Mr. Marco Aleman
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World Intellectual Property Organization
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Dear Mr. Aleman

As an observer to WIPO's Standing Committee on the Law of Patents (SCP), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) appreciates the opportunity to provide inputs on the document SCP/26/7 "Constraints faced by 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"

IFPMA represents research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry researches, develops, and provides medicines and vaccines that improve the life of patients worldwide.

Access to medicines is complex, multifaceted challenge

The challenge of access to medicines is a multiple and complex one, inseparable from the equally complex challenge of poverty from which it arises and to which it leads. It is a cycle that is hard to break. Poverty perpetuates the problem of inadequate healthcare provision and ill health, whereas health brings wealth, and vice-versa. The aim of universal access to healthcare, Sustainable Development Goal 3.8, cannot effectively be realized without a holistic approach to tackling the myriad determinants and challenges at play in this context. To succeed, it is essential for the global health community to work together, in line with the Sustainable Development Agenda's call for a "revitalized global partnership".

The inadequacies that remain in global healthcare provision are undeniable. One-third of the world's population does not have reliable access to products on the WHO's Essential Medicines List. [1] In many of the world's poorest countries, that figure rises to half of the population.[2] Approximately 400 million people - and 56% of people living in rural areas - lack access to basic health services and vulnerable groups such as women, children and people living in rural communities are disproportionately affected. [3] Overall, there is a global shortfall of 7.2 million healthcare workers. Lack of qualified workers and poor disease awareness, alongside weak regulatory structures, supply chain bottlenecks, poor physical infrastructure and inefficient service delivery are all major obstacles to access to health. Likewise, trade barriers, inadequate healthcare spending by local governments, lack

[1] Hogerzeil, Hans V., and Zafar Mirza. "The World Medicines Situation 2011: Access to Essential Medicines as Part of the Right to Health." World Health Organization, 2011. http://apps.who.int/medicinedocs/documents/s18772en/s18772en.pdf.
[2] Ibid
[3] World Health Organization, and World Bank. "Tracking Universal Health Coverage: First Global Monitoring Report," June 2015. http://apps.who.int/iris/bitstream/10665/174536/1/9789241564977_eng.pdf?ua=1.

of universal health insurance and the absence of nationwide healthcare policies all contribute to the problems of affordability of medicines.

The research-based pharmaceutical industry continues to work alongside partners in the global health community to build local capacity and address the most fundamental barriers to access posed by inadequate health systems. Intellectual property plays only a very limited role in the overall challenge to ensure access to medicines. Rather than over-emphasizing the importance of using "to the full" the TRIPS flexibilities, a much more productive focus would be on scaling up proven and sustainable initiatives to:

- streamline regulatory procedures; unlock supply chain bottlenecks and create leaner distribution systems;
- improve healthcare education and the training of healthcare workers;
- raise disease awareness and ensure early detection;
- strengthen physical infrastructure;
- partner in the establishment of social business models.

Framework for the interpretation of TRIPS obligations

Under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), WTO Members are required to implement a minimum level of patent protection while retaining the freedom to provide "more extensive protection". The TRIPS Agreement was carefully crafted to safeguard policy space, particularly in the vital area of public health. By allowing for some flexibility in implementation,[4] the Agreement recognizes that WTO Members may wish to adopt measures necessary to protect public health and nutrition, and offers TRIPS-consistent avenues to pursue these objectives.[5] Additionally, the Doha Declaration on the TRIPS Agreement and Public Health[6] confirmed TRIPS coherence with public health by affirming that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health[7]. In a further attempt to reinforce this coherence, WTO Members recently amended the TRIPS Agreement to implement Paragraph 6 of the Doha Declaration on TRIPS and Public Health, an amendment which entered into force in January 2017.[8]

The TRIPS Agreement thus reflects a carefully negotiated balance between IP protection and public health objectives[9]. It is also to be recalled that the TRIPS Agreement is part of a "single undertaking", meaning that the TRIPS Agreement not only embodies a delicate internal balance, but is also part of a larger negotiated balance involving the entire range of WTO Agreements. As such, while interpreting the TRIPS Agreement[10] – including, for the purpose of identifying flexibilities – it is

[4] Key options include transition periods for LDCs, differing IP exhaustion regimes, refining the criteria for grant of a patent, pre-grant and post-grant opposition procedures, as well as exceptions and limitations to patent rights once granted, including "Bolar" exception to facilitate market entry of generics, compulsory licenses (CLs), and government use. See: 'Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade' (WTO, WIPO, WHO, 2012), https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.

