

## Section VII:

### Role of the Ministry of Health

Given the above, we identify here three major roles that could be played by the Ministry of Health in ensuring that public health safeguards are a concern and that access to essential medicines and other devices are not constrained by Intellectual Property Rights.

#### 7.1 Prior Consent of Ministry of Health in Promoting Access

Study and adopt the Brazilian system regarding the determining of patentability of a pharmaceutical substance. In 1999, Brazil introduced the mechanism of prior consent into the Brazilian Industrial Property Act, whose article 229-c provides for:

"The grant of patents for pharmaceutical products and processes shall depend on the prior consent by the National Sanitary Supervision Agency - ANVISA".

Applications for pharmaceutical patents in Brazil are filed at the INPI (National Institute of Intellectual Property), which analyses if the applications meet the formal as well as the patentability requirements. Once the analysis is completed, the applications that meet the formal conditions and the patentability requirements are forwarded to ANVISA for a second technical report. The ANVISA, in its turn, (re)analyses the patent requests, verifying if the patentability requirements have been met by the applicant. If there is a conflict of conclusions between the ANVISA and the INPI, a technical meeting is organized between members of the two federal bodies in order to attempt to homogenize their position. If a consensus is not achieved, the pharmaceutical patent is not granted by the INPI. The applicant can then file an administrative or judicial appeal against the decision. It means that ANVISA has "veto power" over the granting of pharmaceutical patents in Brazil.

The main difference between the analysis carried out by INPI

and the one carried out by ANVISA arises from the diversity of content of the patentability guidelines adopted by each body. While the INPI adopts patentability guidelines that reproduce the practice of the European Patent Office, the ANVISA has drafted its own guidelines, which are much stricter than the ones followed by INPI.

## 7.2 Determining When to Issue Compulsory License for Government Use

Along with patentability, compulsory license is the key to ensuring access to essential medicines. In this regard the model being pursued in Thailand is worth emulation. In Thailand, the "Subcommittee to implement the Government Use of patent on drugs and medical Supplies" established in 2006 is a mechanism to consider which drugs to issue Government Use of patents. The criteria to determine which drugs to issue a Government Use of patent includes drugs and medical supplies that are:

- ◆ listed in the National Essential Drug List, or
- ◆ necessary to solve important public health problems, or
- ◆ necessary in emergency or extreme urgency, or
- ◆ necessary for the prevention and control of outbreaks/ epidemic/pandemics, or life saving

The price of these drugs and medical supplies must be too high to be affordable by the government to supply to the beneficiaries of the national health insurance schemes to achieve the universal access policy. The level of royalty fees payable to the patent holders have been set at between 0.5 to 2 per cent of the sale value. This is the common range used in most developing countries in the case of public non-commercial use. For those drugs with high retail value, the royalty will be set at the lowest level of 0.5 per cent. For those with low retail value, the royalty will be set at the top level of 2 per cent.

A similar model, adapted to the Indian situation can see the Ministry of Health play a major role in ensuring access to essential medicines which are under Patent protection.