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UPDATE OF DOCUMENT SCP/31/5 (REVIEW OF EXISTING RESEARCH ON PATENTS AND ACCESS TO MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES)

Document prepared by the Secretariat

INTRODUCTION

1. The Standing Committee on the Law of Patents (SCP), at its thirty-third session, held in Geneva from December 6 to 9, 2021, agreed that the Secretariat would submit, at the thirty-fourth session of the SCP, an update of document SCP/31/5 containing the review of existing research on patents and access to medical products and health technologies, extending the period under review and covering the period between 2019 and 2021, consistent with the terms of reference set out in document SCP/28/9 Rev.[1] (see first bullet point under "patents and health" in paragraph 24 of document SCP/33/5).

2. Pursuant to the above SCP decision, the Secretariat prepared the said update of document SCP/31/5, which is contained in Annexes to this document for the Committee's discussions at its thirty-fourth session to be held in Geneva from September 26 to 30, 2022. In line with the decision of the Committee at its thirty-third session, the update was made in accordance with the terms set out in document SCP/28/9 Rev.

[1] Document SCP/28/9 Rev. is a proposal by the Delegations of Argentina, Brazil, Canada and Switzerland to conduct such a review for Committee's consideration under the agenda item "Patents and health".

3. As mandated by the Committee, studies included in the review relate to the following topics:

- The relationship between patents and other related issues and the affordability and availability of medical products and health technologies;[2]

- The role of the patent system, including patent quality mechanisms, in incentivizing and promoting the development of new medicines and health technologies to address the global disease burden, facilitating access to medical products and health technologies, and ensuring the supply of quality products;

- The role of the intellectual property system in fostering knowledge spillovers and technology transfer in the medical products and health technologies sector;

- The role of compulsory and voluntary licensing mechanisms and patent pools in facilitating the affordability and availability of medical products and health technologies; and

- The availability of essential medicines in countries where those medicines are not under patent, taking into consideration the variety of other factors both on the supply and demand side that affect availability and affordability.

4. Each study was summarized to provide a factual synopsis of the analysis, key conclusions and recommendations of the author(s) of the study in Annex I. The list of studies included in the review is presented in Annex II to this document.

5. In conducting this update, a search methodology similar to the one used for producing document SCP/31/5 was employed. Thus, in addition to the works of the WHO, WIPO and WTO, the search was conducted on publications prepared by, or commissioned to external researchers by, the following intergovernmental organizations (IGOs), among others: European Union, UNCTAD, UNAIDS, OECD, UNDP and South Centre. With respect to the academic literature, the search was conducted on more than 80 peer-reviewed journals, taking into account the relevance of their fields to the mandated topics.

6. This document is structured into three main sections: (i) studies prepared by the WHO, WIPO, WTO and other relevant intergovernmental organizations, including studies prepared by external researchers commissioned by these organizations; (ii) peer-reviewed academic research (economic literature); and (iii) peer-reviewed academic research (legal and general literature).

7. In total, over 50 studies have been identified to be relevant to the above topics. Most of the literature identified was relevant to the following topics: (i) the relationship between patents and other related issues and the affordability and availability of medical products and health technologies; (ii) the role of compulsory and voluntary licensing mechanisms and patent pools in facilitating the affordability and availability of medical products and health technologies; and (iii) the role of the patent system in incentivizing and promoting the development of new medicines and health technologies to address the global disease burden. A lesser amount of studies focus on the role of the patent system in fostering knowledge spillovers and technology transfer in the medical products and health technologies sector, although various issues relating to patent licensing are relevant to technology transfer. Some studies cover more than one topic, or analyze a specific subject regarding its impact on both access to innovative products

[2] For the purposes of this review, “medical products and health technologies” refers to medicines, vaccines, diagnostics and medical devices.

and incentives to innovate. Comparable to the finding in the first review contained in document SCP/31/5, no studies specifically focusing on the availability of essential medicines in countries where those medicines are not under patent protection appear to have been published during the period under this review, reconfirming a lack of research on that topic.

8. Similar to document SCP/31/5, the readers should be mindful of the fact that no quality assessment of the contents of the identified publications and peer reviewed academic studies included in this update has been made by the Secretariat. Additionally, as mandated by the SCP, the update does not include working documents, drafts, blogs, commentaries and opinion pieces, etc. which are not considered to be peer-reviewed academic research.

[Annex I follows]

UPDATE OF DOCUMENT SCP/31/5: A REVIEW OF EXISTING RESEARCH ON PATENTS AND ACCESS TO MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES

Studies Prepared by World Health Organization (WHO), World Intellectual Property Organization (WIPO) and World Trade Organization (WTO) and Other Relevant Intergovernmental Organizations, including Studies Prepared by External Researchers Commissioned by These Organizations

Overarching study relevant to patents and public health

1. The second edition of the trilateral study (2020) prepared by the WHO, WIPO and WTO Secretariats seeks to reinforce the understanding of the interplay between the distinct policy domains of health, trade and intellectual property, and of how they affect medical innovation and access to medical technologies. The second edition comprehensively reviews new developments in key areas since the initial launch of the study in 2013. Due to the fact that the text of the study had been completed prior to the COVID-19 outbreak, a special insert provides cross-references to the relevant sections of the main text in relation to the challenges on integrated health, trade and IP policy frameworks posed by the outbreak. Some of the main general findings of the study include the following: access to essential medicines is an element of the right to health; lack of access is rarely due to a single factor but is related to a multitude of factors; preserving the integrity of global trade is critical to ensure equal access to health technologies and will support the countries' recovery of the crisis; the global IP system as an incentive framework can encourage urgent needed innovation; in relation to supporting R&D of and access to technologies, the sharing of health-related data and manufacturing knowledge and technology transfer are essential; regulatory assessment and approval of health technologies are an essential part in every health system; ensuring transparency and availability of up-to date information on measures taken by governments are critical.
[*Reference to study is in paragraph 51 of Annex II*]

Patent-related policy options, measures and tools specifically addressing the COVID-19 pandemic

2. The WIPO commissioned study by Conti, commented by Hall and Metzger, (2021) on the Determinants of COVID-19 Vaccine Success points out that vaccine success or failure, insofar as the development process is concerned, is based on a variety of determinants. IP is identified as one important element, among others. The study particularly highlights the importance of IP licenses for supporting R&D and manufacturing collaboration. Some of the key messages of the study are: (i) The successful development of vaccines depends on private sector willingness to bring vaccines to the market and public sector willingness to support it with push and pull incentives; (ii) Patents in themselves are not sufficient to support vaccine success; (iii) IP and in particular, the licensing of patents, played an important role in the successful development and production of currently available COVID-19 vaccines; (iv) The combination of patented technology and open science-based tools and techniques may have a critical influence to vaccine success; (v) The lack of access to existing COVID-19 vaccines is unjust, given the public sector investment that had de-risked private company investment; (vi) The decisions to abandon vaccine candidates are driven by scientific and business rationales; and (vii) There are concerns over vaccine nationalism. As recommendations for future work, the author names, *inter alia*, a study of best practices in, among others, licensing IP, and an analysis of publicly-funded research and development with a view to the achievement of global access and production.
[*Reference to study is in paragraph 10 of Annex II*]

3. In Section 2 of a Staff Working Paper on patent-related actions taken in WTO members in response to the COVID-19 pandemic (WTO, 2020), an overview of the patent landscape of medical treatments and technologies related to COVID-19 and of the patent status of two investigational medical treatments (remdesivir and lopinavir/ritonavir) is provided. Section 3 of the paper presents several patent-related actions taken by legislators, policymakers, industry sectors, and civil society organizations in WTO members since the outbreak of the pandemic, including amendments in the laws of some members. Furthermore, the paper elaborates, in Section 4, on patent-related policy options provided by the TRIPS Agreement, and WTO members' national implementation and utilization of these options in their response to the COVID-19 pandemic. In this regard, the paper especially underlines that the absence of definitions of key concepts, including invention, novelty, inventive step, prior art and *ordre public,* in the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) leaves a deliberate policy space for WTO members to design their own patent systems according to their national economic and social development – as long as they meet the TRIPS minimum standards. As an example, by referring to the application for new use of remdesivir in China and the application for invalidation of a patent for the use of the compound in India, the paper underlines that the outcome of both issues will largely depend on how the respective Patent Offices interpret the concepts of novelty and inventive step and what standards they set for patentable subject matter. Further, the paper stresses the possibilities of limiting patent rights based on Articles 6, 30, 31, 66.1 and 66.2 of the TRIPS Agreement.
[*Reference to study is in paragraph 53 of Annex II*]

