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Council for Trade-Related Aspects of Intellectual Property Rights

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INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST: PROMOTING PUBLIC HEALTH THROUGH COMPETITION LAW AND POLICY

COMMUNICATION FROM SOUTH AFRICA

The following communication, dated 31 January 2019, is circulated at the request of the delegation of South Africa.

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1. This communication continues the *ad hoc* item on "Intellectual Property and the Public Interest: Promoting Public Health Through Competition Law and Policy" that was introduced by the co-sponsors in documents IP/C/643 and Add.1 of 24 May and 29 May 2018 respectively; IP/C/W/649 and Add.1 to Add.3, dated 26 October 2018, 7 November 2018 and 19 November respectively.

2. The proponent wishes to continue the discussion on the linkage between intellectual property and competition law and policy based on the documents referenced in paragraph 1 above, with specific reference to exploitative excessive pricing and restrictive practices such as reverse payment agreements, strategic patenting and more lately, the evolution of niche pricing of off-patent pharmaceuticals.

3. The discussion has gone through various phases of debate, based on underlying guiding questions. During the TRIPS Council meeting of 5 and 6 June 2018, co-sponsors endeavoured to enhance the understanding of Members of the various approaches to competition law and policy and how competition norms are used to prevent or deter practices such as collusive pricing or the use of abusive clauses in licensing agreement that unreasonably restrict access to new technology and prevent the entry of generic companies and may result in higher prices for medicine.

4. It was pointed out that competition law is one of the least discussed flexibilities within the WTO's TRIPS Agreement, noting that while the TRIPS Agreement sets "minimum norms" for standards of IP protection that significantly limit Members' discretion on a large number of IP rights issues, it is however not the case with competition law. Questions discussed during the relevant TRIPS Council meeting included issues around the legal basis that Members use to address abusive practices in their domestic markets; whether Members had established policies to deal with technology transfer pricing and other aspects of transfer of technology transactions and whether compulsory licenses had been used by Members' competition authorities to restore competition in cases involving the exercise of IP rights.

5. During the TRIPS Council meeting of 8 and 9 November 2018, co-sponsors intensified the debate by pointing out that over the course of time clearer competition policy treatment of IPRs has evolved through either iterative processes or the evolving practice of competition authorities. This development, it was argued, underscored the need for further debate and analysis since competition law and policy is no longer the preoccupation of only a few jurisdictions. Members were encouraged to share best practice in respect of the subject of the control and remedies of excessive pricing and whether context-specific methodologies were employed by Members to determine whether such prices were indeed excessive and how such situations where remedied.

6. In order to further develop Members' capacity in this area, co-sponsors posed several questions that were designed to assess to what extent technical assistance and capacity building could

contribute to the delivery of more effective policies by Members in the field of competition law in order to address the abuse of IPRs.

7. At the meeting of the TRIPS Council of 13 and 14 February 2019, the proponent proposes to advance the discussion outlined above through questions which are set out herein below. As demonstrated before, the TRIPS Agreement explicitly permits WTO Members to employ specific measures in order to protect public health and nutrition, and to promote the public interest. Various flexibilities are provided to Members to adopt measures to prevent abuse of IPRs. In recent times, excessive pricing in the pharmaceutical industry has been under the spotlight and there has been a number of competition enforcement cases regarding exploitative excessive pricing.

8. A recent publication of the European Commission entitled "Competition Enforcement in the Pharmaceutical Sector (2009 – 2017)" sheds lighter on the efforts of European competition authorities to ensure affordable and innovative medicine.[1] It should be noted that not all jurisdictions prohibit exploitative excessive pricing, however excessive pricing models may often be indicators of underlying competition problems. Unlike the binding minimum standards of intellectual property protection and enforcement contained in the TRIPS Agreement, there is no equivalent international legal instrument for competition law that would provide such minimum standards of protection.

9. Competition policy has an important role to play in ensuring fair access to medical technology and fostering innovation in the pharmaceutical sector. WTO Members have absolute policy space under international law to design their national competition laws in accordance with their domestic interests and needs and the level of their development.

10. The proponent once again urges Members to share their national experiences and examples of how competition law is used to achieve public health and related national objectives. Debate and information exchange could serve to enhance the understanding of Members of various approaches to the use of competition law and policy to prevent or deter practices such as: collusive pricing or the use of abusive clauses in licensing agreements that unreasonably restrict access to new technology, the use of measures that prevent the entry of generic companies and result in higher prices for medicines, reverse payment agreements and strategic patenting, patent thickets and product switching.

11. Capacity building and technical assistance remain the most important means to enable WTO Members to increase their capacity to administer and implement policies that ensure access to medicines within the TRIPS flexibilities framework.

Guiding Questions

12. The questions are designed to build on previous questions circulated in document IP/C/W/643 and IP/C/W/649. Delegations are invited to share their experiences of using competition law regimes to address anti-competitive practices that affect access to medicines and medical technologies or to share challenges that they face in the enforcement of competition law issues that affect access to medicines or medical technologies.

(1) When dealing with exploitative excessive pricing in the context of anti-trust or competition enforcement in the pharmaceutical and medical technology sector, should competition/anti-trust authorities become quasi price regulators? What are the practices or guidelines that Members have followed to address exploitative excessive pricing in their respective markets with specific emphasis on actions undertaken by competition/anti-trust authorities?

(2) What examples of best practice can Members identify on the subject of the control and remedies for exploitative excessive pricing? Are there context-specific methodologies employed by Members for determining if prices are excessive, and what mechanisms are used to remedy and control pricing abuse?

[1] European Commission "Competition Enforcement in the Pharmaceutical Sector (2009 – 2017)" European Competition Authorities working together for affordable and innovative medicine. (dated 28 January 2019). http://ec.europa.eu/competition/publications/reports/kd0718081enn.pdf

(3) To what extent can abusive practices currently prevalent in the pharmaceutical industry be addressed through improving the patent system, by for example, raising the bar of patentability requirements or increasing registration fees? What have Members' experiences been with these types of measures or other approaches that have been followed?

(4) Have any Members recently conducted market inquiries into the pharmaceutical sector to assess its impact on access to medicine or more generally the impact of the pharmaceutical sector on competition in particular market segments? If so, what were the findings and what remedial actions were recommended or taken?

(5) To what extent can technical assistance and capacity building contribute to the delivery of more effective policies by WTO Members in the field of competition law to address the abuse of intellectual property rights? What role can international organisations play in this regard, including the WTO?