1. Introduction

Science is the most reliable guide in life
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BACKGROUND

The origins of pharmaceuticals can be traced back to ancient times. The practice of medicine was at a relatively advanced stage in ancient civilisations. Naturally occurring substances were often used to heal wounds and to relieve pain and treat infections. Medicines were compounded from a variety of substances including the remains of animals, plants, and minerals, as well as from other traditional sources, for example, honey.

The urbanisation process, which occurred following the Middle Ages, contributed to the development of the specialised field of apothecary, a method of formulating and dispensing materia medica\(^1\) for healing purposes. The process of drug manufacturing was associated with apothecaries, who specialised in preparing and dispensing drugs according to recognised standards. In the centuries that followed, these apothecaries became known as ‘chemists’ and ‘druggists’, many of whom initiated the process of drug discovery in their back-street shops.

The Industrial Revolution, which began in the 18th century, changed the way of doing things dramatically. There was a clear shift from manual home productions to machine-based manufacturing that took place in factories. The development of new industries and factories coupled with the usage of new machinery contributed to the rising level of economic growth in Europe and North America.

The Industrial Revolution began initially in Great Britain. It then spread throughout other European countries such as Germany, France and Switzerland, and also reached North America. At this time, a significant amount of technology transfer took place, moving from Great Britain to all the latecomer countries. This technological and economic catch up was based on borrowing, copying and modelling. Flexible legal systems

\(^1\) ‘Materials of medicine’ in Latin.
and supportive government policies appreciably contributed to the industrialisation process.

In the late 19th century, German dye companies emerged as the vanguard of a new generation of pharmaceutical companies. German companies initially transferred knowledge and technology from Great Britain. These companies imitated British manufacturing methods. Nevertheless, the German companies invested heavily in research and development (R&D). Importantly, the companies established research collaboration agreements with the universities. When compared to their British rivals, the German companies were more successful in using their capital efficiently and avoiding legal wrangles regarding patents. The German companies expanded their R&D activities into the chemistry area. The firms developed techniques in relation to synthesising and the development of chemical compounds. These efforts later led to the nucleus of the modern pharmaceutical industry. By the early 20th century, the German dye industry had become a global powerhouse that effectively dominated the world chemical and pharmaceutical market.

The rise of the German dye industry was a turning point in the history of the pharmaceutical industry. It prompted the investment of tremendous resources in pharmaceutical R&D in other countries. The discoveries of penicillin and insulin revolutionised the course of drug discovery. The emergence of new technological opportunities for drug development and increased R&D activities enabled American companies to grow into pharmaceutical world powers.

Over the course of the 20th century, most European countries as well as Japan had completed their industrialisation process. These countries made remarkable achievements in the areas of drug discovery and development. The pharmaceutical companies in the US, Western Europe and Japan became the dominant inventors and suppliers of the world drug market. This Western shift from a position of being a borrower to being an innovator created a global market for intellectual property rights (IPRs) protection. Patent protection, in particular, became vital to the continuation of the innovative pharmaceutical company model. The high profit margins associated with pharmaceuticals lent consistency and continuity to the industry. The respective national governments soon realised the industry's huge potential in creating an attractive growth market for investment, employment and exports. Thus, the pharmaceutical industries in developed countries started to play an influential role in developing social, political and economic issues of national and international importance.
During the last quarter of the 20th century, the social and economic distinction between industrialised developed countries, and the non-industrialised developing countries became much clearer. The scientific and technological gap between these two categories of country became apparent, particularly in the area of life sciences. Some of the developing countries invested a great deal of effort towards narrowing this widening gap by building up their local capacities. These countries explored alternative approaches as a means to close the gap and they pushed hard on the development side. At that time, it appeared that the best option was to follow the traditional development path taken by most of the developed countries. This traditional process includes a learning process that largely involves imitation. Over the course of the industrialisation process, all developed countries have ultimately relied heavily on imitation in order to build up their own technological capacities and to assimilate knowledge. At the time, conventional wisdom suggested that imitation was a stepping-stone to innovation. In fact, industrialised country experiences suggest that imitation or free riding is indeed an essential and primary part of the catching up process. Hence, as part of this process, the first thing for a country to do was to establish a legal environment conducive to the development goals of the country. Most of the developing country economies at the time were unable to deal with the increased population and health care costs. Due to an increasing number of health crises, access to affordable medicines emerged as an important policy issue. There was a constant public interest in serving national supply requirements.

