**Introductory remarks**

Let me thank KEI and the South Center for having invited me to participate in this panel on assessing the state of implementation of the Doha Declaration on TRIPs and Public Health 10 years after it was adopted.

This is a challenging topic.

On the one hand, it is true, as stated in a policy brief recently circulated by the South Center on the matter, that the Doha declaration “remains a landmark achievement for clarifying the relationship between IP and public health as well as a useful policy tool for policy makers to take TRIPS-compatible public health measures”. On the other, the jury is probably still out on whether or not the Declaration has fulfilled all the expectations placed on it.

 Rather than trying to make myself an overall assessment of the Doha Declaration during that period, I will try to bring you a national perspective, focusing on how Brazil has made use of it. Since I am the only representative of a Government in this panel, I think it will be more useful for all participants if I can share with you the concrete experience of my country in implementing TRIPS flexibilities on public health grounds.

**The current state of play in IP multilateral negotiations**

Before I do that, let me make a few remarks on the current state of play in multilateral IP negotiations. The Doha Declaration, together with the Development Agenda approved by WIPO in 2007, are the only significant multilateral IP instruments negotiated over the past ten years. None of then is, however, a legally binding instrument. Why is that?

Let me go back a little further. As is widely known, intellectual property was introduced at the WTO as a result of the TRIPS agreement, following the completion of the Uruguay Round in the mid-nineties. Within the single undertaking of the Uruguay Round, the TRIPS agreement was widely seen as a victory for the developed countries, a victory that represented the culmination of a long process led by a few countries that were under intense pressure from a few of their industries - mostly the software, the pharmaceutical and the entertainment ones.

That process that led to TRIPS had an agenda of strengthening intellectual property rights. It involved a mix of different initiatives - conducted both bilaterally and in multilateral fora - added to threats of unilateral retaliations. I will not recall the whole process of the TRIPs negotiation here, as it is both well known and well documented.

What remains paradoxically odd, however, is that the apparent winners of the TRIPs negotiations do not appear to be satisfied with the outcome. The implementation of the TRIPS has barely been completed. Yet, over the past few years, developed countries have been pushing for more, for the so-called “TRIPS plus” disciplines in several areas such as extending the validity of copyrights, broadening the scope of patents to include new areas such as “business methods”, including stronger protection for geographical indications in bilateral free trade agreements, and secretively negotiating among themselves the Anti-Counterfeiting Trade Agreement – ACTA. There seems to be no end, in brief, to the drive for ever more stringent rules to advance the protection of intellectual property.

Carolyn Deere[[1]](#footnote-1) refers to the bitter debates over TRIPS between developed and developing countries as a “history of contestation”. That history started during the TRIPS negotiation in the eighties and nineties and was later extended to the implementation stage of the TRIPS agreement. It is played on a stage where a war of ideas, of convictions, of ideologies usually takes precedence over both factual assessments and empirical evidence. Arguments either in favor of or against protection of intellectual property constitute frequently a battle for winning hearts and minds rather than an informed debate capable of leading to concrete action. And this is perfectly understandable given the “history of contestation” of TRIPS.

That is not to say that, after TRIPS, intellectual property has ceased to become a dynamic field of international law today. This is not true. One has to bear in mind, however, that most of the new standards are being negotiated either in bilateral agreements or in plurilateral ones such as ACTA. Only a handful of initiatives are being pursued multilaterally, and most of them can be viewed as attempts to bridge gaps identified a long time ago rather than to break new ground.

 At the WTO, there are three topics under discussion in the Doha Round, namely (i) the extension of geographical indications to products other than wines and spirits, (ii) the creation of an international register for geographical indications, and (iii) the interplay between TRIPS and the Convention on Biological Diversity. All of those three issues under discussion in the Doha Round fall within the category of “outstanding implementation issues” and, by definition, will not change the legal landscape created by TRIPS dramatically.

It is important to bear in mind, against this apparent deadlock in intellectual property negotiations at the WTO, that one has to deal with existing international instruments for the time being. Me must implement them and explored all the possibilities offered by them. That is why initiatives such as this panel are very timely and appropriate.

**A Brazilian Experience**

Let me now turn to the case involving the use by Brazil of a compulsory license under article 31 of TRIPS.

Brazil started procedures leading to the compulsory licensing of the patent of the anti-retroviral drug Efavirenz in the first half of 2007. As it had been the case on previous occasions, the Brazilian Government had chosen to achieve a solution through direct negotiations with the company Merck, Sharp & Dohme, the supplier of Efavirenz. The Ministry of Public Health held several rounds of talks this process and all of them failed to result in an agreement as to what might be reasonable terms and conditions to meet public interest.

Efavirenz is essential in the treatment of HIV/Aids patients and constitutes a basic component of the National Programme on Sexually Transmitted Diseases and AIDS (Programa DST-Aids). The Brazilian program for treating HIV/Ais is globally renowned for its universal and free access to treatment. Efavirenz is one of the most-frequently used medicines in the anti-retroviral therapy. At the time the compulsory licensing was issued on Brazil, 38% of patients made use of it.

Due to the growth of the population infected with HIV/Aids in Brazil, the maintenance of Efavirenz prices was threatening the continuation of Program for STD/Aids. By the current prices at that time (US$ 1.59 each dose), the purchase of Efavirenz (600 mg) within the program would have cost approximately US$ 42,9 millions to the Brazilian Government, that is to say, US$ 580 per patient/year. Proposals received from international organizations regarding the acquisition of such medicine from laboratories pre-qualified by the WHO varied from US$ 163.22 to US$ 166.36 per patient/year. These proposals would represent an annual reduction of around US$ 30 million in the government expenditures in 2007. With the compulsory license of Efavirenz, estimated savings by 2012, expiring date of the Efavirenz patent in Brazil, will have reached US$ 236.8 millions.

Presidential Decree No 6,108, published on May 4th 2007, contains the following provisions:

Article 1 - It is hereby granted, ex officio, public interest compulsory license over patents number 1100250-6 and 96088397. The compulsory license referred to in this article is granted on a non-exclusive basis and for public non-commercial use, within the framework of the National STD/Aids Program, for a period of five years, renewable for until the same period.

Art. 2 - The remuneration due to the holder of the patents mentioned in the preceding article is hereby established in one and five tenths percent (1,5%) of the cost of the medicine produced and finished by the Ministry of Health or of the price of the product delivered to the latter.

Art. 3 - The holder of the patents licensed as per article 1 is obliged to make available to the Ministry of Health information necessary and sufficient to the effective reproduction of the protected objects, being the Union responsible for ensuring the applicable protection of such information against unfair competition and dishonest commercial practices.

Art. 4 The patents licensed as per the present Decree can be exploited either directly by the Union or by third parties duly contracted or accredited, the reproduction of its objects for different purposes remaining forbidden, under penalty of being deemed illicit.

Art. 5 Where the public interest situation cannot be addressed with the product available in the internal market or where the production of the whole or parts of the patent object is not viable by the Union or by contracted or accredited third parties, the Union can import the patent objects without prejudice to the payment of the remuneration referred to in article 2.

In concluding, Brazil has used compulsory licensing only once. The decision followed a very careful and detailed process and was taken at the highest political level. One should not underestimate the difficulties and complexities involved in the process, especially those related to start manufacturing the medicine locally, which has taken approximately one and a half year in Brazil.

1. DEERE, Carolyn – *The Implementation Game: the TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries.* Oxford: Oxford University Press, 2009, p. 5-11. [↑](#footnote-ref-1)