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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 26 October 2018, 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 cosponsors in documents IP/C/643 and Add.1 of 24 May and 29 May 2018 respectively.

2. IP protection *per se* cannot be presumed to confer market power or to indicate anti-competitive behaviour. IPR holders are for this reason, as a general rule, not prevented from exercising their exclusive rights. Different approaches are taken by various jurisdictions regarding the interface of competition law and policy and IP. A recent WTO staff working paper[1] found that despite different levels of development, constitutional systems and/or economic structures and industrial profiles in jurisdictions surveyed[2] displayed a pervasive interest in the interface between competition law and policy and IP. All the jurisdictions surveyed in this study have rudimentary rules that have a bearing on potential anti-competitive abuses of IPRs. It is also apparent that clearer competition policy treatment of IPRs has evolved over time through either iterative processes or evolving practice of competition authorities.[3] This evolution is informed by jurisdictional cross-fertilization and peer learning as evidenced by greater interest in and concerns with ensuring an appropriate balance between IP and competition law and policy in these jurisdictions. This development underscores the need for further debate and analysis since competition law and policy is no longer the preoccupation of only a few jurisdictions.

3. During the June 2018 TRIPS Council session, the cosponsors demonstrated that there are various pro-competitive provisions in the TRIPS Agreement, including Article 6, Article 8.1, Article 31(k) and Article 40. There is no doubt that these provisions leave WTO Members broad policy space to apply competition law in respect of acts related to the acquisition or exercise of IP rights. As a consequence of accommodating the variety of potential competition approaches, remedies available to address anti-competitive behaviour may permit a broader range of remedial action than some other public health-related flexibilities associated solely with patents. Competition policy has an important role to play in ensuring 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.

4. The use of competition law is not without difficulties, since many developing countries may not have the capacity to administer or enforce such a system. Since a substantial body of precedent

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[1] WTO Staff Working Paper ERSD-2018-02 entitled "Competition Agency Guidelines and Policy Initiatives Regarding the Application of Competition Law vis-à-vis Intellectual Property: An Analysis of Jurisdictional Approaches and Emerging Directions", p. 63.

[2] United States, Canada, the European Union, Australia, Japan, Korea, Brazil, China, India, Russia and South Africa.

[3] WTO Staff Working Paper 2018, p. 64.

exist, the sponsor of this document wishes to demonstrate that many WTO Members already use competition law to address various anti-competitive practices that affect access to medicines and medical technologies. Practices that have been identified as detrimental include, but are not limited to the following instances: (i) abuses of IPRs due to a refusal to deal with or imposition of overly restrictive conditions in medical technology licensing; (ii) preventing generic competition through anti-competitive patent settlement agreements; (iii) mergers between pharmaceutical companies that lead to undesirable concentration of research and development and IPRs; (iv) cartel agreements between pharmaceutical companies, including between manufacturers of generics; (v) anti-competitive behaviour in the medical retail and other related sectors; and (vi) bid rigging in public procurement.[4] In this respect, not all jurisdictions follow the same approach, for instance, refusal to license may amount to an abuse of dominance in some jurisdictions while others consider this within the rights of IPR holders.

5. The "objectives" and "principles" enshrined in Articles 7 and 8 of the TRIPS Agreement form central elements of the interpretation of the TRIPS Agreement, especially with regard to the relevant provisions that recognize flexibilities to legislate at the national level. In the WTO case of *Canada – Patent Protection for Pharmaceutical Products*[5], the panel noted that "the exact scope of Article 30's authority will depend on the specific meaning given to its limiting conditions." To this end, the goals enumerated in Articles 7 and 8.1 are relevant when doing so.

6. The Panel in *Australia – Tobacco Plain Packaging* referred to the report in *Canada-Patent Protection for Pharmaceutical Products* regarding the interpretation of the terms of Article 30 of the TRIPS Agreement in light of its object and purposes.[6] It noted that paragraph 5 of the Doha Declaration is formulated in general terms, thereby inviting the interpreter of the TRIPS Agreement to read "each provision of the TRIPS Agreement" in light of the object and purpose of the Agreement, as expressed in particular in its objectives and principles.[7] Fundamentally, the panel concludes that paragraph 5 of the Doha Declaration constitutes a subsequent agreement of WTO Members within the meaning of Article 31(3)(a) of the Vienna Convention on the Law of Treaties.[8] This finding may have important consequences for how flexibilities in the TRIPS Agreement are interpreted.

7. Competition law and policy remains an important topic and is subject to much multilateral focus and discussion. The United Nations Conference on Trade and Development (UNCTAD) produces seminal work on this subject-matter and provides technical assistance in order to improve worldwide cooperation on competition policy matters. Each year, an Intergovernmental Group of Experts (IGE) on Competition Law and Policy meets to discuss ways of and enhancing convergence through dialogue. UNCTAD produces a list of competition laws and annotated commentary contained in the Handbook on Competition Laws (Volume II) (UNCTAD/DITC/CLP/2009/2).[9] It also has a Model Law on Competition which is available in all the UN languages.[10]

8. The World Intellectual Property Organisation (WIPO) has actively discussed the issue of IP and competition.[11] At its thirteenth session (3 – 5 September 2018), the WIPO Advisory Committee on Enforcement discussed, *inter alia*, the interface between IP enforcement and competition law. Brazil and Peru presented case studies of competition on administrative approaches to address the interplay of IP enforcement and competition law.[12] Through concrete examples, the contributors discussed the limitations of unfair competition laws in relation to the exercise of IP rights as well as

[4] WHO, WIPO, WTO, Promoting Access to Medical Technologies and Innovation - Intersections Between Public Health, Intellectual Property and Trade (2013), pp. 75–76.

[5] WT/DS114/R, 17 March 2000, par. 7.26.

[6] Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging (28 June 2018) WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R, par. 7.2402. The DSB adopted the panel reports concerning the complaints by Cuba and Indonesia on 27 August (DS458 and DS467, respectively). Honduras and the Dominican Republic have appealed certain findings by the Panel (DS435 and DS441, respectively).

[7] Ad par. 7.2408.

[8] Ad par. 7.2409. In their respective appeals, Honduras (WT/DS435/23) and the Dominican Republic (WT/DS/441/23) claimed that the Panel erred in finding that paragraph 5 of the Doha Declaration on the TRIPS Agreement and Public Health constitutes a subsequent agreement within the meaning of Article 31(3)(a) of the Vienna Convention on the Law of Treaties.

[9] https://unctad.org/en/Pages/DITC/CompetitionLaw/National-Competition-Legislation.aspx

[10] https://unctad.org/en/Docs/tdrbpconf7d8_en.pdf

[11] http://www.wipo.int/ip-competition/en/

[12] http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_13/wipo_ace_13_5.pdf

interventions of competition rules in cases where the IP system was abused to prevent competitors from entering or remaining in a market.

9. The sponsor urges Members to once again 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 agreement that unreasonably restrict access to new technology, and the use of measures that prevent the entry of generic companies and result in higher prices for medicines. Capacity building and technical assistance remain the most important means to enable WTO Members to increase their capacity to administer and implement competition law regimes.

**Guiding Questions**

10. The questions are designed to build on previous questions circulated in document IP/C/W/643. Some delegations indicated that they may revert to some of the questions that were posed during the last TRIPS Council session. Bearing this in mind, 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) What types of behaviours do WTO Members consider abuses of intellectual property rights in the pharmaceutical and medical sectors? Has there been any evolution in the approaches that WTO Members take to assess such types of behaviours?

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

(3) What examples of best practice can be identified through national competition laws and practices? Are there certain common trends that can be identified across various jurisdictions?

(4) 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?

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