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Review of Patent Legislation of India, Indonesia, Sri Lanka and Thailand

Measures to Safeguard Public Health



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PREFACE

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is one of the Agreements of the World Trade Organization (WTO) which is being debated worldwide by civil society and also by certain inter-governmental organizations. Following implementation issues raised at governmental levels jointly by several developing countries, the Council for TRIPS also started discussing in 2001 the implications of the TRIPS Agreement on access to medicines. The main purpose of these discussions was to clarify the flexibilities in TRIPS to which the Member States were entitled to for incorporation in their national patents legislation. Consequent to the debate in Council for TRIPS and further extensive discussions at the Ministerial Conference held at Doha in November, 2001, a Declaration on the TRIPS Agreement and Public Health was adopted by the Ministerial Conference on 14th November 2001. This Declaration is an important landmark for the developing and least developed countries as the gravity of the public health problems has been recognized, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. The Declaration *inter alia* clarified that the TRIPS Agreement did not and should not prevent members from taking measures to protect public health. The Declaration also reaffirmed the right of the members to use to the full, the provision in the TRIPS Agreement which provides flexibilities for this purpose. It also stated that members were free to determine the grounds upon which compulsory licences could be granted. Similarly, the legitimacy of parallel imports have also been expressly confirmed so that Member countries could legislate this provision applying the doctrine of international exhaustion. The full text of the Doha Declaration on the TRIPS Agreement and Public Health may be seen at Annexure 1

The World Health Organization's, Regional Office for South-East Asia, (SEARO) has held several regional and sub-regional meetings on the subject of the potential impact on the access to essential drugs, specifically in developing countries. Consequent to the implementation of the TRIPS Agreement in their national patent legislation, SEARO had recommended that Member countries should review their national patent legislation in the context of public health and that WHO could assist them in this exercise.

EXECUTIVE SUMMARY

TRIPS is a most contentious agreement of WTO which is being debated worldwide in developing and developed countries and also in many important international organizations. The major focus of the debate is on the accessibility and affordability of medicines in developing countries. The issues were hotly debated in the Doha Ministerial Conference in November 2001 and the result was the Doha Declaration on TRIPS Agreement and Public Health. The Declaration has recognized the gravity of the public health problem affecting many developing and least developed countries especially those related to HIV/AIDS, tuberculosis, malaria and other epidemics. The Declaration also clarified the flexibility and freedom available to Member countries about the grant of compulsory licenses and the freedom to determine the grounds upon which such licenses could be granted.

This review deals with the identification of measures necessary to safeguard public health interests in the patent legislations of India, Indonesia, Sri Lanka and Thailand keeping in view the TRIPS Agreement, Doha Declaration and national health, pharmaceutical and research and development policies. In order to comprehend the issues, extensive discussions were held with concerned officials in these countries, representative of the pharma industry and other stakeholders. Simultaneously the current patent laws of these countries were also examined in depth to ascertain as to how far the public health interests could be effectively protected.

The relevant components of the patent laws which would safeguard public interest have been identified as follows:

- (1) Scope of patentability in relation to pharmaceutical substances, identification of inventions which are not patentable to ensure that frivolous claims are not entertained and appropriate definition of patent terminologies.
- (2) Structuring of provisions relating to voluntary licenses, compulsory licences and authorization of right within the

parameters of the Paris Convention, TRIPS Agreement and Doha Declaration. Issues relating to royalty payable on grant of these licenses.

- (3) Issues relating to parallel imports, export of patented products and pricing of patented products.

It is observed that the patent laws of all the four countries are weak from the point of view of scope of patentability, grant of compulsory licences to domestic enterprises and their role, parallel imports and export of patented products. Though the Doha Declaration on TRIPS Agreement and Public Health has clarified the flexibilities and freedom which could be exercised by Member countries for taking measures to protect public health, the Indian Patents (Second Amendment) Act 2002 has not been formulated to fully take advantage of the spirit of the Declaration. The grounds to realize the role of domestic enterprises in the availability and affordability of medicines are weak and need to be strengthened Chapter XVI on compulsory licence in the Patents (Second Amendment) Act 2002 should have provided the following possibilities of licensing patented products to domestic enterprises:

- (1) Grant of voluntary licence by the patentee who may not himself like to establish his own infrastructure in the country to promote his product;
- (2) Grant of compulsory licence because of abuse of patent rights by the patentee in various regions of the country as India being a large country sub-licensing is essential for establishing production facilities in various regions of the country;
- (3) Grant of compulsory licensing because of unsuccessful attempt by an enterprise with the patent holder to obtain licence for commercial activity on reasonable commercial terms and conditions;
- (4) Grant of licence separately for each contingency relating to national emergency, circumstances of extreme urgency (health and environmental emergencies) or in case of public non-commercial use. It is important that the term of these licences should be co-terminus with the term of patent.

The other important aspect about the scope of patentability needs to be formulated on the basis of specific recommendations of the Pharmaceutical

Research Committee headed by Dr R.A. Mashalkar, a senior scientist and Secretary to the Government of India.

As regards the Patents Act 2001 of Indonesia there is a need to provide for patenting of new pharmaceutical substances which should include New Chemical Entity/New Medical Entity or new bulk drug involving inventive steps and capable of industrial application. Similarly, there is also a need to strengthen the scope of exclusion of inventions from patentability so that frivolous claims are not entertained. The Articles which stipulate right to grant licences need to be revised making appropriate provision relating to compulsory licences on account of abuse of patent rights by the patent holder, unsuccessful attempt by local enterprises to obtain licences from the patent holder for commercial activity on reasonable commercial terms and conditions. The grant of licences during national emergency, circumstances of extreme emergency and public non-commercial use also need to be provided separately and adequately for each contingency.

An analysis of the Intellectual Property Bill, 2003, of Sri Lanka, indicates that there is no specific provision for grant of patent for new pharmaceutical substances which could be only for New Chemical Entity/New Medical Entity. There is no specific provision for grant of compulsory licence in the Bill. There is a need to provide for the same to cover voluntary licensing, compulsory licences due to abuse of patent right, grant of compulsory licence due to unsuccessful attempt by a domestic enterprise and grant of licences due to national emergency, circumstances of extreme emergency and public non-commercial use. There is also a need to specifically provide for parallel imports to meet demands and also if the patented products are available at cheaper prices in other countries.

As regards the patent laws of Thailand of 1999, there is no specific provision for patentability of new pharmaceutical substances which could be for New Chemical Entity/New Medical Entity. The scope of inventions which are not patentable also needs to be enlarged. The provision relating to compulsory licensing needs to be strengthened in cases of national emergency or circumstances of extreme emergency or public non-commercial use. The provision in regard to these contingencies needs to be provided in an explicit manner and separately for each contingency.

Keeping the Doha Declaration in view, various possibilities of strengthening national patent legislation in these four countries has been spelt

out in Chapter IV. If these countries provide for various possibilities, the question of accessibility and affordability of medicines would be met to a considerable extent. Similarly, the goals and objectives of the national health, pharmaceutical and R&D policies could be smoothly achieved.

INTRODUCTION

The TRIPS patent system envisaged in the TRIPS Agreement has multi-dimensional implications particularly for developing countries. This WTO agreement is being debated world-wide in developing and developed countries and also in many important international organizations. The discussions have focused on the concerns of stakeholders such as the general public, small and medium industries in developing countries, scientists and transnational corporations. The nature and perceptions of these stakeholders differ widely. While the transnational corporations are concerned with high profits, the general public seeks easy access to medicines at affordable prices. The scientists and small and medium industries want freedom to play a substantive role respectively in their countries. The need is for a balanced patent system which would satisfy the aspirations of all the stakeholders including the general public. To a considerable extent this has since become possible for developing countries due to clarifications provided in the Doha Declaration on TRIPS Agreement and Public Health.

The national health laws and policies on health care, national pharmaceuticals and research and development policies have an intense co-relation with the national patent system. None of these laws and policies can be framed and successfully implemented in isolation. The primary objectives of co-relation should be to help in the smooth implementation of these policies and application of patent laws. An extremely careful approach is therefore necessary in framing these laws and policies.

A major focus has since emerged about combating diseases like HIV/AIDS, tuberculosis, malaria and other epidemics. During the past two/three decades, there have been laudable contributions by science and technology to successfully tackle many health problem areas. While there is a substantial unfinished agenda on the health front in developing and least developed countries, new formidable challenges have been thrown up by the multilateral treaty on all pervasive economic and social aspects in the policy of international trade liberalization, globalization and privatization of services related to health care, drinking water and sanitation and, in particular, to adopt the patent system as incorporated in the TRIPS Agreement.

The setting up of the WTO, with a new comprehensive mandate contained in 28 legal texts (Agreements), has brought up a totally new environment for policy and law-makers at national and international levels. In particular, the TRIPS Agreement is the most contentious and comprehensive international instrument on all types of intellectual property rights (IPRs). Tough standards being practiced in technologically advanced countries have been laid down in this Agreement in order to obtain worldwide protection for the innovations generated in those countries by their corporations. According to a paper¹ published by the World Health Organization (WHO), the standards stipulated in TRIPS Agreement are not necessarily appropriate for all countries' level of development. The important feature of the various new IPR regimes is for strengthening the rights of the owners of IPRs whereas their obligations have been significantly diluted. The Member countries of WTO are under obligation to enact or amend their domestic legislation for various IPRs to conform to the provisions of the TRIPS Agreement.

Worldwide, national governments in the past used their sovereign prerogative to evolve their own approach towards their patent systems, particularly for drugs and pharmaceuticals. They gradually modified the patent laws related to their stage of development. IPR laws in these countries, therefore, were compatible with their developmental objectives. The right to subserve the public interest in these countries prevailed over the intellectual property right whereas in the developed countries the welfare objectives are no longer their concern – profiteering is the sole objective of the transnational corporations through patent monopolies. In this background the patent systems of countries as such differed widely from one another. National laws have been gradually upgraded in the developed countries to provide for greater protection to their scientific and technological achievements. For example, Italy, UK, Germany, Switzerland and Japan changed over to the product patent from process patent system in the pharmaceutical field only recently. The evolution of IPRs standards has been particularly tangible following changes in the relative technological strength of different industries in these countries.

The TRIPS Agreement expects WTO Member countries to adopt minimum standards on patent laws as stipulated therein. The Doha

¹ A.P. Series No. 7 – November 1997: Globalization and Access to Drugs - Implication of TRIPS Agreement.

