to enter into FTA negotiations and to accept at times controversial trade-offs are complex. Therefore, it appears important that the discussion on this issue involves assessment of the FTA as a whole in terms of wealth creation and improved living standards.^{19 20}

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 has provided a clearer context for specific operational choices for the use of policy options under the TRIPS Agreement.²¹ 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 understanding about the full range of options available for their implementation.²²

¹⁸ 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 Center <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.

¹⁹ WHO, WIPO, and WTO Study, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, 2012, p. 190.

²⁰ 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.

²¹ WHO, WIPO, and WTO Study, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, 2012, p. 73.

²² See, for example, Bulletin of the WHO, *Access to AID Medicines Stumbles on Trade Rules*, available at: <http://www.who.int/bulletin/volumes/84/5/news10506/en/>; Anand Grover, *Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights. Including the Right to Development*, 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.

Complexity of practical implementation

23. The practical implementation of any patent flexibility has its own complexity. For example, a mechanism to enable compulsory licensing expressly for exports of medicines to countries confronted with no or limited domestic capacity, the “Paragraph 6 System”, 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.²³ It has been part of the TRIPS Agreement, on par with all other flexibilities, with the entry into force of the amendment to the TRIPS Agreement on January 23, 2017. To date, the System has been used only once, as a consequence of which some WTO Members have expressed the view that the System is overly complex and have questioned its practical applicability.²⁴ Various views have been presented as to whether constraints on its use were built into the system, or whether it was a consequence of how individual countries chose to implement the System.²⁵ The entry into force of the amendment has spurred a renewed discussion in the WTO TRIPS Council as to how to make effective use of the System and to overcome any constraints on its use.²⁶ Another recent factor is the increasing number of countries, that are traditional exporters of medicines, have introduced new legislation to enable exports under the System. It is expected that those developments support demands from Members to look into how to make the Paragraph 6 System effectively work in practice. The WTO Secretariat notes 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.^{27 28}

²³ Dedicated webpage on the WTO decision of 30 August 2003:

https://www.wto.org/english/tratop_e/trips_e/public_health_e.htm.

²⁴ 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.

²⁵ The views expressed by WTO Members on the operation of Paragraph 6 System can be found in WHO, WIPO, and WTO Study, *Promoting Access to Medical Technologies and Innovation, Intersections between Public Health, Intellectual Property and Trade*, 2012, p.179 and 180.

²⁶ TRIPS Council Minutes of Meeting, IP/C/M/85.

²⁷ 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.”

²⁸ 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.

Operation of law and administrative framework

24. 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.²⁹ For the operation of law, sufficient details are required in order to ensure legal certainty and predictability.

25. 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.³⁰ Where more than one administrative body is involved, the clarity of their responsibilities and mandates might be also important for a clear decision-making process.

Institutional capacity

26. 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”.³¹ 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”.³² 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 experts, and the provision of targeted technical assistance to Member States, particularly to developing countries and LDCs.³³

27. 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. Recently, the need to reinforce technical assistance and capacity building to Members of the WTO was raised by some Members 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.³⁴

²⁹ 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.”

³⁰ See also Articles 41.2 and 62 of the TRIPS Agreement.

³¹ Document SCP/19/8, paragraph 91.

³² Document SCP/25/6/Prov., paragraph 165.

³³ See documents SCP/16/7, SCP/16/7 Corr. and SCP/24/4.

³⁴ TRIPS Council Minutes of Meeting, IP/C/M/84/Add.1.

28. 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.³⁵ In addition, WIPO’s technical assistance and capacity building activities cover not only 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.^{36 37}

29. 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.³⁸ For example, one study states 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.

National governance and internal coordination

30. 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 and the protection and enforcement of intellectual property and those responsible for public health.³⁹ Various

³⁵ See document SCP/18/5.

³⁶ During the period from January 2010 to September 2016, legal advice, comments and draft laws were provided in response to requests from the authorities of 48 countries. In the same period, advisory missions and outreach missions on IP laws were undertaken in 22 countries, 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.

³⁷ 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.

