MISSION REPORT
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VIET NAM

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4. INTERNAL AGREEMENT

A. INTENT AND OUTCOMES

The intent of the proposed agreement is to promote international cooperation in the field of electronic commerce. The agreement aims to establish a framework for the exchange of information and the sharing of best practices among signatories. It seeks to facilitate the development of common standards and protocols that will enable the integration of national and international electronic commerce systems.

B. IMPLEMENTATION

1. OBJECTIVES

- To create a common set of guidelines and standards for the electronic commerce industry.
- To promote the adoption of best practices in the management of electronic commerce.
- To provide a framework for the development of national and international electronic commerce initiatives.

2. ROLES AND DUTIES

- The signatories shall be responsible for implementing the agreement and ensuring its compliance.
- The signatories shall cooperate in the development and dissemination of best practices.
- The signatories shall provide technical assistance and support to each other.

C. ASSESSMENT

The agreement shall be reviewed annually to assess its effectiveness and to identify areas for improvement.

D. ENFORCEMENT

Disputes arising under the agreement shall be resolved through a process of mediation and arbitration.

E. TERMINATION

The agreement may be terminated by any signatory upon six months' notice to the other signatories.

The mission of the proposed agreement is to enhance the development and adoption of electronic commerce by facilitating international cooperation and the exchange of information among signatories.
1. Membership of Multilateral Treaties
   - The Paris Convention for the Protection of Industrial Property;
   - The Patent Cooperation Treaty;
   - The Convention establishing the World Intellectual Property Organization;
   - The Madrid Agreement Concerning the International Registration of Marks.

2. Bilateral Treaties
   - Viet Nam and Switzerland signed a bilateral agreement in 2000-2001 dealing with the provision of technical assistance on intellectual property.
   - Viet Nam and U.S. Bilateral Trade Agreement (BTA). Signed on July 13 2000 and entered into force on December 10, 2001. It will run for three years and then be automatically extended unless either party renounces the treaty. The BTA allows for the temporary extension of MFN to Viet Nam. Under US trade law MFN has to be renewed for each year that the BTA is in place. Chapter 2 of this bilateral contains standards of intellectual property that are similar to those to be found in TRIPS.

At our meeting with representatives from the Department of Civil and Economic Law we were informed that Viet Nam participates in the meetings of the Benelux Union and that it is moving towards participation in UPOV (it has an ordinance implementing UPOV, but is not yet a member).

Most importantly all of Viet Nam is in the midst of WTO accession. This process began in 1996. Viet Nam is aiming to become a member by the end of 2005. The WTO process will mean that the US and Viet Nam will have in effect another bilateral negotiation. One critical outcome of Viet Nam joining the WTO will be that it will gain from the US permanent and unconditional MFN status.

   - The Civil Code of 1995 (Part 6, Chapter II deals with Industrial Property);
   - The Decree on Industrial Property of 1996 (No 63-CP) as amended and supplemented by Decree No.06/2001/ND-CP of 1 February 2001. (These decrees implement the Code);

We were also pointed to the following circulars and decisions that relate to parallel importation or the importation of medicines.

5. Reform of IP Laws
At our meeting with officials in the Department of Civil and Economic Law, we were informed that the Chapter in the Civil Code dealing with intellectual property is being redrafted. The Ministry of Science, Technology and Environment has primary responsibility for the Industrial property chapter of the Code, with the Department of Civil and Economic Law playing an oversight role. The Ministry of Health is not directly involved in this drafting process.

6. PARALLEL IMPORTATION
As we suggested earlier Viet Nam is highly dependent upon the importation of medicines. Local production remains weak. The goal of the Ministry of Health is to try and meet 60% of domestic demand through local production. According to media reports the price of imported medicines has been high. The basic problem relates to the way in which the importation and distribution of medicines has been organized. In September of 2001, Zuellig Pharma Viet Nam was given an exclusive right to import medicines into Viet Nam. Zuellig Pharma is a Swiss owned company that distributes drugs for 27 multinational companies including Pfizer and GSK. This arrangement has resulted in high drug prices. Zuellig’s import monopoly will reportedly cease in September of 2004. The government has issued a regulation on the parallel importation of medicines and appointed three state-owned enterprises to carry out such importation. This move has attracted the criticism that it simply shifts monopoly rents from foreign distributor companies to local ones. This criticism probably has some point. During our interview at the VPCA we were told that state-owned enterprises play a leading role in the distribution of pharmaceutical products and that finding a good distribution system was a government priority. It may be that local elements in this current network of distribution see gains in displacing Zuellig and others, but not in liberalizing the distribution system.

