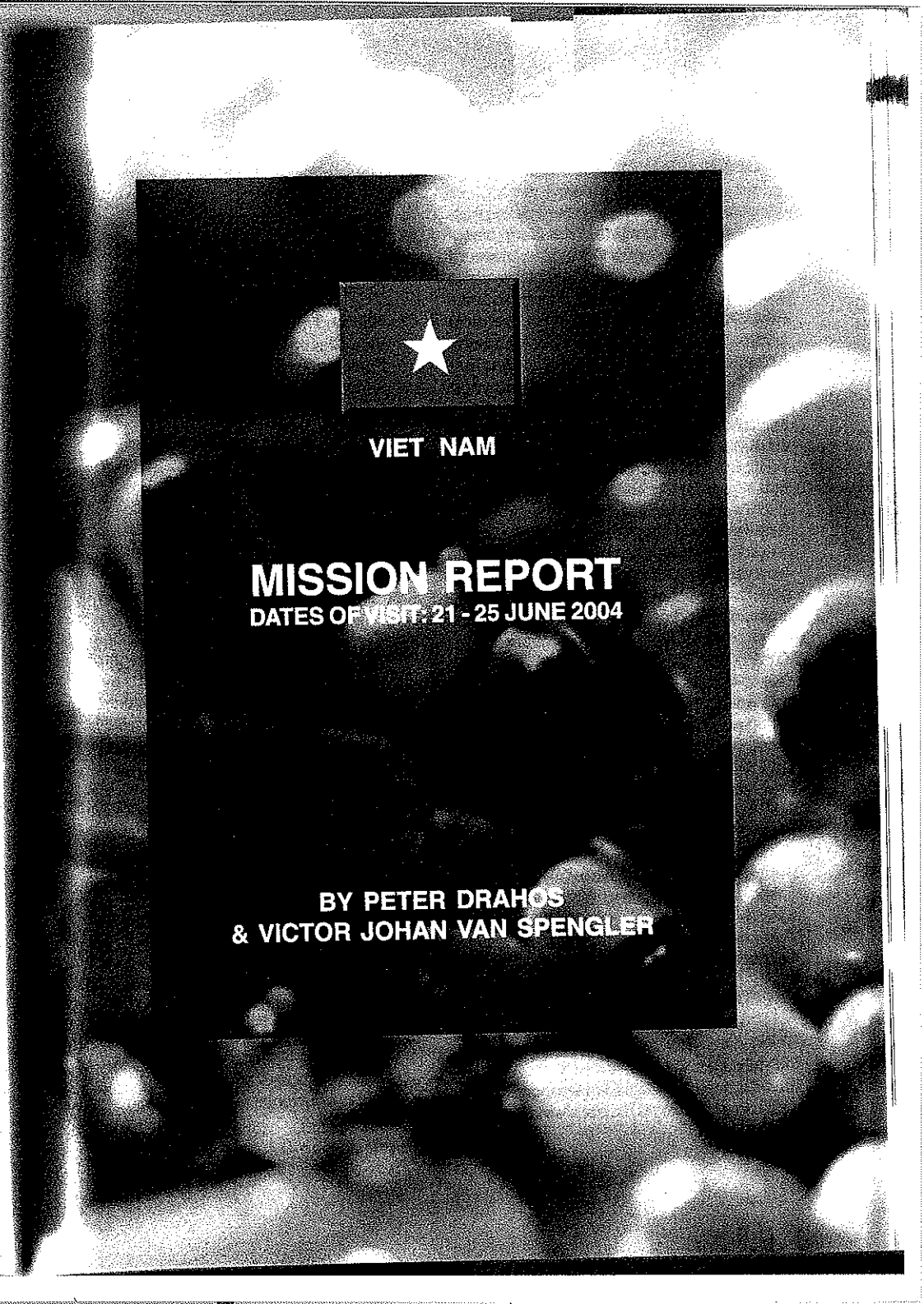
VIET NAM
MISSION REPORT
DATES OF VISIT: 21 - 25 JUNE 2004
BY PETER DRAHOS
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1. DESCRIPTION OF THE FIELDWORK

The mission commenced with a briefing from the Drug Administration of Viet Nam (part of the Ministry of Health). During the course of the week we interviewed representatives from the Department of Civil and Economic Laws (Ministry of Justice), the Pharmaceutical Companies Association, the Department of Legislation in the Ministry of Health, the Drug and Cosmetic Registration Division, the General Department of Preventive Medicine and HIV/AIDS Control, the Ministry of Trade, the National Office of Industrial Property, the WHO in Viet Nam, UNAIDS. We met with one NGO, the Policy Project in Viet Nam.

