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TRIPS Agreement and its Impact on Health

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INTRODUCTION

The WHO Regional Office for South-East Asia, in collaboration with the Ministry of Health, Government of the Union of Myanmar, held a national workshop on TRIPS and Its Impact on Health from 13 to 15 October 2003. The main aim of the workshop was to increase awareness about WTO, the multilateral trade agreements, and their implications on Public Health, Pharmaceuticals, Traditional Medicine and Biotechnology, as well as to strengthen the coordination mechanism between related ministries regarding the international agreements. The workshop participants analysed the problems and impact of TRIPS agreement on Myanmar's public health, and explored ways to mitigate the negative impact of the trade agreement. Two consultants, Dr Jakkrit Kuanpoth and Dr B K Keayla assisted in the conduct of the workshop. As part of their assignment they prepared reports on the workshop which are annexed – Annexes 1 and 2 respectively.

Annex 1

PRESENTATIONS BY DR JAKKRIT KUANPOTH

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1. BACKGROUND

TRIPS is a comprehensive agreement containing new multilateral rules and disciplines with relatively high standards of intellectual property protection. It has linked trade measures to the enforcement of intellectual property rights, requesting Member parties to ensure that their laws conform to the WTO standards. The Agreement requires all WTO Members to provide patent protection for “any inventions, whether products or processes, in all fields of technology”, including foods, pharmaceuticals, micro-organisms, and micro-biological and non-biological processes. However, animals and plants, as well as any essentially biological processes for producing them, can be excluded from patentability. The exclusion may also cover inventions contrary to public order or morality, health or welfare, and medical methods of diagnosis, therapeutics and surgery.

Patent protection for both product and process invention must be available for 20 years from the filing date. Member parties are permitted to apply any legal measures, including compulsory licence, parallel import, competition law and price control mechanisms, to combat abusive practices or enforce local working of patents, provided that certain conditions stipulated in the Agreement are fulfilled.¹

TRIPS stipulations for patent protection for pharmaceuticals is of particular concern for many developing countries. Pharmaceuticals are basic requirements for the population and stricter protection would allow firms to increase their market share, which, in turn, will lead to overpricing and restricted supply of the essential products in the country. To protect the health of the people, these products must be made available at the lowest possible price.

¹ Rein, J. “International Governance Through Trade Agreements: Patent Protection for Essential Medicines”, 21 *Northwestern Journal of International Law & Business* 379 (2001).

When a group of African countries requested a special session on access to medicines at the WTO TRIPS Council, it led to the adoption in November 2001 of the Doha Declaration on the TRIPS Agreement and Public Health. The Declaration expresses concern of Member countries over "the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." It clarifies some of the ambiguities with respect to the relationship between the TRIPS Agreement and Members' rights to protect public health, and reaffirms the "right of WTO Members to use, to the full, the provisions in the TRIPS Agreement", including taking advantage of TRIPS' compulsory licence provision. This clarification is a significant step forward for public health, because, while Article 31(b) of TRIPS permits the use of compulsory licence, it seems unclear what circumstances will qualify as a national emergency or urgent situation for the purpose of granting compulsory licence.

The Doha Declaration stipulates that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." It goes on to recognize that WTO Member countries are free to use the flexibilities under TRIPS in order to promote access to medicines. For example, Article 6 of TRIPS clarifies that each Member is free to establish its own regime for the use of exhaustion of rights. This means, in effect, that WTO Members can incorporate the principle of international exhaustion into their national legislation in order to encourage parallel importing of pharmaceuticals at the lowest price.

The Doha Declaration has extended the provisional period for the least-developed countries to comply with TRIPS obligations until 2016. But the developing countries that did not provide patents for pharmaceutical products before TRIPS entered into force will have enjoyed a grace-period until 2005. This means that, after 2005, major exporters of generic products will no longer produce cheap versions of drugs, and sources of supply of generic drugs will be limited.

The Declaration has instructed WTO's TRIPS Council to recommend a solution to the problem faced by countries with insufficient or no manufacturing capacities in the pharmaceutical sector by the end of 2002.

However, the negotiations so far have revealed differences among Member nations. While developing countries are calling for increased flexibility in implementing the TRIPS Agreement, the more advanced nations seem to prefer negotiations towards maintaining intellectual property rights.

2. TRIPS AND PUBLIC HEALTH IN MYANMAR

The following is a brief summary of the findings on TRIPS and public health relating to Myanmar:

2.1 Patent Law

Date of application – Myanmar must adopt a law to protect various kinds of IPRs before 1 January 2005 (TRIPS, Art. 66). Currently, only trademark and copyright laws exist in the country. Myanmar is required to adopt the law on patent and industrial design. It must also ensure that geographical indications, layout-design of integrated circuits and undisclosed information are adequately protected in line with relevant provisions in TRIPS. However, since Myanmar is considered a least developed country, it is entitled to delay patent protection for pharmaceutical products until January 1, 2016 as authorised by the Doha Declaration and Public Health (Doha Declaration, para. 7). During the transitional period, Mail Box for patent applications dating back to 1 January 1995 must be established. It is also required to grant exclusive marketing right on the applications for a period of five years or until the patent is granted or rejected (TRIPS, Art. 70(8)(9)).