Declaration on TRIPS Agreement and Public Health recognizes the gravity of public health problems afflicting the poor countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. For core areas of concern the Declaration provides that each country has the right to grant compulsory licenses and have also freedom to determine the grounds upon which such licenses are to be granted. Further, it is also stated in the Declaration that in applying the customary rules of interpretation of public international laws, each provision of TRIPS Agreement should be read in the light of its objectives and principles. In the background of the flexibility and freedom available to Member countries as stated above the national legislation on patent laws in India, Indonesia, Thailand and Sri Lanka could ensure that there is proper co-relation of the amended patent system with the National Health Policy, Pharmaceutical Policy and Research and Development Policy so that the objectives of these policies are fully accomplished.

Indonesia and Thailand amended their patent laws before the Doha Declaration was announced. Sri Lanka also since amended its patents law only recently. India amended its patent law after the Doha Declaration. It has to be examined as to how far the spirit of the Doha Declaration on TRIPS Agreement and Public Health clarifying the flexibilities and freedom are reflected in these laws. In the subsequent chapters the health scenario, status of the pharmaceutical industry and research and development and the relevant policies have been analyzed. Thereafter, the core issues of concern arising from TRIPS Patent System and the relevant features of the national legislation have been examined in-depth in two separate chapters. In conclusion, it is for the countries' concerned to decide as to what extent they would like to strengthen their patent laws keeping in view the possibilities available as discussed in Chapter IV to achieve the objectives of easy accessibility of drugs and medicines.

Chapter I

Health Scenario and Health Policies: India, Indonesia, Sri Lanka and Thailand

- 1.1 The World Health Organization (WHO) defines² health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”. Public health refers to all organized measures to prevent disease, promote health, and prolong life of the population as a whole.
- 1.2 Health is humankind's most basic and essential need. It is the most precious possession, next perhaps only to life itself. Good health is important for a variety of reasons. Health and the linkages between health policies and trade related issues are the major concern of mankind especially for the vast masses living in developing and least developed countries. Public health is rapidly emerging at the centre stage of health care in every country. WHO is playing a major role in determination of public health policies, strategies and implementation of relevant programmes.
- 1.3 WHO estimates³ that currently one third of the world's population lacks access to essential drugs and that over 50 per cent of people in poor countries in Africa and Asia do not have access to even the most basic essential drugs. According to WHO⁴, access to essential medicines and vaccines depends on four critical elements:
 - (1) rational selection and use;
 - (2) sustainable financing;
 - (3) reliable supply systems; and
 - (4) affordable prices.

² WTO Agreement and Public Health – Published by WTO VII-2002 – Introduction

³ WTO Agreement and Public Health – Published by WTO Secretariat VII – 2002 (p.16)

⁴ *ibid*

Drug prices are likely to be influenced by some of the WTO Agreements. For example, WTO negotiations led to the elimination or reduction of import duties on drugs, vaccines and other medical supplies in Member countries. This would help in lowering prices in the importing countries. However, TRIPS Agreement will establish monopolies, which would lead to an increase in drug prices due to more stringent patent protection. It will also effect the role of the domestic pharmaceutical enterprises in making available drugs at competitive prices.

- 1.4 Since the inception of GATT more than 50 years ago, Article XX of GATT guaranteed Members the right to take measures to restrict imports and export of products when those measures are necessary to protect the health of humans, animals and plants. TRIPS does not contain any exception for health purposes per se, but it does allow measures necessary to protect public health and nutrition, provided they are consistent with other TRIPS provisions (Article 8 -Principles). Doha Declaration on the TRIPS Agreement and Public Health also aims at the concern expressed about the possible implication of the TRIPS Agreement for access to drugs. It does so in a number of ways, such as that 'TRIPS Agreement does not and should not prevent members to protect public health and confirms the right of members to use in full the provisions of TRIPS Agreement for this purpose'. Thus it is now for the Member countries to ensure that their patent laws are framed in such a manner that the objectives of health – care are not hampered in any way. Health scenario and health policies parameters of the four countries have been specifically analysed to focus that framing of patent laws is an important exercise to achieve health care objectives and goals.

India: Health Scenario

- 1.5 The major cause of concern in the health area in India is the ever-growing population which now exceeds 1,000 million. India thus ranks 2nd in global population after China. The average growth rate of population declined from 2.14 per cent in the 80s to 1.93 per cent in the 90s. The census of 2001 estimated the population of India at 1,027 million – 531 million male and 496 million females. India's GDP was US\$ 464.6 billion during 2000 and its per capita income during the same year was US\$ 459.

- 1.6 HIV/AIDS has emerged as one of the most serious public health problems in the country. In mid-2001 the total number of HIV cases was 3.97 million. A multi-sectoral approach has been adopted to tackle this problem. HIV/AIDS is also accompanied by social stigma, which leads to other social and psychological problems. Because of this reason, detection of such cases and timely treatment becomes rather difficult. To overcome this problem, creating community awareness is being emphasized. In the sphere of leprosy elimination of leprosy an intensive media campaign was launched. The prevalence rate declined from 57 per cent per 10,000 population in 1981 to 3.74 cases per 10,000 population in March 2001. The objective is to reach elimination at national level by 2004. As regards activities under the revised national tuberculosis control programme the population coverage increased from 120 million to more than 440 million in 2001 with the help of a World Bank assisted project. The government has a plan to expand coverage to 700 million population.
- 1.7 In the above context, the government initiatives in the public health sector have recorded noteworthy successes. Smallpox and Guinea-Worm disease have been eradicated from the country. Polio is on the verge of being eradicated. Leprosy, kala-azar and filariasis can be expected to be eliminated in the foreseeable future. There has been a substantial drop in the total fertility rate and infant mortality rate. The success of these initiatives is seen in the progressive improvement of many demographic/epidemiological and infrastructural parameters over time as reflected in the following table.

Achievements between 1951 and 2000

Indicator	1951	1981	2000
Demographic Changes			
Life Expectancy	36.7	54	64.6
Crude Birth Rate *	40.8	33.9	26.1
Crude Death Rate *	25	12.5	8.7
Infant Mortality Rate *	146	110	70

* per 1000 population

India: Health Policy

1.8 The main objective of the health policy announced by the government in 2002 is to achieve an acceptable standard of good health for the people. The approach would be to increase access to decentralized public health system by establishing new infrastructure in deficient areas, and by upgrading the existing infrastructure. Overriding importance has been given to ensure a more equitable access to health services across the social and geographical expanse of the country. Emphasis will be given to increasing the aggregate public health investment through a substantially increased contribution by the Central government. It is expected that this initiative will strengthen the capacity of the public health administration at the state level to render effective service delivery. The contribution of the private sector in providing health services would be significantly enhanced, particularly for the population group which can afford to pay. Primacy will be given to preventive and first-line curative initiatives at the primary level through increased allocations. Emphasis will be laid on rational use of drugs within the allopathic system. Increased access to tried and tested systems of traditional medicine will be ensured. Within these broad objectives, the new Health Policy – 2002 will endeavour to achieve the time-bound goals provided therein.

Indonesia – Health Scenario

1.9 The population of Indonesia was 204 million according to the 2000 census making it the fourth most populous country, after the Republic of China, India and United States. The population growth rate was 1.35 per cent annually during the period 1990-2000 compared to 1.97 per cent annually during the 1980s. The GDP of Indonesia in 2000 stood at US\$ 152.2 billion and the per capita income was US\$ 738.

1.10 In the general context⁵ during the last 30 years the standard of health has shown a meaningful improvement despite a sharp disparity between inter-regional and inter-population groups. Life expectancy at birth

⁵ Strategic plan for Health Development 2001-2004, Ministry of Health 2001 (pages 10 and 16)

during the period 1967-1997 increased approximately from 45.7 to 64.2 years. For the period 2000-2005, the projection of life expectancy indicates an increase up to 68.2 (approximate). The infant mortality rate showed a consistent decline starting from 71 during 1990 to 51 during 1995 and finally to 41.4 during 1997 per thousand live births. The child mortality rate also declined from 111 to 81 per thousand under the age group of 5 during the period 1986-1993. The maternal mortality rate declined from 540 per 100,000 live births during 1986 to 390 during 1994. The crude death rate also declined from 7.9 per 1000 population during the period 1985-1990 to 7.1 during 1990-1995. The Strategic Plan for Health Development 2001-2004, aims to elaborate the relevant laws to identify intervention programme strategies reflecting conformity, commitment, cooperation, coordination and integration amongst the internal and external elements to achieve the goals of health development.

- 1.11 Indonesia faces problems of infectious and parasite diseases. Malaria is endemic with the annual incidence fluctuating from 20 per cent in 1995 to 16.1 per cent in 1997 and finally to 21.6 per cent in 1998. Dengue haemorrhage fever (DHF), was reported for the first time in 1968, the number of cases increasing sharply thereafter. During the period 1995-1999 the number of dengue cases fluctuated from 35,102 in 1995 to 72,134 in 1998 and finally to 21,134 in 1999. The incidence rate of Anthrax among humans declined from 88 in 1992 to 18 during 1996. In some provinces, Anthrax among animals remains endemic/sporadic.
- 1.12 As regards HIV/AIDS, reported for the first time in 1987, the number of positive cases rapidly increased during the period 1991 to 2000. The number of HIV/AIDS cases increased from 24/23 in 1991 to 438/1,083 during 2000. The distribution of AIDS cases by age group indicate a relatively high proportion among young adults aged 20-29. The number of tuberculosis cases reported in Indonesia during 1998 and 1999 are 40,497 and 69,064 respectively. Similarly, the number of smear-positive cases reported during the same period are 32,280 and 49,170. The smear-positive cases are capable of spreading the disease to other people.

Strategic Plan for Health Development 2001-2004

1.13 To tackle the health problems the government evolved a strategic plan for health development during 2001-2004. The paradigm of health management which used to be very centralistic has completely changed now following the issuance of Laws – No. 22 and 25 of 1999. In practice, both laws have withdrawn the major exclusive authority of the central government in formulating health and other social policies. The local governments have now been given the authority to develop a health policy that is more responsive to the specific needs of their population.

Sri Lanka - Health Scenario

1.14 The mid-year population of Sri Lanka in 2000 was estimated at 19.4 million. The population growth rate since 1981 has been approximately 1.7 per cent. The GDP in 2000 was US\$ 16.3 billion with a per capita income of US\$ 882. In 2000 the economy expanded strongly due to revival of economic activity that commenced in 1999 and recorded a real growth rate of 6 per cent which was significantly above the 4.3 per cent rate of growth in 1999.

1.15 According to the Annual Health Bulletin 2000, life expectancy at birth increased from 70 years in 1981 to 73 years in 1996. The crude birth rate declined significantly from 28.2 in 1981 to 20.7 in 1991 per thousand population.

1.16 The network of health facilities has been of a satisfactory level. As of December 2000, there were 558 medical institutions with inpatient facilities⁶ and 404 central dispensaries compared to 556 and 383 respectively in 1999. The number of hospital beds increased from 55,195 in 1999 to 57,027 during 2000. The National Hospital of Sri Lanka located in Colombo, is the largest hospital in the island. In 2000 it had 2,881 beds. This hospital provides for a number of specialities and sub-specialities.