³⁸ 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: <http://www.who.int/bulletin/volumes/84/5/news10506/en/>; 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://www.msh.org/sites/msh.org/files/mds3-jan2014.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/>.

³⁹ 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.

publications have stressed the need to take a nationwide collaborative approach, involving all stakeholders for effective implementation of the TRIPS flexibilities into national laws.⁴⁰ 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.⁴¹

Extrinsic influences

31. During the SCP session, 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.⁴² Some publications also cite those cases, most of which are the cases of Brazil, India, South Africa, Thailand and most recently, Colombia.⁴³ One publication, while noting the concerns about possible negative reactions from developed countries' governments and their implications for trade or political relations, questions the generalization of the negative effect and the scale of such extrinsic influences.⁴⁴

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

32. 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.

⁴⁰ *Ibid.*

⁴¹ 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.

⁴² 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).

⁴³ Anand Grover, *Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights. Including the Right to Development*, 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: <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).

⁴⁴ 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/>. Referring to the cases of Ecuador and Indonesia, which had granted several compulsory licenses without any known negative repercussions, the author stated that such concerns might be exaggerated. The author noted that no complaints had been submitted against countries that granted such licenses under the WTO dispute settlement rules indicating their legitimacy under the TRIPS Agreement, particularly after the confirmation made by the Doha Declaration.

Ambiguity and uncertainty of national law

33. It appears that 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 those points with respect to the use of compulsory licenses.⁴⁵

Technical and technological capacity

34. 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.⁴⁶

35. 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.

36. 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.⁴⁷ This point was raised by TWN with respect to use of exceptions and limitations in general.⁴⁸

Identifying relevant patents and their status

37. In order to determine whether a patent license is necessary to legally manufacture or import a pharmaceutical product, first, relevant patents covering that product should be identified, and then, the legal status of such patents should be determined. Particularly, in

⁴⁵ 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 Cecilia 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.

⁴⁶ See document SCP/25/3, paragraph 6.

⁴⁷ See document SCP/21/4, paragraph 66. The Questionnaire as well as the responses received from Member States are available in full on the website of the SCP electronic forum at:
<http://www.wipo.int/scp/en/exceptions/>.

⁴⁸ See document SCP/25/3, paragraph 6. The said document also contains, in paragraph 27, the following observation by TWN: “[...] a lack of technological capacities, especially manufacturing capability, prevents many WIPO Member States from using exceptions and limitations to patent rights. For instance, the vast majority of the developing countries and all LDCs, except Bangladesh, lack the manufacturing capacity in the pharmaceutical sector.”

developing countries and LDCs, such information is not easy to obtain.⁴⁹ Even if legal status information is made available to the public, the format of such information varies.⁵⁰ Often, a good knowledge of patent procedures in a given country is necessary to fully understand the legal status of the patent concerned. The difficulty faced by those who do not have sufficient technical and IP expertise in unequivocally identifying patents covering a specific pharmaceutical product or process has been fairly known. 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.⁵¹ 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.⁵²

38. In some countries, 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.⁵³ While it sounds relatively straightforward, in reality, the experience in Europe shows otherwise. It was reported that only half of the Member States of the European Patent Office (EPO) had been communicating the up-to-date legal status information of the European patents in their national phase to the EPO so that the EPO could incorporate that information in the European Patent Register.⁵⁴

Other aspects that affect the use of compulsory licenses

39. It was reported that the number of compulsory licenses granted in developing countries and LDCs has been low despite the fact that national laws of those countries provide for different modalities of compulsory licensing. In some cases, the low number of such grants may not necessarily relate to constraints on its use as such, but may be due to the reasons described in paragraphs below.⁵⁵

(i) No patents

40. Whether to file a patent application in a specific country or not is primarily an economic and business decision of the technology holder. Therefore, patent applications on pharmaceutical products and processes may be filed in some countries but not in others. In addition, since the patentability criteria are not exactly the same in all countries, a patent may be granted on a given invention in some countries, but not in others. One of the main reasons behind the low number of compulsory license grants in the East African Community was

⁴⁹ The Medicines Patents and Licences Database of the Medicines Patent Pool (MPP) launched in 2016 provides information on the intellectual property status of some medicines in developing countries. MedsPaL includes patent and licensing data on HIV, hepatitis C and tuberculosis treatments covering 4,000 national patent applications in more than 100 low- and middle-income countries. See <http://www.medspal.org/>. The WHO published a guide on how to conduct patent searches for medicines: <http://apps.who.int/medicinedocs/en/d/Js17398e/>.

