CHAPTER SUMMARY

In this chapter, Michael Ravvin discusses the ways in which the existing intellectual property system discourages the innovation of, and access to, essential medicines for the poor in developing countries. He begins by surveying the features of the existing pharmaceutical patent system that give rise to the problems. He then offers critical analysis of some reform proposals. He argues that some existing mechanisms intended to mitigate the limitations of the current pharmaceutical patent system are inadequate and perhaps even counterproductive over the long term; while others are often inefficient and limited in scope. He believes that approaches that offer reward for successful pharmaceutical innovations are the most promising mechanism for overcoming the barriers to access and benefits for the poor in developing countries. He discusses two such approaches in particular, the use of priority review vouchers and the Health Impact Fund.

RELATED READINGS

Introduction: Justice, Access, and Equality (2.6.2)
Other Chapters: Fritz Allhoff, The Coming Era of Nanomedicine (Ch. 11); Kenneth Himma and Maria Bottis, The Digital Divide (Ch. 22)

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1. INTRODUCTION

Millions of the world’s poor die every year from preventable, curable or treatable illnesses. This is partly due to the existing intellectual property regime, which discourages the innovation of, and access to, essential medicines for the poor in developing countries. There are two crucial areas in which the current system must be improved. The first is access. Under the current pharmaceutical patent system, the market exclusivity guaranteed to patented drugs makes them inaccessible to the poor due to high prices. Drugs that are available to the poor through philanthropic and other efforts often face challenges of distribution. Second, it is essential to devise a mechanism that incentivizes innovation of pharmaceuticals for diseases that predominantly afflict the poor in developing countries. Currently, potential innovators have no financial incentive to invest in R&D for poor country diseases, since those who need these medicines will not be able to afford the monopoly prices that are necessary to recover costs. A successful proposal to reform the existing system must address the challenges of access and innovation. This article provides a survey of the problems with the existing pharmaceutical patent system and a critical analysis of some recent proposals to remedy them. I will conclude with some thoughts on the most promising directions for reform, and the challenges that remain.

2. PROBLEMS IN THE CURRENT SYSTEM

The existing pharmaceutical patent regime is defined primarily by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), signed at the end of the Uruguay Round of WTO negotiations in 1995. This agreement governs nearly all aspects of intellectual property in international trading and the domestic law of states parties. TRIPS requires all WTO member states to adhere to strict patent protection laws for pharmaceuticals that guarantee at least 20 years of market exclusivity for patented drugs.

Prior to TRIPS, different countries had different patent laws, which often reflected their level of development and social goals. Developed countries typically had very robust patent laws, providing strong protection for monopoly manufacturing and sale of patented products. In developing countries, looser patent protection allowed generic drug manufacturers to provide safe and affordable generic versions of drugs still under patent protection in developed countries. Many countries had no patent protection for pharmaceuticals at all. In the absence of patent protection and alternative reward mechanisms, innovators had no way to recover costs and make profits on pharmaceuticals developed for diseases that predominantly afflict the developing world. It is therefore no surprise that little R&D was devoted to poor country diseases. Nonetheless, poor countries had some access to cheap and reliable medicines that were under patent protection.

This generic industry was effectively shut down in 2005, when the 10-year compliance window for TRIPS closed for all but the least developed countries. WTO members were required to bring their domestic patent laws up to TRIPS standards, effectively universalizing the strong patent protection favored in developed countries. The provisions of this treaty have been supplemented by bilateral TRIPS-plus agreements that often extend the effective life of patents well beyond