⁶ Issued by Department of Health Services, Sri Lanka

1.17 Cases of deaths from notifiable diseases are received from government medical institutions. In 2000, 83 cases of Japanese encephalitis were reported from medical institutions. Immunization programmes for children were carried out in almost all provinces. During 2000, 3,343 cases of dengue fever and dengue haemorrhagic fever were reported from government institutions. Measles is an important childhood disease. Five years after introduction of the measles vaccine in 1990, the overall immunization coverage had increased to 80 per cent. Over the years, the coverage gradually increased and in 2000 it reached 100 per cent. Malaria continues to be a major public health problem. Leprosy continued to decline in spite of a slight increase in the case detection rate. This indicates that leprosy transmission is still not completely interrupted.

Thailand – Health Scenario

1.18 Thailand had a population of 61 million in 1997. The GDP stood at US\$ 152.2 billion in 2000 and the per capita income was US\$ 2,018. Thailand is a developing country with a market-oriented health system⁷.

1.19 The selected health and socio-economic indicators of Thailand during 1997 were as follows:

Infant Mortality Rate per 1,000	30
Death under age 50 as percentage of total	39
Life expectancy at birth (years)	69
Adult literacy rate, percentage (1995)	93.8
Public expenditure on health Percentage of GDP 1990-1995	1.4

(Source: World Development Report, 1998/99 and the WHO Report 1998)

⁷ Papers prepared at inter-regional workshop on Trade and Health (1999) by Dr Janjaroen, Professor of Economics and Associate Dean, College of Public Health, Chulalongkorn University.

Thailand: Health Sector Development Plans

1.20 The Thai Food and Drug Administration staff total 492 of which 25 are administrators, 285 comprise pharmacists, nutritionists and food technologists and 43 are professionals. By 2006, FDA has the following vision:

"...the FDA will be the principal organization of Thailand that the population can trust in its mandate about consumer health protection - Towards scientific based and proper technology; this will ensure the safety of health products and empower consumers' behaviour."

The Ministry of Public Health is concerned⁸ with the operational framework of the Public Health Development Plan in accordance with 'the Ninth National Economic and Social Development plan for the period 2002-2006'. In fact, the strategic planning process of the Ministry of Public Health has been classified into two levels:

- The Ninth National Health Development Plan
- Plan 9 of Ministry of Public Health

The intent of both plans is to reflect in an organized and systematic way, the purpose, goals, strategies, actions, accomplishments, environment and challenges with the aim of making choices about allocating resources and aligning their constituents towards a desired future.

1.21 The 1997 Constitution of the Kingdom of Thailand and other legislative measures, political reforms as well as public sector administrative system reforms have had a significant impact on the health of population. Presently, there is an increase in noncommunicable diseases and the socio-economic-related diseases, such as suicides, homicides, violence and drug abuse. The Ninth National Economic and Social Development Plan places emphasis on holistic development based on the people-centered development approach together with the royal initiative of His Majesty the King on the "Philosophy of sufficient economy".

⁸ plan 9 of Ministry of Health.

The objectives of strategic plans are:

- (1) To foster proactive health that centres on health promotion, and life safety in terms of food safety and security, occupational health and safety, consumer protection and disease control.
- (2) To establish a security net that protects population health from economic and social impacts as well as developing and establishing a safety net for equal access to quality health services, especially for the poor and the deprived.
- (3) To strengthen the capacity of individuals, families, communities and society in caring for and promoting their health, creating learning and participatory approaches and strengthen health system administration.
- (4) To promote innovative mechanisms and measures for health development through research and development by integrating international knowledge and Thai folk wisdom for health self-reliance.

1.22 To achieve the above objectives the following targets have been laid down in respect of quality of life upgrading:

- (1) Maintaining an equilibrium of demographic structure
- (2) Availability of social security system for the Thai people at every stage of life.
- (3) The proportion of the indigent shall not exceed 12 per cent of the total population in 2006.
- (4) Infant mortality rate shall not exceed 15 per 1,000 live births.
- (5) Maternal mortality ratio shall not exceed 18 per 100,000 live births.
- (6) Life expectancy at birth; Female: from 74.9 to 77 years; Male: from 69.9 to 72 years
- (7) No polio cases

- (8) Prevalence rate of HIV/AIDS infections in
 - Male military recruits shall not exceed 1 per cent
 - Fertile females shall not exceed 1 per cent
- (9) Morbidity rate of tuberculosis: contaminated phase (positive sputum smear) shall not exceed 60 per 100,000 population
- (10) Morbidity rate of malaria nationwide shall be less than 1 per 1,000 population.

Observation

- 1.23 The health goals of all the four countries are laudable. Since the financial resources are limited, it is vital that there are least impediments in easy access to drugs at affordable prices to the general public. Impediments from the patent system need to be understood and the maximum flexibility available utilized in national legislation.

Chapter II

Pharmaceutical Industry Perspective: India, Indonesia, Sri Lanka and Thailand

- 2.1 In this review it is necessary to understand the capacities of the pharmaceutical industry to meet the new challenges arising from the TRIPS Agreement. The pharmaceutical industry in the past did not face any rigours of strong patent systems. The new situation is going to be totally different. A co-relation between the pharmaceutical policy and the patent laws has to be established to the maximum extent so that the industry is able to play its role adequately to facilitate easy access to medicines at competitive prices.

Pharmaceutical Industry: India

- 2.2 The pharmaceutical industry in India has been identified as one of the most important knowledge-based industries. Since the 1980's the industry has grown rapidly due to enactment of the Patents Act 1970 and announcement of the Drug Policy of 1978. The industry grew rapidly in every sector i.e. large-scale sector, medium-scale sector and the small-scale sector besides the public sector during the 1980s and the mid-1990s. The number of manufacturing units registered in this sector has since grown to over 22,000. The industry has recorded a growth of about 15 per cent annually during the last decade. Table 1 indicates⁹ the production of bulk drugs and formulations during this period:

⁹ Source: Report of the Working Group on Drugs and Pharmaceuticals for the 9th Five-Year Plan (1997-2002)

Table 1

Year	Bulk drugs production (in Indian Rs)	Formulation production (in Indian Rs)
1993-1994	13,200	69,000
1998-1999	31,480	138,780
2000-2001	45,330	183,540
2001-2002	54,390	211,040
2002-2003*	65,290	241,850

*Estimated

2.3 The industry has also shown significant growth in export of drugs to developed and developing countries. The quality of drugs produced and exported has been of world-class standards. The following table¹⁰ shows the export potential of the industry. The imports have also been shown for the purposes of comparison.

Table 2

Year	Exports (Rupees in millions)	Imports (Rupees in millions)
1992-1993	14,901	11,374
1998-1999	61,520	30,473
1999-2000	72,302	15,020
2000-2001	87,299	20,325
2001-2002*	104,759	25,812

*Estimated

¹⁰ Source: Report of the Working Group on Drugs and Pharmaceuticals for the 9th Five-year plan (1997-1990-2001-2002)

- 2.4 The drugs and pharmaceutical industry in India is facing new challenges on account of liberalization of the Indian economy, globalization of the world economy and on account of obligations undertaken by the government under the WTO Agreements. The process of liberalization which was set in motion in 1991 and the WTO obligations required substantial reduction in the tariff barriers (custom duties) and totally removed the non-tariff barriers on imports. Similarly, foreign investment was also raised from 51 per cent to 74 per cent in March 2002 and the same has since been raised to 100 per cent. The other obligations in WTO Agreements requires drastic changes in the Patents Act 1970 which has been amended twice to meet the obligations. The future scenario for this important sector has thus been drastically changed.
- 2.5 In view of these challenges, a new Pharmaceutical Policy was announced in 2000. The main objectives of this policy are:
- (1) Ensuring availability at reasonable prices of quality essential pharmaceuticals of mass consumption.
 - (2) Strengthening the indigenous capability for cost-effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.
 - (3) Strengthening the system of quality control of drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals.
 - (4) Encouraging R&D in the pharmaceutical sector compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an environment conducive to canalising a higher level of investment into R&D in pharmaceuticals in India.
 - (5) Creating an incentive framework for the pharmaceutical industry to promote new investment and encourage the introduction of new technologies and new drugs.

Research and Development

- 2.6 As regards encouragement to research and development, there are sufficient incentives available. However, in order to encourage basic research in pharmaceuticals there is a need for substantial financial support from the government.
- 2.7 In the new scenario, the Patents Act 1970 needs to be amended to ensure that the poor are not affected by high prices of medicines and that the pharmaceutical industry is further strengthened.

Pharmaceutical Industry: Indonesia

- 2.8 The pharmaceutical industry in Indonesia comprises the pharmaceutical industry, traditional medicine industry and the small-scale medicine industry. The Indonesian Health Profile 2000 indicates how the different sectors of this industry have grown during 1991- 1998. The data is given in the following table:

Table 3

Type of industry	Number of units			
	1991	1994	1997	1998
Pharmaceutical industry	256	224	224	198
Traditional medicine industry	4	23	76	79
Small-scale traditional medicine industry	372	458	555	607

In 2002 the number of pharmaceutical manufacturers remained the same i.e. 198. These manufacturers consist of:

Government-owned companies	4
Multinational companies	32
National companies	162
	198

2.9 The domestic pharmaceutical industry can meet nearly about 90 per cent of the national demand for medicines. However, 90 per cent of the raw material requirements to produce the formulations are imported. Although the availability of medicines is not affected, the dependence on imports has caused sharp price volatility. In fact, during the prolonged multidimensional crisis, the production of medicines as well as traditional drugs decreased whereas the distribution facilities had grown. The pharmaceutical market size in terms of value has increased as follows:

Year	Indonesian Rp (in billion)
1999	7,560
2000	9,944
2001	12,629
2003 (estimated)	15,965

For some years, dependence upon imports will continue.

Pharmaceutical Industry: Sri Lanka

2.10 The pharmaceutical industry in Sri Lanka is very small. The State Pharmaceutical Corporation (SPC) imports both the finished formulations and bulk drugs. It imports about Rs 4 billion worth of medicines for the Directorate of Health Services. It also imports about Rs 0.7 billion worth of raw materials for the private sector. There is also a State Pharmaceutical Manufacturing Corporation (SPMC) which mostly formulates drugs imported by the SPC. The local manufacturers produce about Rs 1 billion worth of pharmaceuticals.