4. The information note on the TRIPS Agreement and COVID-19 (WTO, 2020) elaborates on the role and key contributions that the global IP system, with its policy options and flexibilities as implemented in domestic law, can make in addressing the COVID-19 pandemic. Referring to Articles 7 and 8 of the TRIPS Agreement as well as the Doha Declaration, the information note stresses that the global IP system provides a framework in which innovation in relation to COVID-19 may be encouraged, shared and disseminated. The note also underlines that not only patent systems but also protection of trade secrets and clinical trial data in each WTO member can be critical in ensuring that new technologies are carried forward without overly burdening generic followers. Further, the note provides an overview of IP-related measures taken by WTO members since the start of the COVID-19 crisis. In the area of voluntary collaborative effort, examples on sharing IP and clinical trial data, open-source licensing, open access initiatives and technology pools are mentioned. It also refers to: (i) administrative measures taken by IP Offices, such as relaxing procedural deadlines and/or fee requirements and organizing hearings through videoconferencing; (ii) government policy actions under the flexibilities in the patent system and other IPRs, for example, exceptions to patent rights, including compulsory or government-use licenses; and (iii) transparency of IPR measures and of IPR information.
[*Reference to study is in paragraph 54 of Annex II*]

5. The update of the COVID-19 information note (2021) published by the WHO, WIPO and WTO aims to update the information contained in the special insert of the above-mentioned trilateral study (2020). It maps the challenges posed by the COVID-19 pandemic in relation to the integrated health, trade and IP policy framework in the light of the more recent developments as of August 30, 2021. Considering the dramatic impact of the COVID-19, the policy challenges of ensuring equitable access to healthcare products and technologies, including protective equipment, in sufficient quantities worldwide as well as the free flow of vaccines and inputs, are described. With respect to discussions and responses in various jurisdictions about maintaining effective international trade and meeting the demand for health technologies and medical services, particular emphasis is placed on the activities of competition authorities. In the section concerning IP aspects, the note outlines the incentive framework of the global IP system that may encourage innovation relating to COVID-19. The possible use of a wide range of policy options and flexibilities built into the international IP regime, as well as the importance of disclosure and accessibility of patent information are discussed. It also

underlines the relevance of international initiatives to promote R&D and equitable access to COVID-19 technologies, and describes various global patent information databases, international collaborative efforts and multi-stakeholder initiatives. Further, the note highlights that transparency and availability of up-to-date information on measures taken by governments are of critical importance, and presented initiatives and mechanisms of the three Organizations in that regard.
[*Reference to study is in paragraph 52 of Annex II*]

6. An OECD policy response to Coronavirus (COVID-19) (2020) explores measures needed to ensure equitable and universal access to future SARS-Cov-2 vaccines and treatments for the disease for all those in need worldwide. Following an overview of vaccine and drug candidates in the R&D pipeline at the time of the brief's publication, it presents several tools that governments can use to ensure that IPRs do not present barriers to access. Among the tools referenced are open innovation models and patent pools, which accelerate technological progress by encouraging universities and companies engaged in early-stage R&D to make their IP available to companies investing in follow-up clinical trials and product development. The document also refers to voluntary licensing. Linking public R&D funding to conditions for accessibility and affordability of IPR licensing, as well as affordability and access to final products, is also mentioned as an option. In addition, reference is made to the possibility of designing national legislation to implement the flexibilities regarding the scope of patent protection, including compulsory licensing, especially in cases where voluntary licensing is rejected.
[*Reference to study is in paragraph 35 of Annex II*]

7. A South Centre research paper (No. 114, 2020) endeavors to outline legal and policy solutions to overcome hurdles in ensuring equitable access to health technologies and in particular health technologies targeting COVID-19. Following the summary of the state of the pandemic situation, the paper examines the patent regime, in particular, Articles 27 and 28 of the TRIPS Agreement, and discusses whether countries should allow patent rights in times of a global pandemic where equitable access to health technologies for COVID-19 treatment needs to be particularly ensured. Noting the global effort to develop health technologies (especially, vaccines and medicines) in order to overcome the pandemic and the role of IPRs, such as patents, the paper underlines that IPRs, can incentivize the creation of health technologies. However, the concern about a "business as usual" approach where health technology developers would exclusively dictate the market is mentioned. The author fears that without considering all existing or future COVID-19 related drugs, diagnostics, vaccines and health products as global public goods, these health technologies will not be available for everyone, everywhere, at the same time. Further, the paper discusses, among others, a proposal by Costa Rica to set up a voluntary COVID-19 IP pool at the WHO.
[*Reference to study is in paragraph 43 of Annex II*]

8. A South Centre research paper (No. 129, 2021) discusses the TRIPS waiver proposal as an efficient option to ensure timely, sufficient, and affordable access to technologies developed to fight COVID-19 pandemic. Highlighting the challenges the international community faces in finding a strategy to ensure equitable access to vaccines and other medical technologies relating to the COVID-19 pandemic, the paper summarizes global initiatives, such as the COVID-19 Technology Access Pool (C-TAP). In its view, C-TAP does not work due to the low commitment of developed countries and lack of interest from the large multinational companies. The paper introduces the TRIPS waiver proposal in the light of barriers caused by IP in the access to necessary COVID-19 technologies. Summarizing the different positions in the waiver discussion, the paper argues that the use of compulsory licenses and government use in the context of the pandemic would be ineffective, due to, in particular, the complex negotiation involved in obtaining compulsory licenses, the fact that such licenses only apply to technologies that are already patented and the inability of many countries to deal with them. Further, the paper briefly explains the role of South-South cooperation as an important strategy for building

an IP system more closely aligned to developing countries' long-term developmental needs and interests in emergencies, and particularly highlights the need to rethink the global R&D system for the development of medicines and other health technologies.
[*Reference to study is in paragraph 45 of Annex II*]

Affordability and availability of medical products, TRIPS flexibilities (including compulsory licensing), free trade agreements

9. A South Centre research paper (No. 85, 2019) explores the access to medicines and the experiences with compulsory licenses and government use relating to Hepatitis C. The paper critically discusses the impact of high prices on the availability of medicines and the role of intellectual property rights, in particular patents and any possible inconsistencies with the human right to health. Further, it presents the background, main aspects and obstacles to the achievement of the objectives of the Doha Declaration on the TRIPS Agreement and Public Health (2001) and examines the experiences of compulsory licensing and government use regarding patents in Latin America (particularly in Ecuador, Peru and Colombia). Among others, the paper draws the conclusion that the use of the TRIPS flexibilities, as confirmed by the Doha Declaration, is one of the available ways to reconcile public and commercial health interests at stake. Concerning the analysis of compulsory licenses in Ecuador and requests in Colombia and Peru, the paper concludes that the feasibility of obtaining these licenses and their impact on access to medicines depend strongly on the applicable legal framework, including the possibility of requests by non-governmental organizations. Further, the paper underlines the alternative to opt for government use instead of compulsory licensing and raises concerns about political and commercial pressures to avoid its use.
[*Reference to study is in paragraph 39 of Annex II*]

10. A research paper published by the South Centre (No. 100, 2019) focuses on access to medicines and IP. It critically discusses the outcome of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA), approved by the World Health Assembly in 2008. The paper describes the background of the negotiations, and underlines one of the objectives of the GSPOA, i.e., to substantially reform the pharmaceutical innovation system in order to enhance the production of affordable medicines for diseases that affect the greater part of the world's population living in developing countries. The paper particularly notes that the current patent system under the TRIPS Agreement has a significant impact on the entire pharmaceutical sector and, more specifically, on medicine prices to an extent that may hamper access to medicines for the poorer populations in countries of the South. In its conclusions, the paper states that IPRs as required by the TRIPS Agreement has become obstacles in access to medicines and that a substantial reform of the pharmaceutical R&D system in view of its failure to produce affordable medicines for diseases affecting the majority of the world's population living in developing countries, is needed.
[*Reference to study is in paragraph 40 of Annex II*]

11. The South Centre published a research paper on the legal treatment of second medical use patents and public health (No. 101, 2019). The paper aims to give an overview of the debate surrounding the patentability of new therapeutic uses for known active ingredients, both in developed and developing countries. After examining the international patentability standards, the paper observes increasing acceptance of second medical use patents, seemingly resulting from strategic patent filing of pharmaceutical companies, extending *de facto* the life of existing patents on a given compound. The paper underlines the impact of these practices on the access to medicines and the public health, in particular, in developing countries. It is argued that a reasonable patent policy in line with an enhanced access to medicines, should – if at all – support second medical use patents only if several safeguards are applied in order to avoid excesses and evergreening. In that regard, among others, the paper particularly underlines the importance of strict patentability standards and flexible conditions for initiating a nullity action. As alternatives, the paper highlights that countries could consider

granting alternative kinds of protection for second medical uses, for a limited duration, which should be determined based on economic studies and should take into account the average investment in research and development to discover a new use for an existing compound. [*Reference to study is in paragraph 41 of Annex II*]