[5] TRIPS Agreement, Article 8.

[6] Declaration on the TRIPS Agreement and Public Health, Adopted on 14 November 2001 (WT/MIN(01)/DEC/2) https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[7] The Doha Declaration underscored the significance of the objectives and principles to interpretation is under paragraph 5(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." Therefore, the Doha Declaration cannot be used to reduce, weaken or even nullify the expressed obligation to act in consistence with the TRIPS Agreement

[8] WTO General Council, "Amendment of the TRIPS Agreement – Decision of 6 December 2005," WT/L/641; See WTO, Amendment of the TRIPS Agreement, available at https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

[9] SOLOVY, Eric M, KRISHNAMURTHY, Pavan S. TRIPS Agreement flexibilities and their limitations: A response to the UN Secretary General's High-Level Panel Report on Access to Medicines. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2984951#

[10] SNODIN, Mike. Pharmaceutical innovations and obligations under TRIPS. Journal of Intellectual Property Law & Practice (2017) 12 (6): 489–501. DOI: https://doi.org/10.1093/jiplp/jpx049

important that the interpreter remains faithful to the Agreement[11], and use tools of interpretation recognized by international law[12]. A departure from these legally recognized, and commonly accepted, tools of interpretation would introduce insecurity, unpredictability, and arbitrariness into the framework, which would be counterproductive, both for public health objectives and for innovation policies[13].

Issues related to the use of flexibilities

The debate related to the full use of flexibilities is two-fold, focusing on (i) national implementation and transposition of international law by governments, and (ii) the use of national provisions by stakeholders. On both levels, various reasons exist why countries may not make full use of the existing policy space. Many of these have been discussed in the document prepared by the Secretariat, but we wish to highlight a few issues:

Weighing policy options

The challenge of developing and implementing effective policy measures for innovation and public health is dynamic by its very nature. Faced with a choice of the most optimal mechanisms to pursue different policy goals, governments have multiple policy options at their disposal, each with its own set of trade-offs. While the availability of patent flexibilities can be useful in limited contexts, like health emergencies, their use is not an optimal strategy to attain better access to medicines in the long-term.

Indeed, various examples exist which show that reliance on flexibilities implemented in national systems has not led to the intended outcome of improving access to medicines.[14] This is particularly the case with compulsory licenses, as the experiences in Ghana, Kenya and Zimbabwe, cited by the Secretariat reveal.[15] Moreover, another study indicated compulsory license prices exceeded the median international procurement prices in 19 of the 30 case studies, often with a price gap of more than 25 per cent.[16] Compulsory licensing often delivered suboptimal value when compared to the alternative of international procurement, especially when used by low-income countries in the manufacturing of medicines locally.[17]

Additionally, as noted by the Secretariat,[18] government policy pursues various public policy goals and chooses policy options in view of an overarching policy. It was expressed in the World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) that the use of flexibilities needs to be considered in conjunction with its impact on innovation.[19] IP policy is one important element of creating more robust innovation ecosystems which can contribute, in the long-term, to better health outcomes[20].

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[11] "The object and purpose is that which is found in the wording of the treaty. The WTO has confirmed that it need not apply other rules of international law if applying 31(1) provides the answer. In particular, supplementary material, such as travaux preparatoires, is not the first port of call to illuminate the context." See: Susy Frankel, 'The WTO's Application of "The Customary Rules of Interpretation of Public International Law" to Intellectual Property', *Victoria University of Wellington Legal Research Papers* 46, no. 1 (2014).
[12] Understanding on the Rules and Procedures Governing the Settlement of Disputes, Article 3.2; Eric M. Solovy and Deepak Raju, 'A Manufacturing-for-Export Exception to Patent Protection: A Proposal for Exporting Violations of the TRIPS Agreement and Beyond', SSRN Scholarly Paper (Social Science Research Network, 18 July 2017), https://papers.ssrn.com/abstract=3004845.
[13] See Eric M. Solovy and Deepak Raju, 'A Manufacturing-for-Export Exception to Patent Protection: A Proposal for Exporting Violations of the TRIPS Agreement and Beyond', SSRN Scholarly Paper (Social Science Research Network, 18 July 2017), https://papers.ssrn.com/abstract=3004845.
[14] 'Constraints Faced by Developing Countries and LDCs'.
[15] Ibid.
[16] Reed F. Beall, Randall Kuhn, and Amir Attaran, 'Compulsory Licensing Often Did Not Produce Lower Prices For Antiretrovirals Compared To International Procurement', *Health Affairs* 34, no. 3 (1 March 2015): 493–501.
[17] Ibid.
[18] 'Constraints Faced by Developing Countries and LDCs'.
[19] *Global Strategy and Plan of Action: On Public Health, Innovation and Intellectual Property* (Geneva, Switzerland: WHO, 2011).
[20] See: ICC's Principles on Creating and Nurturing Innovation Ecosystems for High-Tech Industries. https://iccwbo.org/publication/icc-principles-on-creating-and-nurturing-innovation-ecosystems-for-high-tech-industries/