⁵⁰ The Committee on WIPO Standards has established a Task Force for the preparation of a proposal to set a new WIPO standard for the exchange of patent legal status data by industrial property offices.

⁵¹ The statement made by the Representative of KEI (document SCP/25/6/Prov., paragraph 52).

⁵² See Ellen F.M 't Hoen, *Private Patents and Public Health, Changing Intellectual Property Rules for Access to Medicines*, 2016, p.72.

⁵³ 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.

⁵⁴ The statement made by the Delegation of Ireland (document SCP/25/6 Prov., paragraph 181).

⁵⁵ Ellen F.M 't Hoen, in *Private Patents and Public Health, Changing Intellectual Property Rules for Access to Medicines*, 2016, presents data on compulsory licenses and government use authorizations granted between 2001 and 2014.

explained by the fact that all the pharmaceutical products produced and/or sold locally were generics.⁵⁶ Another study examining the use of compulsory licenses in Latin American countries noted that the reasons of limited use of such licenses in the region may relate to the fact that many medicines under patent in developed countries had not received protection in Latin America in the pre-TRIPS era and, hence, the need for compulsory licenses and/or government use may have not been so pressing.⁵⁷

41. Similarly, in relation to the implementation of the Paragraph 6 System, a study focusing on Africa reports that most countries in the region procure their first-line treatment for HIV/AIDS from India, where most of those medicines were not patented.⁵⁸ However, some WTO Members have expressed their concern that the implementation of full patent protection for pharmaceutical products in India, coupled with the expiry of the transition periods in LDCs, could make it more difficult in the future to procure generic versions of new medicines.⁵⁹

42. The research conducted by the University of Ottawa on the WHO Model List of Essential Medicines (MLEM) found that, of the 375 items on the 2013 WHO MLEM, 95% are not under patent protection in most lower-income countries, meaning that patents with respect to these medicines have expired, or were not filed in the first place.⁶⁰ Authors noted, however, that in the long-term, the proportion of patented products on the MLEM would likely increase. While such general statistics might provide an overall picture of patenting activities on essential medicines, impacts of a small number of patented essential medicines on public health can only be assessed case-by-case in each country concerned.

(ii) No need to resort to a compulsory license

43. In some cases, the reasons why compulsory licenses have not been issued can be related to the fact that the possibility of issuing such licenses has led to price reductions for pharmaceuticals or making them otherwise available, for example, through the voluntary licensing. 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.⁶¹ In Latin America, some cases where the announcement of the intention to use compulsory licenses led to price reductions for medicines without the need to resort to compulsory licenses are also documented.⁶²

⁵⁶ The expert noted that the situation may 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/>.

⁵⁷ South Centre, *The Use of Compulsory Licenses in Latin America*, 2013, available at:

<https://www.southcentre.int/question/the-use-of-compulsory-licenses-in-latin-america/>.

⁵⁸ 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, The World Bank, 2008.

⁵⁹ WHO, WIPO, and WTO Study, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, 2012, p. 179, indicating observations made by the WTO members on whether the Paragraph 6 System is fulfilling its intended function. Following a decision taken by the WTO General Council on November 30, 2015, the transitional period applies until January 1, 2033 (WTO document WT/L/971).

⁶⁰ Reed F Beall and Amir Attaran, *Global Challenges Report: Patent-based Analysis of the World Health Organization's 2013 Model List of Essential Medicines*, WIPO, available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=334437.

⁶¹ Document SCP/20/13, paragraph 104.