2.11 There are only nine local manufacturers which include Glaxo, and Smith Kline Beecham. These two companies are the subsidiaries of foreign companies. Inter Pharma is another pharmaceutical company which manufactures pharmaceuticals on licence basis from a foreign company. In addition to these three companies which have foreign links, there are only six other pharmaceutical manufacturing companies. The total turnover of the pharmaceutical industry is as follows:

SPC imports	Rs 4 billion (Sri Lankan Rupees)
Private sector imports	Rs 3.5 billion
Private sector imports through SPC	Rs 0.7 billion
Local manufacturer's turnover ex-factory	Rs 1.2 billion
Total availability including surgical devices	Rs 10.3 billion

The pharmaceutical industry is thus totally dependent upon imports. There is no basic drug production in the country and this situation is likely to continue.

Pharmaceutical Industry: Thailand

2.12 The pharmaceutical industry in Thailand is at a disadvantage in relation to the world market mainly due to patents and tax barriers especially for pharmaceutical products that have been classified as Fast Track items.

Although pharmaceutical production has steadily increased with a growth rate of 13 per cent per annum before the economic crisis, this rate has been declining since 1999 to an average of 9 per cent per annum in the period 2000-2002. Additionally, the national health plan with its wider scope provides better access to basic health care. The aim is to provide equal access to health care for all with free medical services to the poor. This places the onus on health service providers to improve the quality of their services, bearing in mind that at the crux of the new health policy is the quality of service and satisfaction of the patients.

2.13 The hospitals are required to provide quality medication at the lowest price possible, hopefully leading to the use of pricing by pharmaceutical companies in their selling strategies. As a result, the Thai pharmaceutical manufacturing industry is facing difficulty as profit margins are reduced, precluding further research and development. The government pharmaceutical sector has allocated increased funding for R&D which in 2001 saw an increase of more than Thai baht 14 million for research into antiretroviral drugs, herbal medicines, and various drug delivery systems.

2.14 The number of drug manufacturing enterprises during 1989-1999 were as follows:

Year	Number of manufacturers
1989	191
1993	181
1997	175
1998	176

The value of production and importation of modern medicines in Thailand during 1988-2000 has shown substantial growth as follows:

Year	Production (in million Bahts)	Importation (in million Bahts)
1988	6,890	2,164
1992	11,082	5,797
1996	18,647	12,064
2000	21,678	19,219

2.15 The production and import of traditional medicines has also increased and has been as follows:

Year	Production (in million Bahts)	Importation (in million Bahts)
1988	244	75
1992	265	90
1996	319	140
2000	677	125

2.16 Thailand has also been active in export of pharmaceuticals as seen in the following data:

Year	Export (in million Bahts FOB value)
1988	545
1992	1,194
1996	1,785
2000	3,733
2001	4,322

Expenditure on R&D

2.17 Thailand's R&D expenditure in 1999 was 522 million bahts, an increase of 4.4 per cent compared to 1997.

Observations

2.18 The potential of the pharmaceutical industry in India is such that it is capable of meeting new challenges provided the constraints which can arise from the amended patent laws are suitably rectified. Both the 'scope of patentability' and 'compulsory licensing' provisions need to be carefully framed. Appropriate suggestions in respect of these issues have been incorporated in Chapter IV which ought to be adopted in the national legislation. Similarly the patent laws of other countries viz. Indonesia, Sri Lanka and Thailand could also be modified adopting the same suggestions. This will help in the growth of the pharmaceutical industry and for it to meet new challenges of easy access to medicines at competitive prices.

Chapter III

Important Features of Patent Laws of India, Indonesia, Sri Lanka and Thailand Relating to Access to Pharmaceuticals and Suggestions for Strengthening Relevant Provisions

3.1 In this chapter, relevant provisions of the patent laws of the four countries relating to access to pharmaceuticals have been analyzed. The scope of the review however, is limited to the following issues:

- (1) Patentable subject matter relating to pharmaceuticals;
- (2) Inventions not patentable;
- (3) Important definitions of technical terms;
- (4) Compulsory licensing;
- (5) Parameters of royalty payment on licensing;
- (6) Parallel import of patented pharmaceuticals, and
- (7) Export of pharmaceuticals.

Before the patent laws are analyzed keeping the above issues in view, it is relevant to state the historical perspective of the patent laws in these countries.

Patent Laws of India

History of Evolution

3.2 In India, the first Act relating to patent rights was enacted in 1856. This Act granted certain exclusive privileges to inventors for a period of 14 years. This Act was, however found defective and was modified in 1859.

Under the 1859 Act, patent monopolies were called 'exclusive privileges'. An inventor of a new manufacture under the provisions of this Act was granted exclusive privileges of making, selling and using the invention in India and also authorizing others to do so for a term of 14 years from the time of filling specification of invention. In 1872, the Patents and Designs Protection Act was passed followed by the Protection of Inventions Act of 1883. These Acts were consolidated by the Inventions and Designs Act of 1888. Subsequently, the Indian Patents and Designs Act 1911 was passed replacing all the previous Acts.

- 3.3 After India attained independence, the basic purpose of the patent system was reviewed. There were two¹¹ Enquiry Committees established to examine the Patent Laws relevant to the country's developmental needs. The committees recognized that although India had a patent system in some form or the other for over a century, the country did not derive much benefit from the previous or the then existing systems. Accordingly, modifications of the law relating to patents were recommended to make the patent system an effective catalyst of industrial and economic growth.
- 3.4 The Patents Act 1970 was based on the recommendations contained in the two detailed Reports considered as a landmark in the industrial development of India. The Act was mainly designed to preserve the continuing interest of the inventor in his creation, the social interest in encouraging research, the consumers' interest in enjoying the fruits of inventions at reasonable cost and the creation of conditions for the acceleration and promotion of the economic development of the country.
- 3.5 In order to fulfil the obligations of TRIPS Agreement during the ten-years transitional period, the Patents Act was amended by the Patents (Amendment) Act 1999. Comprehensive amendments to the Patents Act 1970 were, however, enacted by Patents (Second Amendment) Act 2002. Yet another amending Bill will be enacted before 1.1.2005 to introduce a product patent system in the areas which were not covered by product patent as on 1.1.1995.

¹¹ Bakshi Tek Chand Committee - Patent Enquiry Committee (1948-50) and Justice Ayyangar Committee - Patents Revision Committee (1957-59)

Features of Patents Act 1970 before Amendments of 1999 and 2002

3.6 The important features of the Patents Act 1970 before amendments relating to access to pharmaceuticals were as follows:

- (1) In the field of pharmaceuticals, food, insecticides, chemicals, etc. the Act provided only for process patent and not for product patent.
- (2) The terms of the process patent was only 7 years from the date of application or 5 years from the date of sealing of the patent, whichever was shorter.
- (3) The process patent regime wherever applicable was covered by 'licenses of right' which provided a legal right to any enterprise to exploit the patent. Only the terms of these licenses were required to be mutually agreed upon between the patent holder and the licensee. In case the parties did not mutually agree to the terms of the license, the Controller had the right to settle the terms.
- (4) The royalty payment for any invention used by the central government or any other person authorized by government for such use, was to be compensated by royalty and other remuneration not exceeding 4% of the net ex-factory sale price in bulk.

The Patents Act 1970 during its operation for over 25 years on the basis of the above provisions helped the pharmaceutical industry to grow very rapidly. Not only would the domestic demands for pharmaceuticals of all therapeutic groups met by the industry at the lowest price in the world, the industry developed significant potential for export of pharmaceuticals to various developed and developing countries.

Important features of Indian Patents Act 1970 after amendments in 1999 and 2002

3.7 As stated earlier, the Patents Act 1970 has been amended by the Patents (Amendment) Act 1999 to fulfil the TRIPS obligations during the transitional period. The amendments under this Act mainly provided for:

- (1) Establishing of 'Mail Box' facility as from 1.1.1995 to receive product patent applications in the field of pharmaceuticals and agro-chemicals. This amendment was necessitated from 1.1.1995, as India did not provide product patent protection in two areas.
- (2) The other amendment established 'Exclusive Marketing Rights' provision in respect of patent applications filed for patent protection in pharmaceuticals and agro-chemical products in the 'Mail Box' referred to at (1) above.

3.8 The Patents (Second Amendment) Act 2002 made comprehensive amendments to various Sections of the Patents Act 1970. These changes in relation to access to pharmaceuticals are broadly as follows:

- (1) The term of all patents whether product or process, shall be 20 years from the date of filing of patent application.
- (2) The 'licensing of right' system which was available earlier has been abolished.
- (3) Chapter XVI relating to working of patent, compulsory licenses, licensing of right and revocation of patents have been totally replaced.

Compulsory licenses will now be available on any of the following grounds:

- (1) If the reasonable requirement of the public in respect of the patented invention has not been satisfied or that the patented invention is not available to the public at a reasonable/affordable price or that the patent invention is not worked in the territory of India.
- (2) The compulsory license can also be granted if the central government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use. The government will make the notification to that effect, in the official gazette before applications for licenses are entertained.
- (3) Compulsory license will also be granted where the Controller is satisfied on consideration of the application that it is necessary in

the circumstances of national emergency or circumstances of extreme urgency or in a case of public non-commercial use, which may arise or is required as the case may be, including public health crisis, relating to HIV/AIDS, tuberculosis, malaria or other epidemics.

- (4) As regards the royalty payment, the patentee shall be paid not more than adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent.
- (5) The license will be issued with a provision that the same is predominantly for supplying in the Indian market. However, in the case of semi-conductor technology, the license granted is to work the invention for public non-commercial use and in the case of license granted to remedy a practice determined after judicial or administrative process to be anti-competitive, the licensee shall be allowed to export the patented product.
- (6) The Central Government, in public interest, can direct the Controller to authorize any licensee to import the patented article.
- (7) It is also provided that importation of a patented product by any person from a person who is duly authorized by the patentee to sell or distribute the product shall not be considered as an infringement of patent right.

Observations

- 3.9 The Doha Declaration on TRIPS and Public Health has clarified the flexibilities and freedom which could be exercised by Member countries for taking measures to protect public health. The Declaration also provides that the TRIPS Agreement should be interpreted and implemented in a manner supportive of Member countries' right to protect public health and, in particular, to promote access to medicines for all. In this direction, Member countries have the right to grant compulsory licences and also have freedom to determine the grounds upon which such licences could be granted. Similarly, what constitutes national emergency and other circumstances of extreme urgency can

also be determined by Member countries. They could also make provision relevant to exhaustion of Intellectual Property Rights.

3.10 Keeping the above in view it is observed that the scope of patentability as provided by the Patents Amendment Act 1999 needs to be changed to provide for patentability of only new pharmaceutical substances which include New Chemical Entity/New Medical Entity or new bulk drug involving inventive step and capable of industrial application. This specific recommendation is also based upon recommendations of the Pharmaceutical Research Committee headed by Dr R.A. Mashalkar, a senior scientist and Secretary to the Government of India.