To a certain extent, in an effort to facilitate imitation and borrowing and to cut increasing healthcare costs, most of the developing countries opted not to grant patents for pharmaceuticals products and/or processes. The absence of patent protection assisted the progress of local pharmaceutical industries in developing countries. Companies within these countries specialised in generic medicines and built up capacities in drug manufacturing. Certain countries such as India and China became the exporters of generic drugs to Africa and other developing countries/continents.

Soon enough, the Western pharmaceutical companies experienced a significant decline in their global market sales. This led to trade deficits.

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for developed countries, and the US economy was particularly affected. Eventually, what became known as the ‘other drug war’ came to the forefront of US policy. Using its strong lobbying power, the pharmaceutical industry wanted the US government to take measures against developing countries and the generic companies therein. Thus, the US government initiated trade sanctions against certain developing countries in order to force them to introduce and enforce IPR protection for pharmaceuticals. By then, the good policies of the past became the bad policies of the present day. Although the US was once itself an imitator country, in recent times the US industry has vowed to take a zero tolerance policy towards borrowing and imitating. The outcome of the bilateral dialogues was not successful. In other words, it was not sufficient enough to protect the global market for IPRs. Hence, the developed countries, led by the US, took the issue to the multinational setting in order to create an ambitious and comprehensive agreement on standards for the protection of IPRs of all kinds.

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was a package deal, whereby countries made certain concessions in exchange for trade benefits. It stands as the first multilateral treaty that sought to use IPRs as commodities in the area of international trade law. TRIPS set the standards for the global market of IPRs and it established the minimum standards for protection. The placement of IPRs in trade agreements has led to strict restrictions on knowledge diffusion and transfer. The historical record of industrialised countries shows that traditionally knowledge was transferred freely across national borders, during the period when the developed countries were themselves developing countries. Nevertheless, after TRIPS, knowledge became a trade-related commodity, subject to strict rules. To put it differently, TRIPS changed the nature of the game to one where the winner takes all.

It was particularly controversial that TRIPS made patents available for pharmaceutical products. The advocates of the agreement have claimed that strong protection of pharmaceutical products is necessary to ensure greater technology transfers and foreign direct investment (FDI) in R&D in developing countries. Undoubtedly, such a confrontational approach ruled out the possibility of catching up using the traditional process of industrialisation through imitation and adaptation. This process is historically proven to be an effective strategy for developed countries. Another emerging problem was the foreseeable negative consequences of a strengthened patent regime on healthcare costs and access to medicines. This was one of the unique circumstances that characterised...
the TRIPS negotiations. The developed countries stayed totally indifferent in relation to addressing the negative outcomes of a strong patent regime on developing countries. Even though there were attempts to overcome such problems, the global solution has remained elusive. Arguably, the solution is still at the mercy of developed countries and multinational pharmaceutical companies.

Nevertheless, this does not necessarily mean that developing countries have run out of options. At an individual country level, a degree of optimism still exists. Some developing countries have encouraged a sustainable local pharmaceutical industry. This provides heartening evidence that developing countries may yet be able to change the nature of the game to one where the winner does not necessarily take it all.

The relationship between patents, innovation and developing countries is a complex, multi-faceted and multi-disciplinary one. The impact of the IPRs regime on local innovation and economic development has been an issue of controversy in recent years. The role of IPRs in the innovation process has recently been challenged by economic studies. These studies have demonstrated that patents do not act as a determinant of R&D investments in many industrial fields. Moreover, the post-TRIPS experiences of developing countries have made it evident that the global IPRs alone have delivered little more than broken promises to developing countries.

Nevertheless, developing countries still have a number of options for surviving the post-TRIPS period and the potential to boost their current levels of pharmaceutical innovation. The research on IPRs and TRIPS to date has tended to focus on legal issues rather than practical issues, that is, the national innovation strategies and systems.

The national innovation system greatly contributes to the growth of the economy. This contribution includes increasing the flow of technology and knowledge and raising levels of socio-economic development. It has become evident that unless IPRs are well supported by other complementary socio-economic essentials, the existence of an IPRs regime is unlikely to support innovation and development within a country. Thus, countries are well advised to create effective innovation strategies that utilise the relevant TRIPS flexibilities, enhance their local capabilities and prioritise technology transfer and information flow.

To this end, this book sets out a number of recommendations on how this can be achieved. This is done in relation to the key development objectives of promoting the technological and scientific advancement of the country, enhancing local pharmaceutical innovation capacities, providing wide access to medicines and knowledge, safeguarding public health interests and fostering innovation.