In 1987, the Ministry of Justice enacted a Ministerial Decree concerning well-known trademark protection, even though the Trademark Law No. 21 of 1951 did not provide any provision to support the above decree. However, the cited decree was acknowledged as part of regulation in trademark law, especially for protecting the owner of well-known trademark from counterfeiters. This decree was no longer in force after the previous trademark law was amended by the Trademark Law No. 19 of 1992 which provided well-known trademark protection as an implementation of Article 6 bis of the Paris Convention.

The Indonesian Patent Law provides Compulsory License and Government Use provisions. It is also supported by the Doha Declaration. Therefore, we consider that these laws are our references and sufficient reasons for taking legal action for issuing a “joint decree” if the Government does not enact government regulations on Compulsory License and Government Use as soon as possible. We believe that the “Joint Decree” is the last resort for the Food and Drug Agency and the Ministry of Health, and could be issued anytime by the Food and Drug Agency and the Ministry of Health if they face emergency situation in the field of public health in certain region.
to issue a non-voluntary licence in cases of lack of exploitation or insufficient exploitation in Lao P.D.R. However, the patent owner may escape issue of a non-voluntary license if he shows justification for non-exploitation. Given the size of the domestic market in Lao P.D.R., this would probably be possible in most cases.

In short, the current Decree offers patent owners of pharmaceutical products and processes a high degree of protection with few restrictions on their rights. We were told that this Decree was drafted by the IP Office, with the assistance of WIPO. So far this Decree has not had an impact on Lao P.D.R., because Lao P.D.R. has not been a position to accept patent applications.

6. THE DRAFT IP LAW

6.1. The Legislative Process

Lao P.D.R. is in the process of replacing its current decrees in intellectual property with a law that will take the form of an IP Code. According to discussions with the IP Office, the IP Code has been drafted. We were unable to obtain clarity on the role that WIPO has played in the drafting process, except that it seems that WIPO has offered some assistance. One person in the IP Department told us that WIPO had sent a model patent law to Lao P.D.R. in 1998. It is also worth noting that if its answers to WTO members Lao P.D.R. has stated that “All intellectual property laws are based on WIPO model laws.” The draft has not been seen by the other people that we interviewed. An internal meeting in the IP Office has taken place concerning the draft. The next stage is consultation with various ministries (Industry, Justice, Commerce, Culture Finance, Customs, Agriculture and Health).

The draft will also be sent to the provincial administrations for their comments and then finally to the National Assembly. The aim is to have the IP code enacted by 2006.

Our conclusion was that a Decree Health Department or the Food and Drug Department have had no opportunity to feed into this process. We raised the issue of the Health Department’s participation in the process at the workshop and recommended that the Health Department, the Food and Drug Department and the IP Office along with people from the Ministry of Commerce form a core group to track the passage of this legislation.

6.2. Status Politics

It is not possible to be confident that departments outside of the Intellectual Property Department will have a significant influence on the shape of the IP Code. One person we spoke to explained that steering a piece of legislation through the National Assembly was seen to be a very significant achievement. Once a department has draft language there is sufficient reluctance to alter it, to share information about it in case this triggers too much interference. Moreover, in the case of IP there is the complicating factor that this legislation is integral to Lao’s plans for WTO accession and the desire of Lao P.D.R. to achieve normal trade relations with the US.

Our discussion with the IPO left us in doubt that the IPO understood that intellectual property law could have a significant impact on access to medicines. More generally there was an understanding that moving quickly on the implementation of IP law might not necessarily be advantageous for Lao’s economy. The real question, however, is to what extent this sensitivity will translate into action.

7. THE US-LAO P.D.R. BILATERAL

In 1997 the US and Lao P.D.R. negotiated and signed a bilateral trade agreement. This agreement never came into operation. On the 18th of September of 2003 the US and Lao P.D.R. signed a revised bilateral. We were not able to obtain a copy of this revised bilateral, but were told that the intellectual property provisions were the same as those negotiated in the 1997 agreement (which is available on the USTR’s website). From a public health perspective, the key points about this bilateral are as follows:

Article 18(1) obliges Lao P.D.R. to protect all inventions in any field of technology. Under Article 30 Lao P.D.R. must enact implementing legislation within 27 months of the bilateral agreement coming into force. It follows that if the US Congress approves this agreement Lao P.D.R. will not be able to take advantage of paragraph 7 of the Doha Declaration that allows LDCs to suspend Sections 7 and 5 of Part II of TRIPS so far as pharmaceutical patents are concerned till at least 1 January 2016.

Article 18.2 offers the US the option of protecting pharmaceutical patents in Lao P.D.R. in existence in the US up to 17 years prior to the date of agreement. Article 18.8 gives Lao P.D.R. the option of not having a compulsory licence provision and Article 18.10 gives Lao P.D.R. the option of extending patent terms.

Article 20 requires that undisclosed test data submitted by companies during the process of obtaining market approval for pharmaceutical products be protected for a minimum of five years.

One reason for the US imposing these tough conditions on Lao P.D.R. may be that it is worried about the possibility of generic companies in Vietnam or Thailand investing in Lao P.D.R. If Lao P.D.R. were to take advantage of the Doha Declaration. The local pharmaceutical manufacturers are state-owned, expect for one which is a joint venture with a Vietnamese firm.

7.1. The Broader Context

Lao P.D.R. has signed this bilateral. It is desperate to achieve normal trade relations with the US (currently the US is the second biggest investor in Lao P.D.R.). A number of the people we interviewed spoke about the importance of achieving “NTR” with the US. Clearly the decision to commit Lao P.D.R. to achieving NTR has been taken in the upper reaches of the political decision-making process. The potential cost to Lao P.D.R. of departing from the IP standards set out in the bilateral would be that Congress would not approve the agreement. Realistically health officials will have to operate in the parameters set by the bilateral agreement.