Objectives and principles – Myanmar's patent law should adopt provisions that reflect TRIPS' objectives and principles of intellectual property protection as stipulated under Articles 7 and 8.

Scope of patentability – Myanmar needs to protect both pharmaceutical products and process. For process patents, it is recommended that only the manufacturing process is protected. Patents on the use of existing products, such as dosage forms, new use, new formulations or second indications, should be prohibited on grounds of being methods for the treatment of humans and animals. All kinds of medical methods, including surgical, diagnostic and therapeutic, should be excluded from patent protection. Patentability of plants, animals, and inventions relating to life

forms, including genes, gene sequences, extraction from humans, animals or plants should be prohibited. In addition, biological processes, including microbiological processes, should be excluded from patent protection on grounds that Article 27.3(b) is under revision by the TRIPS Council.

Definitions – Proper definitions for terms like “invention”, “novelty”, “inventive step”, and “industrial application” should be adopted. The distinction between discoveries and invention must be clarified. A substance found in nature, even if purified or isolated from its natural surrounding, shall be regarded as a discovery, and not be patentable.

Publication of application – Patent applications must be published for public scrutiny. The system of pre-grant opposition should be introduced into the national law in order to curtail the granting of invalid patents. The law may provide for administrative procedures for challenging invalid patents at patent office. This will help to avoid more costly judicial procedures.

Compulsory licence – In order to increase wider use of compulsory licence, Myanmar should provide various grounds for granting of compulsory licence, including government use, non-working or insufficient working, abusive practice, refusal to deal, anti-competitive practice, emergency, public interest, etc. In order to increase access to essential drugs and medicines, a compulsory licence should be wide enough to cover both non-voluntary licences for import and export. In addition, expeditious licensing procedures such as establishing clear and transparent procedures for issuing the compulsory licence, setting up an administrative body to review the decisions taken by the licensing authority, etc. should be followed.

Parallel import – The patent law should incorporate the doctrine of international exhaustion. This principle will facilitate parallel import of drugs into Myanmar. Although parallel imports are desirable and encouraged, it has to be ensured that the quality of the parallel imported drugs is maintained to reduce adverse effects of importing counterfeit and substandard medicines.

Forfeiture of patent rights – Compulsory licence should not be the only mechanism to curtail the abusive practices of the right holder. The patent law of Myanmar should constitute forfeiture of rights or the provision for revoking patents.

Requirement for full disclosure of patented invention – The patent law should require that all applications must disclose details of the invention to the fullest extent so that a person with the necessary skills in the discipline covered by the patent can replicate the invention. The best mode requirement should also be included in the law.

Exceptions to patent rights – The law should adopt wide ranging exceptions to exclusive rights so as to foster innovation, promote the diffusion of technology, or facilitate access to medicines at the lowest possible prices. The exceptions that should be incorporated include the Bolar provision, prior users' rights, experimental use, private use, exhaustion of rights, etc.

Establishing a committee on drug prices – A committee to supervise the price of medicines should be established under patent law. This will not violate the provision of Article 27.1 of TRIPS as the Doha Declaration explicitly discriminates the field of technology.

The capacity of the national patent office – In order to better utilize the patent system, a strong system of patent granting is required. This, in turn, requires improvements in the capability of the national patent office. Myanmar should attempt to: (1) develop human resources in various fields of technology, (2) encourage wide use of patent documentation and database as a source of technical information, and (3) adopt a proper system of patent granting and repealing.

2.2 Traditional Medicine

Adopting a sui generis law – As it is difficult to protect traditional medicinal knowledge and herbal medicines under the mainstream intellectual property laws, it is advisable that Myanmar should adopt a specific law on this issue. The law may provide for the registration of traditional medicinal knowledge and constitute a criminal sanction for those found to be violating the law.

Adopting other legal instruments – In line with the sui generis law, Myanmar needs to adopt contractual arrangements to complement the traditional medicine law. The contract such as the material transfer agreement, can be used to lay down rights and obligations of the parties in relation to bioprospecting activity and the transfer of traditional medicine.

Database system – Myanmar should establish a documentation system on traditional medicine. The database will not only help maintain and preserve the traditional knowledge, but also enable patent examiners to check for prior art in the form of native knowledge as the knowledge has been compiled in an easily accessible form. The database would also facilitate equitable benefit sharing and improvement of the use and quality of traditional medicine within the health care system, etc.

National policy on traditional medicine – Traditional medicine has become increasingly more significant. Myanmar should consider a national policy on traditional medicine. This will be an important landmark not only to achieve the goal of self-sufficiency in the health care system, but also to realise additional gains from the traditional innovation. Ideally, the policy may include government support for the further development of TM and for research based on existing traditional medicine.

International convention on traditional medicine – The national law on traditional medicine will not be enforceable outside the country. Thus, the only solution is to have a binding international arrangement on the issue. Myanmar and other developing countries should be engaged in negotiations with an aim of developing an international legal instrument for the protection and promotion of traditional knowledge in general, and traditional medicine in particular.

