# *Patents & Innovation In the Pharmaceutical Industry: Literature Review*

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## Introduction

In light of recent health epidemics (e.g. H1N1) and the reality of an ever-aging population,[1] policy makers in both developing and developed countries are confronted with the challenge of stimulating the discovery and research of drug therapies for a wide variety of illnesses. Consequently, questions have been raised regarding the extent to which a strong patents system positively encourages "broad" and "deep" innovation in the pharmaceutical industry (Lilja et. al. 2008, p. 83). By "broad" innovation I am referring to the *variety* of drugs created and diseases treated, while "deep" innovation denotes the *degree* and *rate* of R&D being invested towards a particular drug.

In response to this question, two primary paradigms have been formed: 1) those that argue patents do in fact promote broad and deep innovation, which contrasts 2) those that argue patents only moderately, if at all, promote broad and deep innovation. Here these arguments will be presented and reviewed, with an outline given for the empirical investigation of the accuracy of each paradigm's claim.

## The Paradigms

### Strong Patent Legislation

"*Although a public good, science is not a 'free' good*" ~Gambardella, 1995 (Comanor 2007, p. 57)

The principal argument asserted by proponents of a strong patent system centers on the belief that patents offer enticing incentives that strongly encourages a diverse and deep range of innovation (Snyder 2009, p. 203). As a multi-billion dollar industry, many pharmaceutical companies argue that their enormous output of resources would "not be justified unless there were incentives in place to reward such research and development

[1] While this problem is most acute in developed countries, the median age of both developed and developing countries in the world has significantly risen (UN Human Development Report, 2005)

(R&D)" (Snyder 2009, p. 203). Patents, it is argued, create these rewards by guaranteeing a sales monopoly for a number of years (usually 20) (Lilja et. al. 2008, p. 83). By doing so, patents can minimize the risk factors that high R&D expenses entail (Lilja et. al., p. 113). Consequently, it is often argued that strong intellectual property (IP) rights offers the primary incentive for pharmaceutical innovation by providing the "means through which a pharmaceutical company can *protect* its developments," and in doing so protect its profits (Snyder 2009, p. 203). As such, patents give the motivation for pharmaceutical companies to pursue *deep* innovation of their products.

A second related argument presented by those supporting strong patent legislation involves the claim that patents encourage innovative competition by forcing companies to "discover and develop drugs efficiently and within the shortest time span" (Ng 2009, p. 11). This stems from the contention that the maximization of a positive return of revenue only occurs when a firm is the first to discover a new or significantly better drug, creating a competitive environment that forces companies to seek a *broad* form of innovation (Ng 2009, p. 11). What occurs after a patent has expired is often pointed as evidence of this phenomenon. Once a patent expires, generic drugs from other companies are "unencumbered by patent rights infringement and can encroach on the profitability of the company that developed the original patented drug" (Ng, 2009, p. 11). Thus, it is "crucial that drugs are marketed as quickly as possible to ensure there is a maximum patent coverage period and to be 'first to market' to establish a premium position" (Ng 2009, p. 11).

In other words, patents encourage companies to invest greatly in the R&D of new products in order to have the initial competitive advantage of a product monopoly. The

opposite holds true for when patent protection is no longer present. For instance, when cimetidine (Zantac) was no longer protected in the United States, 90% of sales were lost within the first four years (from $2.085 billion in 1995 to $227 million in 1999) (Ng 2008, p. 11). One problem that I can foresee for this line of reasoning, however, is that it seems to imply combining two contradicting forces (monopoly and competition) into one cohesive supporting argument. It will be up to the data to show whether this relationship holds up under the scrutiny of closer observation.

Weak Patent Legislation

"*Benefits of stronger intellectual property rights (IPRs) are most likely to accrue principally to those who own the existing IPRs…at the expense of those who must rely on their ability to acquire/use those technologies at minimum cost*" ~ Harmsen and Subramanian (Abdelgafar 2006, p. 4)

In contrast to those supporting the merits of a strong patent system, proponents of weaker IP legislation argue that patents only moderately, if at all, promote broad and deep innovation. Moreover, this group also contends that strong patent systems are not only ineffective, but also *harmful* to the innovation process. First, critics argue that patents lead to uncompetitive monopolies, which prevents new and potentially more innovative firms from entering the industry thereby reducing the chances of *deep* innovation (Lilja et. al. 2008, p. 102). With the rising capital costs associated with developing new technologies, fledgling firms are often unable to commit groundbreaking research on a new drug and thereby are incapable of earning the all-important patent rights. This reinforces the trend of concentrating patents in the hands of a few large firms (Lamoreaux & Sokoloff 2007, p. 234). Consequently, it has become increasingly difficult for independent investors to justify expenditures on explorations for new discoveries

(Lamoreaux & Sokoloff 2007, p. 234). Artificial monopolies, it is argued, are the result of this concentration of patents and capital, as "new technology shifted inventive activity away from independent inventors towards large companies," which has led to a decline in patenting rates per capita (Lamoreaux & Sokoloff 2007, p. 236).

