1. DESCRIPTION OF THE CONSULTATIVE PROCESS WITHIN BRUNEI DARUSSALAM

The mission in Brunei Darussalam was shortened by one day from the original five days and therefore there were two days available for consultative meetings, besides a two-day workshop. We experienced that the government of Brunei Darussalam is very well organized which made the consultative process efficient and pleasant. The high quality of the Brunei Darussalam presentations in the workshop easily compensated for the one day less of consultation-meetings.

In the morning of Monday 28 June, the day before the workshop, we had an introduction meeting at the Ministry of Health with key persons from the National Project Coordination Committee (NPCC) and, afterwards, a meeting with the complete NPCC to discuss the project.

On Monday-afternoon, we made a visit to the Ministry of Industry and Primary Resources (MoIPR). We were able to discuss trade-issues and Intellectual Property Rights (IPRs) in Brunei Darussalam. Representatives from the Attorney General’s Chamber, which is entrusted with the registration/administration of IPRs in Brunei Darussalam, also attended the meeting.

A two-day workshop was held on Tuesday and Wednesday 29-30 June. Most participants in the workshop were from the Ministry of Health (MoH). The MoIPR and the Attorney General’s Chamber were well represented and there were also participants from the Ministry of Finance. Seeing the lively discussion in the workshop, there was a lot of interest in the subject from all sectors.

On Thursday 1 July, we had a de-briefing with the NPCC-members and discussions about the finalisation of the draft country report.

2. PEOPLE INTERVIEWED

While we met with NPCC-members in several meetings, we were not able to meet with the Permanent Secretary for the MoH Health (Chairman of the NPCC).

The members of the NPCC:
- Dato Paduka Haji Zainal Haji Momin, Permanent Secretary for the MoH – Chairman
- Datuk Paduka Dr Hj Idris Haji Md Salleh, General Director of Health Services, MoH – Vice Chair
- Dr Haji Affandy POKSDP Hj Abdin, General Director of Medical Services, MoH – Vics Chair
- Yusof Amba, Acting Director of Policy and Planning, MoH – Member
- Dr Haji Kalsom Abid, Director of Health Services, MoH – Member
- Aminah Haji Md Jasdar, Director of Pharmaceutical Services, MoH – Member
- Dr Haji Rahmah Haji Md Said, Acting Director of Environmental Health Services, MoH – Member
- Hajah Norsiah Haji Johari, Assistant Director of International Affairs Section, MoH – Secretary
- Naimah binti Mohd Ali, Assistant Solicitor General, Attorney General’s Chamber – Member
- Dato Siti Nurlaini PDP Hj Tangah, Deputy Senior Counsel International Law Division, Attorney General’s Chamber – Member
- Shahrom Hj Mohd Yussof Khan, Deputy Registrar - Registry of Trademark and Patents, Registry Division, Attorney General’s Chamber – Member
- Vincent Kong Sui Fong, Assistant Director International Relations and Trade Development, MoIPR – Member
- Noramal Dato Paduka Hj Jumali, Special Duties Officer International Relations and Trade Development, MoIPR – Member

Besides the members of the NPCC who are based in the MoIPR, our Monday-afternoon visit to MoIPR was attended by the NPCC members from the Attorney General’s Chamber.

As indicated above, also the workshop appeared to be a rich source of information, thanks to presentations and discussions with members of the NPCC. Besides presentations of NPCC-members, the presentation of Dr. Han Soo Yin (Senior Pharmaceutical Chemist, Directorate of Pharmaceutical Services) and follow-up discussions were especially informative.

3. INTRODUCTION, INTELLECTUAL PROPERTY AND PUBLIC HEALTH IN BRUNEI DARUSSALAM

Brunei Darussalam is a country of half a million people on about 5,500 square kilometres of land. It has a healthy economy because of oil and natural gas exports. Brunei Darussalam also earns considerable revenue from overseas investment. Besides the energy-sector, domestic (industrial) production is limited.

Although Brunei Darussalam has one of the highest per-capita GDP of less developed countries, there is no production-capacity for pharmaceutical products in the country. The main reason for this may be the market-size of only 400,000 to 500,000 people. Medicines are imported, mainly from Malaysia, Singapore, Australia and the United Kingdom.

The government provides all medical services for the people of Brunei Darussalam. Besides the mere fact that most medicines in Brunei Darussalam are bought out of the government's budget, there are more factors that make IPRs and Public Health a relevant topic, e.g.:• the annual medicines-expenses, of currently 36-million BS, is growing approximately one-million BS/year-on-year;• while 95% of tendering is done based on generic names, 80% of the procured pharmaceutical items are branded;• it is estimated that the 80%-share of branded products could be brought down to 54%;• 67% of the pharmaceutical products are bought from originator-companies, who may hold patents elsewhere. This means that, while there is no relevant patent in Brunei Darussalam, the medicines are often bought at patent premium-prices;• tendering is mostly done locally amongst 17 licensed suppliers.