A half day workshop was held on Thursday 24 June. The workshop was well attended by representatives from the various government departments with a stake in this issue. On Friday 25 June we met with the Minister of Health for a briefing session.

The consultants were aware of a recent report entitled 'Affordable ARV Drugs for People Living with HIV/AIDS in Viet Nam: Legal and Trade Issues', June 2004, by Kuanpoth and Duong, which covers much the same ground as the present one. In consultation with ASEAN Secretariat it was decided not to duplicate the work done in the context of that report, but instead to complement it and 'fill the gaps'. This approach also allowed more time for capacity building. Our report comes to similar conclusions as the one by Kuanpoth and Duong. The two reports should be read together.

2. PEOPLE INTERVIEWED

Unfortunately this list is not complete because the individuals we interviewed did not always have business cards and the opportunity to obtain their full details did not always present itself.

Nguyen Binh
Deputy Director of Dept of Civil and Economic Laws, Ministry of Justice.

Dong Viet Thang
Chairman, Viet Nam Pharmaceutical Companies Association.

Nguyen Trong De
Vice-Chairman, Viet Nam Pharmaceutical Companies Association.

Pham Thi Binh Minh
Head, Drug & Cosmetic Registration Division, Ministry of Health.

Nguyen Xuan Tien
Drug Administration of Viet Nam, Ministry of Health.

Phan Cong Chien
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Cao Minh Quang
Director, Drug Administration of Viet Nam, Ministry of Health.

Vu Thi Loi
Drug Administration of Viet Nam, Ministry of Health.

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General Department of Preventive Medicine and HIV/AIDS Control.

Bui Huy Son
Head of ASEAN Division, Ministry of Trade.

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Patent Examiner, National Office of Industrial Property of Viet Nam, Ministry of Science and Technology.

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Deputy Director, Department of International Cooperation, Ministry of Health.

Nancy Fee
Country Coordinator, UNAIDS.

Dominique Ricard
Medical Officer, WHO.

Nguyen Quynh Trang
Policy Project Viet Nam.

3. THE PHARMACEUTICAL INDUSTRY IN VIET NAM

The following information is based on our discussion with the Viet Nam Pharmaceutical Companies Association (VPCA). Obviously we were only able to gain an impression of the industry from the VPCA.

In Viet Nam state-owned pharmaceutical companies are being privatized, foreign investment is being encouraged and partnerships between foreign companies and local companies are occuring. For example, the company Sanofi-Synthelabo has a joint venture with the VPCA. Aventis, United Pharma as well as Japanese and Korean companies have established local production. Overall there are about 200 pharmaceutical companies in Viet Nam and 89 of these are members of the VPCA. The companies that are not members are small scale. Approximately 40 companies have production capabilities. All meet standards of good manufacturing practice. The principal sources of raw materials for the Vietnamese industry are China and India.

We were unable to get detailed information about the size of the market in Viet Nam, except that we were told that Viet Nam imported about $400 million in pharmaceutical drugs. Local production amounted to about $200 million. If these figures are right then they show clearly that for the time being Viet Nam is highly dependent upon importation of medicines.

There is almost no investment in R&D in Viet Nam.

The industry until recently has not been concerned about intellectual property rights. As one interviewee put it, "Vietnamese companies did not care much about the patent". Trade mark infringement was also rife. With the prospect of WTO accession looming, the VPCA has begun to organize training courses on TRIPS. Generic companies in Viet Nam, we were told, are not really doing patent searches. The VPCA's information about TRIPS comes either from government or the International Pharmaceutical Research Manufacturers Association. At the time of our visit the VPCA had not had a chance to examine the draft intellectual property laws that relate to the process of Viet Nam's accession to the WTO. Basically, it would appear that the VPCA and its members are counting on the government to look after their interests in the WTO accession process.

