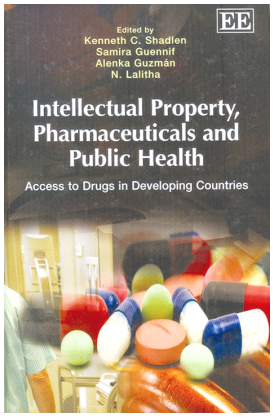

Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries. Kenneth C. Shadlen *et al.* (eds). Edward Elgar Publishing Limited, The Lypiatts, 15 Lansdown Road, Cheltenham, Glos, GL50 2JA, UK. 2011. xi + 338 pp. Price not mentioned. ISBN: 978 1 84980 014 3.

The book under review is an edited collection of research and review work on an industry that has been instrumental in making the world use intellectual property (IP). From the title, the book has an ambitious target to develop a framework that can balance the three axes – social, industrial and national needs.

The breakthrough technological innovations in genomic medicine, nanotechnology and biotechnology coupled with patent regime shifts, accord a marked change in the IP strategies followed in the pharmaceutical industry. This requires appropriate IP policies which would balance the industrial and humanitarian goals of a nation. The book has approached this challenge by providing rich empirical data for innovation and IP economists, policy makers and industrial economists to relate, understand and design appropriate IP policies that enhance social well-being. Researchers would benefit from the rich data sources available in the book.

The focus of the book is to understand the impact of globalization and harmonization of IP on the growth of the respective national pharmaceutical sector and public health. Every chapter gives a robust list of references which helps the interested reader to explore in-depth. It has chosen chapters that discuss the policy approaches of many of the developing countries in their quest to balance IP and public health. Case studies from South Africa, Morocco, Columbia, Mexico, Brazil, India, China, Thailand and Bangladesh have been woven along with the learning from Canada, a developed country, which has utilized TRIPS flexibilities in an effective way.

The book provides new data and cases especially from developing countries across the continents. The primary focus of the various chapters is to convey how nations have grappled with the problem of TRIPS and advancing IP protection against access and coverage of drugs to the public. An example of this is the effect of having generics in the US leading to a saving of US$ 9 billion (Leibowitz, 2009). Firms have a simple exit strategy for any type of regulation that a country brings in due to the public nature of the good. Examples of price regulations and their effect have been discussed in all the chapters. With detailed and rich sources of empirical information, this book is useful for academicians, students and policy makers to understand the dynamics of IP regimes on public health and innovation challenges faced by the pharmaceutical industry.

The introductory chapter discusses the attributes of pharmaceutical industry, rationale for TRIPS, and the difference in the pharmaceutical innovation capability across nations. The authors rightly point out the wide gap between developed and developing nations in terms of research infrastructure, disease types, health needs and capabilities, legal institutions and related policies. They suggest that the benefit of reverse engineering and imitation practices that are followed in developing countries due to a weak legal structure would impact the innovator and the innovating pharmaceutical organizations. The authors also raise the point of 'neglected diseases' being a major concern for public health policies in developing countries. TRIPS flexibility, DOHA declarations such as compulsory licenses and period of transition to a TRIPS compliance are discussed with a view to operationalize a nation's IP regime.

South Africa is the country that is analysed in the second chapter. Having very little drug manufacturing capability and with HIV pandemic, it is essential for the government to have a public health policy that emphasizes access to essential medicines. Various factors and policies like the government funding programme of USA for access to antiretroviral medicine, and other national acts to develop the pharma sector in South Africa are discussed in detail. The next case of Morocco shares the changing scenario of legal and policy framework. The modification of patent law of Morocco to align with TRIPS requirement and the various options taken are discussed in detail.

Moving to South America, the book includes studies from Columbia, Mexico and Brazil. The proliferation of Free Trade Agreements (FTAs) that are linked with a stronger IP regime (like TRIPS plus) has an impact of creating non-trade regulatory and non-IP lobbies in Columbia. The chapter on Colombia is rich and comprehensive with new information on generic equivalents, data exclusivity and public interest driven IP policy. Mexico has been a country of low-cost manufacturing to cater to its demand. Using its imitation capabilities, Mexico has utilized its IP systems to first enhance its industrial innovation capabilities with emphasis on access and healthcare systems. Brazil, the largest of the South American block to be discussed, is the first country to modify its patent law according to TRIPS compliance, albeit by taking care of its humanitarian needs. Compulsory licensing and universal AIDS treatment are examples of the state administration's approach to ensure that its IP regime benefits the nation by adapting the various TRIPS flexibilities available.

The trade policies of major countries in South and Latin America have been impacted through the liberalized NAFTA agreement that envisages an IP regime over and above with developed nations. This requires both strong institutions and power structure which understand and put a nation's needs first. Brazil and Mexico are studies in contrast – how the local pharma industry aligned with the social and industrial needs under mounting external political pressures of TRIPS, FTAs. Brazil designed to incorporate the various flexibilities available, while Mexico took the ownership rights route. Similar information on how other countries have approached the three aspects of generic equivalents, data exclusivity and public interest would have strengthened the book.