2.3 Pharmaceuticals and Access to Medicines

In order to facilitate access to medicines, especially essential drugs, the following are recommended:

- (1) Adopt a national drugs policy which is fundamental to planned and logical activities in medicines
- (2) Encourage generic substitution and the use of generic names to ensure that prices of drugs are not artificially raised under brand name
- (3) Implement vigorously legal controls and closely monitor drug advertisements

- (4) Control excessive spending on drug promotion by drug suppliers and do not allow direct-to-consumer-advertising of prescription drugs
- (5) Adopt a centralized procurement system which will give the government agency ample opportunities to select appropriate quality and price
- (6) Enhance the policy of procuring products at the best prices wherever available in the world market
- (7) Adopt price control mechanisms, especially for essential drugs, including: (1) the establishment of global and regional databases on drug prices for the establishment of price controls, (2) regulating the prices of individual drugs, (3) voluntary discount agreements between drug suppliers and the government, (4) international tendering among pre-qualified suppliers, (5) direct profit control: for example, curbing high prices by limiting the profitability of sellers, and (6) training on negotiation on drug procurement and purchasing supported by other countries and international agencies like WHO.
- (8) Apply appropriate policy on TRIPS, including applying flexibility and introducing a public health perspective into national intellectual property laws and regulation, delaying implementing TRIPS obligations until the expiry of the provisional period, adopting a common and united stand among different government agencies on improving access to medicines and giving public health priority over trade interests.

3. CONCLUSIONS AND RECOMMENDATIONS

A functioning system of patent protection does not exist in Myanmar. A coherent administrative system to implement the patent law is required. Myanmar must adopt a law to protect various kinds of IPRs before 1 January 2005. While currently only trademark and copyright laws exist in the country, Myanmar is required to adopt the law on patent and industrial design. It must also ensure that geographical indications, layout-design of integrated circuits and undisclosed information are adequately protected in line with TRIPS' relevant provisions.

Like in many developing countries, a stringent patent regime if adopted will not foster domestic research, but will promote R&D and protect research results in developed countries. Patents are likely to be used by foreign drug companies as a mechanism for overpricing. For this reason, Myanmar needs to incorporate all available legal measures into national law in order to facilitate the domestic production of patented inventions and, at the same time, prevent a single company dominating the market.

Efforts have to be made by the government to step up the efficiency of the national Patent Office, when established. The Patent Office should have two roles. One would be to carry out the various activities relating to granting of patents and the other to administer transfer of technology issues. Since the function of the Office is essentially related to several fields, it is necessary to ensure the availability of personnel in legal, technical and economic areas. Although it may be difficult to recruit qualified national staff, participation in training programmes organised by international organisations like WIPO, UNCTAD, as well as the assistance from other developed countries' Patent Offices, could be very helpful in upgrading the capacity of the national Patent Office. Apart from the recruitment and training of specialized personnel, a modern system of information technology should be developed. This, when accomplished, would facilitate the use of patent documentation as a source of technical information.

In order to be self-sufficient in pharmaceutical production, Myanmar has to formulate a rational and coherent national drug policy as part of its overall development strategies. The pharmaceutical industry is vital to a nation's survival and should not be left at the hands of free enterprise or foreign interests. Experience in many countries shows that direct price controls lead to a substantial reduction of medicine prices in the market. Therefore, the government should initiate a policy of drug price control, especially for essential drugs. It must also monitor the prices of other drugs; excessive profits on other drugs may be used for over-promotion and to decreased use of essential drugs.

Apart from the continuous use of the essential drug list and the operation of a central procurement system, the government should establish a scheme for cooperative action in the field of pharmaceuticals with other developing countries, especially those at a higher technological level.

International cooperation among developing countries may include research projects of drug development, production of medical substances, procurement of drugs suitable to the needs of the developing countries, and testing and checking the quality and effectiveness of drugs.

For centuries, Myanmar has used traditional medical practices and indigenous medicines for preventive and curative treatment of ailments before it turned to Western drugs. In addition, Myanmar, like many other developing countries, possesses significant tropical natural resources such as herbs and other botanical products which have tremendous potential for use as raw material in industrial pharmaceutical production. Most of such natural resources "have not been fully explored or appreciated in modern, science-based therapy". Apart from adopting a law to protect traditional medicinal knowledge, Myanmar must initiate medical research projects aimed at discovering the therapeutic value of such indigenous resources and developing these materials into medically useful compounds. In addition, the government must incorporate traditional medicine and its methods of treatment into the national health-care plan. In essence, there should be co-existence between traditional and modern medicine.

It is recommended that the following feasible operational options regarding TRIPS and public health should be taken by Myanmar: (1) organizing national workshop/training on access to medicines, involving health and trade policy-makers to enhance country capacity and capability to deal with trade-related matters influencing access to essential drugs and medicines; (2) technical support in the area of legislation and regulation related to TRIPS and trade globalization; (3) inter-country meeting on TRIPS and trade globalization; and (4) monitoring of policies, legislation, and other factors in relation to the TRIPS Agreement and public health.