We are unable to point to any data concerning the price of pharmaceuticals in Viet Nam. However, the increasing cost of medicines is an issue in Viet Nam. In response the Government has made changes to the rules on parallel importation in order to encourage such importation to take place (see the discussion on parallel importation).

4. VIET NAM'S INTELLECTUAL PROPERTY FRAMEWORK

4.1. International Agreements

Viet Nam is progressively integrating itself into the international intellectual property regime.

i. 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.

ii. 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 contain 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 Berne Union and that it is moving towards participation in UPOV (it has an ordinance implementing UPOV, but is not yet a member).

Most importantly of all Viet Nam is in the midst of WTO accession. This process began in 1995. 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.

4.2. National Intellectual Property Laws

- 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);
- The Government's Decree 54/2000/ND-CP of 3 October 2000.

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

- Ministry of Science, Technology and Environment's Circular 825/2000/TT-BKHCNMT of 3 May 2000;
- Ministry of Health's Decision No: 1906/ 2004/QD-BYT of 28 May 2004;
- Circular No.13/1998 by Ministry of Health of October 1998 guiding the reception and management and usage of foreign medicinal aid to Viet Nam.

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.[1] According to media reports the price of imported medicines has been high.[2] 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.[3] 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.[4] 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.

The problems that have arisen in Viet Nam relating to parallel importation do not stem from intellectual property, but rather from the fact that only one company has been authorized to engage in parallel importation. Regulation 1906/2004/QD-BYT is aimed at encouraging Vietnamese enterprises to take advantage of the fact that the patent law of Viet Nam does not constitute a bar to parallel importation. The regulation applies to Vietnamese and foreign enterprises importing medicines (see Article 2) and outlines a procedure for obtaining authority to import. Importantly, an application for import must be dealt with in 15 working days.

Currently Article 803 of the Civil Code as implemented by Article 52(1)(b) of Decree 63/ CP establishes a principle of international exhaustion for industrial property. The BTA with the US does not change this position. Our interviewee at the Trade Ministry had participated in the BTA negotiations. He informed us that the US had pushed for a prohibition on parallel importation. One possibility is that the US might re-open the issue of parallel importation at the expiry of the BTA. On the face of it the BTA is the subject of automatic extension.[5] Our interviewee seemed confident that extension of the BTA would be more or less automatic.

7. COMPULSORY LICENSING

Compulsory licensing is the single most important tool that a government can use in

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[1] *'Domestic firms treat ailing industry', Viet Nam News, Tuesday June 22, 2.*

[2] *Vu Long, 'Parallel imports may shift medicine monopoly to state-run enterprises', Viet Nam Investment Review, June14-20, 2004, 10.*

[3] *See Margot Cohen, Viet Nam seeks to reduce drug costs, The Wall Street Journal, Wednesday, August 18, 2004. This article also reports that aside from Zuellig, the German company Diethelm and the Thai company Mega Products are also involved in distribution.*

[4] *Vu Long, 'Parallel imports may shift medicine monopoly to state-run enterprises', Viet Nam Investment Review, June14-20, 2004, 10.*

[5] *Article 8.2 of Chapter VII of the BTA provides as follows: This Agreement shall be extended for successive terms of three years if neither Party notifies the other Party of its intent to terminate this Agreement at least 30 days before the end of term.*

the context of public health regulation in order to obtain access to patented medicines. Obviously in order for compulsory licensing to be effective governments have to be prepared to issue licenses or threaten their use. Our interview at the patent office revealed that no compulsory license has ever been issued. The Vietnamese Patent Office (VPO) has been receiving patent applications since 1982. We were told that the Office had received 1754 applications in Class A61 (Medical and Veterinary Science) and 1214 applications in Class A61K (Preparations for Medical Purposes). The paper by Kuanpoth and Duong points out that 22 ARV drugs are either patented or the subject of patent applications in Viet Nam. We were also informed that there were two applications for patents on tuberculosis and 11 for malaria. These figures are no substitute for a detailed study of pharmaceutical patenting in Viet Nam, but they do show that pharmaceutical patenting is taking place and taking place in significant areas.

