The authority. The Vietnamese law places responsibility for issuing Compulsory Licenses with the Ministry of Science and Technology. In cases involving healthcare and, to a lesser extent, the Ministry of Health. The Ministry of Health is likely to be most attuned to public health issues, and have the expertise to address the public health claims and interests underlying a request for a Compulsory License for a medicine or other healthcare technology. The DAV says it agrees that concurrent authority would be desirable.

Time specificity and the appeals process: The Vietnamese law does seem to contain statutory deadlines for consideration of compulsory licensing applications. These are contained in the 1996 decree, and these provisions appear to still be in effect.

The Vietnamese law also includes a prescribed approach to appeals of compulsory licensing decisions. The 2001 decree does not, however, specify if injunctions will be allowed. The DAV says that the injunction question is handled on a case-by-case basis. That is, can a Compulsory License use the license while the case is on appeal? It is important to grant the Compulsory Licensee such a right; otherwise, even a successful applicant may find their case mired in lengthy delay that would undermine their ability to make effective use of a Compulsory License - as well as undermine the public's interest in seeing speedier introduction of generic competition.

Compensation: The 2001 decree's compensation standard of 'equivalent to the economic value of the use right under such license or to the price of contractual transfer of voluntary license with a similar scope and duration' is open to interpretation. The standard of compensation equivalent to what would be arranged in case of a voluntary license is reasonable, though it may well lead to compensation arrangements that are higher than required under TRIPS or might be obtained under other TRIPS-compliant provisions. More uncertainty surrounds the first part of the standard: 'equivalent to the economic value of the use right under such license.' It may be interpreted as roughly the same as the economic value of a voluntary license. But some may argue instead that it should be interpreted to compensate the patent holder for his or her lost profit due to the licensee's sales. As Harvard University Professor F.M. Scherer notes, the effect of such a measure would be to limit dramatically the value of compulsory licensing, as second-entrant generic firms would have to charge prices roughly comparable to those of the patent holder.

Especially if the compensation standard is designed to give patent holders roughly what they would have obtained in case of a voluntary license, adoption of compensation guidelines that provide a more precise range of royalty options, at least in the case of healthcare technologies, will increase authorities' comfort level with issuing Compulsory Licenses.

3.3.9.3. Parallel Importation
Viet Nam permits parallel importation. Article 803.2 establishes that Viet Nam follows the doctrine of international exhaustion. The 2001 decree specified that parallel importation would be permitted for products placed on the foreign market either voluntarily by the patent holder or involuntarily pursuant to a Compulsory License. (Article 23) A 2004 decision from the Ministry of Health provides detailed rules by which parallel importation may occur. The Ministry of Health decision creates a process for issuing licenses to permit parallel importation. It appears that such licenses will be granted where the imported medicine is cheaper than the price charged for the medicine in Viet Nam, and where the importer can meet basic assurances of quality.

Commentary
If bureaucratic complications are kept to a minimum, the parallel importation regulations appear to position Viet Nam to exercise its rights to parallel importation effectively.

3.3.9.4. Bolar Provision
Viet Nam does not have a Bolar provision.

Commentary
Failure to implement a Bolar provision will meaningfully delay the introduction of generic competition. DAV says a Bolar provision is absent from the draft law. But that it will recommend inclusion.

3.3.9.5. Data Exclusivity
Viet Nam does not appear to grant data exclusivity, though its free trade agreement with the United States does require five years of exclusivity at least for undisclosed test data.

So long as the country prohibits misappropriation of marketing approval data, this is consistent with Viet Nam's exercise of its flexibilities under TRIPS.

