

**BOOK REVIEW****INTELLECTUAL PROPERTY, PHARMACEUTICALS AND PUBLIC HEALTH: ACCESS TO DRUGS IN DEVELOPING COUNTRIES**

*By Kenneth C. Shadlen, Samira Guennif, Alenka Guzmán and N. Lalitha (Editors)*

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Intellectual property, pharmaceuticals and public health – taken separately these fields encompass vast areas, with ever shifting scope. Tackling the intricacies of the access to medicines in an expansive number of developing countries, editors Shadlen, Guennif, Guzmán and Lalitha have produced a piece which has succeeded in giving a comprehensive picture of the influencing factors in this area.

This collection examines the political, economical and industrial contexts of the pharmaceutical industries, health policies and access to medicines in developing countries through a series of chapters on national experiences. Owing to the experience of individual authors in their chosen country/countries, the resulting piece manages to give an in-depth, comprehensive assessment of these issues.

Divided into twelve chapters spanning across Africa, Asia, and the Americas, this book highlights the disparate approach of developing countries to the strengthening of intellectual property rights (IPRs) protection and the effect this has had on their access to medicines. Chapters vary distinctly in focus and scope so whilst they complement each other as a whole, there is little repetition between the chapters overall - the most interesting aspect is this diversity between the various national experiences.

Since the signing of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) in 1994, member states of the World Trade Organisation have been required to implement global minimum standards of protection for IPRs. A transitional period was put into effect for developing countries and least developed countries extending the date of implementation to 2000 and 2013 (2016 for pharmaceutical patents) respectively. These minimum standards, as shown throughout this collection, were new to many developing countries and therefore many new legal regimes were introduced in order to comply with the agreement.

The book opens with a general overview by the editors on globalisation, IPRs and pharmaceuticals. As an introductory chapter, this discussion gives the reader a grounding in the topics and debates that will be discussed in further detail with regard to specific countries in the forthcoming chapters – those of patents & innovation, global health needs, and policy alternatives to protect public health. It provides a general overview of the problems faced in developing countries with regard to pharmaceuticals in a globalised world.

The first chapter deals with pharmaceutical production and access to medicines in South Africa. In the face of the HIV/AIDS pandemic, access to essential and affordable medicines is imperative for South African citizens. In the post-Apartheid era, attempts were made to introduce a legal regime to this effect; however, these attempts were opposed by the pharmaceutical industries. A common thread running through the text is the battle between government attempts to introduce beneficial regimes to achieve greater access to drugs, and the opposition of major pharmaceutical firms and industry striving to protect their profits. Klug points out that the situation is difficult owing to South Africa's lack of capacity in reverse engineering to boost local production – dependence is on foreign funding and licensing.

Remaining within Africa, the next chapter considers the Moroccan situation of a paradox in policy. Krikorian shows that the new Moroccan legislation, along with the US free trade agreement (FTA), has made patent law more restrictive than TRIPs in certain areas including compulsory licensing due to pressure from the developed world. This is further exacerbated by the restriction on parallel imports and no "Bolar" provision. However, a range of new policies and practices have also been introduced to develop better health care and pharmaceutical products. This includes universal medical coverage and access to antiretroviral medication. However, these policies are under increasing financial pressure. Krikorian suggests an improvement in the balance of Moroccan laws and policies, and reform of the current legal situation to improve public health and access to affordable medicines.

The next section discusses these issues in the Americas. The first case study is Columbia in which Andia highlights a number of developments leading to the new pharmaceutical regulatory era therein. This involves two separate, yet related, trends: the proliferation of FTAs which advocated the strengthening IP protection; and non-IP and non-trade related measures to regulate biotechnological drugs and price controls.

The FTAs faced extensive lobbying from health NGOs and local industry, leading to the reversal of measures strengthening IPRs. The non-IP and non-trade regulations included those on price controls, marketing approval and data protection for biotech drugs, which Andia considers essential to fostering local pharmaceutical production and enhancing access to health care. However, the Columbian experience shows the price regulatory system ultimately increased IP rights. An interesting finding is the lack of coordination among lobby groups in this area; it seems that it may be easier to come together over international pressures than local regulatory initiatives.

In subsequent chapters, case studies move on to Mexico and Brazil. Guzmán shows the challenges of promoting access to medicine in Mexico; Flynn examines Brazil's use of TRIPs flexibilities for its national AIDS program; and Shadlen ties both countries together in a contrast between the politics of patents in both countries.

Guzmán argues that Mexico's IPR reforms favour foreign companies and reduce incentives to invest in local R&D. The strengthening of patents is also raised as a concern that could deepen technological dependence, becoming a barrier to the entry of imitative activity due to the related high cost. The pharmaceutical market has gone from being a globally strong market player to facing issues with new regulations. These regulations included the termination of the similar generics market and the

cancellation of the plant request. The balance of trade is also an issue for Mexico; exports may be significant, however, imports have reportedly grown even more.

IP law reforms have also sullied the situation regarding access to drugs making it extremely difficult to obtain a compulsory licence and imposing patent linkage. These changes seem to have reduced the availability of cheaper generics and so too access to medicines. The governance of the health system is also seen as a barrier to medicines. Although programmes have been introduced to help, Guzmán identifies backwardness in the coverage and financing of health.

