

bilateral trade-agreements, and may not be easily forced to do so, already being a member of the WTO.

- IP legislation in Myanmar is still in a very early stage and therefore Myanmar has the possibility to base it on sound public health and innovation-policies, taking note of the experience (and mistakes) of other developing countries.

#### 6.2. Opportunities, Risks and Challenges

For the pharmaceutical sector in Myanmar it is important to be aware that the WTO Doha Declaration on the TRIPS Agreement and Public Health (Doha - November 2001) allows LDCs to exclude medicines from patent protection, at least, until 1 January 2016.

This period without medicine-patents could be used to build local (innovative) capacity for the production of medicines.

#### 6.3. National Public Health and IPRs Development Strategy

As it is for other fields of technology, Myanmar does not have a lot to gain from IPRs protection in the pharmaceutical field.

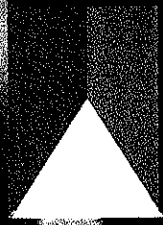
Myanmar does not have innovative pharmaceutical industry and almost all medicines are imported. Patent protection in the field of pharmaceutical products in Myanmar would therefore only lead to a price increase of imported medicines: higher cost for patients and the Ministry of Health.

#### 6.4. Coordination of IPRs Legislation

No legal expertise is available in the Ministry of Health (MOH) and in the Ministry of Science and Technology (MOST) within the departments that deal with IPRs policy making and legislation. It may not always be

possible for the Ministry of Justice to fill this capacity-gap.

It could therefore be helpful to provide the MOH and MOST with their own legal expertise on trade and IPRs issues. This way it will be easier to make effective use of exchanges with other ministries in the area of IPRs policy-making and implementation



THE PHILIPPINES

**MISSION REPORT**  
DATES OF VISIT: 3 - 7 MAY 2004

BY PETER DRAHOS  
& INSAN BUDI MAULANA

## 1. DESCRIPTION OF THE CONSULTATIVE PROCESS WITHIN THE PHILIPPINES

### 1.1. Meeting with the NCCP (Monday 3 May 2004)

The consultants met with members of the National Project Coordination Committee (NPCC) of the Philippines. An informative whole day workshop took place. The following members of the NCCP attended:

Rodericke Poblete  
from the Philippine National AIDS Council Secretariat presented an overview of the AIDS situation in the Philippines.  
Louie Calvario and Zany (the Chief Examiner of the Biotechnology Division) from the Intellectual Property Office  
Made a joint presentation on the IP law of the Philippines.  
Dr Timoteo Badoy  
Director, National Drug Program.

Mr Leodegario Alabarca  
Bureau of International Trade Relations, Department of Trade and Industry.  
Dr Florante Trinidad  
Chief, Bureau of International Health Cooperation.

Dr Josephine Sarau  
Medical Specialist, Bureau of Food and Drugs.  
Ms France Laboy  
Information Office, Bureau of Food and Drugs.

Dr Nertissa Dominguez  
WHO, the Philippines.  
Mr Leslie A. Cruz  
National Economic Development Authority.

Ms Lolie Gavino  
Office of ASEAN Affairs,  
Department of Foreign Affairs.

Following the presentations a free-flowing discussion took place concerning the problems of access to medicines, the use of compulsory licensing, the problems of importing drugs into the Philippines and so on.

### 1.2. Other Meetings in Manila

#### Tuesday 4 May

Roberto Ruiz  
Positive Action Foundation Philippines Incorporated (PAFPI) (Project Coordinator).

Jason Encabo  
PAFPI (Project Coordinator).

#### Wednesday 5 May

Genesis M. Adaric  
Food and Drug Bureau.  
Dr Ferdie Salcedo  
Health Development Policy, Health Department  
Dr Rontgene Solarte  
San Lazaro Hospital.  
Jean-Marc Olivé  
WHO Representative in the Philippines.

Armparo C. dela Cruz  
Institute of Philippine Culture.  
Edeliza Hernandez  
Medical Action Group.  
Carmelia Canila  
Consumers International and Filipino Consumers' Will.  
Tom Agento  
Filipino Consumers' Will.

Noel Pascual  
Pinyo Plus Association.