3.11 The grounds on which compulsory licence can be granted within the TRIPS Agreement and Doha Declaration are also weak and need to be strengthened. The chapter on compulsory licence in the amended Patents Act should provide for:

- (1) Grant of voluntary licence by the patentee;
- (2) Grant of compulsory licence because of abuse of patent rights by the patentee;
- (3) Grant of compulsory licences because of unsuccessful attempt by an enterprise with the patent holder to obtain licence on reasonable commercial terms and conditions.
- (4) Grant of licences separately for national emergency, circumstances of extreme emergency and in case of public non-commercial use.

The term of these licences should be co-terminus with the term of the patent.

3.12 Regarding provision for export of pharmaceuticals by the domestic enterprises and parallel imports, the provision made in the law needs to be adequately reframed.

All the issues mentioned above have been discussed in detail in Chapter IV. The suggestions could be considered for changing the amended Patents Act 1970 which will help in the availability of medicines at competitive prices through domestic enterprises.

Patent Laws of Indonesia

Brief History

3.13 The Constitution of the Republic of Indonesia provides an objective "to realise a just and prosperous society, equitably oriented both materially and spiritually". It also provides "that in the framework of implementing national development in general and economic development in particular, technology has a very important role in the improvement and advancement of industry. In view of the importance of the role of technology in the improvement and advancement of industry, it is necessary to create a more favourable climate for activities of technological discoveries and means for providing legal protection of said activities. Thus, in order to create the said climate and means of legal protection, it is considered necessary to devise patent legislation in the form of law". With this constitutional background, the Minister of Justice announced in 1953 a law for regulation of patents. This announcement was replaced by a regular Patents Act 1989, which was enforced with effect from 1 August 1991. This Act was further amended in 2001 to conform to the TRIPS provisions.

Patents Act 1989: Indonesia

3.14 The important features of the Patents Act 1989 were:

Section 2 provided that 'patent would be granted for a new invention containing an inventive step and applicable to industry. Invention was to contain an inventive step if the said invention constituted an unforeseeable matter to a person possessing common technical expertise'.

Section 3 provided that 'an invention would not be deemed new if, at the time of filing of a patent application the:

- (1) said invention had already been published in Indonesia or outside Indonesia in a written form enabling an expert to carry out said invention, or
- (2) said invention was published in Indonesia verbally or by demonstration of its application or by any other method in such a form as to enable an expert to carry out the said invention'.

Section 7 stipulated that patent would not be granted to:

- (1) an invention on a production process or product of which its publication and use or implementation is contrary to laws and regulations in force, public order or morality;
- (2) an invention on a production process or product of food and drink(s), including products in the form of raw material made by chemical process with the aim to produce food and drink for human and for animal consumption;
- (3) an invention on a new species or variety of plant or animal or any other process that can be used to cultivate plants or animals, including products thereof;
- (4) an invention on methods of examination, nursing, medication and surgery applied to people and animals, excluding any products used with or related to those methods;
- (5) an invention being a theory or methodology in the field of science and mathematics.

Section 9 provided that the patent would be granted for a 14 (fourteen) year period commencing from the date of filing of application.

Section 13 provided that an inventor was entitled to receive reasonable compensation based on the economic value that can be generated from the said invention.

Section 18 provided that the patent holder was required to carry out (work) his patent in the territory of the State of the Republic of Indonesia.

Section 20 provided that the imports of patented products or products made by a patented production process would not constitute a patent implementation.

Section 82 provided that 'compulsory licence application would be filed on the grounds that the said patent had not been implemented in Indonesia by the patent holder even though there had been opportunity for commercial implementation of the patent which should have been

utilised. Compulsory licence could be granted for a time period no longer than the length of time period of the patent application and the same would be stipulated. The implementation of a compulsory licence was accompanied by payment of royalties to the patent holder. The amount of royalty to be paid and the method of payment was to be determined by the District Court issuing the compulsory licence’.

Section 94 provided that the patent office could declare a patent revoked by law in the following cases:

- (1) Non-implementation within 48 months from the date of issue of the patent.
- (2) Non-payment of annual fees within the time frame stipulated by the law.

3.15 Under pressure from the USA, Indonesia took necessary steps to enact the new patent law to replace the Patents Act of 1989 as amended by the law of 1997. The amended law which is supposed to conform to the TRIPS provisions was finally passed and ratified in December 2000. The new law was published in the official State Gazette of the Republic of Indonesia on 1 August 1 2001 and came into effect from that date.

Patents Act 2001: Indonesia

3.16 The important features of the Patents Act of 2001 are as follows:

Article 1 deals with a number of definitions such as: Patent, Invention, Inventor, Patent holder, Examiner, Director-General, Filing date, Priority Right, Licence, etc.

These definitions are not enough in the sense that many other technical terms also need to be defined under this Section.

Article 2 stipulates that a patent shall be granted to an invention, which is novel, involves an inventive step and is capable of industrial application.

Article 7 stipulates the inventions which are not patentable. The section reads as follows:

"A patent shall not be granted to an invention regarding:

- (1) any process or product of which the announcement and use or implementation contravenes the prevailing rules and regulations, religious morality, public order or ethics;
- (2) any method of examination, treatment, medication, and/or surgery applied to humans and/or animals;
- (3) any theory and method in the field of science and mathematics; or
- (4)
 - (i) all living creatures, except micro-organism
 - (ii) any biological process which is essential in producing plants or animals, except non-biological process or microbiological process".

Article 8 stipulates that the period of patent shall be 20 years from the filing date and this period cannot be extended.

Article 12 stipulates that the inventor shall be entitled to receive just compensation by considering the economic benefit that can be obtained from the invention and the amount of compensation would be in a lump sum amount, or percentage, or a combination or a lump sum together with a gift or bonus, or a combination of percentage with a gift or bonus or any other form agreed by the parties, the amount of which shall be determined by the parties concerned. If there is no agreement between the parties on the amount of compensation, the commercial court may be requested to decide the matter.

Article 16 stipulates the rights of a patent holder these are the usual rights as stipulated in the TRIPS Agreement. There is an exemption from the exclusive right on the use of patent for the sake of education, research, experiment, or analysis, as long as it does not harm the normal interest of the patent holder.

Article 17 stipulates an obligation that a patent holder shall make products or use the process that has been granted on a patent in Indonesia, provided it is only suitable to be implemented in a regional scale.

Article 24 provides that the patent application shall be filed with the Director-General in writing in the Indonesian language.

Article 27 stipulates that the priority right will be regulated as in the Paris Convention i.e. the application must be filed within 12 months commencing on the date on which the first application was filed in any country.

Article 69 stipulates that the patent holder shall have the right to grant a licence to another person on the basis of a licensing agreement in order to permit the licensee to perform acts as referred to in section 16 dealing with exclusive rights. This licence shall continue for the term of the licence granted and shall be effective for the entire territory of the Republic of Indonesia.

Article 75 stipulates that any party, after expiration of a period of 36 months may file a request for compulsory licence on the ground that the relevant patent has not been implemented by the patent holder or the licensee in a form and manner that contravenes public interest.

Observations

- 3.17 It is observed that the Patents Act 2001 of Indonesia does not specifically provided for patenting of new pharmaceutical substances which should include New Chemical Entity/New Medical Entity or new bulk drug involving inventive steps and capable of industrial application. Considering the importance of pharmaceuticals in public health the scope of patentability should be restricted as product.
- 3.18 The scope of exclusion of inventions which are not patentable also needs to be enlarged so that frivolous claims are not fielded.

The article which stipulates the right to grant a licence needs to be revised to provide that compulsory licences would be given by the Director-General:

- (1) if there is abuse of patent rights by the patent holder
- (2) or there is unsuccessful attempt by an enterprise to obtain licence from the patent holder on reasonable commercial terms and conditions.

- (3) Similarly, the provision with regard to grant of licences during national emergency, circumstances of extreme emergency and public non-commercial use also needs to be provided separately and adequately.

The flexibilities available under the Doha Declaration on TRIPS Agreement and Public Health have not been reflected in the Patent Act of 2001 which seems to have been enacted before the Declaration became available.

There is a need to provide for parallel imports for meeting the shortages in the country and also to import patented drugs if they are available elsewhere at a lower price. This also arises from the Doha Declaration which provides that members have the right to establish their own regime for exhaustion of intellectual property rights without challenge.

- 3.19 All the above points have been dealt with in Chapter IV. The Government of Indonesia may like to consider the suggestions for strengthening their Patents Act which will help them in better availability of patented products at competitive prices through the role of their domestic pharmaceutical industry.

Intellectual Property Act of Sri Lanka

History

- 3.20 All the laws relating to industrial designs, patents, marks, trade names and unfair competition which were enforced prior to 1979 were codified under Code of Intellectual Property Act No. 52 of 1979. This Code was subsequently amended by Act Nos. 30 of 1980, 2 of 1983, 17 of 1990, 13 of 1997 and 40 of 2002. A comprehensive draft of the Intellectual Property Act has since been drafted by the government which has to go through various stages of enactment before it becomes law and is published in the Gazette.

Main features of Code of Intellectual Property 1979 relating to Patents

3.21 Various sections relating to patents are contained in Part (IV) of the Code. Part (VI) of the Code also deals with certain other provisions relating to patents. The important provisions relating to patent law are as follows:

Section 59 indicates that an invention may be or may relate to a product or process. The following inventions are not patentable:

- (1) discoveries, scientific theories and mathematical methods;
- (2) plant or animal varieties or essentially biological processes for the production of plants or animals, other than micro-biological processes and the product of such processes;
- (3) schemes, rules, or methods for doing business, performing purely mental acts or playing games;
- (4) methods for the treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body.

Section 60 provides that an invention is patentable if it is new, involves an inventive step and is industrially applicable which have been defined in Sections 61, 62 and 63.

Section 73 provides for the right of priority, pursuant to the provision in the Paris Convention.

Section 80 provides that a patent shall expire 15 years after the date of its grant. A grace period of 6 months can also be allowed after the date of expiration of the patent date on payment of surcharge.

Section 81 stipulates that the owner of the patent shall have the following exclusive rights:

- (1) to exploit the patent invention;
- (2) to assign or transmit the patent;
- (3) to conclude licence contracts.

It is also provided that no person shall do any of the above acts without the consent of the owner of the patent. As regards the exploitation of the patented invention, it would mean any of the following acts in relation to a patent:

- (1) when the patent has been granted in respect of product
 - making, importing, offering for sale, selling and using the product;
 - stocking such a product for the purpose of offering for sale, selling or using;
- (2) when the patent has been granted in respect of process
 - using the process;
 - doing any of the acts referred to in paragraph (1), in respect of a product obtained directly by means of the process.

Section 82 stipulates limitation of the owner's rights as follows:

- (1) extend only to acts done for industrial or commercial purposes and, in particular, not to acts done only for scientific research;
- (2) not preclude a person having the rights referred to in section 83 or a licensee from exploiting the patented invention;
- (3) not extend to the presence or use of products on foreign vessels, aircraft, spacecraft, or land vehicles which temporarily or accidentally enter the waters, airspace or territory of Sri Lanka.

