

(Abstract)

Towards a New Development Model for the Asian Drug Industries: A Comparison of Latecomers, Late-latecomers and Outliers

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The rise of the generic drug industry has afforded a new opportunity for economic growth for a number of emerging markets in Asia. Indeed, though the United States and the European Union are both major consumers of generic drugs, it is now India that is the world's largest producer. With the rapid aging populations in many nations worldwide coupled with the growing middle class in emerging economies, the market for generic drugs is likely to become a high growth sector for many firms—regardless of their country or region of origin. The FDA states that “A generic drug is identical—or *bioequivalent*—to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.” (Food and Drug Administration) In this paper, “generic” will be defined as a medicine to which no one company or individual can claim *exclusive ownership* rights as opposed to other possible definitions such as bioequivalence.

Apart from a select group of companies in developed nations such as the United States, some European nations and Japan, there are few firms capable of launching novel, globally marketable medicines. The main reasons for this are obvious: the high rates of failure combined with the growing cost of launching a new branded pharmaceutical. (DeMasi, Hansen, Grabowski, p. 151) Nonetheless, some companies in developing countries have been able to enter the generic drug sector successfully and in some cases make considerable inroads for two reasons.

The first reason is relatively low entry barriers. Branded pharmaceutical producers invest heavily in the development of new drugs, while generic companies need only make modicum investments in (1) R&D (research and development) and in (2) marketing, the two most costly expenditures in the development and launch of a new product. (DiMasi et al, pp. 153-154) Thus by scaling up production capacities, generic drug manufacturers in some latecomer nations in Asia such as India and Thailand, have succeeded in expanding their sales channels both regionally and in other emerging economies worldwide. Ironically, some Indian drug manufacturers even export to the developed nations—the United States and Europe—where the same drugs they now produce were initially invented.

The second reason is changes in public health policies in developed countries, designed specifically to curtail healthcare costs. This shift has fostered a more favorable institutional and regulatory environment for the use of generic drugs. On the other hand, domestic policy changes in developing countries, namely the introduction of universal healthcare systems, have also provided an improved

business climate for some local generic drug manufacturers thanks to increased demand for medicines. One example is Thailand whose government put in place a universal healthcare scheme in 2001. The Thai government currently provides free treatments including medicines to those who formerly had no healthcare coverage. (Health Insurance Research Office, p. 19) This has sparked an increase both in the demand for medicines and growth in the domestic industry.

The implications of the emergence of a global generic drug industry differ greatly according to the firm in question. For companies in emerging markets, the generic drug industry signifies a promising new sector of growth. However, for those in developed economies it is often synonymous with the end of a product cycle and the decline in the innovative capabilities of a once overwhelmingly dominant branded pharmaceutical industry. While one might associate generic drug production as an industry of emerging economies such as India, in recent years, the situation has been changing considerably. Because of the expiration of the patents of many of the so-called blockbuster drugs combined with the dearth of new innovative alternatives, some large-scale pharmaceutical producers in developed nations have joined the generic drug industry as a new strategy for diversification, globalization, and, as some may assert, survival.

The primary purpose of this paper, which is divided into three sections, will be to examine the emergence and transformation of the global drug industry from a historical perspective. The first section will trace the process by which small-scale producers of generic drugs in developed countries, specifically the United States were transformed into large-scale manufacturers of branded drugs thanks to the introduction of a patent system in the early postwar period. This process essentially began in the United States, whose companies were able to take an early lead and expand their operations into overseas markets. The second section will investigate the reasons for the emergence of global generic drug manufacturers. The third section will provide a brief analysis of three Asian nations and the impact of the introduction of stricter intellectual property regimes on the development of the generic drug industry in that particular nation. While bearing in mind the findings of the previous two sections, the writer will use the findings of the three case studies to determine the correlation between the timing and type of drug patent system and the disparities in the development trajectories of the drug industry across nations in the same region.

Notes

DeMasi, J.A., Hansen, R.W., Grabowski, H.C., (2003) 'The Price of Innovation: New Estimates of Drug Development Costs,' *Journal of Health Economics* 22, 151-185.

Food and Drug Administration (FDA) (1), *Generic Drugs Questions and Answers*.

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm>

Health Insurance Research Office, (May 2012) *Thailand's Universal Coverage Scheme: Achievements and Challenges, An Independent Assessment of the first 10 years (2001-2010)*, Synthesis Report.