#### Thursday 6 May

Jose Asa Sabili  
Secretary General of the Philippine Medical Association

Jose T. Sanchez  
President of the Philippine Medical Association

Marliou Buensuceso  
President of Elm Pharmaceuticals and Member of PCPI

Esther Velarde  
Lloyd Lab.

Ed Ocampo  
Philippine Chamber of Pharmaceutical Industry

Michael Dela Cruz  
President, Philippine Chamber of Pharmaceutical Industry and CEO of Sydenham Laboratories

Luzyviminda Fontanilla  
Intellectual Property Office

*Friday 7 May* - Workshop organized by the NCCP. This workshop brought together members of the NPCC to discuss the country report and to discuss possible policy options. In attendance were:

Rodericke Poblete  
The Philippine National AIDS Council Secretariat.

Louie Calvario  
Intellectual Property Office.

Dr Timoteo Badoy  
Director, National Drug Program.

Mr Leodegario Alabarca  
Bureau of International Trade Relations, Department of Trade and Industry.

Dr Florante Trinidad  
Chief, Bureau of International Health Cooperation.

Dr Nertissa Dominguez  
WHO, Philippines.

Mr Leslie A. Cruz  
National Economic Development Authority.

Roberto Ruiz  
Positive Action Foundation Philippines Incorporated (PAFPI), Project Coordinator.

Noel Pascual  
Pinyo Plus Association

## 2. PHARMACEUTICAL INDUSTRY IN THE PHILIPPINES

While a detailed analysis of the structure of the pharmaceutical industry in the Philippines is beyond the scope of this report it is worth highlighting some of its main features.<sup>1</sup> The size of the market for pharmaceutical products is approximately \$1 billion dollars. There are somewhere between 30 and 50 manufacturers based in the Philippines. The leading manufacturers are represented by multinational companies or companies that undertake manufacturing for multinationals. They are United Laboratories, Glaxo Smith Kline, Wyeth Philippines, Astra Zeneca, Bristol Myers Squibb, Novartis, Abbott Laboratories, Roche Philippines and Boehr Ingelheim.

While we were not able to obtain exact numbers there appear to be about 30 local

<sup>1</sup> The information presented here is based on interviews with the Philippine Chamber of Pharmaceutical Industry and information presented by Dr Timoteo Badoy, the Director of the National Drug Program, the Department of Health.

manufacturers in the Philippines. They have recently formed one association of generic manufacturers.

Local generic manufacturers do not carry out research on molecules, but rather concentrate on minor improvements in the packaging and formulation of existing products. These manufacturers obtain their raw materials from China or India. Some local manufacturers export small quantities to countries such as Viet Nam, Cambodia and Singapore. The Philippines imports drugs from a number of developed countries: Germany (10%), Switzerland (9%), UK (9%), France (8.75%), US (6.95%), Singapore (6.69%) and Australia (6.24%).

India, which was used by the Philippines government as a source of supply in its parallel importation program, accounts for 5% of total drug importation.

In the case of the Philippines, the local manufacture of ARVs is not feasible. The demand is small (according to the AIDS Registry there are 2009 individuals with HIV of whom 645 have AIDS) and in terms of export a local manufacturer would have to compete with efficient producers of ARVs in India and Thailand. It follows that ARVs will have to be imported by individuals and organizations in the Philippines.

### 2.1. Prices of Pharmaceuticals

Were told by a number of the people we spoke to that the Philippines had high prices for pharmaceuticals compared to other ASEAN members. Prices of generic products remain persistently high and unbranded generic drugs occupy about 5% of the market. In a meeting with NGOs working on a campaign called 'Cut the Cost-Cut the Pain' we were told that a family of 6 in the Philippines has an income of about 250-260 pesos a day.

The treatment for TB for one person is about 50 pesos a day.

Obviously we are not in a position to report on the prices and the factors that account for those prices in the Philippines. This is a matter for detailed economic study. However we would draw attention to some possible factors:

- There seems to be a surprisingly high rate of pharmaceutical patenting in the Philippines. The IPO reported to us in the pharmaceutical field it had received from 2002 to March 2004, 1,262 applications in the pharmaceutical field. These are PCT applications. Published pending publications consist of 131 relating to HIV/AIDS, 6 for TB and 9 for malaria. These numbers are larger than one might have expected.

- To some extent the price of generic products seems to track the price of branded products. The high price of branded products is allowing generic companies more scope to charge higher prices.