⁶² Carlos Correa, *The Use of Compulsory Licenses in Latin America* by Carlos M. Correa, 2013, available at: <https://www.southcentre.int/question/the-use-of-compulsory-licenses-in-latin-america/>. See also Ellen F.M 't Hoen, *Private Patents and Public Health, Changing Intellectual Property Rules for Access to Medicines*, 2016, p.71.

44. It was reported that 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).⁶³

Other challenges where use of flexibilities has not led to intended policy outcomes

45. In some cases, use of a national patent system that has implemented policy options has not led to the intended outcome of improving access to medicines. There were cases in 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.⁶⁴ 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."⁶⁵

46. The academic literature also notes other internal challenges. For example, 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 access to such medicines: even non-patented drugs have not been easily accessible, they have expired in the central storage facilities or they have been misappropriated.⁶⁶

47. In general, common risk factors associated with manufacturing and commercial activities cannot be eliminated by use of flexibilities. Oftentimes, the technological ability to make and use the patented invention is one thing, and the capacity to produce a marketable product at the commercial scale in a sustainable manner is another thing.^{67 68} Developing and bringing a generic product to market also requires a substantial investment, even if generic producers do

⁶³ 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. The Report notes that as of September 2015, PEPFAR was supporting antiretroviral treatment for nearly 9.5 million people worldwide and that as of mid 2015, the Global Fund has provided HIV/AIDS treatment to 8.6 million people. See footnote 120 of the Report, p.45. 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.

⁶⁴ 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.

⁶⁵ 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.xv.

⁶⁶ 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.

⁶⁷ 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".

⁶⁸ 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.

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. Taking those risk factors into consideration, governments could take certain policy measures, for example, the introduction of the regional mechanism in the Paragraph 6 System⁶⁹ or the government's commitment to procure a certain quantity of medicines. These issues, however, are outside the scope of this study.

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

48. The literature review on the subject has shown that no meaningful empirical studies have been published to date that would allow credible conclusions to be drawn about the impact of constraints to the full use of patent flexibilities on access to affordable and especially essential medicines in developing countries and LDCs. 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. The summary of those studies can be found in document SCP/21/8, pages 21 and 22. Leaving the impact of the constraints aside, even empirical studies providing a systematic assessment of impact of patent flexibilities on access to medicines in various countries are also very scarce.

49. Although the latter is beyond the scope of this paper, several countries' experiences regarding the impact of the use of certain patent law provisions on access to medicines are reported during the SCP sessions and in some publications:

(i) The Delegation of Brazil reported to the SCP that the compulsory license that the government had issued to local producers on antiretroviral drug efavirenz in 2007 reduced spending in 2007 by about 30 million US dollars, and that the estimated savings for the Brazilian government by 2012 had reached \$236.8 million US dollars.⁷⁰ The Delegation of Ecuador also reported that as a result of compulsory licenses granted in 2014 for antiretroviral drugs, Ecuador had achieved between 30% and 70% in savings for the Ministry of Health.⁷¹ The assessment carried out by the government of Thailand on the effect of the compulsory license with regard to a cancer drug imatinib concluded that by 2009, the increased availability of that drug in the Thai health care system resulted in a gain of 2,435 quality adjusted life years.⁷²

(ii) The grant of compulsory licenses does not automatically lead to increased access to medicines, as described in paragraphs 45 to 47, above. In addition, some stakeholders claim that the grant of a compulsory license may have a chilling effect on research-based companies in terms of undertaking risky research and attractiveness of the market, potentially hurting patients who may require new and innovative life-saving therapies.⁷³

⁶⁹ Article 31bis.3 of the TRIPS Agreement.

⁷⁰ Document SCP/21/12, paragraph 58.

⁷¹ Document SCP/21/12, paragraph 59.