7. COMPULSORY LICENSING
Compulsory licensing is the single most important tool that a government can use in...
Basically the VPO (and most probably many other developing country patent offices) is caught up in a game of follow the leader. Developing countries could if they so chose set about changing the examination culture of their patent offices. But we would have to (1) invest in creating different guidelines and the training of examiners, (2) invest more in pharmaceutical examination, (3) be prepared to absorb the costs of resisting the leadership of the EPO and US PTO (for example, the costs of added trade pressure). All this seems unlikely for the time being.

9. THE DRUG REGISTRATION AUTHORITY AND DATA PROTECTION

There are two important issues in this area. The first is the obligation that the Drug Registration Authority (DRA) has with respect to the use of data that is submitted to it by an applicant for the registration of a medicine that is to be sold in Viet Nam. The second relates to the policy that the DRA follows on the issue of a third party patent that might relate to the product in relation to which the applicant is applying for registration. On the first issue the BTA contains a TRIPS plus provision (see Article 9.6). The BTA does not deal with the second issue.

It is not clear whether Viet Nam has actually implemented its obligations under Article 9.6. We were not pointed to any implementing provision. We were not able to discover what the actual practice of the DRA is on the protection of data. Our impression of the DRA was that of a busy, understaffed office struggling to understand its obligations with respect to test data.

On the second issue there does seem to be an evolving practice of the DRA consulting with the VPO to check whether there are third party patent claims that relate to the applied for product. This practice appears to have been stimulated by complaints from foreign patent owners that the products in question amounted to infringements of their patents. Somewhat surprisingly foreign patent owners have in some cases complained about infringement of patents not registered in Viet Nam but elsewhere. The process of consultation between the DRA and the VPO results in a letter from the VPO to the DRA informing it of the patent status of the relevant product. The VPO also provides a view as to whether the product in question infringes the patent. The DRA may withdraw the registration of a product if a foreign patent owner registers a patent for that product. Article 26 of the Regulation on Drug Registration appears to provide some support for this practice. However that article states that the registration of a drug may not be cancelled if a drug violates the rules in industrial property. In other words, this article operates on the basis of established infringement rather than mere registration of the patent.

The practice of the DRA has the potential to cause huge problems for the Vietnamese generic industry. This practice is not an obligation under the BTA. Clearly it sets up an incentive for foreign patent owners to register large numbers of patents. This will make it difficult for generic companies in Viet Nam to obtain marketing approval for many drugs on which the basic patent has expired. Larger companies may simply apply for patents of doubtful validity. The DRA is not in a position to evaluated such patents and relies on the VPO to give a view on the infringement issues. This practice by the Vietnamese patent office is an informal one.

10. NEGOTIATING FOR THE FUTURE OF HEALTH

The next crucial hurdle for access to medicines in Viet Nam is the WTO accession process. Viet Nam has already agreed to some TRIPS plus standards (test data protection), but this is on the issue of the others (parallel importation). The Trade Ministry sees TRIPS as the basic standard and has no wish to move beyond it. This is always the possibility of a future bilateral trade negotiation with the US outside of the context of the WTO.

The critical question is how well is Viet Nam prepared for a negotiation on intellectual property on these two frontiers? From the perspective of public health regulation the question is how well is the Ministry of Health integrated into the trade negotiation process?