- Importation by the government from India did lower prices for some drugs, but this program of importation has run into opposition. Competition through importation has not been easy to achieve in the Philippines.

- There are tie-ups between doctors and the large pharmaceutical companies, as well as tie-ups between pharmacists and generic companies. When doctors prescribe branded drugs pharmacists will sometimes offer the patient a generic version as an alternative. The generic that the patient is offered may be influenced by a financial arrangement that the pharmacist has with a generic company and may not be the cheapest generic available.

- Generic products appear to have a persistent image problem. They are seen by many consumers as being of a lesser quality. The generic companies we spoke to acknowledged this image problem.

Several years ago the government introduced a program to import cheap medicines from India and distribute those through the public hospitals. This program did have an effect on prices, but it also brought the government into litigation with multinational pharmaceutical companies. One of the problems was that the Rules and Regulations that implemented the Special Law on Counterfeit Drugs (Republic Act 8203) stated that if an "unregistered imported drug product has a registered counterpart brand in the Philippines, the product shall be considered counterfeit".<sup>2</sup> The drugs, as we understand it, were imported from Indian generic companies. We assume that the owners of the registered brands in the Philippines sued. We are unable to report on the outcome of this litigation.

### 3. IMPORTATION OF MEDICINES INTO THE PHILIPPINES

#### 3.1. Present Situation on Importation

There are approximately 75 individuals on AVR treatment in the Philippines. Since the cost of treatment using proprietary AVRs was in the order of \$US 12,000.00 per year and this cost had to be privately met, the NGOs in the Philippines working on AIDS issues turned to the importation of fixed dosed combinations from the Indian company, CIPLA. Importation has proven to be a hugely complicated exercise requiring certificates and clearances from a number of departments

(for example, a certificate of tax exemption, clearances from the Bureau of Food and Drugs, Department of Trade and Industry and Department of Health). Importation of ARVs has also attracted duties, although a recent amendment to the law has actually lowered tariffs on the importation of ARVs.

#### 3.2. Present Stumbling Block

Because of the small numbers required those seeking to import ARVs have sought to rely on a compassionate use exemption. This compassionate use exemption, however only applies to medicines that are not registered with the Food and Drug Bureau (FDA). A recent application for Indinavir and Combivir as well as the medicines Azithromycin and Fluconazole have been denied a Compassionate Permit because those medicines are registered with FDA.

Basically individuals wishing to engage in small-scale importation of ARVs and related medicines face one of three choices; find the money for proprietary treatments; forgo treatment, or engage in backdoor importation (counting on some officials to turn a blind eye along the way).

#### 3.3. Large Scale Importation

The importation which has taken place to date of AVRs has only been feasible because of the small numbers of patients involved. Small scale privately organized importation will not be able to meet the growing demand in the Philippines for ARVs. Over the next few years the number of HIV infected individuals is expected to rise to around 6,000. More generally, there is a demand for lower priced medicines in the Philippines. The

<sup>2</sup> Section 3, paragraph (h) has been amended. The reference to such products being counterfeit has been dropped. See the Amendment to the Rules and Regulations Implementing Republic Act No. 8203, 31 January 2000.

Government itself has experimented with the parallel importation of medicines from India under a program called GMA/50.

### 3.4. Parallel Importation

One option for countries wishing to lower the price of medicines in their domestic market is to have intellectual property rules that allow for the importation of a parallel stream of products by someone other than the intellectual property owner or his licensee. In the case of the Philippines, the intellectual property rules that affect importation are based on a principle of national exhaustion. Section 72 of Part II of the Intellectual Property Code (dealing with the Law of Patents) employs the language of national exhaustion in relation to patents. Similarly in discussion with a member of the Intellectual Property Office we were told that trade mark law could also be used to prevent parallel importation in those cases where the owner of the trade mark was different to that of the owner of the parallel stream of products.

The practical effect of national exhaustion is that it places consent to importation in the hands of the intellectual property owner. Another possibility is for the government to override this power of consent by using its powers of compulsory licensing (see below).

### 4. COMPULSORY LICENSING

The provisions on compulsory licensing in the Philippines are to be found in Chapter 10, part II of the Intellectual Property Code. Section 74 of the Code also provides for government use of an invention. These provisions incorporate much of the language of Article 31 of TRIPS. The IPO takes the view that these provisions comply with TRIPS.