In fact, by permitting WTO Members to provide "more extensive protection" than required,[21] TRIPS acknowledged that such protection may be beneficial towards developing an enabling environment for innovation in particular markets.[22] Some fear that so-called "TRIPS plus" provisions in bilateral and regional free trade agreements (FTAs) could undermine health outcomes.[23] Increasingly, however, such agreements include public health safeguards[24], and assessing the impact of specific chapters of FTAs in an isolated manner might disregard the overall architecture of the agreement. The focus should instead be on the assessment of an agreement as a whole, in terms of wealth creation and improved living standards, of which access to a performing healthcare system is a key part.[25]

Importantly, because circumstances in each Member State are different, any flexibility in international treaties needs to be considered in the light of the circumstances of a particular country.[26] In that respect, there is no one-size-fits-all in the use of flexibilities by a government (or even for the same government at different times). For some countries, flexibility may mean use of patent exceptions (e.g. like "Bolar"), while for others TRIPS-plus provisions may constitute the optimal choice. At the same time, it is important that Members make their own tailor-made policy choices within the range of permissible options under the TRIPS Agreement.

Limited capacity

As noted by the Secretariat, insufficient local institutional, legal, and technical expertise to implement TRIPS flexibilities into national law as well as how to use them can be an obstacle in making full use of patent flexibilities.[27] Without well-trained individuals with high levels of knowledge and expertise, it is not possible to accurately judge what kind of policy measures will be capable of attaining the intended goals, assess their impact, and trade-offs. Once implemented, nuanced use of flexibilities requires sophistication of expertise and ability to align their use with other public policy objectives.

Moreover, lack of capacity can also occur at a technical and technological level. As the evidence cited by the Secretariat indicated, in relation to the regulatory review ("Bolar") exception, even in countries that have enacted it, the exception is not necessarily used by generic companies due to lack of awareness of patent issues, among others reasons.[28] On a technological level, the challenge of insufficient or lack of technological capacity on the part of local industries to produce generic pharmaceutical products can make an exception or limitation to patent rights unusable.[29] As correctly observed by the Secretariat, common risk factors associated with manufacturing and commercial activities cannot be eliminated through the use of flexibilities.[30] As the Secretariat helpfully recalls, even developing and bringing a generic product to market requires a substantial investment, notwithstanding that generic producers do not incur R&D costs.[31]

Disincentives for voluntary licensing

[21] TRIPS Agreement, Article 1.1.
[22] Manisha A. Desai, 'Compulsory Licensing: Procedural Requirements under the TRIPS Agreement', in *The Globalisation of the Pharmaceutical Industry*, ed. J. L. Valverde and Eduardo Pisani (IOS Press, 2016).
[23] See for example: Richard D. Smith, Carlos Correa, and Cecilia Oh, 'Trade, TRIPS, and Pharmaceuticals', *The Lancet* 373, no. 9664 (February 2009): 684–91; Beatrice Lindstrom, 'Scaling Back TRIPS-plus: An Analysis of Intellectual Property Provisions in Trade Agreements and Implications for Asia and the Pacific', *New York University Journal of International Law and Politics* 42, no. 3 (2010).
[24] 'Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade'.
[25] Ibid.
[26] *GSPA-PHI*.
[27] 'Constraints Faced by Developing Countries and LDCs'.
[28] Ibid.
[29] Ibid.
[30] "Even developing and bringing a generic product to market requires a substantial investment, even if generic producers do not need to incur R&D costs. Economies of scale and associated marketing costs are just a few examples of economic factors that might affect return on investment and consequently, business decisions." Ibid.
[31] Ibid.