12. On the occasion of the 18th anniversary of the Doha Declaration on the TRIPS Agreement and Public Health, the South Centre published a research paper (No. 103, 2020) providing an overview of the situation in the African continent in respect of the implementation of the TRIPS flexibilities, specifically those regarding access to medicines. After an introduction to the background of IP in Africa and of the WTO, the paper provides an overview of the situation in African countries and proceeds to give an account of the role of regional policy frameworks and IP organizations. Further, the paper outlines the various TRIPS flexibilities that are available before the grant of a patent (pre-grant flexibilities) and TRIPS flexibilities regarding exceptions to patent rights (post-grant flexibilities). The paper presents the pre-grant flexibilities (such as adoption of the LDC transition period, patentability criteria and pre-grant opposition) and post-grant flexibilities (including, among others, the Bolar exception, the research exception, compulsory licensing and government use) in national legislation and the extent to which they have been utilized. It further makes recommendations as to how States may maximize their use of public health-related flexibilities. Flexibilities outside IP and industrial property legislation, i.e., competition policy and law are also discussed. The paper concludes that, *inter alia,* many countries have greatly improved the access to healthcare through the utilization of the TRIPS flexibilities, but that their use are still far from optimal. Additionally, the paper underlines that beside the legal measures and implementation of the TRIPS flexibilities in national systems, access to medicines will finally be dependent on the overall resilience of health systems. [*Reference to study is in paragraph 42 of Annex II*]

13. In a South Centre research paper (No. 127, 2020), concerns about a patent term extension and data exclusivity and their impact on access to medicines are highlighted. In particular, the paper argues that the respective clauses in European Union (EU)'s free trade agreements (FTAs) are far-reaching and could have serious implications for access to medicines in developing countries. The paper, *inter alia*, provides a historical review of patent term extension and data exclusivity in the US and the EU, showing how they reflect the cross-pollination of legal norms from the US to the EU and, in turn, from the EU to developing countries through free trade agreements. It also discusses the differences in perspectives and approaches of developing and developed countries to the TRIPS requirements and flexibilities and the impact of FTAs to them. Further, it outlines the example of India, as a country that has not introduced a patent term extension and data exclusivity through FTAs. The paper specifically underlines that an introduction of data exclusivity provisions in India through FTAs, would prevent the country's generic industry to produce cheaper versions of originator drugs. Examining possible impact of the EU's FTAs, the paper concludes that a right balance between the protection of *sui generis* IP rights, such as patent term extension and data exclusivity, and the policies promoting generic medicines should be sought in order to ensure medicine availability and affordability. It also suggests to introduce in FTAs compulsory clauses on, for example, Bolar exception and transitional arrangements for developing countries specific to IP. [*Reference to study is in paragraph 44 of Annex II*]

14. A South Centre research paper (No. 132, 2021) explores the interpretation of the TRIPS flexibilities. The implementation of these flexibilities is considered to be critical for the design of a pro-competitive intellectual property system and, in particular, to the achievement of public health objectives as explicitly recognized in the Doha Declaration. The paper discusses the concept of TRIPS flexibilities, the possible types of such flexibilities in developing and developed country legislation, the references to such flexibilities in the WTO jurisprudence, some interpretive principles relevant to the application of international treaties. Turning to the legal status of the Doha Declaration, the author is of the opinion that the Panel Report in DS 435, 441, 458 and 467, Australia, Tobacco Plain Packaging (2018) confirmed the legal status of

the Doha Declaration as a “decision” reached by consensus that constitutes a “subsequent agreement” among the WTO members. The paper stresses that this is an important development as it indicates that the TRIPS Agreement must be interpreted in light of public health.
[*Reference to study is in paragraph 46 of Annex II*]

15. A South Centre research paper (No. 141, 2021) examines the extent to which legal and policy frameworks related to the TRIPS flexibilities have been adopted and implemented to facilitate access to medicines in the African Intellectual Property Organization (OAPI) countries and the Middle East and North Africa (MENA) region. Subsequent to the analysis, the paper provides recommendations for maximizing the use of flexibilities to advance public health objectives. The paper states that, for the OAPI member states, while 2015 Revision of the Bangui Agreement was a step in the right direction, it is not sufficient for the purpose of utilization of the TRIPS public health flexibilities. The paper therefore recommends, among others, to institute substantive examination and adoption of strict patentability requirements at the OAPI level. Throughout the OAPI Member States, the adoption of the general and pharmaceutical transition periods, the expansion of the grounds on which non-voluntary licenses may be granted and the institution of a streamlined and user-friendly administrative procedure for the grant of non-voluntary licenses are recommended. Similarly, to the African Members of the MENA region, the paper recommends, for example, expansion of the grounds for granting compulsory licenses, allowing third parties to request a compulsory license and improvement of the administrative procedure for processing requests for non-voluntary licenses.
[*Reference to study is in paragraph 47 of Annex II*]

16. A South Centre training paper (No.1, 2019) underlines that since the entry into force of the TRIPS Agreement, the possibility of price determination by the patent owner in the absence of competition and its possible result leading to unaffordable medicines for the majority of the population in developing countries raise particular concerns. The training paper states that while patents are by no means the only barriers to access to life-saving medicines, they can play a determinant role. In its first part, an introduction to key issues in the field of access to medicines and IP is provided. In a second part, basic terms and concepts of the trade-related aspects of IPRs that govern the research, development and delivery of pharmaceuticals and health technologies in general are described. The paper concludes that the success in securing effective access to medicines in developing countries particularly depends on the implementation of IP rules optimizing the TRIPS flexibilities in national laws and whether or not the necessary policy decisions and measures will be taken.
[*Reference to study is in paragraph 48 of Annex II*]

Peer-Reviewed Academic Research (Economic Literature)

<u>Incentivizing and promoting the development of new medicines and health technologies</u>

17. The paper by Sampat and Williams (2019) analyzes the impact of patent protection on human gene sequences on follow-on innovation and product development. The results suggest that patents had on average no important impact on follow-on innovation measured as scientific publications or commercial product development measured as pharmaceutical clinical trials and diagnostic tests. As an explanation, the authors suggest that the combination of effective disclosure of information in gene patents required by the U.S. Patent and Trademark Office and a relatively well-functioning market for licenses of gene patents has prevented any negative effects of patent exclusivity on follow-on innovation.
[*Reference to study is in paragraph 38 of Annex II*]

18. The paper by Reisinger et al. (2019) shows theoretically that the impact of parallel trade on R&D by originators depends on the degree to which demand for pharmaceuticals in poorer countries is similar to demand in richer countries. If demand is sufficiently heterogeneous,

parallel trade has a negative effect on R&D, because lower prices (due to price caps) in poorer countries will depress prices in richer countries through parallel trade. As a result, originators have incentives not to sell their drugs in poorer countries if parallel trade is permitted. If parallel trade is not permitted, it is profitable for the originator to also sell in the poorer countries, as a lower price there does not affect the price charged in the richer countries.
[*Reference to study is in paragraph 37 of Annex II*]

Affordability and availability of medical products, TRIPS flexibilities (including compulsory licensing and exhaustion)

19. Bond Eric and Kamal Saggi (2020) use a North-South model to analyze the effect of two flexibilities built into TRIPS: compulsory licenses and exhaustion policies. The stylized model consists of the government in the South and a firm in the North. The model generates the following main results: (i) the South institutes patent protection if it is necessary to induce the Northern firm to enter the market in the South, as the quality differential between the Northern firm and local imitation in the South in the absence of patent protection is sufficiently large; (ii) patent protection in the South positively affects R&D investment of the firm in the North, which has positive effects for Northern consumers as well; (iii) when the Northern firm enters the South even in the absence of patent protection, it would be welfare enhancing for the South to institute patent protection (because of the positive impact on R&D in the North). However, if the Northern firm does not enter even when there is patent protection in the South, patent protection is welfare reducing, since it prevents Southern consumers of accessing local imitations; (iv) with respect to compulsory licensing, the paper finds that its impact on welfare depends on its effect on the Northern firm's R&D investment. Compulsory licensing can have a negative impact on welfare if it deters the Northern firm from entering the Southern market. However, it has a positive impact if the Northern firm has no incentive to enter the Southern market to begin with; and (v) the analysis also finds that overall welfare is larger under national (as opposed to international) exhaustion. National exhaustion leads to lower prices in the South, higher prices in the North, and larger incentives for investment in R&D.
[*Reference to study is in paragraph 8 of Annex II*]