⁷² See Ellen F.M 't Hoen, *Private Patents and Public Health, Changing Intellectual Property Rules for Access to Medicines*, 2016, pp.66-70. In March 2012, a compulsory license was issued by the Controller of Patents in India to its domestic generic drug producer, Natco Pharma Limited, on patented in India by Bayer Corporation cancer medicine, sorafenib. The impact of the compulsory licensing order is that the price charged for the drug by Natco would not exceed \$176 a month (which is about three percent of the price charged by Bayer for the drug). See <http://www.gibsondunn.com/publications/Documents/CompulsoryLicenseGranted-IndianPatentOffice.pdf>.

⁷³ See <http://www.businesswire.com/news/home/20070504005566/en/Merck-Statement-Brazilian-Governments-Decision-Issue-Compulsory>; *A Bitter Pill*, available at: <https://www.theguardian.com/commentisfree/2007/may/08/abitterpill>; and *The campaign for use of*

(iii) Some empirical work on parallel trade exists, focusing on the case of the European Union (EU). In principle, the legalization of parallel imports, as well as the elimination of exchange rate fluctuations resulting from the Euro adoption, should have reduced price dispersion across EU countries. However, empirical evidence of the effect of EU integration on price dispersion shows mixed results.^{74, 75}

(iv) The European Commission report on the pharmaceutical sector found that certain strategies to create “patent clusters” might impede the launch of generic versions of the patented product, therefore implicating access and further innovation in the pharmaceutical sector.⁷⁶ In this regard, the Commission on Intellectual Property Rights, Innovation and Public Health commented that “demarcating the line between incremental innovations that confer real clinical improvements, therapeutic advantages or manufacturing improvements, and those that offer no therapeutic benefits is not an easy task. But it is crucial to avoid patents being used as barriers to legitimate competition”.⁷⁷ With respect to patents related to one active pharmaceutical ingredient, one study found that, in Australia, a mean of 49 patents were associated with each active pharmaceutical ingredient of 15 high-cost drugs, and three-quarters of those patents were owned by companies other than the drug’s originator.⁷⁸

50. 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;

[Footnote continued from previous page]

- compulsory licensing in Thailand*, available at: <http://makemedicinesaffordable.org/en/the-campaign-for-use-of-compulsory-licensing-in-thailand/>.
- ⁷⁴ Ganslandt & Maskus (2004) show that parallel imports have resulted in a reduction of the prices of original products for the top 50 drugs in Sweden. However, Kanavos et al. (2004) finds parallel imports have had little effect on prices in the EU for the 20 top-selling drugs. By and large, parallel imports of these drugs were not sold at much of a discount to original products. The authors point out that parallel imports do not generate significant savings either to patients or to national health systems in most cases. Kyle et al. (2008) finds no reduction in the price dispersion of a large sample of pharmaceutical products within the EU relative to a control group of countries without parallel trade. This suggests that parallel trade did not induce originators to alter their pricing decisions on existing products very dramatically, nor did parallel imports substantially lower average (quantity-weighted) prices. See Margaret Kyle, *Product Diversion in Pharmaceuticals: Report to DfID and IGFAM*, February 24, 2015.
- ⁷⁵ In addition, some studies note that allowing parallel importation of pharmaceuticals could potentially enable firms to reverse engineer such imports available on the market. See, for example, Keith E. Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries* (Final Report to WIPO, 2001), p. 41. On the other hand, some other studies suggest that wide availability of parallel import products may discourage foreign right holders from investing in the domestic market, depending on the characteristics of such market. See, e.g., Rod Falvey and Neil Foster, *The role of intellectual property rights in technology transfer and economic growth: theory and evidence*, UNIDO Working Paper, 2006.
- ⁷⁶ In a European Commission report on the pharmaceutical sector, the Commission found that companies reportedly filed a significant number of patents on variations of the same product, especially for blockbuster medicines late in the life cycle of a medicine when the main patent was about to expire. This practice reportedly made it difficult for generic competitors to develop a generic version without infringing one of the patents filed around a medicine, and increased the likelihood of litigation between generic and originator companies. See European Commission Competition DG, *Pharmaceutical Sector Inquiry: Final Report* (European Commission, 2009).
- ⁷⁷ Commission on Intellectual Property Rights, Innovation and Public Health (WHO, 2006b) cited in WHO, WIPO, and WTO Study, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, 2012, p. 131.
- ⁷⁸ <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0060812>.