Moving from Mexico to Brazil, differing developments have emerged. Flynn provides an assessment of the access to AIDS medication in Brazil which shows the use of TRIPs flexibilities. He argues that Brazil is ahead of its time in providing access to AIDS treatment using compulsory licenses. However, in the same year as the implementation of a free and universal AIDS treatment program, Brazil passed a highly restrictive patent legislation due to intense foreign pressure from developed countries. Subsequently “flexibilisation” was pursued when the high price of patented medicines began to threaten the sustainability of that program. Pressure from civil society organisations has assisted with the fight for access to medicines, as have threats of compulsory licenses. What can be gathered from the Brazilian case is that developing countries need to ensure the preservation of TRIPs flexibilities in order to ensure access to medicines.

Shadlen reinforces the differences between Brazil and Mexico – in the political context – in the standout chapter of this book. Whereas Brazil adjusted the IP system to improve the effects of drug patents, Mexico introduced few adjustments which ended up intensifying the effects of drug patents. The crucial variant was who led these initiatives for change – the local pharmaceutical sector versus IP owners. The key lesson to emerge is not only to look at the legal changes but also the broader political economy framing international agreements; traditional variables need to be taken account of, especially a comparison of the health-related aspects of patent regimes. Where Brazil made compulsory licenses easier to obtain, Mexico made it more difficult; Brazil introduced the early working provision, whereas Mexico introduced patent linkage. The key to patent system reform to increase access to medicines is an economically and politically autonomous national pharmaceutical industry that advocates such reforms.

Morin and Forcier offer up the Canadian experience as a possible exemplar for developing countries. Its unique former patent policy could be an option for large countries with generic manufacturing capabilities, foreign investment in the pharmaceutical sector, investment in drug discovery, IP obligations and constant pressure from the US to develop strict patent laws. The authors point to the use of compulsory licenses, the introduction of the early working provision, as well as the stockpiling exceptions and a unique price regulation scheme. They argue that the Canadian experience could ensure quality production of drugs, price control and access to genetics.

This collection continues its investigation with an analysis of Asian case studies including on India, China, Thailand and Bangladesh.

Lalitha focuses on India and discusses steps taken by government, IPR issues and international initiatives to improve access to generic drugs. It is found that although the government have introduced systems and health measures to assist with access to medicines, these schemes are not widely prevalent in every state government. Using a number of notable case studies contesting Section 3d of the Indian Patent Act, Lalitha argues that a removal of this provision – restricting the scope of patentability – would be detrimental to access to medicines. Lalitha states that India must resist pressure from developed countries and use more compulsory licensing to provide access to medicine, reflecting a recurring theme of the text.

The double track system of drug listing in China and its related institutions is the basis of the next chapter. Watanabe and Shi explain the problematic scenarios where hospitals have a strong preference to prescribe more expensive drugs because their revenue depends on dispensing drugs with high profit margins. Despite sufficient access to medicines, prices remain high. It is argued that the double track system has increased the number of firms entering the market but due to the income structure of hospitals, drug prices will remain at an unattainable level and so reforms are recommended.

Despite the introduction of TRIPs measures in Thailand, Guennif concludes that difficulties remain in providing affordable medications. The blame is not placed entirely on the patent system, but also on the shrinking national production structure and dependence on foreign supply. Thailand previously succumbed to international pressure to strengthen IP protection via bilateral trade agreement, banning parallel imports and limiting compulsory licenses. After the introduction of TRIPs the situation was improved, but patents on pharmaceuticals were also implemented. As a result, the proportion of locally produced medicines steadily declined. These standards have acted as a barrier to national actors and have had damaging effects on the access to medicines. Guennif also discusses the future challenge of the Thai/US FTA, rightly advising caution and avoidance of any TRIPs plus provisions.

The collection's shortest case study also happens to be one of the most intriguing due to the fact that Bangladesh has yet to introduce pharmaceutical patents. Having an established pharmaceutical industry dominated by local firms, with a wide range of generics, Bangladesh is different to the vast majority of developing countries. Compliance with TRIPs is mandated by 2016 and so Sampath examines the changing strategy towards pharmaceuticals and health innovation in light of this obligation. Bangladesh faces a lack of capacity in producing active pharmaceutical ingredients, decreasing competition, and no capacity in reverse engineering; acting as the best protection for foreign firms entering the market. The problem in Bangladesh points to a shortage of scientific and physical infrastructure and institutional failure. The policy framework needs dynamism and a restructuring to balance local innovation with greater access to medicines in the future.

The structure and multi-regional analysis of this collection ensures a series of insightful and complementary case studies. An effective feature throughout the text is the skilled use of country data and resulting graphs to give an overview of a nation's overall status regarding patents, prices of medicines and related health statistics. As a result, concise broader (visual) outlines of the state of play in the various case studies emerge.

*Intellectual Property, Pharmaceuticals and Public Health* is an impressive and comprehensive book which gives the reader an insight into the convergence of IP and public health, backed up with data and statistics throughout. Owing to the globalisation of trade and introduction of TRIPs, developing countries have to be attuned to how best to ameliorate their legal regimes. The importance of ensuring international best practice is paramount for these nations. Shadlen, Guennif, Guzmán and Lalitha's text shows both how, and how not to, go about ensuring such success.

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