Viet Nam does provide trade secret protection

4. PUBLIC HEALTH: HUMAN RIGHTS AND INTELLECTUAL PROPERTY PROTECTIONS

Intellectual property rights are not ends unto themselves. They are designed for the purpose of spurring innovation and promoting the dissemination of technology. These social purposes for the conferment of intellectual property rights are recognized in the TRIPS Agreement, which defines its objectives as:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of all producers and users of technological knowledge, and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.14

Patent and other intellectual property rights inevitably embody a balance, between society's interest in giving inventors an incentive and reward for innovation, and in the social interest in disseminating technology. Patent systems seek to strike the balance in part by requiring disclosure of information as a condition of the grant of a patent monopoly. They strive to achieve balance also by setting a fixed term on the length of the patent monopoly, and by giving governments the right to authorize competition before the expiration of the monopoly.

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15 Viet Nam-United States Free Trade Agreement, Chapter II, Intellectual Property Rights, Article 9.6.
16 TRIPS, Article 7.
VIET NAM

MISSION REPORT

DATES OF VISIT: 21 - 25 JUNE 2004

BY PETER DRAHOS
& VICTOR VAN SPENGLER
1. New Framework

A NEW Framework is needed to address the challenges and opportunities of the future. This framework should be comprehensive, flexible, and adaptable to changing needs. It should include metrics and indicators that are relevant to the industry and can be easily understood and tracked. The framework should be supported by robust data collection and analysis capabilities. It should also include a mechanism for regular review and updating to ensure that it remains relevant and effective.

2. Key Elements

- Industry Landscape: A comprehensive analysis of the industry's current and future landscape, including trends, challenges, and opportunities.
- Stakeholder Engagement: Regular and effective engagement with all stakeholders, including customers, suppliers, government, and the public.
- Innovation and Technology: A focus on innovation and technology to drive growth and competitive advantage.
- Sustainability: Incorporating sustainability considerations into all aspects of the industry.
- Governance: Strong governance structures to ensure accountability and transparency.

3. Implementation

The implementation of the new framework will require a multi-stakeholder approach, involving government, industry leaders, and other stakeholders. It will also require a phased approach to ensure that all aspects of the industry are covered and implemented effectively. The framework will be regularly reviewed and updated to ensure that it remains relevant and effective.

The mission of the National Academy of Engineering is to promote the engineering profession and to support engineering education and research. This framework is a valuable tool for achieving these goals and will be a key component of the Academy's strategic plan.
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 runs 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 of all 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.

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);

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, Zueilig Pharma Viet Nam was given an exclusive right to import medicines into Viet Nam. Zueilig 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. Zueilig'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 Zueilig 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 190/2004/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 medicinal products. 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. 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...
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 choose set about changing the examination culture of their patent offices. But to 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 may 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, the practice depends on the registration of a drug, it may be cancelled if a drug 'violates the rules on product name'. 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. Largely companies may simply apply for patents of doubtful validity. The DRA is not in a position to evaluate 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 seems 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 role 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 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 National Committee for International Economic Co-operation were 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 accessions 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 argured 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 cooperation 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
We believe that there are profound philosophical and theological justifications for the connection between spiritual and philosophical thought. This connection is not a matter of personal opinion, but rather a fundamental aspect of human existence. 

The idea that spiritual thought and philosophical thought are interconnected is not new. In fact, many of the great philosophers of the past have recognized the importance of spirituality in their work. For example, Aristotle believed that the highest form of knowledge was not just theoretical, but also practical and moral. Similarly, Augustine of Hippo saw the connection between religion and philosophy in his work on the nature of God and the human soul.

In this spirit, we propose a new perspective on the relationship between spiritual and philosophical thought. This perspective emphasizes the importance of spiritual thought in the development of philosophical ideas. It suggests that spiritual thought can provide the foundation for philosophical inquiry, and that philosophical thought can complement and expand spiritual ideas.

In conclusion, we believe that the connection between spiritual and philosophical thought is a fundamental aspect of human existence. We hope that our work will contribute to a deeper understanding of this connection, and that it will inspire others to explore the rich interplay between these two fundamental aspects of human thought.
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 new) 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.

1. Member Countries, together, can advance shared public health objectives.
2. I.e. Thailand’s IP Code has a太极 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.

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