One issue that arose in discussion was whether the government use provision would

allow the government to import an invention patented in the Philippines. We expressed the view that the right of importation fell within the meaning of "exploit". The member of the IPO at the meeting was, of course, unable to express an official view but acknowledged that the right of importation could fall within the meaning of exploit.

#### 4.1. The Practical Experience with Compulsory Licensing

In the meeting with members of the generic industry it was reported that obtaining a compulsory licence was difficult. Litigation was costly and slow. Lying at the heart of the problem seemed to be the fact that there were few lawyers in Manila who really understood pharmaceutical patenting. One of the members related a story of how he had embarked on litigation to obtain a compulsory licence only to find that after two years his lawyer was applying for the wrong molecules.

The IPO reported in its answers to our questionnaire that the IPO had received a total of seven applications for a compulsory licence. One feature of the system seems to be that it takes a long time to reach a decision concerning the application. The first application was filed on 18 February 1985 and decided on 11 April 2002 and the last decision was filed on 8 December 1992 and decided on 19 December 2001. This corroborates the view of the generic companies that obtaining a compulsory licence is difficult in the Philippines.

### 5. DATA PROTECTION

We were unable to achieve a clear picture on what the position concerning data protection is in the Philippines. At the first workshop the officials from FDB stated that data submitted during the drug registration

process by an originator company is not the subject of protection based on an exclusive right to that data. This is probably the position. In the legislation that we looked at we were unable to find provisions of the kind to be found in FTAs that require data exclusivity. At the interview with the generic companies we were told that generic companies are required to submit a lot of their own data, except that they are not required to provide studies showing bio-equivalence.

### 6. BOLAR PROVISION

There is no Bolar provision in Philippines law at the moment.

### 7. THE FOOD AND DRUG BUREAU - THE PUBLIC POLICING OF PRIVATE PATENT RIGHTS

Currently FDB issues certificates of drug registration subject to the proviso that the validity of the certificate depends on the registered drug not infringing any patents. Large pharmaceutical companies have been pressuring the FDB not to issue certificates of registration on products that are the subject of patent claims. As one person in the FDB put it "every day these companies ring the Bureau to remind them of their patent rights".

The reform that is being proposed is that the applicant obtain clearance from the Intellectual Property Office that the application is not affected by any patent claims. We were told that this solution was likely to be adopted. There are problems with it. At the level of principle it, in effect, puts the FDB and the IPO in the position of policing what are private rights. Private rights should remain a matter of private enforcement. This public policy argument we suggested should be used to resist the proposed changes to the FDB's registration procedures.

The proposed solution is also likely to be the subject of game playing by companies. The FDB stated its suspicion to us that large companies are making and reporting many patent applications to the FDB in an effort to slow down the system of registration. This is also consistent with the large number of pharmaceutical patent applications that we discovered in the IPO. We can give a practical example of what is likely to happen.

#### *The case of Co-Amoxiclav*

A representative from Lloyd Lab, Inc. a generic manufacturer described how she had carried out a search at the IPO for patents relevant to the antibiotic Co-amoxiclav. Three days of searching in the IPO turned up 12 patents on Co-amoxiclav. Acting on the basis of a lawyer's advice that none of the patents would be likely to be upheld Lloyd Lab went ahead and made the product.

If Lloyd Lab had sought clearance from the IPO it would not have received it. The IPO would simply have reported the existence of 12 patents and made no assessment as to their validity. The FDB would then have denied Lloyd Lab a certificate of registration.

It follows that the proposal that generic companies obtain clearance from the IPO for their products has the potential to act as a barrier to entry into the market and to reduce competition in the marketplace.

### 8. THE IPO AND PHARMACEUTICAL PATENTING

Carlos Correa in a number of publications has pointed out that TRIPS leaves it open to WTO members to decide many fundamental issues of patent protection such as the question of novelty and new use of known substances. The Chief Examiner of the biotechnology section attended the workshop

on the first day and so we were able to discuss the IPO's approach to pharmaceutical patents. She pointed out that the Patent Examiner's Manual reflects European practice on the examination of pharmaceutical patents (The manual was prepared as part of the EC-ASEAN Patents Programme to assist developing countries in the modernization of industrial property systems). So, for example, pharmaceutical uses of known substances and second uses of known pharmaceutical products are patentable.