20. The paper by Urias and Ramani (2020) summarizes existing evidence in the literature on the impact of compulsory licensing on drug prices. Information extracted from 15 articles on 24 compulsory licensing events in 8 developing countries for 16 drugs (mostly HIV/AIDS drugs) reveals a price drop between 6.7 and 98% as a consequence of compulsory licensing. The results also suggest that the price drop is larger if the drugs for which compulsory licenses have been issued are procured from abroad instead of local manufacturing.
[*Reference to study is in paragraph 49 of Annex II*]

21. The study by Motari et al. (2021) analyzes patenting trends at the two African regional Patent Offices: the African Regional Intellectual Property Organization (ARIPO) and the *Organisation Africaine de la Propriété Intellectuelle* (OAPI). The data show a steep increase in patent filings in the mid-1990s and a levelling off in the 2000s. The top-3 disease categories covered by medicinal patents include inflammatory diseases, cancers, tumors, and cardiovascular diseases. The top-10 list of countries of origin of patent filings includes only non-African countries with the exception of South Africa. The paper also reviews the implementation of TRIPS flexibilities by African countries and reports that the majority of countries have legislation allowing for compulsory licensing and parallel importation of medicines, while the least legislated flexibilities were explicit exemption of pharmaceutical products from patentable subject matter, new or second use of patented pharmaceutical products, imposition of limits to patent term extension and test data protection. Thirty-nine countries have applied TRIPS flexibilities, with the most common being compulsory licensing and least developed country transition provisions.
[*Reference to study is in paragraph 33 of Annex II*]

Market entry of new or generic medicines

22. Ding and Zhao (2019) propose a game-theoretic model that allows for endogenous entry decisions by generic producers to analyze the impact of pay-for-delay settlements (P4D) on competition, innovation, and consumer surplus. P4D typically involves reverse payment from an originator patentee to a generic firm to delay pre-expiration entry. The model shows that P4D may increase competition: as generic firms expect higher profit, it may increase incentives for generic companies to attempt to enter the market before an originator patent expires. Because settlement between the potential generic entrant and the originator sometimes fails, this can lead to more actual generic entry. The impact of P4D on innovation by the originator (i.e., an innovation incentive being a premium of a high-quality patent over a low-quality one) depends on the entry cost (i.e., the cost associated with challenging the originator patent for example through litigation) and other factors. When the entry cost is at intermediate level, P4D has a positive impact on the innovation by the originator, while allowing P4D decreases innovation incentives when the entry cost is low. Finally, P4D might increase or decrease consumer surplus. Where entry costs are intermediate, P4D may enhance both competition and innovation at the same time. In contrast, when the entry cost is relatively low, *ex ante* innovation is weighed against *ex post* competition, and the impact of P4D on consumer surplus further depends on the originator's innovation cost. When the entry cost is sufficiently low, consumer surplus might fall.
[*Reference to study is in paragraph 13 of Annex II*]

23. The paper by Chintan et al. (2020) analyzes the timing of generic entry in the US for 69 brand-name non-biologic drugs that were expected to lose patent exclusivity during the period 2010-2016. For 17% of those 69 drugs, generic entry occurred earlier than expected. For 38%, entry occurred during the quarter after the expected expiry of the respective patents. For 29% of drugs, generic entry was delayed by at least one quarter and no generic entry occurred for 16% of drugs by the end of 2016. The authors find that patent litigation was the main cause of delayed entry. They estimate that for those drugs where entry was delayed, excess Medicaid expenses due to the delay amounted to US$761 million over the 2010-2016 period.
[*Reference to study is in paragraph 12 of Annex II*]

24. Dai and Watal (2021) use data on 578 molecules (which were protected by product patents in at least one country in the sample) over the period 1980-2017 to analyze the impact of the availability of product patents on the introduction of these drugs in a set of 70 countries. They find that the introduction of product patents accelerates the launch of innovative drugs. However, this result does not hold for low-income countries. Availability of product patents does not affect the introduction of innovative drugs in these countries. Using price data for 2007- 2017, the authors find that prices of both originator and generic drugs adjust little to lower income levels. However, prices of generics that treat HIV/AIDS, malaria, and tuberculosis are significantly cheaper in low income countries. The authors interpret this as the result of specific global policy responses that promoted access to cheaper generics.
[*Reference to study is in paragraph 11 of Annex II*]

Peer-Reviewed Academic Research (Legal and General Literature)

Patent-related policy options, measures and tools specifically addressing the COVID-19 pandemic

25. The study by Abbas (2020) discusses and critically evaluates the proposal of Costa Rica submitted to the Director-General of the WHO for the creation of a global pooling mechanism in order to facilitate access to and use of intellectual property, trade-secrets, know-how, etc. that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic. The study reports that, though its implementation will require substantial work, Costa Rica's proposal

for the pooling mechanism is neither novel nor impractical. The findings show that the two key concerns with regard to control and treatment of the COVID-19 pandemic are the urgent development of needed health technologies and the equitable and affordable access to existing and new health technologies. Hence, Costa Rica's proposal for a global IP pooling mechanism deserves serious consideration, because it addresses both of these key concerns. According to the author, as compared to the already existing pooling mechanisms, such as the Medicines Patent Pool, Costa Rica's proposal is more realistic and practically feasible. Thus, the study anticipates that, in the near future, the WHO will take practical measures to implement this proposal for the benefit of the whole global community.
[*Reference to study is in paragraph 1 of Annex II*]

26. The publication by Abbott and Reichman (2020) proposes legal mechanisms for addressing critical issues facing the international community in providing equitable access to vaccines, treatments, diagnostics and medical equipment, in light of the COVID-19 pandemic. According to the authors, the COVID-19 pandemic has highlighted the gaps in global preparedness to address widespread outbreaks of deadly viral infections, which reflect a general problem with preparing for low-probability, high-risk events. The paper argues that exclusive rights in technologies should not be allowed to stand as obstacles to production and distribution of vaccines, treatments, diagnostics and medical equipment to address global public health needs. In this regard, the paper sets out proposals for addressing both the supply and demand sides of the problems regarding access to essential health technologies, which may work well in tandem, but may also function independently, if necessary. On the supply side, the establishment of mandatory patent pools ('Licensing Facilities') on a global or regional, or even national basis, is proposed. The authors suggest that the Licensing Facilities preferably be constituted by government parties through some form of international agreement. The authors also discuss the importance of creating shared production facilities. On the demand side, the authors propose the establishment of Regional Pharmaceutical Supply Centers (RPSCs) for implementing the pooled procurement strategies of different participating governments over time and for the need to coordinate the issuance of necessary compulsory licenses for production and/or importation. The authors envisage that RPSCs should assist in overcoming difficulties that individual countries may encounter in addressing administrative and technical issues in procuring supplies, as well as creating improved bargaining leverage with potential suppliers. Finally, the authors discuss the problem created by the decision of various high-income countries to 'opt out' from eligible importing countries under the Article 31*bis* of the TRIPS Agreement.
[*Reference to study is in paragraph 3 of Annex II*]

27. The article by Adewopo (2021) overall examines the legal framework for patent protection of pharmaceuticals and especially vaccines, designed to meet public health challenges, such as those presented by the COVID-19 pandemic, referencing African countries and Nigeria in particular. The first part of the article discusses the need to recognize the balance between the economic interests of patent holders in return on their investment in R&D, and the public interest in making the vaccines available at an affordable cost, especially in the context of the global race for COVID-19 vaccines amongst the major pharmaceutical companies. Thereafter, the author discusses the framework of compulsory licensing (with special focus on the African continent and Nigeria), which is broadly defined to include government use (public non-commercial use) and provided for under most national patent laws as well as international patent law. In the last part of the paper, the author recommends the adoption of government use executive instruments in Nigeria as a viable patent law mechanism for making COVID-19 vaccines available to over 200 million Nigerians and by extension over 1.3 billion people in Africa who are potentially in need of the vaccine.
[*Reference to study is in paragraph 5 of Annex II*]