The chapter of Canada's experience is a welcome addition to understand how a developed country has approached the issue of IP in public goods. The uniqueness of Canadian patent policy is the presence of compulsory licensing, patented medicine prices review board, patented medicines regulations and

related aspects. These aspects of the IP policy balance the various FTAs in which Canada is a signatory. Such a presence in a developed (G-8) nation is an indicator of how political will and policy can ensure a balanced IP regime in a nation. Unfortunately, the developing countries push towards compulsory licensing and other public good supportive mechanisms are not encouraged. As the author suggests, a valuable export of Canada would be the expertise developed to design health and patent policy that incorporates the social values, economic priorities, industrial ambitions and unique legal environment.

Moving to Asian countries, this book has chapters on India, China, Thailand and Bangladesh. The chapter on India's approach deals with patent linkages, automatic licensing and open-source drug development activities that balance the non-IP-based market interventions practised. Contributing 20% of global generics and 8% of global pharma manufacturing, India's main concern is access to drugs that get limited due to the monopolistic tendency of IP. Recent case laws and modifications to the Indian Patent Act post TRIPS like Section 3(D), the abbreviated new drug application process and other government initiatives have been discussed. However, due to the lack of cases being finalized at the time of publishing this book, most of the case laws discussed are not complete.

The chapter on China presents the case of double-track system that was used for boosting Chinese pharmaceutical industry. The healthcare reforms of 2000 answered the growing social discontent with respect to medicine availability. Through its double-track system of providing an equivalent protection for patented drugs, China ensured a larger competition in the market. This ensures that the drugs are available through multiple manufacturers. With its drug price setting process, the demand was being met. However, the interesting facet of China's experience has been the marked high cost of medicines despite state control. This is attributed to the perception in hospitals and patients to buy high-cost medicines, restricted medical insurance, lack of doctors and services and absence of drug price control. China faces the typical agency problem wherein it has increased the number of agents (drug manufacturers) without a framework to manage the self-interests and needs of the principal – the user and the state. This is contrary to India's experience of having a generics market which ensured drugs becoming accessible, available and improvement in the innovation capabilities of its industry.

The case study of Thailand draws the readers' attention to the role of good manufacturing practices and IP regime to promote its pharmaceutical industry. Similar to African and other developing nations, obstacles of an IP regime which do not focus on access to medicines are stressed upon using Thailand's case. Thailand has not seen the increase in technology transfer or capabilities being strengthened post TRIPS implementation, nor has it seen increase in IP protection. Rather, it had to fight aggressively through parallel importation to reduce the drug prices.

Lastly, the book takes up the case of Bangladesh's pharmaceutical sector. By virtue of being present in the least developed countries list of the UN, Bangladesh faces tremendous challenge on three fronts, namely poverty alleviation, human resource capabilities and economic vulnerability. It faces systemic constraints in the health sector in the form of lack of scientific and research infrastructure, skilled people, industries and hospitals. While it followed India's approach towards drug control, Bangladesh did not continue with the necessary industrial support measures. This has resulted in the lack of active pharmaceutical ingredient production in Bangladesh. This leads to importation of the basic raw material for drug production and reduces the competitiveness of the country's pharmaceutical industry.

This book gives practical insights supported with empirical data on how various countries have approached the tricky aspect of balancing innovation, social and industrial perspectives, especially for public good. Detailed discussion on Canada's approach to IP and pharmaceutical industry alone makes this book important for policy makers to read and get insights and leverage the flexibilities available in the global political treaties.

However, notwithstanding the benefits, the book could have improved in certain areas. In its introductory chapter, the book discusses about creating a framework integrating the learning from various countries. However, the framework is hidden in the myriad data and empirical information that the book provides. There is no schematic way and hence it is laborious for policy makers to read through multiple chapters, before comprehending the components of the framework. Similarly, it was surprising to see that the editors did not have a concluding chapter that assimilated the key points from each country's experience towards developing a framework. The case of Columbia is one such example. This would have helped in creating the envisaged framework or minimally, created a checklist.

The book though having new data, is case-based, with no models proposed. Similarly, the India chapter does not discuss in detail the uniqueness of Section 3(d), a landmark approach not present in other countries, while focusing on pricing and market access regulations followed. The title of the book suggested a stronger, detailed analysis and learning from Section 3(d) related cases.

In conclusion, this book has provided a platform for health and patent policy experts and researchers to translate the framework and develop implementable models that incorporate the social values, economic priorities, industrial ambitions and unique legal environment faced in a developing country, especially for public goods.

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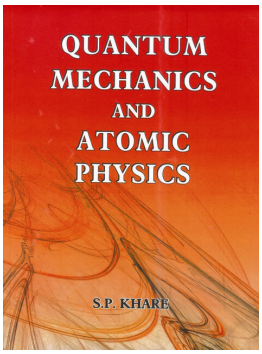

Quantum Mechanics and Atomic Physics. S. P. Khare. Published by Rakesh Kumar Rastogi for Rastogi Publications, 'Gangotri', Shivaji Road, Meerut 250 002. 2014–15. xiv + 360 pp. Price: Rs 245.

The book under review should be useful for the target audience of university