In theory the IPO could take a different approach to the patentability of pharmaceutical substances. But, as the Chief Examiner pointed out, it would be difficult, especially for a developing country office, to adopt an approach to pharmaceutical patentability that differed from the approach taken by lead patent offices such as the EPO and USPTO.

The practice of the IPO is perhaps emblematic of a broader truth about developing country patent offices. These offices receive hardware, software, manuals and training from pro-IP organizations such as WIPO and the EPO. Once trained in these systems they are hardly likely to deviate radically from them. Amongst other things, this could have implications for future support. In terms of examining practice for individual patent applications they are likely to follow the decisions of the Trilateral Offices. They may also grant pharmaceutical patents in cases where they have been refused by one of the Trilateral Offices. The least likely possibility is a developing country office refusing a patent where it has been granted by one or more of the Trilateral Offices.

#### 9. THE IPO AND PATENT INFORMATION

The generic manufacturers we spoke to all

complained about the difficulties of discovering information about patents in the IPO. For the time being the IPO does not have electronic search facilities. Searching for patents files in the IPO is time consuming.

One option we put to the manufacturers is to approach the IPO as an association and ask the IPO to provide a special service for members of the association in respect of pharmaceutical patents. The association could be notified of pharmaceutical patents about to expire, those for which a renewal fee had not been paid or new applications. The association could pay a fee for this. This kind of information would help members develop plans for new products that they might manufacture locally.

#### 10. CO-ORDINATION BETWEEN HEALTH, TRADE AND THE IPO

Our interviews in the Health Development Policy section revealed that to date there had been no co-ordination between the IPO and the Health Department. The Health Development Policy unit was basically focused on implementing a large health sector reform agenda. IP was not really a part of this agenda. Similarly there was no co-ordination between Trade and Industry and the Department of Health.

One of the real benefits of the two workshops that we participated in was that health, trade and IP officials were able to gain some understanding of the relevance of their work to other departments. We also formed the view that a committee made up of representatives from these departments (including the FDB) would make a very useful addition to the strategic planning capacity of the Philippines as well as enabling departments to co-ordinate on legislative initiatives.

#### 11. CONCLUSIONS

- a. The current compassionate use provision in the Philippines is not working especially well to enable HIV positive individuals to bring in medicines for personal treatment. It should be redrafted taking into account the long term treatment needs of some types of patients. Minimizing duties on importation under such provisions should also be looked at.
- b. Obtaining compulsory licences in the Philippines has proven to be difficult in the Philippines because of factors such as lack of expertise, costs of litigation and the ability of patent owners to drag out the proceedings. Basically there is no tradition of compulsory licensing in the Philippines. Of course there may well be bargaining around the threat of the issue of a compulsory licence, but we were not able to establish this in the course of our visit.
- c. The Philippines Food and Drug Authority is coming under considerable pressure from patent owners to implement procedures that will see authority, in effect, policing applications for registration on behalf of patent owners. This has grave implications for generic companies wishing to register new products.
- d. Local generic manufacturers do not carry out research on molecules, but rather concentrate on minor improvements in the packaging and formulation of existing products. These manufacturers obtain their raw materials from China or India. The Philippines government has also looked to India as a source of importation in its attempt to lower drug prices. Clearly what happens in India once India meets its TRIPS obligations in full in 2005 will have significant implications for the Philippines. Pharmaceutical patenting
- e. Coordination between the patent office, health and trade areas in the Philippines could be very much improved.
- f. The Philippines does not have a Boliar provision and it is currently not preparing to take advantage of the system of importation agreed to by WTO members as part of the paragraph 6 negotiations under the Doha Declaration. It should address both these issues.





## 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<sup>1</sup> to adopt laws (review and amend existing or legislate one) with corresponding implementing regulations and administrative rules to facilitate the use<sup>2, 3</sup> 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<sup>4</sup>.
  - 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.*

<sup>1</sup> Member Countries, together, can advance shared public health objectives.

<sup>2</sup> I.e. Thailand's IP Code has a Bolar provision.

<sup>3</sup> 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.

<sup>4</sup> 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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