Annex 2

PRESENTATIONS BY MR B.K.KEAYLA

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1. FEATURES OF TRIPS AGREEMENT

The presentation covered the following aspects:

- The introduction of intellectual property rights is the prerogative of national governments under which rights and obligations of the patent holders balanced with the public and national interest. The rights of the patent holders have been strengthened and the obligations diluted in this Agreement.

2. OBLIGATIONS DURING TRANSITIONAL PERIOD

The obligations during transitional period in the national legislation on patents were analyzed as follows:

2.1 Date of Application of TRIPS Agreement for all IPRs in Myanmar

According to Article 66 of the TRIPS Agreement, national legislation on all IPRs including the patent laws should be in position and enforced from 1 January 2005 in Myanmar. In case it is not possible to complete the process of enacting legislation on various IPRs, a motivated request could be made with the Council for TRIPS for according extension beyond the stipulated date.

2.2 Application of Product Patent Provisions on Pharmaceuticals

The Doha Declaration on TRIPS Agreement and Public Health in para 7 provides that 'the least developed countries will not be obliged with respect to pharmaceutical products, to implement or apply sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these sections until 1 January 2016 without prejudice to the right of least developed country members to seek other extensions of the transitional period as provided for in Article 66 of the TRIPS Agreement'. The Myanmar Government will have to make suitable provisions on the scope of patentability for pharmaceutical

products also in the patent legislation which, of course, will be enforceable from 1 January 2016, but product patent applications in the Mail Box will be allowed to be filed on the basis of the stated scope of patentability during the transitional period.

2.3 Obligations About Mail Box

Para 8 of Article 70 of the TRIPS Agreement provides that where a member country (irrespective of the fact whether it is developing or least developed country) does not make available as on 1 January 1995, patent protection for pharmaceuticals and agricultural chemical products commensurate with its obligations under Article 27 of the TRIPS Agreement, that member shall establish Mail Box facility from 1 January 1995 (date of establishment of WTO) to receive product patent applications for these inventions irrespective of the date of application of TRIPS Agreement as provided in Article 66 and application of product patent system in least developed countries as provided in Para 7 of Doha Declaration on TRIPS Agreement and Public Health. Since, patent legislation in Myanmar will be in position as from 1 January 2005, and as no patent application for pharmaceuticals would have been filed prior to that date, (as no patent system existed in Myanmar) the Mail Box facility will, in actual practice, start from that date i.e. 1 January 2005.

2.4 Obligations About Exclusive Marketing Rights

Para 9 of Article 70 of TRIPS Agreement provides that for applications received in the Mail Box, Exclusive Marketing Rights (EMR) shall be granted for a period of five years after obtaining marketing approval in Myanmar or until a product patent is granted or rejected whichever period is shorter. The other criteria applicable for grant of EMR are that subsequent to the entry into force of WTO Agreement (i.e. 1 January 1995), a patent application has been filed and a patent granted for that product in another member country and marketing approval obtained in such other country.

2.5 Examination of Mail Box applications

Para 3 of Article 70 of TRIPS Agreement provides that 'there shall be no obligation to restore protection to subject matter which on 1 January 2005 has fallen into public domain'. The public domain angle will be applicable in case the patentable subject matter has already been used in any country.

Since pharmaceutical product regime in Myanmar will be established as from 1 January 2016 applying Sections 5 and 7 of the TRIPS Agreement, according to Para 8 (b) of Article 70 there will be no examination of Mail Box applications before 1 January 2016. In connection with the examination of the pharmaceutical product applications, the right of priority shall also be applied as provided in Article 4 of the Paris Convention. The right of priority available for patents is 12 months. This right is available to all applicants for registration of patent application in all countries of the world. In case there is delay in filing the application for any period beyond 12 months, the applications for patent claim can be refused or rejected on that ground. This is an important provision for rejection of patent application received in the Mail Box with a delay beyond 12 months from the date of first patent application filed in any other country. The other criteria such as novelty, inventive step and capable of industrial application will be applicable on such applications.

The period of patent protection for Mail Box applications which would be examined after 31 December 2015 and which would satisfy the criteria for patent grant is stated in para 8 (c) of Article 70 of the TRIPS Agreement. It will be as from the date of grant of the patent (after 1 January 2016) for the remainder of patent term counted from the filing date in accordance with Article 33 of TRIPS (i.e. 20 years from the date of filing). This means that an application received in the Mail Box on 1 January 2010 and finalized for grant of patent on 1 January 2017 shall have patent protection only for 20 years minus 7 years i.e. equal to 13 years. However, during the transitional period it would have enjoyed EMR for five years.