One of Viet Nam's current goals is to develop a strong domestic pharmaceutical industry. The experience of the Canada shows that this is not really possible in the absence of an efficient compulsory licensing mechanism. India was also able to build a strong generic industry. A crucial factor in India's success was the absence of product patents on pharmaceuticals. TRIPS forecloses this option but it does not prevent the development of a smooth and easy to use system of compulsory licensing.

The paper by Kuanpoth and Duong describes in detail the compulsory licensing options that Viet Nam has available to it. They conclude their analysis by saying that Viet Nam's compulsory licensing laws are more restrictive than they need be. We agree.

The BTA with the US contains a provision on compulsory licensing that duplicates Article 31 of TRIPS. From a public health perspective the most important grounds for obtaining a compulsory license relate to national emergency, other circumstances of extreme urgency and cases of public non-commercial use. The advantage of compulsory licensing based on these grounds is that there is no requirement that the proposed user of the patent make attempts to obtain permission from the patent owner prior to use. The fact that it is government use rather than commercial use will also act to reduce the level of remuneration payable to the patent owner, especially in developing countries where the economic value of the license is not what it would be in a developed country market.

During our interview at the VPO we were told that the Office takes the view that the provision on compulsory licenses can be interpreted to include public non-commercial use. It might also be said that the BTA with the US allows for the issue of such a license provided a government authority follows the conditions that are outlined in the BTA for such licenses. However, it would be better to remove this issue from the realm of interpretation (and therefore uncertainty) and enact an easy-to-use administrative procedure for government use. Such a procedure would also help Viet Nam to take advantage of the Doha paragraph 6 implementation decision by members of the WTO.

8. THE VIETNAMESE PATENT OFFICE AND PHARMACEUTICAL PATENTING

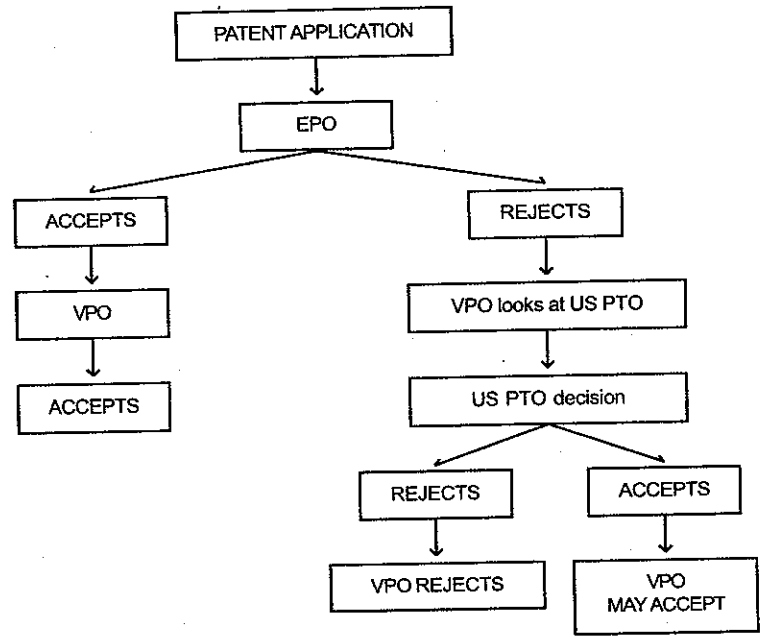
As a number of writers have pointed out developing countries could if they were so minded develop stricter standards of novelty and inventiveness that would make it more difficult for companies to obtain patents on pharmaceutical products and processes. The policy arguments for developing countries to do this are strong because lower standards of novelty and inventiveness lead directly to the problem of 'evergreening' of patents that in turn affects the ability of generic companies to enter the market.

The report by Kuanpoth and Duong points out that the VPO allows claims to pharmaceutical compositions, claims on first indications of known substances and claims on second indications of known pharmaceutical substances. Allowing such claims does little to aid the development of a generic industry.