4. INTERNATIONAL INTELLECTUAL PROPERTY AGREEMENTS

Brunei Darussalam is member of the WIPO (WIPO Convention, since April 1994);• Member of the WTO and as such also a Signatory to TRIPS Agreement (January 1995);
8. EXPERIMENTAL USE, BOLAR PROVISION

A Bolar provision in a Patent Law allows competitors of the proprietor of the patent to process an application for marketing-approval, while the proprietor’s patent-term has not yet expired.

There is no Bolar-provision in the Patent Act. While Section 56.2 sub-b Patent Act allows for the experimental use of patented inventions, it may not be allowed to use the patented invention to prepare test-data or to provide samples of the patented product to the authorities for drug regulatory approval.

If generic medicines-producers can only submit applications for marketing-approval for off-patent medicines after the patent-term has expired, they can only place their product on the market after the completion of the medicine approval-process.

9. PRIVATE NON-COMMERCIAL USE

Any acts with regard to a patented invention, which are done privately and not for commercial purposes, do not constitute an infringement, even though those acts may have otherwise been considered infringing (Section 66.2 sub-a Patent Act).

This means that individuals can bring in as much (generic) medication as they would like, as long as it is for private use (and not for sale or other commercial purposes).

10. USE OF THE PATENTED INVENTION WITHOUT THE AUTHORISATION OF THE RIGHT HOLDER

The Patent Order has extensive provisions for use of the invention without authorisation of the right holder: compulsory licensing and use of patented inventions for services of the government.

10.1. Compulsory Licensing

Three years from the date of the grant of a patent or four years from the date of filing of the patent-application, whichever is the later, and after reasonable efforts to acquire a voluntary license on reasonable terms and conditions from the proprietor of the patent, any interested person may apply to the court for the grant of a compulsory license. Grounds upon which a compulsory license may be granted by the court:

- The patented invention is not, or at least insufficiently, made available in Brunei Darussalam;
- The patented invention is not made available on reasonable terms.

In determining whether it is appropriate to grant a compulsory license, the court shall take into account:

- The nature of the invention (e.g. is there a market for the invention in Brunei Darussalam?);
- The time that has elapsed after the grant of the patent (did the proprietor "neglect" the Brunei Darussalam market for a long time?);
- The measures already taken by the proprietor to make use of the invention (were there serious attempts to sell the patented invention?);
- The ability of the potential compulsory licensee to work the invention to the public advantage (how is the public interest affected?); and
- Investment and other risks involved for the applicant of the compulsory license.

Except in cases of anti-competitive behaviour of the right holder, the compulsory license can only be used to predominantly for the supply of the market in Brunei Darussalam. The licensee has to pay compensation to the right holder as agreed or as determined by the court at their request. The right holder, or any other interested person, can request the court to terminate the license for the reason that the ground upon which the license was granted has ceased to exist and is unlikely to recur. In terminating the compulsory license, the court shall take into account the legitimate interests of the licensee.

In the medium term, the importance of compulsory licensing in the pharmaceutical area may be limited in Brunei Darussalam, seeing that:

- The market size for pharmaceutical products in Brunei Darussalam is very small, and
- The absence of an existing chemical/pharmaceutical industry that can easily start producing medicines under a compulsory license.

This situation may change if a pharmaceutical industry would be established in Brunei Darussalam and the IPR regulatory-framework would be adapted so that exports of generic medicines to countries with insufficient manufacturing capacity would be possible.

However, in the meantime the opportunities for compulsory licensing for local consumption may be very limited (due to small market size).

10.2. Use of Patented Inventions for Services of the Government

Seeing the structure of the public health system in Brunei Darussalam, there are important opportunities to use the Patent Order provisions for the use of pharmaceutical product patent, etc. by the government. It is easier for the government to use patented technology than for others to acquire a compulsory license.

The most important differences with a compulsory license are:

- Government departments and persons that are authorized by a government department can use the patented invention, without making a prior request to a court;
- If the use of a patented invention for the services of the government is limited to "public non-commercial use" (by the government or persons authorised by the government), then there is no obligation to make an effort to acquire a voluntary license on reasonable terms and conditions from the proprietor of the patent;
- Excess products (not anymore to be used for government services) can be disposed off, as if the government were the patent holder and others who acquire products from the government are also not infringing the patent;
- When the patented medicine would be needed by the government for foreign defence-purposes, export of the patented invention is allowed.

A TRIPS-plus limitation of the use of patented inventions for the services of the government is the possibility of any interested party to request that the government use be terminated. The TRIPS Agreement would only require that there is a possibility for the right holder to request for adequate remuneration, but the court need not be authorised to provide for termination of the government use (as it could terminate compulsory licenses).
separate system of independently (privately) funded healthcare/medicines weakens the current strong bargaining-position in matters of medicines procurement and healthcare service provision in general.

