The Denning Law Journal 2014 Vol 26 pp 346-349

BOOK REVIEW

The Legal Duel: The TRIPS Agreement and Drug Access Issues Is the Agreement Actually the Cunning Manoeuvre it has been Dubbed? Kenya-India Case Studies

Dr Brenda P Mey, Peter Lang GmBH, Frankfurt 2013
ISBN 9783631628010 Price £66.00 PB

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The problem of access to medicines became acute with the entry of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in 1995 and caught a number of developing countries around the world, unawares. Brenda P Mey's book on access to drugs issues is a study of this particular problem faced in two developing countries, namely India and Kenya in the aftermath of the implementation of the TRIPS compliant patent legislation. The two developing countries taken up for study are geographically located in two different continents, namely Asia and Africa with differing backgrounds and strikingly similar problems. Dr Mey's book is a brainchild of her PhD thesis of the same title, and a library reference work in every sense. It showcases her talents as a researcher and analyst on the subject matter of lack of access to medicines (in this case India and Kenya) as a direct result from the implementation of TRIPS Agreement, which grants an extended patent protection to pharmaceutical and chemical products besides others.

Most developing countries and least developed countries were not fully aware of the consequences of an extended pharmaceutical patent protection sought to be introduced through the World Trade Organization's (WTO) multilateral trading system, and were hence not fully prepared when the TRIPS Agreement was implemented. India and Kenya, who produce affordable off-patent generic medicines which in turn are widely used in frontline treatment of diseases like HIV/AIDS, malaria, etc., in other developing countries and least developed countries around the world. Both India and Kenya, as members of the WTO were required to introduce TRIPS

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compliant intellectual property legislation into their domestic laws, which was to impact their pharmaceutical industry, particularly their capacity to produce and export generic medicines. Notwithstanding the impact on domestic manufacturing of generic medicines, the TRIPS Agreement had also seriously affected the access to affordable medicines for millions of people around the world due to a multi-fold increase of patented pharmaceutical products. The overall theme of the book focuses on the extent to which the IP rights regime (including flexibilities) introduced under the TRIPS Agreement has been used as a tool for enabling access to affordable medicines in India and Kenya, and the effect of the TRIPS regime on their domestic pharmaceutical industry.

As the book is based on the author's PhD thesis, the groundwork is detailed and the questions raised to achieve the goals set out are clear and specific. The core objective of the book is to find answers to the question posed in the title through the examination of provisions relating to the protection of pharmaceutical patents contained in the TRIPS Agreement, and in the domestic patent law legislations implemented in India and Kenya following the entry of the TRIPS Agreement. The key questions raised on the above theme are, i) what flexibilities are built into the TRIPS to assist the developing country member states (especially to suit Kenya and India), to enable them to pursue pro-public health policies geared at facilitating access to medicines; ii) what are the limits that prevent the application of these flexibilities at national levels; iii) how the obligation to promote and protect the right to health may limit the exploitation of the flexibilities contained in the TRIPS Agreement; iv) how have the two countries, Kenya and India, exploited the flexibilities at national levels to promote cost-effectiveness in their health sectors, while still acting within the overall confines of the TRIPS; and lastly v) what are the problems encountered by Kenya and India in the effective implementation of the flexibilities. The use of a range of research methodologies including exploratory, descriptive, qualitative and quantitative methodologies, and interpretation and analysis of court cases, benefits the work. In particular, Kenya's and India's experience with the actual implementation of the TRIPS has been clearly brought out. The use of different methodologies has been attributed to the fact that the study is interdisciplinary and not limited to intellectual property rights protection.

As a precursor to the case studies, Dr Mey has devoted a chapter of the book to the study of the philosophical foundations/justification for grant of extended protection for pharmaceutical patents under the TRIPS Agreement. This chapter with the analysis of property rights theories, tracing the origins from the utilitarianism to the incentive based economic justifications. Dr Mey covers the theories propounded by Locke, Kant and Hegel, Hume and Bentham to the more recent works of Hettinger Lemley from the twentieth century. This part of the book is probably one of the most important areas of

the study, as it also seeks to balance the justification for patent protection with the right to life contained in various international conventions, including Universal Declaration of Human Rights (UDHR), International Convention on Economic Social and Cultural Rights (ICESCR), and in other regional human rights instruments like the African Charter on Human and Peoples Rights (ACHPR).