3. FRAMING OF SUBSTANTIVE PROVISIONS IN THE NATIONAL PATENT LAWS

Apart from the procedural requirements of the transitional period and the provisions dealt with above the other relevant substantive provisions were also analyzed as follows:

3.1 Scope of Patentability

Article 27 of the TRIPS Agreement deals with the 'patentable subject matter'. Under this Article, the patent rights are enjoyable without discrimination as to

the field of technology. However, the Doha Declaration has recognized the gravity of public health problems afflicting developing and least developed countries. In order to promote access to medicines for all and their easy availability as stipulated in the Declaration, the inventions relating to pharmaceuticals could be singled out for special emphasis. In view of this the national patent laws may provide scope of patentability as follows:

- "Patents shall be available for pharmaceutical substances and other inventions whether products or processes, in all fields of technology provided they are new, involve inventive steps and are capable of industrial application".

The pharmaceutical substance from the patentability point of view may be defined in the national legislation as follows:

- "Pharmaceutical substance includes new chemical entity (NCE) or new medical entity (NME) involving inventive steps".

It is relevant to point out that patent applications are filed only when the researchers reach the stage of new medical entity or new chemical entity which would satisfy the stipulated criteria for patentability. The production and marketing of formulations are the 'use' aspects of the patented product and should not be considered as part of protectable subject matter.

3.2 Definitions of Patent Terms

There are certain important patent terms which should also be carefully defined in the national patent legislation. It is important to do so to avoid representations or disputes due to casual interpretations in the patent laws.

The suggested definitions are as follows:

- (1) Invention may be defined as:
 - "Invention means a new product including machine, apparatus or other article or process including chemical process, biochemical, biotechnological and microbiological processes, involving inventive steps and capable of industrial application".

- (2) New or novelty may be defined as follows:
 - "New or novel invention means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art".
- (3) Inventive step may be defined as follows:
 - "Inventive step means a feature of an invention that involves an important technical advance as compared to the existing knowledge which makes the invention not obvious to a person skilled in the art".
- (4) Capable of industrial application may be defined as follows:
 - "Capable of industrial application in relation to an invention, means that the invention is capable of being made or used in any industry".

3.3 Exclusion of inventions from patentability

Exclusion of inventions from scope of patentability is another important feature of the national patents legislation. There is no decision as yet on the mandated review of Article 27 (3) (b) of the TRIPS Agreement on patenting of 'micro-organisms and non-biological and microbiological processes' which was initiated in WTO in 1999 and, as such, there should be no need to make any provision on their patenting and any other life-form. Patenting of life form is a critical issue and should not be routinely implemented. Research tools particularly related to biotechnology should also be specifically deleted, otherwise biotechnology research could be in jeopardy. It is estimated that over 70% of the turnover of the drugs and pharmaceuticals in the future would be produced through the biotechnology route. The use of these technologies being new will also qualify them for a patent term of 20 years. This could have a serious impact on prices and treatment costs as well as the availability of protected products. Suggestions for exclusion of inventions from patentability are as follows:

- (1) An invention which is frivolous or which claims anything obvious
- (2) Contrary to well established natural laws;

- (3) An invention the primary or intended use or commercial
- (4) Exploitation of which could be contrary to *public order* or morality or which could cause serious prejudice to human and animal health or plant life or to the environment;
- (5) The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living things or non-living substances occurring in nature;
- (6) The mere discovery of any new property or new use for a known substance or combinations of known drugs or new formulations of existing drugs;
- (7) Formulations in any form meant for use as medicine or drug for internal or external use other than such formulations which involve innovative technologies and which may qualify for protection to be covered by process patents;
- (8) A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substances;
- (9) The mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;
- (10) A method of agriculture or horticulture;
- (11) Any process for medicinal, surgical, curative, prophylactic diagnostic, therapeutic uses of human beings or any process for a similar treatment of animals, or plants to render them free of disease or to increase their economic value or that of their product;
- (12) plants, animals and micro-organisms in whole or in part or constituents thereof including seeds, varieties and species and any process, including biological process for production or propagation of plants, animals and micro-organisms (the term micro-organism here includes viruses);
- (13) Inventions which do not strictly meet the criteria of industrial application e.g. onco mouse, stem cell, partial gene fragments, research tools, PCR technique, machine-based embedded bio-informatics software, genomic information and data bases;

- (14) All or parts of natural living beings, micro-organisms in any form and biological materials found in nature or isolated including germ plasm of any living being and any biological process;
- (15) Biotechnological inventions needing the use of biological resources;
- (16) A mathematical or business method or a computer programme or algorithms;
- (17) A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television production;
- (18) A mere scheme or rule or method of performing a mental act or method of playing a game;
- (19) A presentation of information;
- (20) Topography of integrated circuits;
- (21) An invention which, in effect is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community, traditional knowledge or which is an aggregation or duplication of known properties of traditionally known components or compounds and research tools;
- (22) Any other subject matter which might be notified by the government from time to time.

3.4 Working of Patent

Working of patents in the country which grants exclusive rights on the relevant products is extremely important to ensure easy availability and for containing prices of patented products through a competitive environment. Article 27 of TRIPS Agreement has absolved the patent holders from the obligation of working their patents. This specific provision in this Article provides that 'patent shall be available and patent rights enjoyable as to the place of invention, the field of technology and whether products are imported or locally produced'. Thus, in so far as the patent holders are concerned the obligation of working the patents gets satisfied through imports. However, the domestic enterprises must be involved through the national legislation under the system of grant of compulsory licences to ensure domestic working.