A question that I have with this argument stems from its assumption that removing strong patent legislation and thereby increasing the number of fledgling innovators and decreasing the relative power of large firms is a *positive* result. Specifically, how exactly will this stimulate both more *meaningful* and *diverse* drugs? Furthermore, how will these individuals attain the necessary funds to do the same level of research as pharmaceutical conglomerates? I believe I will need to fill this gap within my own paper by offering some possible solutions.

A second argument asserted by those supporting weaker IP legislation states that ordinary patent incentives simply do not work, especially in developing companies, in terms of stimulating *broad* innovation among "neglected diseases" (Hollis 2007, p. 75). These diseases include malaria, tuberculosis, chagas disease, and African sleeping sickness, among others. The root cause of this inattention is often attributed to the lack of profitability that these diseases present because of the reality that most of their victims live in poverty and cannot pay the high prices for life-saving medication (Hollis 2007, p. 76). As argued by Hollis, there is a strong positive relationship between the incomes of those affected by a disease and the amount of research undertaken into pharmaceuticals for that disease (Hollis 2007, p. 77). Consequently, investments in neglected diseases are seen to be unprofitable, and patent incentives fail to fill this gap.

**Conclusion: Validity and the Data Analysis**

In terms of assessing the validity of the above paradigms, two sets of indicators will be used in the data analysis. To measure the broadness of innovation, I will look at whether or not a product is available for an illness (Yes/No). This looks at the *scope* of research being done on a wide variety of prominent ailments. In terms of deepness, I will be using the # of patents/projects per disease.

Two case studies will be examined with both of these sets of indicators in mind. I will first look at the level of pharmaceutical innovation in the United States, which has had a history of strong patent and IP laws. The primary source for statistical data related to the US will come from the Pharmaceutical Research and Manufacturers of America. This will be compared to that of India before 2005, which prior to its IP reform had a long period (1972-2005) of relatively weak patent and intellectual property right laws. Some argue that this led to India becoming the "major producer and source of low-cost but high-quality drugs for the entire world" (Chaudhuri 2005, p. 10). Chaudhiru's examination of India's pharmaceutical sector during this time will provide the bulk of my background and some of my data for this case study. The Organization of Pharmaceutical Producers of India (OPPI) will provide further data. Furthermore, I will be looking at a common set of diseases in order to do an accurate comparison. In short, this analysis will attempt to answer the fundamental question of which paradigm (weak vs. strong patent legislation) provides the ideal conditions for innovation.

**Works Cited**

Abdelgafar, I. Basma.. The Illusive Trade-Off: Intellectual Property Rights, Innovation Systems, and Egypt's Pharmaceutical Industry. *New Jersey: Princeton University Press, 2007.*

Chaudhuri, Sudip. *The WTO and India's pharmaceuticals industry: patent protection, TRIPS, and developing countries*. New Delhi: Oxford University Press, 2005.

Jacobsen, M. Thomas and Wertheimer, I. Albert. *Modern Pharmaceutical Industry: A Primer*. Mississauga: Jones and Bartlett Publishers, 2009.

Lilja, John et al. *Pharmaceutical Systems: Global Perspectives*. West Sussex: John Wiley & Sons Ltd., 2008.

Ng, Rick. *Drugs: From Discovery to Approval*. New Jersey: John Wiley & Sons, Inc. 2009.

Organization of Pharmaceutical Producers of India. "OPPI." http://www.indiaoppi.com/ (accessed November 1, 2009).

Pharmaceutical Research and Manufacturers of America. "PHRMA." http://www.phrma.org/ (accessed November 1, 2009).

Rickles, M. Nathanie et. al. *Social and Behavioural Aspects of Pharmaceutical Care*. Mississauga: Jones and Bartlett Publishers, 2009.

Sheshinkski, Eytan et al. *Entrepreneurship, Innovation, and the Growth Mechanism of the Free-Enterprise Economies*. New Jersey: Princeton University Press, 2007.

Sloan, A. Frank and Hsieh, Chee-Ruey. *Pharmaceutical innovation: incentives, competition, and cost-benefit analysis in international perspective*. New York: Cambridge University Press, 2007.

United Nations Development Program. "Human Development Report: 2005." United Nations. http://hdr.undp.org/en/media/hdr05_summary.pdf (accessed November 1, 2009).