An integrated system for medicines-procurement, be it state-funded or funded by a national (public) insurance, allows for the control of medicines expenditure, in spite of eventual patent-monopolies. A good example of such collective bargaining power is the Pharmaceutical Benefit Scheme in Australia. Prices for medicines are not only determined by market-forces and patent-monopolies, but maximum prices for new medicines are rationed by a neutral formula. If the medicine can not be made available for the maximum price that is justified by the increased life-expectancy (equality), the medicine will not be reimbursed by healthcare financing institutions (such as health insurers).

In a situation with less competition through parallel importation and patent-rights that may not be set aside by public non-commercial use licenses, national bargaining may be the only way to keep medicines-cost at an acceptable level.

12.5. Risks: What to Watch Out For?

It should at least be prevented that commitments are made in international agreements that would compromise possibilities for effective medicines procurement. Brunei Darussalam has signed a Trade and Investment Framework Agreement with the United States of America (USA) in December 2002. This agreement puts the protection of Intellectual Property on the agenda for consultations with the USA.

Other countries that had consultations in the field of IPR with the USA have been asked to increase standards of IPRs—protection significantly above the level of the WTO/ TRIPS Agreement:

- Adding possible subject-matter to what could be considered a patentable invention (especially relevant to pharmaceutical products: new uses of known substances, patenting of second/third medical indication);
- Prohibiting parallel importation;
- Restricting the possible use of compulsory licenses (e.g. to "circumstances of emergency or extreme urgency");
- Creating new intellectual property rights "to protect investment", such as exclusive use of data by government regulatory/approval agencies for the purpose of authorising the marketing of products of the company that has produced the data ("data-exclusivity");
- Stretching copyright-protection beyond 50 years after the death of the author.


Besides the establishment of a centre of excellence for oil-exploration technology to fulfill the traditional industrial needs of Brunei Darussalam, one could think of the development of research-based chemical/pharmaceutical industry. Maybe Brunei Darussalam could consider investing more of its oil-revenue in its own industrial development (instead of investments abroad).

As for Brunei Darussalam's general economic and industrial development policy, there is a need to diversify the economy, besides the exploration of fossil fuel. After acquiring industries for the production of ingredients for oil exploration, such as heavy-duty marine power cables, a strategy could be developed to attract other added-value economic activities. The Brunei Darussalam government could channel a larger amount of the income from oil exports into the development of domestic industries. Countries where the government does not have much control over the income that is generated by its industries (such as also Singapore) would have to engage in a very unpredictable battle for foreign direct investment. The Brunei Darussalam government could simply decide to invest more of the country's oil-revenue inside the country. The lower returns that are the consequence of the current worldwide economic downturn may be an extra incentive for Brunei Darussalam to invest the money at home.

The high level of human resources that can be made available in Brunei Darussalam offers opportunities for the development of research-based industries. Foreign expertise can probably also be attracted because of the high quality of living in Brunei Darussalam, compared to other countries in the region (besides maybe Singapore, where space is getting more and more expensive).

There are WTO/TRIPS compliant mechanisms to facilitate the technology transfer that would be necessary for the establishment of a pharmaceutical industry in Brunei Darussalam. For instance, it would be possible to establish a "patent pool" for pharmaceutical patents. This would mean that (compulsory) licenses of right would be available for all pharmaceutical patents in Brunei Darussalam at pre-determined compensation-rates. It would then be possible for companies to use any pharmaceutical technology without having to negotiate voluntary licenses for each single patent that they would need.

12.7. Involvement of Ministry of Health

To achieve the above objectives, it may be helpful to provide the MoH with its own expertise on trade and IPRs issues and establish permanent links for IPRs policy-making and implementation between the MoH and ministries involved in IPRs, e.g. in the form of an inter-ministerial committee. In this way the negative impact of IPRs on public health can be limited and at the same time possibilities can be explored for creating an environment conducive for the establishment of a domestic pharmaceutical industry.
Recommendations

Regional Workshop on Intellectual Property Laws Related to Public Health in the ASEAN Region

Regional Workshop on Intellectual Property Laws Related to Public Health in the ASEAN Region

Recommendations

1. Enhance awareness and understanding of the PRSPs and the ASEAN Regional Intellectual Property Strategic Action Plan (RISAP)
2. Strengthen mechanisms for monitoring and evaluation of implementation of the PRSPs
3. Develop capacity building initiatives for the implementation of the PRSPs
4. Promote and encourage the development and use of public health-related policies and strategies
5. Enhance cooperation among ASEAN member states in the field of public health
6. Foster partnerships and collaborations with other international organizations and agencies
7. Increase funding for research and development in the field of public health
8. Strengthen regional cooperation and collaboration in the field of public health
9. Improve capacity building and training for the implementation of public health policies and strategies
10. Strengthen institutional mechanisms for the implementation of the PRSPs
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