3.5 Compulsory Licensing System

The compulsory licensing system is the backbone of the patent laws for developing and least developed countries to ensure the role of domestic enterprises to provide adequate availability of patented products at competitive prices. The question of constraints which are likely to emerge after the implementation of TRIPS has been a subject of serious concern and has been vigorously debated in the TRIPS Council of WTO during 2001. The issue was further hotly debated in the Doha Ministerial Conference held in November 2001. The result was the Doha Declaration on TRIPS Agreement and Public Health which clarifies that sufficient flexibilities and freedom to determine the grounds upon which compulsory licences can be granted are available to member countries. It is now for the Member countries to exercise their right and make suitable provisions in their respective national legislation.

There are nine possibilities of structuring the grant of compulsory licences arising from TRIPS Agreement and the Paris Convention. These are:

- (1) Voluntary Licence
- (2) Authorization for meeting government requirements;
- (3) Compulsory licence due to abuse of patent rights by the patent holder;
- (4) Compulsory licence for reason of unsuccessful attempt by an enterprise to obtain voluntary licence directly from the patent holder;
- (5) Compulsory licence due to national emergency;
- (6) Compulsory licence due to circumstances of extreme urgency (health emergency, etc);
- (7) Compulsory licence in cases of public non-commercial use;
- (8) Compulsory licence to remedy anti-competitive practices;
- (9) Second patent for an invention involving important technical advance of considerable economic significance over the existing patents.

If all the above possibilities are suitably provided in the national patent laws it would be possible to develop a competitive environment for drugs and pharmaceuticals in the country. The framing of appropriate provisions on this subject in the national legislation are suggested as follows:

3.6 Voluntary Licence:

On voluntary licensing patent laws may make provision as follows:

- (1) "Any patentee may apply to the Controller for an entry to be made in the register of licences to the effect that any person may obtain licence of his patented substance or technology;
- (2) The Controller shall grant a licence under the patent to any person who applies for such a licence on such conditions, restrictions and royalty terms as may be agreed upon by the patentee and the applicant. If the patentee and the applicant are unable to agree within a period of 90 days the Controller shall grant the licence on such conditions, restrictions and royalty terms as he may deem appropriate".

The above provision should be available in the patent law to meet the needs of a patentee who may not himself like to promote his patented product in the markets of that country due to certain limitations. He would however be interested that his product is sold in that market. The provisioning of voluntary licence in the patent laws would help in meeting this need. To encourage this the laws could also provide for certain incentives for those patent holders who may avail of this provision.

3.7 Authorization for Meeting Government Requirements

Article 31 of TRIPS Agreement clearly provides for use of patentable subject matter or patented substances for meeting government requirements. This can be achieved through government undertakings or other private enterprises authorized by the government to produce and supply. The formulation of provision in the patent laws may be made as follows:

- "For purposes of meeting government requirements , the Controller of Patents will have the right to authorize the use of the subject

matter of patent by the government or by the third parties authorized by the government on such terms and conditions as the Controller of Patents may deem fit."

There will be no need to consult the patent holder while authorizing use of patent for meeting government requirements.

3.8 Compulsory Licence due to Abuse of Patent Rights by the Patent Holder

Article 8 of TRIPS Agreement and Article 5 of the Paris Convention deal with the abuse of patent rights by the patentees. These Articles provide that suitable steps could be taken to remedy the abuse. The abuses arise when the patentee is charging high price for his patented product and that the relevant product is not available in sufficient quantities to meet the domestic demands either through imports or domestic production by the patentee. Formulation of relevant provision could be as follows:

"At any time after the expiration of three years from the date of the sealing of a patent any person interested may make an application to the Controller of Patents for grant of compulsory licence on any of the following grounds:

- (1) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
- (2) that the patented invention is not available at a reasonably affordable price, or
- (3) that the patented invention is not being worked in the different regions of the country.

The terms and conditions for grant of compulsory licence for any of the reasons stated would be settled by the Controller of Patents in consultation with the patent holder".

3.9 Compulsory Licence for Reason of Unsuccessful Attempt to Obtain Voluntary Licence

Article 31 (a) and (b) of TRIPS Agreement provides for compulsory licence due to unsuccessful attempt by a domestic enterprise to obtain voluntary licence

from the patent holder. Formulation of the provision in the legislation could be as follows:

- “Where individual merits of an applicant have been determined by the Controller of Patents to use the patented invention and that the proposed user has made efforts to obtain authorization from the patentee to use the patent on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time, the
- Controller shall at any time after the expiration of three years from the date of sealing of the patent, grant compulsory licence to the applicant on such terms and conditions as he may deem fit;
- The reasonable period after which the applicant may approach the Controller would not be less than 150 days from the date he had approached the patentee. The commercial terms and conditions offered by the applicant shall be considered reasonable by the Controller if royalty and other remunerations offered by him are within five percent of the annual sales turnover of net ex-factory sale price. The term of the licence shall be co-terminous with the patent term available to the patentee”.