28. The paper by Baker (2021) delineates the impediments imposed on a more effective response to the COVID-19 pandemic by the perpetuation of IP and market fundamentalism

across the entire life cycle of medicines. The paper also gives a corresponding account of how the pandemic gives the world a unique opportunity to recalibrate its biopharmaceutical and IP ecosystem to counter the aforementioned impediments. The second part of the paper describes the following global initiatives and proposals which are aimed at mobilizing a more effective and solidarity-based response to this unprecedented global pandemic: (i) TRIPS waiver proposal; (ii) Least developed countries' extended transition period; (iii) TRIPS Article 73 security waiver; (iv) Compulsory licenses; (v) People's vaccine campaign; (vi) COVID-19 Technology Access Pool (C-TAP); (vii) Access to COVID-19 Tools (ACT) Accelerator; and (viii) Regional solidarity efforts. The author argues that many of these initiatives are struggling to find traction because of opposition from industry and developed country governments. Hence, the paper concludes that it is incumbent upon civil society, countries at risk of being left behind, global health institutions and progressive health policymakers to make common cause to disrupt the *status quo*, to pave a path to a more efficient, equitable, and urgent response to the COVID-19 pandemic and to set the stage for even better responses to future global pandemics.
[*Reference to study is in paragraph 6 of Annex II*]

29. The paper by Farquhar (2020) analyzes the possible compulsory licensing fallout over COVID-19 vaccines and pharmaceuticals under the current terms of the TRIPS Agreement. The author argues that despite its intended purpose to aid developing countries in their ability to access life-saving medicines, compulsory licenses issued under Article 31 or 31*bis* of the TRIPS Agreement continue to face significant roadblocks and international red tape since the adoption of TRIPS. It is further argued that these issues with compulsory licenses are likely to affect the COVID-19 pharmaceuticals and vaccines as well. The next part of the paper examines the rise of vaccine nationalism against the backdrop of the WHO's "Solidarity Call to Action" in the current pandemic. Thereafter, the paper analyzes the consequences and deficiencies of the current TRIPS compulsory licensing provisions in disseminating a vaccine quickly and efficiently on an international scale. The author suggests possible improvements to the TRIPS Agreement to promote greater patent protection and international cooperation for countries to gain access to vital pharmaceuticals in pandemics like the current COVID-19 outbreak. These improvements aimed to balance the interests of patent holders with the interests of the global population include: (i) defining terms in the TRIPS Agreement, specifically the scope and duration of the "emergency," as well as the "adequate remuneration" to be paid to patent holders; (ii) creating and implementing a compensation scheme whereby "adequate remuneration" is codified and regulated; and (iii) developing a third-party arbitration mechanism where compulsory licensing disputes may be settled outside of potentially biased importing Members' adjudicatory systems.
[*Reference to study is in paragraph 14 of Annex II*]

30. The work by Gurgula and Lee (2021) aims to expose the fundamental flaws of the current system of pharmaceutical innovation that affect the accessibility of medicines, which is particularly crucial in the time of the COVID-19 pandemic. According to the authors, the current legal framework in the area of pharmaceutical innovation has developed around the model of proprietary research conducted by private pharmaceutical companies, the outcomes of which are typically protected by multiple patents. A major negative consequence of this is that these pharmaceutical companies typically seek to obtain the broadest and strongest patent protection for the results of their research to achieve market exclusivity, which allows them to set the price of their products. In turn, this often leads to problems of accessing these products due to the high prices. The paper states that the WHO has launched an unprecedented cooperation between countries and various institutions, while appreciating that the most pragmatic way to combat the COVID-19 pandemic is through collaboration and data sharing. However, it is argued that these initiatives are lacking the most important key player, i.e. the pharmaceutical industry. The findings of the paper reveal two fundamental flaws in the current system: (i) a proprietary/competitive model slows down success rates, as it prevents researchers from working together in tackling the virus in contrast to a more open and collaborative model by

pooling resources and efforts; and (ii) any resulting therapy developed by pharmaceutical companies will be protected by patents, allowing the companies to control the production and price of as well as access to the vaccines and treatment. For the protection of public health at the national and global level, the authors recommend: (i) short-term mechanisms such as compulsory licensing and government use, which will facilitate better access to patent-protected COVID-19 medicines; and (ii) long-term mechanisms of designing a new innovation model to improve the effectiveness and speed of innovation, such as state-coordinated research and production of medicines and open innovation.
[*Reference to study is in paragraph 19 of Annex II*]

31. The publication by Kianzad and Wested (2021) suggests that the key to understanding the current debates on the intellectual property waiver of COVID-19 related vaccines, treatments and related products lies in a holistic approach to the *ratio legis* of IP rights, innovation policy and health policy. The publication depicts the delicate interaction between the right to health as a basic human right and IP rights, such as patents, on life-saving medicines. This discussion delves into detailing the right-to-health framework, the legal, historical and procedural background of international codification of patents and the compulsory licensing instrument within the TRIPS agreement, as well as some instances of compulsory licensing during COVID-19. Thereafter, the authors recount the recent IP waiver proposal at the TRIPS Council and the arguments for and against the proposal. The final section concludes with some law and policy reflections on the balance between the right to health, IP rights and innovation policy. The main conclusion of the publication is that there is need for a balanced approach guided by real world indicators regarding law and economics of pharmaceutical innovation, procedural feasibility of compulsory licensing and legal applicability of an IPR waiver.
[*Reference to study is in paragraph 26 of Annex II*]

32. The article by McMahon (2021) aims to demonstrate that patents have significant implications for healthcare as patents facilitate patent holders having a private governance function over patented technologies. The author uses the example where Gilead agreeing to provide the United States of America with 500,000 doses of remdesivir jeopardized supplies of life-saving treatments and vaccines for COVID-19 in other countries. Such developments, according to the author, are not simply about States prioritizing their citizens, but also demonstrate the power that patent holders have around key decisions about access to life-saving healthcare, determining who obtains access first and at what price. The article outlines the potential for patent holders' decisions to have significant adverse healthcare implications for COVID-19, and illuminates the power patent holders have over healthcare access in such contexts. The author argues that patents bestow on their holders a governance role over the patented inventions during the period of patent protection. Thus, the tension is heightened in the COVID-19 context, because the best way to deal with the outbreak is to maximize global access to COVID-19 diagnostics, treatments and vaccines for all, the author says. The article then highlights avenues to provide oversight/limits on patent holders' control *via* compulsory licenses or voluntary licensing initiatives and the key obstacles to using such licensing measures. The author questions the extent of control currently given to patent holders in relation to the COVID-19 pandemic, and made the following recommendations: (i) greater awareness and interrogation of existing avenues to intervene with patent holder discretion; and (ii) support for voluntary licensing initiatives, which offer useful global/regional mechanisms to address access issues around COVID-19 health technologies.
[*Reference to study is in paragraph 30 of Annex II*]

33. The article by McMahon (2020) argues that as the race for effective vaccines and treatments for COVID-19 continues, it is imperative that national governments ensure that effective avenues exist to intervene with patent-holder discretion *via* compulsory licensing. The article examines the legal avenues for compulsory licensing and government use in Ireland as a case study in search of effective mechanisms to address the pandemic, whilst remaining in compliance with Ireland's international obligations. The article examines the role of compulsory

licenses in alleviating access issues posed by patents and the overarching international framework for compulsory licensing applicable in WTO members. The author considers that the domestic compulsory licensing framework in Ireland has evident shortcomings when applied to the COVID-19 context. The author also examines the government use provisions under the Irish law as a potential measure to be used to address the COVID-19 pandemic, and suggests reforms that would make this system more effective. The author finds that the practical obstacles for the use of compulsory licenses in Ireland are the EU laws relating to data/marketing exclusivity and the EU's opt-out from the relevant WTO framework under Article 31*bis*. Considering compulsory licensing and government use provisions as one of the important tools for countries to alleviate access issues posed by patents on health-related technologies, including COVID-19 related technologies, the author concludes that national laws must facilitate effective systems for such licensing interventions.
[*Reference to study is in paragraph 29 of Annex II*]

Affordability and availability of medical products, TRIPS flexibilities (including compulsory licensing, exhaustion etc.) and voluntary licenses, free trade agreements

