Introduction

For a long time, there has been a considerable amount of controversy about the balance between the costs and benefits of patents to society. It is widely asserted that patents are a necessary means of providing compensation to inventors for their inventive effort. In addition, patents are also regarded as a potent instrument that usefully serves the industrialization process of a country. However, the view that upholds the significance of the patent system to generate economic and social benefits has come under challenge. The argument against the patent system has been focused on the legal nature of patents that increases the market position of the patent holder and prevents the general public from using the information and accessing the patented article for the duration of the patent right.

There has been increasing concern about the costs and benefits of patents, especially when they are applied to the context of developing countries. It is contended, on the one hand, that patents facilitate research activities and this will lead to increased numbers of inventions in developing patent-granting states. Patents, it is further asserted, also play a crucial role in encouraging foreign technology owners to transfer valuable technologies to domestic entrepreneurs. In other words, by having a strong patent system, a developing country will increase its inventive capacity, which is a prerequisite for economic development. It has been argued, on the other hand, that the patent system is not designed to suit the needs of developing nations and there is no relationship between the availability of the patent system and the existence of technological development in the patent-granting country. The contribution of the patent system to the developing nations is minimal, compared to its costs. Due to the influence of this point of view, in recent years the question of how a developing nation can efficiently utilize the patent system seems to have been replaced by the question of how the profound impacts on the national economy which are derived from patents can be effectively controlled.

Pharmaceuticals are essential to improvement in the standards of living of all people, especially in the present environment, which is characterised by the high growth of population, poor living standards, damage to the environment and the creation of a serious threat to the health and survival of humanity. Since the late 1980s, the importance of pharmaceuticals has increasingly become crucial, when the developed nations, which are
the world’s producers and exporters of medicines, have raised concern about the absence of patent protection for pharmaceutical inventions in a number of countries, particularly in the developing countries. The advanced nations demand adequate and effective worldwide protection of pharmaceuticals and effective enforcement of patent rights throughout the world. The crucial question is whether the extent of patent protection for pharmaceuticals is of any advantage to the long-term improvement of living standards and the provision of health care in the developing countries.

This book attempts to examine the function of the patent system and to assess the contribution and effects of the patent system to the granting states. Attempts will be made to examine the current patent laws and the characteristics of the pharmaceutical industry in two developing countries: India and Thailand. At the beginning, it may be appropriate to point out the reason for examining the patent regimes in these two particular countries. The purpose of this comparative study is neither for the harmonization of law, in order to lessen the existing differences in the patent laws of both countries, nor for strengthening international co-operation in this area of law. Rather, it is aimed at investigating whether the functional patent protection system that has been developed and widely used by the developed world could be adapted for effective use, to maximize the benefits of modern technology, in other countries, which are at a different level of technological and economic development.

The book is organized and divided into eight chapters. The first chapter provides a general view of patents and examines how the patent system operates. It commences by tracing the evolution and development of the international patent system and some regional arrangements regarding the administrative procedures in relation to the harmonization of national patent laws. Chapter 1 also attempts to ascertain who benefits, in practice, from the existing international patent system, and probably why this is so. In addition, it looks at the question of what are the advantages and disadvantages, especially for a developing country, of belonging to international patent arrangements? Chapter two analyses the basic principles of major international agreements, the Paris Convention and the TRIPS Agreement which, so far, have provided the most significant rules regarding international patent protection. Chapter two also covers recent trends in the current global pharmaceutical patent regime. The text here reveals the attempts of developed nations to begin a coherent system of protection for pharmaceuticals at the international level. It discusses the use of unilateral trade retaliation, particularly the suspension of a generalized system of preferences (GSP) benefits and the investigation and threat of trade sanctions under the Special 301 provision of the United States Trade
Act, to curtail unfair foreign trade practices relating to inadequate in-tellectual property protection. Attempts are made to examine how the warning and threats of trade retaliation have influenced national patent regimes in developing countries.

Chapters 3 and 4 are devoted to comparative analysis of the substance and procedure of pharmaceutical patent acquisition under Indian law and the law of Thailand. Chapter 3 analyses the provisions and case law of India’s patent law. India has amended its patent law to bring it in line with WTO TRIPS provisions on patenting of pharmaceutical products. The new Indian patent law was revised with a number of ‘safeguards’ being added to the law. Whether or not the Indian generic companies will continue to produce necessary medicines depends on how some of the law’s provisions will be interpreted. The restraints in generic production in India will affect not only the public health in India, but also the accessibility to medicines of other countries like Thailand and other developing countries which rely on India as the main source of cheaper medicines. Chapter 4 then compares the Indian rules with the current patent law and practice in Thailand. An attempt will be made to examine the efficacies and inadequacies associated with the existing protection system and the effects of such provisions on the national economy.

Chapter 5 outlines the structure of world pharmaceutical production and consumption. It then undertakes an examination of the features of the Indian pharmaceutical industry. This chapter discusses the role of pharmaceutical companies in India in terms of research and development, market competition, and production and distribution of medicines within the country. The main focus of Chapter 5 is to explore the implications of pharmaceutical patents in a developing country with high technological capability by looking at the situation and experience of India, which is one of the world’s major producers and exporters of pharmaceutical products, particularly generic medicines.

Chapter 6 commences by providing an overall picture of the pharmaceutical industry in Thailand. This overview describes the strengths or weaknesses in the system of pharmaceutical production and distribution aimed at satisfying the health requirements of the nation. The chapter undertakes an examination of the performance of multinational pharmaceutical companies in Thailand. It also examines the possible consequences of pharmaceutical patenting in developing countries like Thailand, in particular when patents are utilized by pharmaceutical companies as a marketing technique for their overall business efficiency (that is, used as a mechanism for overpricing, transfer pricing and insertion of restrictive clauses in licensing agreements).

Chapter 7 proceeds to examine the questions of how pharmaceutical
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patent rights affect access to medicine in developing nations, and how to promote innovation by finding the proper balance of competition and patent law and policy. It discusses the legal mechanism relating to non-voluntary use and the compulsory working of patents. It provides a comparison of the national patent laws of India and Thailand on compulsory licensing and government use provisions, and examines the legal and political implications of the compulsory licensing system. Natco’s compulsory licensing case in India and the recent issuance by Thailand of non-voluntary licences on three patented medicines (that is, one for heart disease and two for HIV/AIDS) are discussed. The cases are significant as they reveal that compulsory licensing is the most effective way to reduce drug prices. The system can also be used by the government as a tool to use when negotiating with drug companies to secure lower drug prices. The chapter also discusses statutes and practices of the two countries and draws conclusions about the differing approaches of those nations. The chapter then provides a discussion about each country’s policy on data protection which directly affects the costs of medicines and public health care.

The last segment of the book analyzes and compares the major differences and similarities between the systems of legal protection for pharmaceuticals in the two countries. This book concludes by making some policy recommendations to the developing countries.