The TRIPS Agreement in Article 31(b) deals with the contingencies of national emergency or other circumstances of extreme urgency or cases of public non-commercial use together. The contingencies arise under different circumstances and should be dealt with under different Articles of patent laws as suggested hitherto.

3.10 Compulsory Licence due to National Emergency

Under this circumstance the formulation of provision in the national legislation could be as follows:

- “In the circumstances of notification of the national emergency by the government, the Controller of Patents may issue authorization of rights at any time during the national emergency for working of any patent in the country on application by any enterprise interested to use the patent on such terms and conditions as the Controller of Patents may deem fit”.

3.11 Compulsory Licence Due to Circumstances of Extreme Urgency (health emergency etc.)

Under these circumstances the formulation of provision in the national legislation could be as follows:

- “In the circumstances of extreme urgency which may arise as the case may be including HIV/AIDS, malaria, tuberculosis or prevention or control of any other epidemic among human beings or animals and control of crisis relating to pollution of air or water or soil as notified by the concerned authorities in the Government for the country as a whole or any region of the country, the Controller of Patents shall issue authorization of rights on relevant patented products to any enterprise interested on such terms and conditions as the Controller may deem fit”.

3.12 Compulsory Licence in Cases of Public Non-commercial Use

The circumstances of public non-commercial use are totally different from other contingencies. The formulation in the patent legislation could be as follows:

- (1) “At any time after the expiration of three years from the date of sealing of the patent any enterprise may make an application to the Controller of Patents for grant of compulsory licence for using the patented substance to produce finished formulations from such a substance for distribution/sale on public non-commercial basis i.e. on no profit no loss basis;
- (2) that the concerned enterprise shall furnish a certificate to the Controller at the end of each year that the product has been used for public non-commercial purposes;
- (3) that the term of the licence will be as may be requested by the applicant and may extend to the term as available to the patentee. The royalty payable to the patentee shall be decided by the Controller of Patent in consultation with the patentee”.

3.13 Compulsory Licence to Remedy Anti-competitive Practice

Article 31 (k) provides for procedure for remedying anti-competitive practice. The formulation of this provision could be as follows:

- “Where the situation of resorting to anti-competitive practice by the patentee has been determined after judicial or administrative process and that the need to remedy the practice has been notified by the government in the official gazette, the Controller of Patents will issue compulsory licence to remedy the situation. The terms and conditions of the compulsory licence will be decided by the Controller of Patents”.

3.14 Second Patent for an Invention Involving Important Technical Advance

Where an important technical advance of a considerable economic significance over the first patent has been justified by an interested enterprise to the satisfaction of the Controller of Patents, compulsory licence may be granted to the enterprise in consultation with the first patent holder on such terms and conditions as may be settled by the Controller of Patents.

4. TRANSFER OF TECHNOLOGY

Transfer of technology is another important aspect. Article 66 of TRIPS Agreement provides that “developed country members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country members in order to enable them to create a sound and viable technological base”. Similarly Article 7 of the TRIPS Agreement also provides that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology”. Doha Declaration on TRIPS Agreement and Public Health in para 5 (a) stipulates that “the provision of the TRIPS Agreement shall be read in the light of the object and purpose of the agreement as expressed, in particular, in its objectives and principles”.

Keeping all these factors into consideration the formulation of the relevant provision in the national patent legislation could be made as follows:

- "It shall be incumbent upon the patentee to transfer technology to the licensee to manufacture the patented product for which a compulsory licence has been granted by the Controller of Patents. Any refusal to transfer technology may result in such action as the Controller may decide after giving a due notice to the patentee".

5. PARALLEL IMPORTS

Need for parallel imports arises when availability of patented product is not sufficient to meet the demand. This type of contingency can arise similar to the situation as it arose in USA about the availability of 'Anthrax', availability of HIV/AIDS drugs in African countries. and the most recent phenomena of SARS in China, Hong Kong and certain other countries **There are no effective drugs for SARS so there was no drug to "Parallel Import"; however if there was a drug then there would have been the need. Should this be therefore rephrased or too complicated and simply omit it?** To meet such a kind of contingency it is important that the national legislation must provide for clear cut provision so that no constraint is raised when parallel imports are authorized. Similarly, it should also be possible to import patented products if they are available in foreign markets at prices lower than the prices at which the same are being marketed by the patent holder in the country. According to Doha Declaration the member countries are free to establish their own regime for such exhaustion of right without challenge, subject to National Treatment and Most Favoured Nation Treatment under provisions of Articles 3 and 4 of the TRIPS Agreement.

Relevant provision may be made in the national legislation as follows:

- "For the purpose of this Act importation of patented product at cheaper price or to meet the shortages by any enterprise from an enterprise which is duly authorized by the patentee or the licensee to produce and to sell or distribute the product shall not be considered as an infringement of patent rights provided the same is authorized by the Controller of Patents."