34. The paper by Abbas (2021) examines the legality and practical significance of parallel trade of patented medicines as a price-reducing policy option and evaluates some of the practical hurdles in the actual use of this flexibility. The author firstly discusses how countries can adopt international exhaustion to use parallel trade or parallel importation as an access-to-drugs strategy. The paper suggests that parallel trade in patented medicines has the potential to harness the benefits of the international price discrimination, and to alleviate some of the financial burdens of the COVID-19 pandemic by improving access to cheaper medicines. Considering that the TRIPS Agreement and the Doha Declaration left exhaustion of rights to the discretion of the WTO members, the author specifically discusses the importance and uncertainty of India's Section 107A in the Patents (Amendment) Act 2002. The author discusses the practical hurdles in parallel trade, such as conflicting interests between consumers and IP owners as well as the proliferation of bilateral and plurilateral trade agreements that prohibit parallel importation. The findings show that, practically, parallel importation of patented drugs has remained seriously under-used due to the complexities and pressures involved in such parallel trade. Hence, the paper supports the adoption of international exhaustion of patents as a mandatory rule for the international trading system.
[*Reference to study is in paragraph 2 of Annex II*]

35. The paper by Adekola (2020) makes a case on why the largely undiscussed regional mechanism option under Article 31*bis*.3 of the TRIPS Agreement has become relevant in light of the current trends in the pharmaceutical landscape. The paper further argues that this regional mechanism option offers a more sustainable pathway towards access to patented medicines for low-income countries with limited market size and low purchasing power. The paper initially identifies four reasons why the Doha Paragraph 6 system solution has become more significant in light of the current trends in the pharmaceutical landscape. Thereafter, the paper discusses the nature and prospects of the regional mechanism under the Paragraph 6 system using hypothetical models in South East Asia and Africa. The author also analyzes the shortcomings of the East African Community Regional Pharmaceutical Manufacturing Plan of Action (EACRPMPoA), which is the only ongoing regional alliance that explores the Doha Paragraph 6 system. In the final section, the author argues that Article 31*bis*.3 places reliance on the obligation of developed countries under Articles 66.2 and 67 of the TRIPS Agreement, which could impede its effectiveness. The author recommends that solutions to low-income countries' technological and financial deficiencies should be sought within their regional alliance or outside the scope of developed countries' obligation under the TRIPS Agreement in order to facilitate access to medicines to the most vulnerable populations.
[*Reference to study is in paragraph 4 of Annex II*]

36. The paper by Christie, Dent and Studdert (2020) analyzes secondary patents associated with thirteen blockbuster drugs in Australia. The analyses focused on empirically describing the timing and the duration of the secondary patents. The main goals of the analyses were to compare the secondary patenting activity of the three types of innovators (the active pharmaceutical ingredient (API) originator, other originators and non-originators), and to identify the characteristics of the longest held secondary patents. In particular, the study provides the following findings: (i) the majority of follow-on innovations associated with blockbuster drugs is undertaken by entities other than the drugs originator, and occurs both before and after expiry of the patent over the drugs API and the expiry of associated secondary patents held by the originator of the API; (ii) 27% of the follow-on inventions associated with blockbuster drugs are undertaken by the originator. The study argues that secondary patents held by the originator of the API have greater private value than those held by others, and their typology is consistent with the theorized evergreening behavior of drug originators. The study concludes that the findings support the view that secondary patenting by drug originators can have adverse welfare effects through extending the originator's marketplace exclusivity over the drug.
[*Reference to study is in paragraph 9 of Annex II*]

37. The paper by Garagancea (2021) aims to demonstrate that licenses and contractual limitations play an important role in increasing the potential of parallel imports to enhance access to medicines and it is thus important to analyze their synergies. The main question posed by the author is whether there is an interplay between, on the one hand, parallel imports and, on the other hand, voluntary licenses, compulsory licenses issued for the domestic market, as well as the more recent compulsory licenses for export, created under the auspices of the Doha Declaration, which can work together as a system to enhance access to medicines. The paper first briefly lays out the general considerations necessary for the review of the interplay of parallel imports with compulsory licenses and voluntary licenses in the context of access to medicines. It then discusses how different outcomes of parallel imports may substantiate different policy approaches using a specific case study on how the US changed its exhaustion regime for patent rights and the implications thereof. The author suggests that exhaustion of patent rights is largely decided depending on whether there is a research-driven industry in the country or region or not. The author also enlists some of the implications of parallel imports of medicines. The paper then examines the concepts of voluntary licenses, compulsory licenses and their interaction with parallel importation. It concludes that: (i) one size does not fit all and that policies aiming to enhance access to medicines must concurrently implement several TRIPS flexibilities; and (ii) with regard to parallel imports of medicines, not only should an appropriate exhaustion regime of patent rights be adopted, but also, where an international exhaustion regime is deemed appropriate, it should be coupled with measures pertaining to compulsory licenses (for export) and voluntary licenses.
[*Reference to study is in paragraph 15 of Annex II*]

38. Groux and de Beer (2021) explain how IP provisions in recent trade agreements may impact access to medicines in Canada. The authors discuss that as minimum IP standards have increased through trade law, access to medicines is affected not just in low and middle-income countries but also in high-income countries, like Canada, wherein these countries face rising drug prices. The authors begin by exploring the historical and current context of Canadian Pharmacare and the evolution of Canadian IP law. The authors then analyze that high-income countries, like Canada, are not always the ones pushing for more IP protection. For example, Canada has recently unwillingly signed three trade deals requiring Canada to provide more protection for patents and undisclosed data – the Canada-European Union Comprehensive Economic and Trade Agreement (CETA), the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), and the Canada-United States-Mexico Agreement (CUSMA). The authors depict how these three trade deals have changed Canadian patent and data exclusivity laws in key respects including patent term extensions, market and data exclusivity, and protection for biologics. After summarizing research indicating that the increase in IP protection in Canada due to the three trade deals will likely increase drug prices

but not innovation, the authors conclude with lessons learnt from Canada's challenges and solutions to ensure that IP is not a barrier to accessing medicines.
[*Reference to study is in paragraph 17 of Annex II*]

39. In the light of the COVID-19 pandemic, the paper by Gurgula and Hull (2021) highlights the importance of sharing manufacturing information protected by trade secrets for the acceleration of the complex vaccine production. The authors primarily focus on the practicality and feasibility of a compulsory trade secret licensing mechanism as a tool to share trade secrets related to COVID-19 vaccines on the public interest grounds, in a manner that balances the interests of trade secret holders and the public. The authors consider that compulsory trade secret licensing is in line with the current international law related to trade secrets, and discuss the potential national legal framework and grounds for granting a compulsory license of trade secrets. After examining various types of trade secret licenses in general and analyzing the particularity of the trade secret licenses compared to other IP licenses, the authors outline the contents of a compulsory trade secret license, highlighting some distinctive challenges associated with such a compulsory license. In particular, they raise several issues regarding the enforceability of a compulsory trade secret license, which may be faced by a compulsory licensor (trade secret holder), a compulsory licensee and the government that grants the compulsory license. Despite those reservations, the authors are of the view that it would be feasible to introduce a compulsory trade secret licensing. Referring to the Federal Trade Commission (FTC) case in the US, *Mallinckrodt Ard Inc.(Questcor Pharmaceuticals)*, the authors note that an independent third party might play a role in overseeing access to, and protection of, compulsory licensor's technology in order to prevent trade secret misappropriation and deal with the enforcement of cross-border obligations.
[*Reference to study is in paragraph 20 of Annex II*]

40. The article by Houston and Beall (2019) reports that the Paragraph 6 System of the TRIPS Agreement has proven disappointing in practice. In particular, the article documents a recent and largely unknown attempt by a Canadian generics company (Teva Canada) that almost became the world's second use of the Paragraph 6 System and the lessons to be learnt from this case. Following a brief introduction to the Paragraph 6 System and its implementation in Canada via Canada's Access to Medicines Regime (CAMR), the article examines Teva Canada's partially successful but ultimately abandoned attempt to use CAMR to export products containing tenofovir disoproxil (a drug that is a core component of pre-exposure prophylaxis, a daily medication used as a preventative measure against HIV infection). Filling the gaps in the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, the authors identify the business-driven, rather than purely philanthropic, motivations for generics companies as a way to engage them with the Paragraph 6 system. The article concludes by suggesting potential reforms to CAMR and other Paragraph 6 mechanisms in order to account for the interests of generics companies and thereby encourage their participation in helping provide access to affordable medicines in the future.
[*Reference to study is in paragraph 21 of Annex II*]