(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.

51. The WHO framework for access to medicines includes rational selection and use of medicines, affordable prices, sustainable financing, and reliable health and supply systems with quality, as an underpinning element for access to medical technologies.⁷⁹ Similarly, some academic papers stress importance of approaching the issue of access to medicines holistically.⁸⁰ Those views have been echoed by some Member States during the SCP discussions, stressing the multifaceted nature of the problem. For example, the Delegation of Slovakia, speaking on behalf of the European Union and its Member States, stated that the reasons why people did not get the healthcare they needed could range from under-resourced health systems, a lack of sufficiently qualified and skilled healthcare workers, inequalities between and within countries, exclusion, stigma, discrimination to exclusive marketing rights.⁸¹ The proposal of the Delegation of the United States of America also highlights these other factors, including lack of basic infrastructure, trade barriers such as taxes and tariffs on medicines, discriminatory and non-transparent regulatory regimes, procurement inefficiencies, and the proliferation of falsified and substandard medicines.⁸²

PRELIMINARY CONCLUSIONS

52. In implementing the available flexibilities into their national laws with a view to access to medicines, governments seek to strike a right balance among conflicting interests held by various stakeholders in order to optimize the public interest as a whole, with a view to ensure 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. The debates related to full use of flexibilities are two fold: national implementation and 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, identification of relevant patents and their status and other aspects that might affect the use of legal mechanisms implemented in the respective national law.

53. As it has been 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 cases 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.

⁷⁹ See, WHO, WIPO, and WTO Study, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, 2012, (Chapter IV, Section A.1).

⁸⁰ See, e.g., *Improving Access to Medicines in Low-Income Countries: A Review of Mechanisms*, available at: https://www.researchgate.net/publication/274140504_Improving_Access_to_Medicines_in_Low-Income_Countries_A_Review_of_Mechanisms; Bryan Mercurio, *Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines*, *Northwestern Journal of International Human Rights*, V.5, Issue 1, 2007; and A. Zainol et al, *Pharmaceutical Patents and Access to Essential Medicines in Sub-Saharan Africa*, *African Journal of Biotechnology* V. 10(x), pp.12376-12388, 2011.

⁸¹ Document SCP/25/6 Prov., paragraph 115.

⁸² Proposal submitted by the Delegation of the United States of America, document SCP/17/11.

54. No credible conclusion can be drawn on the impact of full use of patent flexibilities on access to medicines, let alone the impact of constraints to such use, due to lack of data sufficient to permit empirical impact analysis.⁸³ 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 Lex⁸⁴ and a Database on Flexibilities in the Intellectual Property System⁸⁵. In addition, more detailed information on implementation of certain flexibilities has been collected through the activities of the SCP.⁸⁶ 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 straight forward. 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.

55. In addition, the complexity of the subject may be another reason why this area has not been explored. 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.

56. Therefore, in order to obtain a better understanding of the impacts that the flexibilities may have on access to medicines, more data would be needed, sufficient to permit empirical analysis on the use (or non-use) of flexibilities. One way to help inform policy dialogue on these issues could be through reporting by the Member States on implementation and use of patent flexibilities in their territories. Member States could, for example, inform the SCP the specific challenges that governments and stakeholders encountered in implementing and using flexibilities in an optimally desired manner, and consequential impact on access to medicines in their countries. They may also exchange the best practices, although the situation in each country varies. 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 making full use of flexibilities, and provide insights into finding the optimal trajectory to meet national policy goals.

[End of document]

⁸³ Presentation by Dr. Margret Kyle at the Seminar on the Relationship between Patent Systems and the Availability of Medicines in Developing Countries and LDCs during twenty-third session of the SCP, December 2, 2015.

⁸⁴ <http://www.wipo.int/wipolex/en/>.

⁸⁵ <http://www.wipo.int/ip-development/en/agenda/flexibilities/database.html>.

⁸⁶ 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/22/3) and sufficiency of disclosure (SCP/22/4).