The VPO is in terms of its practice much the same as the Philippines patent office (also the subject of a country report as part of this overall project). Like the Philippines office, the VPO has very close ties with the European Patent Office (EPO). During our interview we were told that the EPO provides technical assistance in patent examination. As in the case of the Philippines office, the Vietnamese office follows EPO guidelines on pharmaceutical patenting. The VPO can also follow the decisions of the EPO electronically.

Through years of technical assistance and capacity building the EPO has created a culture of technical leadership on patent examination. The following decision tree illustrates this leadership. It is important to note that well over 80% of the patent applications that arrive in the VPO do so through the Patent Cooperation Treaty.

Patent Applications in the Vietnamese Patent Office



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 they 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 obligation 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 will also 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 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 create 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 held the line on others (parallel importation). The Trade Ministry sees TRIPS as the basic standard and has no wish to move beyond it. There 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 axis 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. Industrial property issues are the responsibility of the National Office of Industrial 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 department 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 technical 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 matters 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

policy from the point of view of their generic industry.

Finally, there is another much larger calculation running in the background. As from 1997 Viet Nam has enjoyed a growing trade surplus with the US.[6] The attainment of MFN status from the US through the BTA was a major achievement from the point of view of trade. However, that MFN status is temporary and has to be renewed each year. Viet Nam will obviously want to gain permanent MFN status by joining the WTO and will probably be prepared to make a considerable number of concessions in order to achieve that status. The WTO accession process will present the US with a good opportunity to press for TRIPS plus provisions.

11. CONCLUSIONS

The report by Kuanpoth and Duong contains a list of recommendations and conclusions with which we basically agree. There is one slight difference between us in the context of the BTA. Kuanpoth and Duong suggest that when the BTA expires at the end of the year Viet Nam should use the opportunity to remove the provision on data exclusivity. Data exclusivity provisions have become standard provisions in the FTAs that the US has negotiated in recent times. Viet Nam's chance of removing it is probably not that great. It might also lead the US to re-open the issues of parallel importation and marketing approval by the DRA when a product is the subject of a patent claim, neither of which are covered by the present BTA. Viet Nam has more to lose than to gain by re-opening the BTA.

We believe that there are priorities that deserve attention.

a. Viet Nam lacks of clear and easy to use provision for issuing compulsory licenses. If an administrative procedure for the grant of compulsory licenses for public non-commercial use were established, it could probably also be used by third parties seeking licences for commercial purposes. Government use licenses are not affected by FTAs and there is a large body of US practice on which to rely.

b. Missing from the current policy development process in Viet Nam is a committee that brings together health and intellectual property expertise and that serves as a technical resource for policy guidance, including during the course of a trade negotiation. The Ministry for Health has a key role in encouraging investment in pharmaceuticals, but if its policies are not tied to an intellectual property framework that encourages the development of a generic industry there are likely to be policy incoherencies. At our meeting with the Minister of Health we urged that such a committee be established.

c. Article 803(1) of the Civil Code establishes an important principle. It allows for the use of patented objects by third parties if '[t]he use of such objects of industrial property is not for business purposes'. Importantly third parties relying on this provision are not obliged to pay remuneration. This provision allows for exceptions such as experimental use. Potentially it could go further, allowing for the importation of generic drugs into Viet Nam that are patented in Viet Nam. That importation would have to be for non-commercial purposes. How far Article 803(1) goes will be affected by Article 7.4 of the BAT (which is itself a TRIPS plus version of Article 30 of TRIPS).

d. The Ministry of Health should obtain an advisory opinion on its scope of operation so that it and others can exploit the provision to the fullest extent. Obviously it would be better if such an advisory opinion came from an official government source such a court or the Department of Civil and Economic Laws. Failing that an opinion from an eminent civil code expert should be sought.

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[6] *See Mark E Manyin, The Viet Nam-US Bilateral Trade Agreement, CRS Report for Congress, December 11 2001.*

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[1] to adopt laws (review and amend existing or legislate one) with corresponding implementing regulations and administrative rules to facilitate the use[2,3] 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[4].

  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.

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[1] Member Countries, together, can advance shared public health objectives.
[2] I.e. Thailand's IP Code has a Bolar provision.
[3] 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.
[4] 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 of the region.

Regional Workshop on Intellectual Property Laws
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