enforcement of patent rights for pharmaceutical products.

3.3.4.1 Government Use

Lao P.D.R.'s decree on patents, petty patents and industrial designs establishes a right for the issuance of Government Use authorizations. The "government" has the right to issue a Government Use License, but the decree does not specify what governmental authority maintains this right. Government Use authorizations may be issued for general public interest reasons, including particularly national security, nutrition, health or development of any vital sector.

Commentary

The decree does not specify if authority to issue a Government Use License rests generally with governmental officials, with any minister, or exclusively with the prime minister. To best capitalize on the flexibility available in the TRIPS Agreement, and to most effectively harness the Government Use authority to advance public interest and particularly public health interests, authority to issue Government Use Licenses should be vested broadly, in a diversity of governmental ministries.

In general, when it comes to use of a patented invention by a particular ministry, that ministry more than any other houses the expertise to determine whether a Government Use is needed. In the case of healthcare, for example, the Ministry of Health should have a more acute awareness of the rationale for a Government Use authorization of a patented medicine than other ministries. Thus, it makes sense for governmental ministries to have authority to issue governmental use orders related to patented inventions they will use to carry out their particular ministerial missions.

The grounds for issuance of a Government Use License are defined broadly. To make the Government Use provision workable, it will be important that these general considerations - national security, nutrition, health or development of other vital sectors - are elaborated either in administrative rules or practice. The general nature of the grounds in the statute could inhibit the Ministry from authorizing Government Use Licenses. Administrative rules that detail categories of situations that meet the statutory standard can overcome this potential problem. For example, an implementing regulation could specify that where significant numbers of Lao people are not able to obtain medicines they need, and where price is a barrier to obtaining access to medicines, then the public interest in health promotion means a Government Use License (or Compulsory License to a third party) should be issued.

The statute specifies that patent holders shall be paid "adequate compensation," but provides no further guidance. In the absence of clarifying rules, this general language may deter government officials from issuing Compulsory Licenses on the grounds that determining compensation is too difficult. 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.

3.3.4.2 Compulsory Licensing

Article 20, which establishes a Government Use right, also establishes governmental authority to issue Compulsory Licenses to advance public interest considerations, including particularly national security, nutrition, health or development of any vital sector of the national economy. It also establishes a right to compulsory licensing to remedy anti-competitive practices. Article 21 establishes lodges authority with the Patents Registrar to issue a Compulsory License in cases of non-working or for dependent patents.

Commentary

Because public interest compulsory licensing is established through the same provision as Government Use licensing, the concerns relating to Government Use licensing also apply to compulsory licensing.

To recapitulate, there are three key issues. First, the statute does not specify which part of the government has authority to issue Compulsory Licenses. TRIPS flexibility will best be exploited if authority is lodged with all ministries, as it relates to their particular areas of responsibility.

Second, the public interest grounds for a Compulsory License are defined very broadly. To make the provision workable, it would be ideal through implementing regulations or otherwise to specify particular circumstances in which Compulsory Licenses will be issued. For example, an implementing regulation could specify that where significant numbers of Lao people are not able to obtain medicines they need, and where price is a barrier to obtaining access to medicines, then the public interest in health promotion means a Government Use License (or Compulsory License to a third party) should be issued.

Third, royalty guidelines would help ease compensation decisions, and increase government officials' comfort level with issuing Compulsory Licenses.

A fourth issue relates to the lack of time specificity in the Lao P.D.R. decree; there is no timetable provided by which a Compulsory License applicant can be assured he or she will get a response. Failure to include such deadlines may result in long delays in decision-making.

3.3.4.3 Parallel Importation

The Lao P.D.R. decree is silent on the issue of parallel importation, not detailing the country's exhaustion regime.

Commentary

This has not been an issue for Lao P.D.R. while it has not granted pharmaceutical patents, but it will become significant if the country does in fact start to grant pharmaceutical patents on new medicines.

3.3.4.4 Bolvar Provision

The Lao P.D.R. decree does not have a Bolvar provision. Article 19 permits experimental use of patented products, but not the preparation of patented goods for the purpose of receiving marketing authorization.

Commentary

If Lao P.D.R. does start to grant pharmaceutical patents on new medicines, failure to implement a Bolvar provision will meaningfully delay the introduction of generic competition.

3.3.4.5 Data Exclusivity

Lao P.D.R. does not have in place any system for protection for registration data.

Commentary

So long as the country prohibits...
In 1987, the Ministry of Justice enacted a Ministerial Decree concerning well-known trademark protection, even though the Trademark Law No. 21 of 1961 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 the 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 in 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 as the 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 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 drafted a law there is a 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 Office 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 LDGs to suspend Sections 5 and 7 of Part II of TRIPS so far as pharmaceutical patents are concerned till at least 1 January 2015.

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 Viet Nam 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), Viet Nam (74) and Malaysia (52).
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 enabling 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 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.
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 legislative one) with corresponding implementing regulations and administrative rules to facilitate the use\(^2\) of the TRIPS flexibilities/safeguards and operationalize 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.

\(^1\) Member Countries, together, can advance shared public health objectives.
\(^2\) I.e. Thailand's IP Code has a tolerable 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.