Section 84 provides for assignments and transmission of patents through an application, made to the Registrar in the prescribed manner to have such an assignment or transmission recorded in the register.

Section 86 provides that the owner of a patent can grant a licence to do any or all of the acts referred in section 81.

There is no other specific provision in relation to the compulsory licensing system.

Intellectual Property Bill (Issued on 28.4.2003)

3.22 The important features of the Intellectual Property Bill are as follows:

Section 2 provides that the Director-General shall be vested with the power of implementation of the provisions of the Act and the control and superintendence of the registration and administration of Industrial Designs, Patents, Marks or any other matter as provided by the Act.

Part (IV) of the Bill deals with the patent provisions.

Section 62 stipulates that for the purposes of patents, invention means an idea of an inventor which permits in practice the solution to a specific problem in the field of technology. Invention may be, or may relate to, a product or process. The following inventions according to the draft Act shall not be patentable

- (1) discoveries, scientific theories and mathematical methods;
- (2) plants and animals other than micro-organisms and essentially biological processes for the production of plants and animals other than non-biological and micro-biological processes;
- (3) schemes, rules, or methods for doing business, performing purely mental acts or playing games;
- (4) methods for the treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body.

Provided however, any product used in any such method shall be patentable;

Section 63 stipulates that an invention is patentable if it is new, involves an inventive step and is industrially applicable.

Sections 64, 65 and 66 define Novelty, Inventive step and Industrially application aspects of invention.

Section 83 stipulates that the patent shall expire 20 years after the filing date of application for its registration.

Section 84 provides exclusive rights of the owner of the patent and are the usual rights as follows:

- (1) to exploit the patented invention;
- (2) to assign or transmit the patent;
- (3) to conclude licence contracts.

For the purposes of "exploitation" of a patented invention means any of the following acts in relation to a patent:

- (1) when the patent has been granted in respect of a product
 - making, importing, offering for sale, selling and using the product;
 - stocking such product for the purpose of offering for sale, selling, exporting or using;
- (2) when the patent has been granted in respect of a process
 - using the process;
 - doing any of the acts referred to in paragraph (a), in respect of a product obtained directly by means of the process.
 - preventing any person using that process or using, selling or importing any product obtained directly by means of that process unless such person is authorized to do so.

Section 86 deals with limitation of owner's rights. It is stipulated that:

The provisions of *Section 84* shall:

- (1) extend only to acts done for industrial or commercial purposes and in particular not to acts done only for scientific research;
- (2) not preclude a person having the rights referred to in *section 87* or a licensee from exploiting the patented invention;
- (3) not extend to the presence or use of products on foreign vessels, aircraft, spacecraft, or land vehicles which temporarily or accidentally enter the waters, airspace or territory of Sri Lanka;
- (4) not extend to acts in respect of articles which have been put in the market by the owner of the patent or with his written consent.

Observations

- 3.23 The analysis of the latest Intellectual Property Bill 2003 indicates that there is no specific provision for grant of patent for new pharmaceutical substances which could be only for New Chemical Entity/New Medical Entity or new bulk drug involving inventive steps and capable of industrial application. It is important to specifically provide for patentability of new pharmaceutical substances.
- 3.24 It is also observed that there is no specific provision for grant of compulsory licences. There is a need to provide for grant of:
- (1) voluntary licence,
 - (2) compulsory licence due to abuse of patent rights by the patent holder,
 - (3) grant of compulsory licence due to unsuccessful attempt by any
 - (4) domestic enterprise to obtain voluntary licence on reasonable commercial terms and conditions from the patent holder,
 - (5) There is also need to provide for grant of licences during national emergency, circumstances of extreme emergency and in case of public non-commercial use. All these provisions arise from the TRIPS Agreement and should be specifically provided for as discussed later in Chapter IV.
- 3.25 For parallel imports also there should be specific provision to meet shortages and also if the patented products are available cheaper in other countries.

All the above provisions are extremely important to ensure accessibility of medicines at competitive prices through the role of domestic enterprises.

Patent Laws of Thailand

History

- 3.26 The Thai Patents Act 1979 was in operation till 1992. This Act was amended in 1992 under pressure from USA. The patent laws were

further amended in 1999 to conform with the provisions of the TRIPS Agreement. Product and Process patents became applicable in the pharmaceuticals field after the Patent Act was amended in 1992.

- 3.27 The Thai government has been under constant pressure. Even after Thailand amended their patent laws in 1999, it was included in the 'watch list' in the Special 301 Report of 2000.

Patents Act 1979

The Patents Act 1979 of Thailand came into force on 12 September 1979.

Under the provisions of this Act (Section 9) the following inventions were not patentable:

- (1) food, beverages, pharmaceuticals or pharmaceutical ingredients;
- (2) machinery for direct use in agriculture;
- (3) varieties of animals or plants or biological processes for the production of animals or plants;
- (4) scientific or mathematical rules or theories;
- (5) computer programmes;
- (6) inventions contrary to public order, morality, public health or welfare;
- (7) inventions prescribed by Royal Decree.

Under the Patents Act 1979, the patentee had the exclusive right to manufacture the patented product or use the patented process and to sell or keep for sale the patented product or the product made by the patented process. These rights were, however, not applicable to:

- (1) manufacture of patented product or use of the patented process for the purpose of education, experiment or research;
- (2) manufacture of patented product or use of patented process where the manufacturer or user, in good faith, has engaged in the

manufacture or has acquired the equipment thereof prior to the publication of the application;

- (3) the sale or keeping for sale of products acquired in good faith.

A compulsory licensing system was also applicable under the Patents Act 1979. After the expiration of three years from the grant of a patent, any person could apply to the Director-General for a licence if it appeared:

- (1) that without sufficient reason, the patented product was not being manufactured or the patented process was not being used in the country; or
- (2) without sufficient reason, the patented products or products produced by the patented process were not being sold in the country or, if sold, are sold at unreasonably high prices or in quantity insufficient to meet public demand.

The basic features of the Patent Act 1979 were thus totally in tune with the public interest. Not only that pharmaceuticals or pharmaceutical ingredients were excluded from the patentable subject matter, the other provisions relating to compulsory licensing were also strong. Public interest about the access to drugs and medicines were thus not hampered in any way under the Patents Act 1979.

Patents Act 1992

In early 1990 there was tremendous pressure from the USA for Thailand to change its Patents Act 1979 as the same did not provide patent protection for pharmaceuticals. There was a lot of agitation in Thailand against US pressure. However, under the threat of trade sanctions, the government agreed to change its Patents Act 1979 and this was done in 1992.

The salient features of the Patents Act 1992 were as follows:

Section 5 patent may be granted only when:

- (1) the invention is new,
- (2) it involves an inventive step, and
- (3) it is capable of industrial application.

Section 7 In so far as the inventions which were not protectable under the Patents Act 1992, only the following were listed under this category:

- (1) naturally existing microorganisms and their components, animals, plants or animal and plant extracts;
- (2) scientific or mathematical rules or theories;
- (3) computer programs;
- (4) methods of diagnosis, treatment and care of human and animal diseases;
- (5) inventions contrary to public order, morality, health or welfare.

3.31. The above would indicate that pharmaceutical products which were earlier exempt from the scope of patentability, were brought under the patenting category for the first time in 1992. The Patents Act 1992 also provided that the inventions protected under the patent system were accorded a term of 20 years from the date of application. The law also provided for compulsory licence on the same terms as was provided under the Patents Act 1979. However, this was subject to the conditions that the applicant for a licence shows proof that he had made efforts to obtain the licence from the patent holder after having proposed conditions and compensation reasonable under the circumstances. The Patents Act 1992 also provided that if no agreement was reached by the two parties within the period fixed, then the Director-General would stipulate such compensation, conditions and restrictions as he may deem appropriate subject to the following conditions:

- (1) the extent and period of time of the licence shall not be more than necessary under the circumstances;
- (2) the patentee shall also be entitled to appoint other licensees under his patent;

- (3) the licensee shall not be entitled to assign the licence to others unless the business or goodwill of the business concerned with the licence is also assigned;
- (4) the licensing shall be aimed primarily at meeting domestic public demand;
- (5) the compensation must be adequate under the circumstances.

Since Thailand is a member of WTO, it became obligatory for it to change its patent law to conform to the TRIPS Agreement. The government enacted another Patents Act in 1999.

Salient features of the Patents Act 1999

3.32. Some of the salient features of the Patents Act 1999 of Thailand relevant to access to drugs and medicines are as follows:

Section 5 of the Patents Act 1999 indicates that a patent may be granted only for invention in respect of which the following conditions are satisfied:

- (1) the invention is new;
- (2) it involves an inventive step; and
- (3) it is capable of industrial application.

Section 9 indicates that the following inventions would not be protected under the Patents Act 1999:

- (1) naturally occurring micro-organisms and their components, animals, plants or extracts from animals or plants;
- (2) scientific or mathematical rules or theories;
- (3) computer programs;
- (4) methods of diagnosis, treatment or cure of human and animal diseases;
- (5) inventions contrary to public order, morality, health or welfare.

The implication of the above two sections is that product and process patents become applicable in the pharmaceutical field.

Section 35 stipulates that the patent shall have a term of 20 years from the date of filing of the application in the country.

Section 36 provides that exclusive rights available to the patentee shall not apply to any act for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent holder.

Section 45 stipulates that any patentee may, in accordance with the rules and procedures as prescribed apply to the Director-General for an entry to be made in the register to the effect that any other person may obtain a licence. In such cases the Director-General shall grant a licence to any person on such conditions, restrictions and royalty terms as agreed upon by the patentee and the applicant. If there is no agreement on the royalty payment within the period as prescribed by the Director-General, the Director-General shall grant the licence on such conditions, restrictions and royalty terms as he may deem appropriate. Appeal against the Director-General decision can be made to the Board as defined in the Patents Act 1999 and the decision of the Board shall be final.

Section 46 stipulates that any time after the expiration of three years from the grant of a patent or four years from the date of application whichever is later, any person may apply to the Director-General for a licence if it appears:

- that the patentee unjustifiably fails to exercise his legitimate rights, or
- that no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high price or does not meet the public demand, without any legitimate reason.

The applicant is however required to show that he has made an effort to obtain a licence from the patentee having proposed conditions

and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

Section 47 provides that where working of any claim in a patent is likely to constitute infringement of a claim in a patent of another person but the invention involve an important technical advance of considerable economic significance in relation to the invention for which the licence is applied, the Director-General may grant second licence. The applicant will, however approach the Director-General only after his efforts to obtain licence from the patentee on reasonable conditions and remuneration have been unsuccessful.