41. The study by Islam *et al*. (2019) reviews the impacts of intellectual property provisions in bilateral and multilateral FTAs on access to medicines in low and middle income countries. The main objective of this study is to systematically review the literature for quantitative evidence in low and middle income countries. The authors examine *ex-ante* review that uses structural models and simulations to predict the likely impact of IP provisions on access to medicines, as well as *ex-post* review that utilizes empirical data to measure the size of the effect. The authors identified 14 studies for the evaluation: seven *ex-ante* and seven *ex-post* studies. Both types of studies report, for the most, an increase in price and a decrease in consumer welfare with imposition of IP protection in FTAs. This paper concludes that: (i) the studies reviewed show that changes in IP policy due to the implementation of trade agreements are associated with changes in price, medicines expenditure and sales, consumer welfare, and ultimately the affordability of medicines; (ii) the reported impacts of IP changes on access to medicines seem

multifactorial; and (iii) the impact of IP provisions manifests itself through the healthcare/pharmaceutical ecosystem. Overall, the authors state that more studies are necessary to fill the gap in understanding which changes in IP affect access to medicines and which outcomes relevant to access are most affected by which type of changes in the IP.
[*Reference to study is in paragraph 24 of Annex II*]

42. In this chapter, Long (2021) argues that, although the trade policies of the TRIPS Agreement – in particular, its strong protection for IP rights in the pharmaceutical sector – continue to drive health costs upwards, potential regulatory doctrines aimed at reducing those costs often remain underutilized or ineffective. The author explores the confluence of factors that has created consistent and pernicious barriers to reasonable access to medicines. The author examines seven "roadblocks" that hinder the creation of effective competitive regulatory mechanisms for controlling pharmaceutical prices, and ultimately capping global pharmaceutical profits in a manner supporting socially just and sustainable innovation. The issues addressed are, for example, reducing the likelihood of improvidently granting patents covering innovations that lack the requisite inventiveness, and establishing limitations on a patent holder's exclusive rights, such as through compulsory licenses, when protected drugs are not "reasonably available" on the domestic market, etc. The roadblocks identified by the author include, amongst others: (i) the natural hesitation to start the daunting process of reform for such a complex issue, including patent law recalibration; and (ii) the adoption of "quick fixes," such as compulsory licenses and gray market imports, without safeguards to ensure necessary continued innovation. The author stresses the need to begin addressing those seven roadblocks.
[*Reference to study is in paragraph 28 of Annex II*]

43. The chapter by Mercurio (2021) is based on the premise that far from representing the limits of protection, the TRIPS Agreement has come to be seen as a minimum standards agreement, which can be altered by members to raise protection. According to the author, the pharmaceutical industry and a select group of powerful countries have pushed for higher standards of protection in FTAs and other stand-alone treaties, by seeking a longer period and increased scope, depth and level of protection. The author states that since amendment of the TRIPS Agreement is difficult and bringing a successful pharmaceutical product to the market is time-consuming and extraordinarily expensive, the pharmaceutical industry is left with no other option but to lobby governments to promote longer, further, and deeper levels of protection, while the governments simultaneously struggle to balance the containment of health costs, reasonable access to medicines, and ever-increasing standards being negotiated into FTAs. The chapter mainly highlights the key provisions in FTAs negotiated by the US and EU that go beyond the minimum standards prescribed in the TRIPS Agreement, in particular, the Trans-Pacific Partnership (TPP) and the EU–Canada Comprehensive Economic and Trade Agreement (CETA), and demonstrate the trend towards longer, further, and deeper pharmaceutical patent protection. The author concludes that although the TPP and the CETA follow the trend of IP standards beyond the TRIPS Agreement, those treaties differ from past treaties by providing additional safeguards that balance the interests of users and the pharmaceutical industry.
[*Reference to study is in paragraph 31 of Annex II*]

44. This study by Mike (2019) adopts a doctrinal methodology to examine, analyze and evaluate the issues that have arisen in the context of patent protection of pharmaceuticals and its effect on access to medicines in Nigeria. The study argues for an improvement of women's access to medicines within the context of patent law, patent rights, available flexibilities in the TRIPS Agreement, and Nigeria's national patent system. The author essentially adds a gender dimension to the problems of access to medicines within the scope of patent law. After outlining the general challenges of the health care system and access to medicines in Nigeria and the distinct health needs of its women, the author argues that any national efforts to improve access to medicines should include a consideration of the ways in which patent rights could affect women's accessibility to affordable essential medicines. The author then examined the

international debate on patents and accessibility to life-saving medicines, in particular, in relation to the TRIPS Agreement that provides patent protection of product inventions regarding pharmaceuticals. The study concludes that while the hindrances to accessibility of essential drugs in Nigeria are multifaceted and demand a multidimensional approach for a lasting solution, the TRIPS flexibilities are a significant means for addressing the challenges of affordable access to important health treatments within the context of patent law. The author emphasizes that Nigeria's patent system should be strategically designed to take full advantage of the available exceptions, safeguards and options.
[*Reference to study is in paragraph 32 of Annex II*]

45. Owoeye (2019) examines the scope of the existing flexibilities in international IP law for promoting access to medicines, with special focus on the TRIPS Agreement provisions on compulsory licensing and parallel importation, and their implications for health and development in Africa. The work analyses the factors accounting for the underutilization of the flexibilities in Africa and the measures that African countries may adopt to address the IP barriers to access to medicines. The author examines the TRIPS compulsory licensing regime and its connection with test data protection to assess the legal flexibilities and impediments to making pharmaceuticals available at affordable rates. Further, the author examines the TRIPS provision on exhaustion of IPRs and the benefits it may offer to countries seeking access to patented pharmaceuticals at affordable rates. The work also discusses the implications of the provisions in the regional trade agreements, which provide a higher level of protection than the TRIPS Agreement, to access to medicines. The author considers that the African Free Trade Area or Economic Community will place the continent in a better position to effectively take advantage of the available options in public international law. Noting the challenges associated with the establishment of such an African Economic Community, generally, the author identifies the problems with the current legal regime in respect of pharmaceutical patents in Africa. The author concludes by recommending that the best way to remedy those problems would be pursuing the goal of an African Free Trade Area within the existing arrangement in the African Union, in order to facilitate economic collaboration, maximize the benefits of the TRIPS flexibilities and promote access to medicines in Africa.
[*Reference to study is in paragraph 36 of Annex II*]

46. The paper by Walsh, Wallace *et al.* (2021) discusses tensions caused by access barriers to IPR-protected subject matter, tools used to reduce such barriers, and their effectiveness. The authors state that the COVID-19 pandemic had re-emphasized the importance of access to IP during a crisis, in particular in the areas of public health, and educational and cultural engagement. After examining the elusive terminology such as "access", "public" and "open", it particularly outlines that there is no simple concept of "public interest", but a plurality of public interests that depend, among others, on the type of IPR-protected subject matter, location, and resources. Further, the paper scrutinizes access barriers to IPR-protected subject matter, questioning whether open access and open innovation movements, such as the Open COVID Pledge and C-TAP, may be sufficient to remove those barriers. Furthermore, the authors discuss certain existing legal doctrines as additional or alternative solutions to open access movements, covering issues such as exclusions from patentability, discretion of courts regarding the stay of an injunction due to public health considerations, as well as compulsory licensing and government use. The paper concludes that a combination of involuntary licenses and open innovation movements is the most promising to address access barriers but nonetheless is insufficient. Hence, it suggests to systematically re-evaluate IPRs and access mechanisms in order to ensure the re-centration of public interest goals and adequate private and public responses to future crises.
[*Reference to study is in paragraph 50 of Annex II*]

<u>Incentivizing and promoting the development of new medicines and health technologies</u>

47. The article by Batista, Byrski, *et al.* (2019) analyzes what changes to IP-based incentives are conceivable in the EU in order to address the so-called antimicrobial crisis. The amicrobial crisis consists of increasing microbial resistance that creates a demand for new drugs, which however is not matched by privately funded R&D. The paper offers a general view of conceivable strategies, namely push mechanisms and pull mechanisms. As the push mechanisms, it refers, among others, supporting open-access research and knowledge-sharing, direct research funding through grants or forgivable loans and public-private partnerships. With regard to the pull-mechanisms, it names outcome-based pull mechanisms, such as patent buyouts (i.e. acquisition of a patent for a new antimicrobial by a funder) and payer licenses (i.e. exclusive license granted by the patentee), and legal and regulatory measures that aim to return investment without interfering in the patent system's market- based pricing, i.e., longer exclusivities for patents, longer duration for supplementary protection certificates (SPC) and a longer period for data exclusivity. Further, it proposes an interdisciplinary research agenda to assess the suitability of analyzed options, which should be considered for the implementation of public policies in this field.
[*Reference to study is in paragraph 7 of Annex II*]