The procedure for consultation in Viet Nam over WTO accession revolves around the work of the National Committee for International Economic Co-operation (NCIEC). The NCIEC is led by the ministers of all the departments that are part of the WTO accession process, with the trade ministry playing a co-ordinating role. Industry property issues are the responsibility of the National Office of Intellectual Property (NOIP) and the head of NOIP is a member of the NCIEC. At our interview in the Trade Ministry we asked about the extent to which the Ministry of Health would be involved in helping to develop a position on industrial property that addressed public health issues. The Minister for Health and the NOIP are part of the consultative process, but it is the Head of NOIP that has ultimate responsibility for TRIPS issues and who has carriage of the negotiations. Ultimately the capacity of the Health Ministry to influence the accession process depends upon its own level of technical expertise and its ability to marshal that expertise to produce a coherent position. As the negotiator we spoke to put it, “I will struggle to the death” to preserve a position that has been put forward by a Ministry and that is well argued and offers to Viet Nam’s national interests.

Probably in the case of health there will not be much need for a struggle. Our interview in the Department of Legislation in the Health Ministry revealed that the Ministry does not possess intellectual property expertise. To date it has not put forward policy objectives relating to the draft intellectual property legislation being developed by the Ministry of Science and Technology. Members of the Legislation branch did say that they had plans to organize a workshop for the purpose of giving comments on the draft intellectual property law.

Within the WTO there is some limited co-operation amongst ASEAN Member Countries. This takes the form of resisting pressures from developed countries to go further than is necessary on TRIPS. However, this limited form of co-operation almost certainly does not carry over into the bilateral context, the other important negotiating frontier. All ASEAN Member Countries have to face. The outcomes of negotiations that have taken place (Singapore, Laos, Viet Nam) show ASEAN members conceding TRIPS plus standards to some degree or another. In the case of Viet Nam and Laos, the basic negotiating tactic of the US has been to counter lack-of-capacity arguments with offers of technical assistance on intellectual property. Viet Nam, for example, has been given US$6 million to implement the entire BTA with the US.

No doubt developing country negotiators play the lack-of-technical-capacity card in the expectation that they will receive some offer of technical aid. But one has to ask whether the modest trickle of technical assistance they receive in exchange for agreeing to higher standards of IP protection amounts to good public health policy or good industrial
Regional Workshop on Intellectual Property Laws
Related to Public Health in the ASEAN Region
Bali, Indonesia, 10-12 December 2004

Recommendations

- The major challenge in the ASEAN Region is how to encourage (in the context of the
  ASEAN structure, objectives, and vision and existing agreements) Member Countries
  to adopt laws (review and amend existing or legislate one) with corresponding
  implementing regulations and administrative rules to facilitate the use of the TRIPS
  flexibilities/safeguards and operationalise them to improve access to medicines.

- In this regard, the ASEAN should consider the following (as) priority undertakings in the
  region:

  1) Facilitate the review and amendment, as necessary, of laws of importing and
     exporting ASEAN countries for the implementation of Doha Declaration Para 6.

  2) Develop and formalize an ASEAN guidelines on key administrative and
     implementation areas that would facilitate effective implementation of TRIPS
     flexibilities i.e., compensation in compulsory licensing, data protection, competition
     policy, administrative issues around compulsory licensing, and implementation of
     Doha Declaration Para 6.

  3) Strengthen intra-country coordination among Departments/Ministries involved in
     IPRs and Public Health – to include private sector i.e., pharmaceutical industries,
     etc.

  4) Strengthen inter-country coordination:
     - On networking and information sharing.
     - Initiate efforts towards regional purchasing of drugs to reduce price.
     - Monitoring the progress of the implementation of the TRIPS and assisting the
       member countries facing the difficulties.

  5) Create and maintain permanent (utilizing existing group of ASEAN experts) to provide
     technical assistance on all aspects of IP and access to medicines.

  6) Review the ASEAN Work Program II on HIV/AIDS (AWPII) and develop an AWPIII to
     include the issues on access to affordable drugs and TRIPS.

Note:
With cooperation from ASEAN dialogue partners.

* Member Countries, together, can advance shared public health objectives.
* I.a. Thalland’s IP Code has a solar provision.
* Malaysia and Indonesia have issued government use authorization for HIV/AIDS drugs – crucial steps in
  helping lower prices and deliver the medicines to people who need them.
* ASEAN Member Countries are engaging in trade negotiations, which often involved IP. This ASEAN group
  of experts can provide technical assistance to member countries to strengthen their capacity and develop
  strategic positions in the context of trade negotiations with parties outside the region.

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