Section 50 stipulates where the licence is granted, the Director-General shall set forth the royalty and the conditions for the exploitation of the patent and the restrictions on the rights of the patentee and the exclusive licence as agreed upon by the patentee and the applicant. If no agreement is reached by the parties the Director-General shall have the right to fix the royalty and prescribe conditions and restriction as he may deem appropriate. The decision of the Director-General is appealable to the Board within sixty days.

Section 50 also stipulates that compulsory licence shall be aimed predominantly for the supply of the domestic market.

Section 52 stipulates that during the state of war or emergency, the Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any right under any patent necessary for the defence and security of the country by paying a fair remuneration to the patentee and shall notify the patentee. Appeal against the order or the amount of remuneration can be made to the court within sixty days from the receipt of the order.

Observations

3.33. The study of Thailand's Patent Act, 1999, indicates that there is no specific provision for patentability of new pharmaceutical substances which include New Chemical Entity/New Medical Entity or bulk drug involving inventive steps and capable of industrial application.

- 3.34. The scope of inventions which are not patentable also needs to be enlarged to ensure that frivolous claims are not filed.
- 3.35. Interpretation of the technological terms usually used in the patent laws need to define other terms also.
- 3.36. Compulsory licensing needs to be strengthened in the cases of national emergency, circumstances of extreme emergency and for public non- commercial use. The provision in regard to these contingencies need to be provided in an independent and explicit manner.
- 3.37. There is a need to provide for parallel imports due to shortages of pharmaceutical products and for reasons of high price being charged by the patentee on their products as compared to their availability in other countries at cheaper prices.

All the above issues have been dealt with in Chapter IV. It is for the Government of Thailand to consider the suggestions and strengthen their Patents Act provisions to ensure easy availability of medicines at competitive prices through the role of domestic enterprises.

Chapter IV

Core Safeguard Issues for Public Health in Relation to National Patent Laws

4.1 The core issues of concern keeping the public health perspective in view under the TRIPS Agreement for the developing countries relates to easy access to medicines. These concerns have to be suitably reflected in the national patent legislations. The Doha Declaration on TRIPS Agreement and Public Health has recognized the gravity of public health problems and provided sufficient lead for the Member countries to take care of relevant issues in their patent laws. This chapter identifies the issues and suggests possibilities for stipulating appropriate provisions in the national patent laws. The concerned countries may consider these suggestions and deal with them as they may deem appropriate.

Core Issues

- 4.2 The core issues in relation to access to medicines are as follows:
- (1) Stipulating scope of patentability specifically in relation to pharmaceutical substances;
 - (2) Ensuring role of domestic enterprises by stipulating provisions pertaining to voluntary licences, compulsory licences and licences of right for products as well as processes patented under the national legislation.

The above issues are dealt with in detail as follows:

Scope of Patentability

4.3 The patentable subject matter keeping particularly the pharmaceutical substances in view could be defined as follows:

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

4.4 The relevant patent terms mentioned above such as invention, patentable pharmaceutical substance and new or novel inventions may be defined as follows:

(1) Invention may be defined as:

"Invention" means basic novel inventions, whether products or processes involving inventive step and capable of industrial application.

(2) Pharmaceutical substances from patentability point of view may be defined as :

"Pharmaceutical substance" includes new drug molecule, new chemical entity or new medical entity involving inventive step.

(3) New or novel inventions may be defined as:

"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.

4.5 Identification of inventions not patentable is another important component of the patent laws. In this regard some inventions which are not patentable have been mentioned in sub-articles 2 and 3 of Article 27 of the TRIPS Agreement. However, there is a need to suitably expand the scope and specify them in the national legislation. These other inventions not patentable could be as follows:

- (1) Patenting of micro-organisms and non-biological and micro-biological processes. (This subject matter and processes are still under mandated review in WTO);
- (2) Research tools for biotechnological research (biotechnology research will be hampered if these tools are not excluded from patentability);
- (3) All life forms: gene sequences, germ plasm, polymorphisms etc. should be specifically excluded;
- (4) Medicinal formulations, combination formulations of existing or new substances excepting formulation involving innovative technology which could be covered by process patent;
- (5) New use of known substances; and
- (6) Exclude all frivolous claims. (government could identify and notify them from time to time)

The above suggestions cover important aspects of scope of patentability which include patentable subject matter, definitions of important patent terms and inventions not patentable. These suggestions may be considered for incorporation in the national patent laws.

Voluntary Licences, Compulsory Licences and Licences of Right

- 4.6 A compulsory licensing system is extremely important for developing and least developed countries to ensure the role of domestic enterprises for providing adequate availability of patented products at competitive prices. The Doha Declaration on TRIPS Agreement and Public Health confirms that each Member country has the right to grant compulsory licences and has freedom to determine the grounds upon which such licences could be granted. The possibilities may be divided under three categories which have been explained in the following paragraphs:

Voluntary Licences

- 4.7 There are certain patent laws which provide for voluntary licences offered by the patent holders. In such cases the patent holder

applies to the Controller of Patents for making an entry in the register maintained by him that any enterprise may obtain a licence and produce the patented product or use the patented process.

This contingency may arise when a patent holder is not in a position to promote his product himself in the country which has granted the patent due to his limitations. The patent holder in such instances would be entitled to royalty payment as may be agreed upon between him and the licensee. In case of any disagreement, the Controller of Patents will decide the quantum of royalty payable. (In this connection Section 45 of the Patents Act 1999 of Thailand may be referred.)

Compulsory Licences

4.8 There are several possibilities for granting compulsory licences based upon Article 5 A of the Paris Convention and Article 31 of the TRIPS Agreement. Working of patents by the domestic enterprises is an important issue for large countries like India, Indonesia, Thailand, etc. through the compulsory licensing possibilities which are discussed hereafter:

Compulsory licence on abuse of patent rights

4.8.1 In such cases, the interested enterprises will make an application to the Controller of Patents and justify the abuse which may arise due to 'non-working or inadequate working of the patent or even no imports or inadequate imports by the patent holder of the patented product. The other aspect of the abuse could be due to high prices of the patented product charged by the patent holder. The Controller of Patents will give an opportunity to the concerned patent holder to contest the plea of the applicant and satisfy himself about the abuse before he issues the compulsory licence on such terms as may be agreed upon in consultation with the patent holder.

Provision in national legislation could appropriately be made as follows:

"At any time after the expiration of three years from the date of the grant 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 requirement of the public with respect to the patented invention has not been satisfied, or
- (2) that the patented invention is not available at reasonable price, or
- (3) that the patented invention is not being worked in the country.

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

4.8.2 Patent laws of France, Israel and many other countries provide for compulsory licences due to abuse of patent rights by the patent holders.

Compulsory licence for reason of unsuccessful attempt by an enterprise

4.8.3 In this possibility which arises from Article 31 (b) of the TRIPS Agreement, the proposed enterprise in the first instance will have to make an effort to obtain voluntary licence from the right holder for use of patented subject matter offering reasonable commercial terms and conditions and has to wait for a response from the patent holder for a reasonable period. If the attempt is unsuccessful or there is no response from the patent holder, the enterprise can approach the Controller of Patents for the grant of compulsory licence. Patent laws of several countries including Argentina, Brazil, China, France, etc. provide for compulsory licence due to the stated consideration. The formulation of the provision under this important category could be as follows:

- (1) Where 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 of Patents shall at any time after the expiration of three years from the date of issue of patent, grant compulsory licence to the proposed user on such terms and conditions as he may deem fit.
- (2) The reasonable period after which the proposed user may approach the Controller of Patents would be not less than 150 days from the date he approached the patent holder.

Compulsory licence to remedy anti-competitive practice

4.8.4 This possibility arises from Article 31 (k) of TRIPS Agreement. The formulation of the provision in the patent law could be as follows:

"Where the situation of resorting to anti-competition practices by the patentee has been determined after a 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 grant compulsory licence to remedy the situation. The terms and conditions of the compulsory licence will be decided by the Controller of Patents".

Compulsory licence for second patent for an invention

4.8.5 This contingency arises from Article 31 (l) of the TRIPS Agreement. The formulation of the provision could be as follows:

"Where an important technical advance of 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".

Licence of Right

4.9 Licence of Right will arise after the government has notified a contingency which may arise due to a national emergency or circumstances of extreme urgency. In these cases according to Article 31(b) of the TRIPS Agreement the requirement of consultation with the patent holder can be waived. He would, however, be informed of licences issued as soon as possible. The patent holder would be entitled to payment of royalty.

Licence of right due to national emergency

4.9.1 The circumstances of 'National Emergency' could arise for various reasons. Promulgation of national emergency would, however, be made by the Head of State. The formulation of the provision could be as follows:

“The Controller of Patents shall issue licence of right on an application made by an enterprise at any time after the notification of the national emergency in the official gazette due to grave emergency whereby the security of the country or of any part of the territory thereof is threatened either by war or external aggression or by armed rebellion to use the patent on such terms and conditions as he may deem reasonable.

Licence of right in circumstances of extreme urgency

4.9.2 Circumstances of extreme urgency may arise as the case may be including public health crises, relating to HIV/AIDS, malaria, tuberculosis or any other epidemic. The circumstances of extreme urgency may be notified as 'Health Emergency'. Similarly, 'Environmental Emergency' may be notified due to crisis arising out of pollution of air, water or soil. The formulation of the provision could be as follows:

At any time after the grant of the patent, the Controller of Patents shall have the right to issue licence of right on any patented product due to public health or environmental crisis as may be notified by the

Government in official gazette invoking 'health emergency' or 'environmental emergency'. The Controller of Patents will decide the terms and conditions of the licence as he may deem reasonable.

Compulsory Licence in cases of Public Non-Commercial Use

4.10 Public non-commercial use could be defined as distribution of formulations of any patented pharmaceutical substance free of cost or at a price without any commercial consideration i.e. at no profit, no loss basis. The formulation of the provision could be as follows:

"At any time after the grant of patent, any enterprise may make an application to the Controller of Patents for using the patented substance to produce products for free distribution or on non-commercial basis to the consumers. The term of the licence will be decided in consultation with the applicant. The concerned enterprise shall furnish to the Controller a certificate at the end of each year that the product has been distributed free of cost or on a non-commercial basis."

Licences of Right on Process Patents

4.11 Article 7 of the TRIPS Agreement relates to transfer and dissemination of technology. Keeping this in view it would be pertinent to apply licences of right for all technologies that are protected under process patent. Scientists expect that in the near future a large number of off-patent products are likely to be produced using the bio-technology route. In such cases process patents for these new technologies will have to be stipulated in the patent laws. The enterprises interested will have to approach the Controller of Patents for issue of licences of right on such terms and conditions including royalty as he may deem reasonable.