Frequently, compulsory licenses are promoted as a flexibility permitted under the TRIPS Agreement that can lead to overcoming "patent barriers" and result in improved access to medicines in developing and least developed countries (LDCs).[32] In reality, most pharmaceutical companies either do not patent in such jurisdictions or do not enforce their rights there (non-assert declarations).[33] Moreover, it is estimated that more than 92% of the medicines on the 2015 WHO model list of essential medicines (MLEM) are off-patent.[34]

Engaging in successful negotiations to obtain a voluntary license also denies the need for the use of this tool.[35] The TRIPS Agreement envisages voluntary licenses being the norm, and compulsory licenses being the exception. In fact, one of the most important rights conferred on a patent owner under the TRIPS Agreement is the right to freely conclude voluntary licenses under Article 28(2) of the TRIPS Agreement. An overuse of compulsory licenses would incentivize local license-seekers to avoid negotiating for voluntary licenses on a good-faith basis, and to instead simply wait for a compulsory license on terms better than the ones dictated by the market. For voluntary licenses to be the norm, it is important that governments (i) abstain from the overuse of compulsory licenses, (ii) not unduly interfere with the freedom of market participants to negotiate voluntary licenses, and (iii) create strong mechanisms for enforcement of license terms. This approach strikes an appropriate balance between public health goals and legitimate rights of innovators.

Patent flexibilities are not a sustainable solution to improving access to medicines

As stated in the introduction, access to medicines is determined by a variety of factors rather than by patent protection alone. Frequently countries cite to the need for better access to health as the reason for using a specific flexibility. However, flexibilities like compulsory licenses do not necessarily bring about better health outcomes, and may even prevent the attainment of optimal public health outcomes on a long-term basis.

Research reveals that intellectual property rights may increase the availability of new treatments to populations in developing countries, by creating increased incentives for marketing efforts by originators.[36] Another study, analyzing data on launches of 642 new molecules in 76 countries, shows that longer duration and stronger, patent rights significantly accelerate diffusion.[37] At the same time, countries that adopt strong pharmaceutical price regulation often experience significantly longer lags in the launch of new drugs.[38]

Cost of medicines is only one aspect relevant to access. An analysis of the Indian market shows that for medicines, low prices can substantially delay access to the benefits of innovation.[39] The long

[32] See: 't Hoen, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha'; 'Overcoming Patent Barriers through Compulsory Measures', *MSF Access Campaign*, July 2011, http://www.msfaccess.org/content/overcoming-patent-barriers-through-compulsory-measures; Lauren Ulrich, 'TRIPS and Compulsory Licensing: Increasing Participation in the Medicines Patent Pool in the Wake of an HIV/AIDS Treatment Timebomb | Emory University School of Law | Atlanta, GA', *Emory International Law Review* 30, no. 1 (2015), http://law.emory.edu/eilr/content/volume-30/issue-1/comments/trips-compulsory-medicines-patent-wake-hiv-aids.html.
[33] See: 'Novartis Position on Access to Healthcare' (Novartis Public Affairs, 2016), https://www.novartis.com/sites/www.novartis.com/files/access-to-healthcare-perspective.pdf; 'GSK Expands Graduated Approach to Patents and Intellectual Property to Widen Access to Medicines in the World's Poorest Countries', *GSK*, 31 March 2016.
[34] Reed F. Beall and Amir Attaran, 'Patent-Based Analysis of the World Health Organization's 2013 Model List of Essential Medicines', Global Challenges Report, (2016), http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_ip_ge_16/wipo_gc_ip_ge_16_www_334437.pdf.
[35] 'Constraints Faced by Developing Countries and LDCs'.
[36] Margaret Kyle and Yi Qian, 'Intellectual Property Rights and Access to Innovation: Evidence from TRIPS', Working Paper (National Bureau of Economic Research, December 2014), doi:10.3386/w20799.
[37] Iain M. Cockburn, Jean O. Lanjouw, and Mark Schankerman, 'Patents and the Global Diffusion of New Drugs', *American Economic Review* 106, no. 1 (January 2016): 136–64.
[38] Ibid.
[39] Ernest R. Berndt and Iain M. Cockburn, 'The Hidden Cost Of Low Prices: Limited Access To New Drugs In India', *Health Affairs* 33, no. 9 (1 September 2014): 1567–75.*

delays reflect domestic policy choices that focus on driving down prices of already available drugs through generic competition, at the expense of curtailing incentives to incur the up-front costs of launching new drugs.[40]

[40] Ibid.