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**Council for Trade-Related Aspects of
Intellectual Property Rights**

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**INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST: REGULATORY REVIEW
EXCEPTION**

**COMMUNICATION FROM THE PLURINATIONAL STATE OF BOLIVIA, BRAZIL, CHILE
AND SOUTH AFRICA**

The following communication, dated 15 February 2017, is circulated at the request of the delegations of the Plurinational State of Bolivia, Brazil, Chile and South Africa.

1. In May 2017, the delegations of Brazil, China, Fiji, India and South Africa circulated document IP/C/W/630 to encourage discussions in the Council for TRIPS regarding the relation between intellectual property and public interest. In this respect, reference was made to the importance of WTO Members making full use of the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to promote access to health technologies when necessary, as confirmed by the Doha Declaration. With a view to continuing discussions of a topic of general interest to WTO Members and to broaden understanding about the complex interplay between intellectual property and public interest, the sponsors of the present communication invite delegations to share their experience regarding the existence and use of the regulatory review exception ("Bolar exception") under their national or regional frameworks.

2. Countries put in place regulatory requirements in certain industries in order to grant authorization for the commercialization of products. The underlying rationale is to ensure the safety and efficacy of such products, thereby protecting consumers. Those requirements are particularly stringent in the pharmaceutical sector, in light of their possible effects on human health. Compliance with regulatory requirements often entails experimental trials and other related preparatory steps by companies so they may acquire data necessary for regulatory approval.

3. In some countries, legislation allows a third party to undertake, without authorization from the patent right holder, measures in respect of a patented product necessary for obtaining regulatory authorization for commercializing that product. The regulatory review exception is also known as "Bolar exception", a term derived from case law in the United States¹. In *Canada – Pharmaceutical Patents* (DS114), the panel held² that Canada's regulatory review exception is fully in compliance with the TRIPS Agreement, in particular with Article 30, which pertains to exceptions to rights conferred. Following the panel decision, numerous Members have introduced a regulatory review or similar exception in their national legislation.

4. The reasoning for such exception is to enable generic medicine producers to make all necessary preparations to enter the market without delay as soon as the patent expires. Absent such an exception, generic manufacturers would be blocked from undertaking the trials required for regulatory approval, taking months, perhaps years, to obtain such approval. In such circumstances, the patent owner would be able to artificially extend the protection beyond the patent term as determined by national law. Not only does this hurt competition, but it also runs

¹ Roche Products Inc. v Bolar Pharmaceuticals Co 733 F. 2d 858 (Fed Cir 1984)

² Document WT/DS114/R.

counter to the delicate balance of interests reflected in Article 7 of the TRIPS Agreement between the interests of inventors and those of the public.

5. As the global burden of disease expands and countries increasingly face the need of providing life-saving medicines at a reasonable cost, an integrated approach that ensures the continuous production of new, innovative medicines without endangering access to off-patent medicines is needed. Under this framework, the Bolar exception is of particular importance and provides a valuable tool for stimulating competition in the market and ensuring the protection of public health.

6. Members are invited to share their experiences and provide information about the general features of the exception in their national or regional legislation, based on the following guiding questions:

- What is the general characteristic of the "Bolar exception" or equivalent regulatory review exception in WTO Members' legislation?
 - Which measures undertaken by legitimate third parties are exempted from the enforcement of patent protection under the exception?
 - Is the exception applicable to a specific industry or is it neutral in that regard?
 - What were the challenges faced by WTO Members in implementing such exception?
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