6. BOLAR EXCEPTIONS AND USE OF PATENTS IN RESEARCH

Article 30 of the TRIPS Agreement on exception to rights conferred provides as follows:

- “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account of the legitimate interest of third parties”.

Certain acts which do not hurt the legitimate interests of the patent holder are for the purposes of experiment, research and imparting of instructions to the students. These acts do not in any way hurt the commercial interests of the patentees.

In 1984, a provision in the U.S. Hatch-Waxman Act reversed a court ruling that prohibited Bolar Pharmaceutical from testing a Roche Product patented drug. Bolar was using the patented drug in tests it needed to seek FDA approval for a generic that would be marketed when the Roche patent expired. This provision in the U.S. Law speeds the introduction of products after expiry of patents.

Since the TRIPS Agreement in Article 30 allows for exceptions which do not unreasonably conflict with the normal exploitation of the patent, provision can legitimately be made in the national legislation to provide for research on the patented product for taking marketing approval. The patented drug would however be marketed by these enterprises only after the patent has expired or compulsory licence is taken from the concerned authorities for exploitation of the patent.

The provision in the national legislation could be made as follows:

- “The grant of patent shall be subject to the condition that any product, machine, or apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used and

any process in respect of which the patent is granted may be used, by any person, for the purpose of experiment or research for taking marketing approval and imparting of instructions to students provided that such a use does not unreasonably conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interest of the patent holder”.

7. FRAMING OF POLICIES

It is important that health policy should specify goals over periods of 5 years and 10 years to achieve the objective of eradication of diseases prevalent in the country. Similarly it is also important to plan for strengthening of matching infrastructure for Health care during these periods. Along-side it is also relevant to formulate Pharmaceutical policy. The demands of pharmaceutical products over a period of 5/10 years of essential drugs and other important drugs should be determined providing annual growth rate. In order to achieve the demand targets appropriate incentives should also be available to the pharmaceutical industry. Thus co-relation of Health policy with Pharmaceutical policy will help in putting objectives of both the policies on firm footings to take care of problems of health-care in the country. This approach will strengthen the self-reliance factor.

R&D is an important component for improving the potential of the pharmaceutical industry. Developing of process technologies both for pharmaceutical raw materials and finished products could be accomplished by encouraging pharmaceutical industry to establish their own R&D base. Suitable incentives should be provided by the government in this direction. It may also be desirable to set up R&D Centre in the public sector independent of the government pharmaceutical companies.

Developing of Import policy is another important component for augmenting the domestic availability of drugs and pharmaceuticals. Since the demand is not large, it might be desirable to establish a government agency for centralized imports. It would thus be possible to import pharmaceutical raw materials and finished pharmaceutical products at competitive prices from abroad if the imports are centralized.

Co-relation of all policies viz., Health Policy, Pharma policy, R&D policy and Import policy must be ensured with the National patent laws. The goals stipulated in these policies would thus be achievable keeping the obligations of smooth implementation of TRIPS patent regime in view. In fact the proposed substantive provisions for patent legislation are in this direction.

8. PRICE REGULATION OF PHARMACEUTICAL PRODUCTS

During discussions on presentations, participants raised an issue regarding price control for pharmaceutical products. In order to ensure that pharmaceutical products are available at affordable prices a system of price regulation in some form or the other could be evolved. To start with, it was suggested that essential drugs could be brought under price regulation system. However, the margins which should be available on these drugs to the industry, distributors and chemists should be such that their interest in these essential drugs does not diminish.

In addition selected drugs whose raw materials are being imported from abroad should also be brought under some system of regulation of prices with slightly better margins to compensate for lower margins for essential drugs. As far as possible the essential drugs should enjoy total tax exemption on imports, production and sales.

Apart from this there should also be a policy for regulation of prices of patented drug in relation to other drugs in the same therapeutic group. TRIPS Agreement has stipulated no constraint on imposing of price control system on patented products.

9. CAPACITY BUILDING

Capacity building is extremely important for successful and smooth implementation of the patent laws. It is extremely necessary that an efficient IPR organization is established well before all the IPR laws are enacted. Well trained examiners of patents in different disciplines should be in position before the new patent system is enforced from 1.1.2005. If need be the

examiners could be trained with the help of similar institutions in other developing countries. There is also a need to establish a data base to ensure examination of validity of the patent claims. A computerized system for registration of patent applications should also be developed soon.

It is important to frame Patent and other IPR Rules to ensure appropriate procedures for submission of applications, examination of claims, grant of patents, grant of compulsory licences and completion of other relevant provisions of the law.

A system of inviting public objections on the validity of the patent claim should also be established in the patent laws so that before the patent is granted it is ensured that frivolous claims on subject matter which has already fallen in public domain are neither entertained nor approved.

To help the capacity building in the government organizations, in the research centres, in the industry and legal professionals participation in national and international seminars is encouraged and sponsored. Similarly the concerned persons could be sponsored to various law universities, institutions concerned with operation of IPR systems in other countries for better exposure on various aspects of the patent system. Efforts should also be made to establish reference libraries in the government and law teaching institutions with various publications, journals and research papers on intellectual property rights.