8. REGISTERING MEDICAL PRODUCTS: THE FOOD AND DRUG DEPARTMENT (FDD)

The interviews at the FDD turned up the following information. There are about 6 local manufacturers of drugs in Lao P.D.R. Raw materials come mainly from China and India. Some rough calculations on the part of the FDD suggest that about 45% of the registered pharmaceutical medicines that are consumed in Lao P.D.R. are produced locally. However, much of the population relies on traditional medicine. There are about 240 local products registered and 760 registered imported products. The imported products come principally from Thailand (350), France (78), Vietnam (74) and Malaysia (52).
9. The Dean's Report

The Dean's report includes an overview of the academic programs, faculty development, and student success initiatives. It highlights the achievements and challenges faced by the faculty and students, and outlines the strategic plans for the upcoming academic year.

8.1 The Strategic Plan

The Strategic Plan outlines the long-term goals and objectives of the university, focusing on areas such as academic excellence, research innovation, and community engagement. The plan is designed to guide the university's operations and decision-making processes.

8.2 The Financial Report

The Financial Report provides an overview of the university's financial status, including revenue sources, expenses, and budget projections. It also includes an analysis of the financial trends and challenges faced by the university.

7.1 The Governor's Address

The Governor's Address is a speech delivered by the Governor of the state, highlighting the key issues and priorities for the upcoming year. It provides a perspective on the state of the economy and education, and outlines the Governor's proposals for addressing these issues.

6.1 The President's Message

The President's Message is a statement delivered by the President of the university, outlining the strategic initiatives and priorities for the upcoming academic year. It also highlights the achievements of the past year and the challenges faced by the university.

5.1 The Faculty Senate Report

The Faculty Senate Report provides an overview of the faculty activities, including academic programs, research initiatives, and faculty development. It also highlights the challenges faced by the faculty and the strategies implemented to address these challenges.

4.1 The Student Body Report

The Student Body Report provides an overview of the student body activities, including extracurricular programs, student organizations, and academic achievements. It also highlights the challenges faced by the students and the strategies implemented to address these challenges.

3.1 The Dean's Report

The Dean's report includes an overview of the academic programs, faculty development, and student success initiatives. It highlights the achievements and challenges faced by the faculty and students, and outlines the strategic plans for the upcoming academic year.

2.1 The President's Message

The President's Message is a statement delivered by the President of the university, outlining the strategic initiatives and priorities for the upcoming academic year. It also highlights the achievements of the past year and the challenges faced by the university.

1.1 The Governor's Address

The Governor's Address is a speech delivered by the Governor of the state, highlighting the key issues and priorities for the upcoming year. It provides a perspective on the state of the economy and education, and outlines the Governor's proposals for addressing these issues.
bring in ARVs, such as: ministry of health, ministry of trade and industry, ministry of finance, customs, etc.

In order to deal with potential problems we suggested that consideration be given to enacting a provision that overrides any rule that would otherwise prevent the successful use of the paragraph 6 solution. The idea behind such a provision is that it would send a signal to a judge to interpret the relevant rule in a way that was consistent with the spirit of the paragraph 6 solution. For example:

For the purposes of implementing paragraph 6 of the Doha Declaration the use of a compulsory license or notification shall override all other provisions in this law or other laws, decrees, regulations that are inconsistent with the implementation of that compulsory license or notification.

9.5. The Health-IP Working Group

Perhaps the most important priority is the formation of a core group made up of representatives from health, the IP Department, the Ministry of Commerce and the Food and Drug Department. Our impression was that the workshop we held was the first time that there had been an exchange of information on intellectual property and health issues. It is vital that these departments continue to co-operate and co-ordinate throughout Lao’s WTO accession process. We also gained the impression that Lao P.D.R. was weak in infrastructures and human resources, therefore they need support from other countries especially from the other ASEAN Member Countries, and improving their coordination inter-departmental and cooperation funded by an outside donor. If we are right in this, then it is likely that the National Project Coordination Committee (NPCC) will have problems in implementing the term of this and other projects.

10. CONCLUSIONS

a. Lao P.D.R. is a small LDC that has very limited manufacturing capacity. In the foreseeable future it will have to meet its medicines requirements through importation.

b. Intellectual property law is undergoing something of a transition in Lao P.D.R. Lao P.D.R. is seeking WTO accession. Normalising trade relations with the US is a matter of priority. Lao P.D.R. has signed a bilateral with the US that limits the capacity of Lao P.D.R. to take advantage of the flexibilities in TRIPS. Congress is yet to ratify this agreement. In particular, the bilateral will make it difficult for Lao P.D.R. to take advantage of the Doha Declaration.

c. As our report makes clear the current Patent Decree offers patent owners of pharmaceutical products and processes a high degree of protection with few restrictions on their rights. We were told that this Decree was drafted by the IP Office, with the assistance of WIPO. So far this Decree has not had an impact on Lao P.D.R., because Lao P.D.R. has not been in a position to accept patent applications. As part of the WTO accession process, Lao P.D.R. has drafted new IP legislation with some input from WIPO. The draft legislation was not made available to us, but given that Lao P.D.R. has a bilateral with the US, one can assume that this draft legislation will not be especially suitable for Lao P.D.R. from a public health perspective.

d. Perhaps the most important priority for Lao P.D.R. is the formation of a core group made up of representatives from Health, the IP Department, the Ministry of Commerce and the Food and Drug Department. Information exchange on IP and health issues is not taking place at the moment. Lao P.D.R., as an LDC, would also benefit greatly from a coordinated ASEAN approach to IP and health issues.
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 (AWP II) and develop an AWP III 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 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 involve 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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