Other Important Issues

4.12 There are a few other important issues which have relevance to easy and affordable access to pharmaceutical products. These issues relate to parallel imports, export of patented products and pricing of patented products.

Parallel Imports

4.12.1 The need for parallel imports arises when availability of the patented product is not sufficient to meet the demands. This type of contingency can arise similar to the situation in the USA about availability of 'anthrax' during 2001-2002. The other possibility could be when a patented product is available in foreign markets at a price lower than the price at which the same is marketed in the country. For meeting such contingencies, according to the Doha Declaration the Member countries are free to establish their own regime for exhaustion of rights without challenge. Appropriate provision with the stated contingencies could therefore be made in the national law and then only it will be possible to resort to parallel imports.

Export of Patented Products that are produced under licence

4.12.2 The various licences granted to domestic enterprises on patented products should have clear rights to produce the patented products predominantly for the domestic market and some quantity for exports. The spirit of Article 31 (f) of TRIPS Agreement does permit production mainly for the domestic market as well as for export. Restraining of trade, in fact, is an abuse under Article 8 of the TRIPS Agreement and appropriate measures can be taken to prevent such abuse.

Pricing of Patented Products

4.12.3 Pricing of patented products is an extremely important issue for developing countries. During the patent protection period the prices are bound to be high due to monopoly control over the market for the product by the patentee. Even if the patented products are covered by licences granted to other domestic enterprises, the prices are bound to be high. There is no bar in the TRIPS Agreement against price control of patented products.

Chapter V

Conclusions

- 5.1 The poor in developing countries are caught in the vicious circle where poor health leads to poverty, and poverty in its turn breeds poor health. This is despite the fact that during the past 50 years there has been rapid improvement in health status worldwide. In developing countries life expectancy increased from 40 to 63 years and under-five mortality decreased from one in four to one in ten. The progress in poor countries, however, could not keep pace with improvements in health with malaria, tuberculosis and HIV/AIDS posing significant challenges¹². The Department for International Development established by the British Government with a responsibility for promoting development and reduction of poverty as stated in its 1997 White Paper, a commitment to the internationally agreed target to reduce by half the population of people living in extreme poverty by 2015. The linkage between improved health and poverty reduction is stated¹³ in the Millennium Development Goals. The key goals are as follows:
- (1) Reduce child mortality (under 5 mortality rate): reduced by 2/3 between 1990-2015.
 - (2) Improve maternal health (maternal mortality ratio): reduced by 3/4 between 1990-2015.
 - (3) Combat HIV/AIDS, malaria and other diseases: have to be halted by 2015.
- 5.2 These are some of the important challenges particularly for developing countries which suffer from many health problems and economic handicaps. The review of four countries indicates that the health scenario is bleak. The resources of these countries are limited whereas the health goals stipulated in their health policies

¹² DFID Paper on Working in partnership with WHO (August 2002)

¹³ Ibid

are significant. The important factor which may adversely affect the attainment of these goals is the implementation of patent system as stipulated in TRIPS Agreement.

The patent system is not linked to the stage of development of countries. With the TRIPS Agreement imposing standards of protection practised by the technologically advanced countries, the health scenario in the developing countries could change quite considerably. The accessibility and affordability of drugs has to be improved.

5.3 The Doha Declaration on TRIPS Agreement and Public Health has clarified the confusion prevailing in the developing countries about the implementation process. As stated in preceding chapters, the Declaration has clarified the most important factor relating to the application of compulsory licensing system. It has indicated the flexibilities and freedom available to determine the circumstances where compulsory licences can be granted to domestic enterprises.

5.4 Chapter IV of this Review has identified two core areas of concern viz.

- (1) Scope of patentability
- (2) Possibility of framing of voluntary licensing, compulsory licensing, authorization of right and licensing of right systems.

The starting point in the implementation of TRIPS Agreement on access to medicines is on what is patentable and what is not patentable. Similarly, how the claims have to be admitted based on established criteria and interpretation of patent terminologies. This aspect is extremely important and should be provided in the patent legislation. It would serve as a major factor for containing the widespread impact of admitting frivolous claims.

5.5 The patent holder must be provided incentives to encourage him to offer his patent for voluntary licensing. Inclusion of this provision in the patent legislation is important. It may set the patent holder to consider this possibility also from the economic consideration as, in any case, he would be entitled to royalty payment even for the voluntary licences.

5.6 Article 5 A of the Paris Convention and Article 31 of TRIPS Agreement provide for grant of compulsory licences under certain

circumstances. These possibilities have also been discussed in detail in Chapter IV. Such options can be exercised for the following contingencies:

- (1) Abuse of patent rights by the patent holder;
- (2) Unsuccessful attempt by an enterprise to obtain
- (3) voluntary licence;
- (4) To remedy anti-competitive practices.

Apart from the above contingencies, authorization could also be granted for use of patentable subject matter by government or by third parties authorized by the government for meeting the government's requirements.

5.7 Authorization of the right system has been proposed for contingencies arising out of a national emergency and circumstances of extreme urgency. These are the situations under which the provisions of patent system become dormant and the role of the patent holder becomes subdued in deciding about the grant of these licences.

5.8 For process patent also, licensing of right system has been suggested. This suggestion is based on the strong objectives stipulated in Articles 7 and 8 of the TRIPS Agreement which require enforcement of intellectual property rights for transfer and dissemination of technology.

5.9 The above possibilities have been analyzed for implementation particularly because of health and economic indices relating to the four countries reviewed being poor. These indices have been stated in detail in Chapter I. The per capita income in these countries is as follows¹⁴:

India	US\$ 460
Indonesia	US\$ 680
Sri Lanka	US\$ 830
Thailand	US\$ 1,970

¹⁴ Source: World Bank: on-line data 2001

While the health indices are poor, the per capita income is also low compared to the developed countries. The value of per capita drug consumption is also low as is evident from the following data:

	Production percentage of world total production	Consumption per capita in US\$
	1990	1990
India	1.20	2.2
Indonesia	0.46	3.9
Sri Lanka	–	1.8
Thailand	0.21	6.6

5.10 Data on the consumption of drugs in USA and Japan in 1990 are \$ 191 and \$ 412 respectively. The low consumption in developing countries has been because of slower growth of drug consumption due to low per capita income and the faster growth of population. Whereas the growth rate of population in developing countries reached 2.1 per cent per year, developed countries growth had been less than 0.8%. In any case the poverty – health nexus in the developing countries is quite strong. For example, 70% of population in India cannot afford modern medicines and this is one of the strong reasons for poor health conditions for its people.

5.11 The analysis of various health and economic indices in this Review reveals some areas of concern. These factors must be given serious consideration. There is thus a strong need for changing the patent system carefully. The detailed analysis in Chapter IV can facilitate the four countries to strengthen their patent laws to achieve the objectives of easy access to drugs and medicines at competitive prices. Prima facie all the patent laws are weak to help meet the essential needs of the people and to provide easy access to medicines at competitive prices through domestic enterprises.

Annex 1

DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

- (1) We recognize 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.
- (2) We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
- (3) We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
- (4) We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement 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.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

- (5) Accordingly and in the light of paragraph 4 above, while maintaining our commitments to the TRIPS Agreement, we recognize that these flexibilities include:

- In applying the customary rules of interpretation of public international law, each 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.
 - Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
 - Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
 - The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.
- (6) We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
- (7) We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members 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 transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Annex 2

LIST OF OFFICIALS AND OTHERS MET

India

Dr R.A. Mashalkar
Director-General
CSIR and Secretary to the Government of India
New Delhi

Mr Sharad Gupta
Joint Secretary
Ministry of Chemicals and Fertilizer
New Delhi

Ms Veena Gupta
Director
Ministry of Chemicals and Fertilizers
New Delhi

Mr R. Srinivasan
Advisor (Economic Division)
Ministry of Commerce & Industry
New Delhi

Mr Manoj Joshi
Deputy Secretary
Ministry of Commerce & Industry
New Delhi

Dr Nagesh Kumar
Director-General
Research and Information System for Non-
Aligned Countries
New Delhi

Ms Sujatha Rao
Joint Secretary
Ministry of Health and Family Welfare
New Delhi

Dr Biswajit Dhar
Professor and Head
Centre for WTO Studies
New Delhi

Dr Rajeev Dhavan
Senior Advocate
Supreme Court of India
New Delhi

Dr Ashwani Kumar
Drug Controller General
Ministry of Health
New Delhi

Dr K. Satyanarayna
Deputy Director-General
and Chief IPR Unit
Indian Council of Medical Research
New Delhi

Ms Samita Bankoti
Advocate
Supreme Court of India
New Delhi

Indonesia

Mr Sampurno
Head
National Agency for Drug & Food Control
(NA-DFC)
Jakarta

Ms Mawarwati Djameluddin
Permanent Secretary
NA-DFC

Mr Dimas Samudra Rum
Head, Bureau of International Cooperation,
NA-DFC

Ms Linda Sitanggang
Director
Drug Evaluation and Registration
NA-DFC

Ms Lucky Slamet
Deputy I - Therapeutic Products and Narcotics
NA-DFC

Ms Linda Sitanggang
Director
Drug Evaluation and Registration
NA-DFC

Mr Udjiyanto
Director
Therapeutic Product Standardization
NA-DFC

Ms Kustantinah
Director
Inspection & Certification of Therapeutic
Product
NA-DFC

Mr Djunari Inggit Waskito
Director for Multilateral Cooperation
Ministry of Trade and Industry (MOT)

Mr Eliver Radjagoekgoek
Director for Regional Cooperation (MOT)

Mr Nurdin Hamid
Deputy Director for ASEAN Economic &
Technical Cooperation (MOT)

Mr Ramelan Subagyo
Directorate General of International Trade and
Ministry of Industry and Trade

Mr Parlagutan Lubis
Directorate of Patent

Ms Dede Mia Yusanti
Patent Examiner
Directorate of Patent

Ms Togi Hutajulu
Head
Sub Directorate of Drug Price Analysis and
Monitoring
NA-DFC

Ms Lina Astuti
Head, Drug Price Monitoring Section
NA-DFC

Mr Budi Djanu Purwanto
Head
Legal Division
NA-DFC

Mr Yos Hudyono
MSH - Independent Consultant

Ms Retno Tyas Utami
Head, Sub Directorate of Copy Drugs &
Biological Products
NA-DFC

Professor Lukman Hakim
Director
Centre for Pharmaceutical and Traditional
Medicine, Research & Development

Ms Karin Timmermans
Pharmaceutical Advisor
World Health Organization

Mr Djojo Sujono
Managing Director
PT. Ferron Par Pharmaceuticals

Mr Hendra Purnomo
General Manager
PT. Dexa Medica

Mr Kai Arief Selomulya
Head
Research & Business Dev.
GP Farmasi

Mr Ferry Soetikno
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