48. The paper by Grimes (2021) critically examines the role of pharmaceutical patents in the US in promoting drug research. While concentrating on the situation in the US, the author underlines the implications of some effects on the patent policies across the world. The paper argues that the COVID-19 pandemic points out generalized weaknesses of the patent system. In the view of the author, the patent monopoly is exploited (through practices such as evergreening and promotion of patented drugs) in a way that the link between societal value and patent profitability is lost. Further, the paper observes a lack of a flexible and nuanced system of rewarding valuable R&D. The paper concludes that another system (such as a prize system) of rewarding medical R&D, which may partially replace or supplement the patent system, needs to be found.
[*Reference to study is in paragraph 16 of Annex II*]

49. The paper by Khachigian (2020) aims to contribute to the understanding that effective incentives to innovate in developed countries can lead to global improvements in access to medicines if the intellectual property system is calibrated to permit this. According to the author, this depends partly on the usefulness of compulsory licensing and alternative mechanisms facilitating global access to drugs. The paper begins by a discussion on the patent incentive theory according to which the essence of any granted patent is the bargain between the patentee and the public. Since the intersection between IP and pharmaceuticals has enduring human rights significance, if IP rights raised prices making drugs unaffordable, this could have serious consequences for the right to health of individuals, the author says. Such potential disconnect between pharmaceutical access and patent protection was supposed to be addressed through compulsory licensing. However, the author argues that compulsory licensing and other TRIPS flexibilities have not been successful and hence, there is need for alternate mechanisms. The paper concludes that incentive theory-fueled IP rights in medical research can be better exploited to harness innovative capacity in the following ways: (i) clear recognition that new discoveries stemming from increased investment in health R&D provides greater opportunity to exploit IP and fuel further R&D; (ii) more funding opportunities for early stage R&D avoids promising drugs and devices from disappearing; (iii) improved training programs to help researchers better understand IP rights facilitate research and commercialization; and (iv) a more flexible approach in handling IP ensures, for example, better utilization of inventions in universities and medical research.
[*Reference to study is in paragraph 25 of Annex II*]

50. The paper by Le and Samson (2021) challenges the misbelief that intellectual property rights, mainly patent rights, are standing in the way of global vaccination supplies. The authors argue that the roadblocks of the vaccination program have nothing to do with IP rights, but the real bottlenecks instead lie in manufacturing capacity, supply chain and export restrictions

issues. The paper begins by discussing the complexity of vaccines and its manufacturing process. The authors argue that the idea that vaccines will be made cheaper and quicker by removing the patent system and other forms of IP rights is both erroneous and unfounded. In their view, as the main cost drivers for vaccine development remain fixed, second-generation vaccines do not lead to the same price reduction as in case of generic drugs. Finally, the authors state that eroding patent protection will do more harm than good because: (i) it will disincentivize R&D in the vaccine industry; (ii) if patented vaccines are in the public domain and are not properly allocated, the ripple effect of the tragedy of common goods will soon be felt; and (iii) it can cause an increase in counterfeit products. The paper concludes that instead of spending time on trying to dismantle the patent system, the focus should rather be on addressing trade restrictions, improving the global manufacturing partnerships between vaccine developers, and strengthening their cross-border supply chains to re-unite a fragmented world. [*Reference to study is in paragraph 27 of Annex II*]

Analysis of issues from the perspectives of incentives to innovate and availability of medical products and technologies

51. The aim of the article by Gurgula (2021) is to discuss the roots of the problem in the current system of medical innovation and access to medicines, including those related to COVID-19, and to provide certain recommendations on how this issue can be resolved. The article begins by explaining the rationale of the existing system of innovation and the justification for strong patent protection traditionally put forward by pharmaceutical companies, and the effect it has on drug prices. The author then discusses the recent evidence produced by the US House Committee on Oversight and Reform that was gathered during the Committee's two-year investigation into pricing practices of pharmaceutical companies and revealed during its hearings in September/October 2020. This evidence directly contradicts the traditional argument of pharmaceutical companies justifying strong patent protection as a vehicle for recouping their R&D investments. The article also examines why it is crucial to urgently solve the problem of effective medical innovation and access to affordable medicines. The article concludes by recommending the following: (i) paying more rigorous attention to pricing and patenting practices by pharmaceutical companies; (ii) ensuring adequate access to medicines developed with the use of public funding; and (iii) assuming the responsibility for public health by governments, instead of exclusively relying on private pharmaceutical companies. [*Reference to study is in paragraph 18 of Annex II*]

52. The study by Hu *et al.* (2020) critically engages with the policy justifications underlying supplementary protection certificates (SPCs), based on an analysis of three medicines for hepatitis C and cancer treatments. The study also analyses access challenges to a hepatitis C medicine and an HIV treatment in Europe, highlighting the social cost of the introduction of SPCs. The article begins with a brief overview of the development of patents and other market exclusivity instruments and their impact on access to medicines. Section two of the paper then introduces the specific case of SPCs, including the recent European Commission review on them. The next section assesses SPCs as a means of offsetting R&D investments using the medicines sofosbuvir, trastuzumab, and imatinib as case studies. Thereafter, the authors present two recent cases (sofosbuvir and the fixed-dose combination tenofovir disoproxil fumarate and emtricitabine (TDF/FTC)) of publicly reported access to medicines challenges in a number of European countries. Finally, the last section explains the rationale and social cost of patent term extensions, such as SPCs, in light of the right to access medicines as an integral part of the realization of the right to health for all. Both the normative and empirical findings demonstrate that the common justifications supporting the SPC regime are highly questionable. Further, the addition of SPC exclusivity has heavily delayed competition and maintained high medicines prices in European countries. This leads to the conclusion that granting such extended exclusive rights on medicines may result in unnecessary suffering and be a factor in the erosion of access to medicines for all.

[*Reference to study is in paragraph 22 of Annex II*]

53. The chapter by Napolitano (2021) defines the elements of the TRIPS Agreement that have been having an impact, over the years, on the generic and biosimilar medicine sector and access to those medicines, both in developed and less developed countries. The author considers that the underlying objectives of the TRIPS Agreement is the protection of IP rights for incentivizing investments in innovative technologies. Accordingly, the question of whether IP rights are perfectly fit for incentivizing investments in R&D and innovation needs to be assessed by a two-fold analysis: first, whether IP rights are always the best possible incentive to innovation; and second, whether other factors have been demonstrated to have driven actual investments in R&D and innovation in a particular territory. The author examines a balance of the rights and obligations in patent law, which is the most controversial element within the membership of the WTO, and stresses that the effort to strike such a balance is a political and moral duty of all the WTO members. Overall, it is concluded that the political debate around whether the TRIPS Agreement is suitable for protecting IP rights while simultaneously allowing the achievement of public health objectives, including universal access to medicines, remains highly sensitive and delicate. The analysis of the chapter is completed with suggestions of a possible way forward, focusing on an equitable implementation of the TRIPS Agreement by WTO members in trade policy initiatives and preferential trade agreements, and more transparent and well-functioning IP systems.
[*Reference to study is in paragraph 34 of Annex II*]

Multi-stakeholder partnership policy

54. The paper by Huneycutt, Lurie *et al.* (2020) describes the process of revising the initial equitable access policy of the Coalition for Epidemic Preparedness Innovations (CEPI), which was developed shortly after its formation. First, the authors describe the initial equitable access policy and describe the concerns of some stakeholders with this policy. On the one hand, potential industry partners considered the initial policy as inflexible and would have preferred more flexible negotiable “guidelines”. Further, developers were concerned about losing access to IP that may have been developed, or planned to be used, for another commercial purpose. They were also concerned about the possibility that without cause, CEPI could take over a project, transfer it to a competitor, or share data or results they preferred to keep private for competitive purposes. On the other hand, some civil society and academic partners felt that any projects funded with public money should be in the public domain, and that CEPI must take definitive steps to set the price of a vaccine to ensure that it would be affordable by low- and middle-income countries. It is stated that due to these differences in perceptions and the wording of the original policy, several vaccine manufacturers refrained from working with CEPI under the provisions of the policy. Secondly, the paper describes the multi-stage review of the initial CEPI access policy. Subsequently, the current policy and its implementation is briefly outlined. In conclusion, it is highlighted that CEPI's targeted and iterative approach to its access policy has promoted CEPI’s overall goal of equal access. Further, the authors expect that CEPI and its stakeholders will continue to learn and adjust the access policy accordingly without veering from its foundational commitment to equitable access.
[*Reference to study is in paragraph 23 of Annex II*]

[End of Annex I, Annex II follows]

LIST OF STUDIES INCLUDED IN THE UPDATE OF THE REVIEW OF EXISTING RESEARCH ON PATENTS AND ACCESS TO MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES (2019-2021)

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