In her quest to seek answers to the above lead questions, Dr Mey carefully presents the historical background of both countries taken up for study. Kenya and India both former British colonies inherited from their common colonial ruler parliamentary democracy, civic administration, and the common-law legal systems (including IP rights legislations and practices). Kenya and India's IP laws mirrored Britain's patent system dating back to 1856, and were replaced in later years in the post-colonial era. One other reason for the comparative study of patent laws in Kenya and India is attributable to the fact that both Kenya (in sub-Saharan Africa) and India (Asia) possess a healthy pharmaceutical industry (developed in their post-colonial era), yet the two countries are worlds apart. The Indian pharmaceutical sector is, in comparison to Kenya's, much more advanced and remains a major supplier of pharmaceuticals products to both Kenya, and other developing countries. Indian pharmaceutical sector, although produces bulk drugs for most disease segments, is still mainly dominated by generics medicines developed on the back of a process patent system introduced in the pre-TRIPS era. This legislation was introduced in India in 1971, on the back of recommendations from the Justice Iyyangar Committee, which recommended a clear departure from the product patent model introduced under British rule. With the above laws from 1971, India was able to address the public health concerns domestically and also at the same time accord the foreign patent holders operating in India some form of protection for their inventions.

All this was to change with the entry of the TRIPS Agreement in 1995, which introduced a product patent system and a 20-year period of patent protection for pharmaceutical products and others. India, till such time it introduced the TRIPS compliant patent laws, had for years been an important supplier of affordable generic pharmaceutical products to many developing countries. To put things in perspective, African countries account for 15% of India's US $8 billion pharmaceutical exports. Kenya, the third-largest African market for generic drugs from India, is estimated to have imported drugs worth more than US $70 million in 2008. The introduction of the TRIPS Agreement had not only seen a rise in the prices of patented pharmaceutical products in developing countries, who don't have a proper health care system, but also has seen the drying up of affordable generic pharmaceutical products from India. One of the populations seriously affected from the problem is those affected by HIV/AIDS and living in developing countries and least

developed countries, and in particular in sub-Saharan Africa, as they are unable to access frontline antiretroviral (ARV) drugs for their treatment.

Coming to the social economic conditions of the Kenya and India, the Dr Mey points out that although Kenya is classified alongside India as a developing country, its industrial development and scientific capacity is not as advanced as India's. She most importantly observes that intellectual property rights can be said to be better established in Kenya than in India through patent laws that are fully TRIPS-compliant. She is also quick to point out that problems of corruption, weak institutional and regulatory frameworks for implementing and enforcing IP rights have "continually restricted the ability of both countries to effectively protect and enforce their IP rights in a manner that allows them to progressively participate in international trade negotiations and international standard-setting processes." The introduction of intellectual property rights protection in the WTO negotiation process and thereafter in the multilateral trading system is dealt with clearly, and so is the opposition from the developing country member states of the WTO. It is very obvious that the work is based on a PhD thesis as demonstrated by the structure, the research questions raised and the methodologies and the style employed. This does not in any way diminish the intensity of the work in addressing the key issue of access to medicines in India and Kenya, with the entry of the TRIPS Agreement.

While intellectual property laws are said to encourage innovation and remains an interesting area of study in the twenty first century, the enforcement of the intellectual property rights relating to pharmaceutical products at the WTO, through the instrument of TRIPS Agreement appears to be strained, and coming at a heavy cost, *i.e.*, human cost. There had been a few titles on the subject of access to medicines, and the plight of the patience in developing countries who suffer needlessly due to the extended protection afforded to pharmaceutical patents under the TRIPS Agreement, but the one under review is different and presents a balanced study of two developing countries who have a developed pharmaceutical sector in the post-colonial era, but have struggled in the implementation of the TRIPS Agreement. For the serious researcher, the book by Dr Mey presents a stark picture of the realities of access to medicines in the developing countries of India and Kenya, and how the reality in the ground had changed since the implementation of the TRIPS Agreement into their statute books. Overall, Dr Mey's book is well researched, presenting a sensitive picture and offering an insight into the legal, political and economic realities of the problems faced by the two countries in their efforts to find a balance in the implementation of the TRIPS Agreement.