WORLD TRADE ORGANIZATION

IP/C/W/643

25 May 2018

(18-3142)

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Council for Trade-Related Aspects of Intellectual Property Rights

Original: English

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

COMMUNICATION FROM CHINA AND SOUTH AFRICA

The following communication, dated 24 May 2018, is circulated at the request of the delegations of China and South Africa.

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1. In September 2015, 193 Member States of the United Nations adopted the 2030 Agenda for Sustainable Development (2030 Agenda). This agenda includes Sustainable Development Goal (SDG) 3 that aims to ensure healthy lives and promote the well-being of all people of all ages. Soon after Member States adopted the 2030 Agenda for Sustainable Development, Ban Ki-moon, then Secretary General of the United Nations, convened an independent High-Level Panel (HLP) on Access to Medicines to investigate the relationship between intellectual property, access to health technologies, incentives for research and development and the opportunities to strengthen governance, accountability and transparency.

2. The HLP issued its report in September 2016 and called for steps to be taken "…to ensure that global intellectual property regimes and the application of the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are fully consistent with and contribute to the goals of sustainable development."[1]

3. The TRIPS Agreement strikes an appropriate balance between the interests of right holders and users. Article 7 of the TRIPS Agreement recognizes that the protection of intellectual property should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of users and producers of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations.

4. The TRIPS Agreement also recognizes that the principles of IP protection are based on underlying public policy objectives. Article 8.1 of the TRIPS Agreement states that WTO Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. Article 8.2 further states that appropriate measures may be adopted by Members to prevent the abuse of IPRs by right holders, or where right holders resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology. It should be noted that Article 8.2 is not exclusively concerned with competition law violations but can be applied more generally as a general concept of abuse of IPRs.

5. The "objectives" and "principles" enshrined in Articles 7 & 8 of the TRIPS Agreement form central elements of interpretation of the TRIPS Agreement, especially with regard to such provisions that leave flexibilities to legislate at the national level. In the WTO case of

[1] United Nations "Report of the United Nations Secretary-General's High-Level Panel Report on Access to Medicine: Promoting innovation and access to health technologies." September (2016), p. 12.

Canada-Patent Protection for Pharmaceutical Products[2] 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. A plethora of safeguards or flexibilities have become integral parts of the TRIPS framework. These flexibilities can be used to pursue public health objectives. However, to implement these flexibilities, action is needed at the domestic level by incorporating them into national IP regimes keeping in mind each country's individual needs and policy objectives. Key TRIPS flexibilities include transition periods for LDCs (extended by the WTO until 1 January 2033), differing IP exhaustion regimes, refining the criteria for grant of a patent (patentability criteria), pre-grant and post-grant opposition procedures, as well as exceptions and limitations to patent rights once granted, including regulatory review exception ("Bolar" exception) to facilitate market entry of generics, compulsory licences and government use. Despite such flexibility, many least developed and developing countries cannot implement competition regimes due to the lack of capacity to use competition law to achieve public health objectives. The WTO, WIPO and WHO report on IP and Public Health notes: "[*S]everal potentially anti-competitive strategies in relation to IP rights involving medical technology have been observed and documented. These strategies mostly are designed to extend patent protection for originator drugs and to prevent market entry by generic competitors after patent expiry.*"[3]

7. Competition law is one of the least discussed flexibilities within the WTO's TRIPS Agreement. The fundamental objective of competition law is to protect the integrity of competitive markets against abusive conduct, and to protect consumers from the effects of such conduct. Even though 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 not the case with competition law. Members are free to design competition laws in such a way so as to take account of their domestic interests and needs, including taking account of their respective levels of development, subject only to the natural limits defined by the territorial limits of such laws.[4]

8. Various other provisions of the TRIPS Agreement are relevant to competition law including Article 6, Article 31(k) and Article 40. As such, these provisions leave broad discretion to Members in how they apply competition law in respect of the acquisition and exercise of IP rights. Article 6 of the TRIPS Agreement authorizes WTO Members to allow parallel importation of health technologies, a major pro-competitive form of activity that can be used to secure the lowest priced products available on international markets. Article 31(k) of the TRIPS Agreement confirms the right of Members to use such licences as anti-competitive remedies. The only condition required by Article 31(k) for the grant of this type of compulsory licence is that the anti-competitive practice needs to have been determined through a judicial or administrative process. The possible use of compulsory licences to deal with anti-competitive practices, as explicitly recognized in Article 31(k) of the TRIPS Agreement, is of particular importance to protect public health in cases, for instance, of excessive pricing of health technologies or refusal to grant a licence on reasonable commercial terms.

9. The sponsors of this communication urge 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 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, prevent the entry of generic companies and may result in higher prices for medicines. The issue of abuse of IP rights remains relevant in the context of the application of national and regional competition law regimes.

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

[3] WHO/WIPO/WTO *'Promoting Access to Medical Technologies and Innovation. Intersections between Public Health, Intellectual Property and Trade*." Geneva 2012, 198 http://www.who.int/phi/promoting_access_medical_innovation/en/

[4] Carlos Correa "*Intellectual property and competition – room to legislate under international law." in Using Competition Law to Promote Access to Health Technologies*. (UNDP: 2014) at p. 36.

Guiding questions:

- What grounds are available in their national laws to pursue competition law and policy to achieve public health outcomes?

- What are the difficulties faced by WTO Members in using competition law policy to prevent or deter abusive practices, including capacity constraints, pressure from other Members and Corporations?

- Unreasonably high royalties may deter the transfer of technology. What policies have Members established to deal with technology pricing and other aspects of transfer of technology transactions?

- Compulsory licences have been used by competition authorities in some countries to restore competition in cases involving the exercise of IP rights. What are the experiences of Members in using compulsory licenses, noting the flexibilities inherent in Article 31(k) of the TRIPS Agreement?