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TRIPS IN INIDIA : REASONS AND RHETORICS

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ABSTRACT

The issue of patents and intellectual property rights (IPR) has occupied a major place in today's development debate. India has recently adopted the Trade Related Intellectual Property Rights (TRIPS) regime. This essay examines the veracity of some of the key arguments presented to implement TRIPS in India. We see that much of the arguments favouring imposition of TRIPS in India are ill founded and contradictory. The essay also raises some questions on efficiency aspects of a strong IPR regime, such as the TRIPS.

Economics as a discipline has been dueling with the issue of appropriating knowledge ever since creativity and innovation were felt as important contributors for growth and development. An economist's concern for effective intellectual property rights emanates from the belief that knowledge is a public good, and may suffer from underinvestment in the absence of suitable appropriability criteria. Although, the practice of granting exclusive right to manufacturing and trading of novelty had its origin in Europe some 500 years ago, the concept of intellectual property rights as a formal institution is a late 18th century US creation. The Patent Act 1793, of United States of America was the first of its kind, with an explicit objective of promoting novelty and innovation. In the words of Abraham Lincoln, the US patent law was designed to "add fuel of incentives to the fire of genius". Quite interestingly, however, as Noble (1977) puts it, within a span of 100 or so years the "fuel of incentive" was divorced from the "fire of genius", where individual scientists became employees of large corporations, and patent became an important vehicle for the creation and prolongation of large corporate monopolies. Since then the debate on patent and intellectual property revolved around its impact on innovation and diffusion of knowledge. Despite a very appealing theoretical basis, impact of protecting knowledge through patent is, at

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best, mixed (Kingston 1990). Not only there exists evidence of patent being important only in handful of industries (Gallini 2002), the length of patent beyond some optimum period is also argued to decelerate technological change (Nordhaus 1969), supposedly, due to the *complacency effect* of a monopolist. Interestingly, the Machulp enquiry for the US senate in 1958 led to the conclusion that "if no patent system existed, it would be a mistake to establish one, but since we do have it we may as well keep it going" (as quoted in Kingston 1990, p. 93). As a matter of fact, however, increasingly stronger intellectual property right has een an omnipresent phenomenon in the last century. The trend of increasingly strengthened and harmonized intellectual property rights across countries culminated into incorporating TRIPS in the WTO framework.

This essay examines some of the arguments provided by the proponents of TRIPS in India, particlularly with reference to its impact on India's health care. We draw upon the existing research on issues of TRIPS, Indian pharmaceutical industry, and health care. Although TRIPS deals with various aspects of property rights, in this paper we focus only on patent since it is the issues pertaining to patent (in particular, the strength of patent) that are going to have a profound impact on India's health care, through prices and availability of medicine in India. This essay has been organised in the following manner: in the next section we provide a brief discussion on the concept of patent strength. Section 3 highlights the main arguments, which have been put forward by the policy makers and the proponents of TRIPS in amending the patent regime in India. Section 4 offers a critical framework to examine the merits of such arguments, and finally section 5 synthesises and concludes.

Strength of Patent: Definition and Evolution

It is necessary to understand the concept of patent strength before discussing impact of TRIPS, since TRIPS is believed to be the strongest form of intellectual property rights protection in the history of IPR and patent so far. In this section we give a holistic overview of the concept of partent starngeth and how it has evoleved out of various country level experiementations in the last century.

Whether a patent regime is weak or strong depends on multiplicity of factors, often discussed under the umbrella of the length and breadth of patents.

While the length of protection essentially discusses the life (duration) of patent, the breadth of protection implies a complex set of issues. At a very elementary level, the breadth focusses on whether the patent is applicable to a whole product as well as its constituent processes, or only to individual processes. Clearly, patent given only to the processes would be treated as less protective than if a patent covers a product in totality. Even within a product or process patent regime there can be narrower definitions of newness/inventiveness leading to different prospects for inventiveness and protection. The strength of a patent system may also depend on such definitions of inventiveness and various other enforcement mechanisms.The case of Japan is well known to many. After developing the patent law along the US line in 1885, Japan adopted the German model since 1905, by considerably weakening the definition of "inventiveness". This change was especially meant for protecting small inventions at a time when Japan's technology lagged behind that of many western nations. While Germany only allowed for process patent with a duration of 3 to 7 years, Japan had both product and process patents (for 5 to 15 years) but had allowances for small inventions built–in in the definition of inventiveness and various lenient enforcement measures.

The trajectory of the patent strength in India is, interestingly, opposite. India (rather the British-India) adopted a strong patent regime as early as in 1911, which was weakened, predominantly, for the pharmaceutical industry in the year 1970 to achieve self-reliance in pharmaceutical production and health care. All other technologically important sectors, therefore, continued to have a stronger version of product patent regime even before the imposition of TRIPS. The impact on the pharmaceutical industry is, therefore, unique and demands a clear understanding on its own merit. A brief look at the history of intellectual property rights indeed reveals that many of today's developed and industrialized countries had sought for weak or no patent protection for a considerably long period to accomplish various national priorities. The Netherlands, for example, did not have any patent system till 1912, despite being a central trading point of Europe. Germany introduced the system of patent in 1877, but continued to have only a very weak patent protection until as late as 1960s, and shifted to a strong one only after developing indigenous technological competence in industries like pharmaceutical and synthetic dye. In fact, the concept of "strength of patent" has

evolved out of all this diverse usage of patents by various countries to foster their own domestic interests.

In the light of the above discussion it is important to highlight that the inclusion of TRIPS in the WTO framework, and the ambition to harmonise the IPRs across the globe seeks to put an end to the existing country level flexibility to use patents and IPRs for achieving various domestic goals. With necessary amendments in the patent law in the beginning of the year 2005, India adopted TRIPS and initiated its transition from a weak process patent regime to a much stronger product patent regime, applicable to the whole product for a period of 20 years.

Justifying Implementation of TRIPS in India: Some Rhetorics

The proponents of TRIPS have largely emphasised on the three following arguments while justifying the implication, and assessing the impact, of TRIPS on India's health care:[1]

(a) A weak patent regime encourages imitation and diffusion and is seen as a threat by innovators. As a result, innovating firms do not show interest to launch new drug in India, jeopardizing the prospect of access to new medical therapy by the Indian patients. This view largely draws its inspiration from a well-known body of economic literature showing negative impact of weak patent regime on foreign direct investment. The access to modern health care is important for economic development (Kremer 2002), and its absence can indeed have serious adverse consequences.

(b) Globally, the cost of R&D has gone up manifolds making it essential to offer much stringent global protection so that innovators are adequately compensated for enhanced expenses and, in turn, are given adequate incentives to continue to invest on drug discovery research to push the frontiers of international medical treatment.

(c) Ironically, however, it has also been claimed that India will not suffer much due to the increase in prices of patented drugs under TRIPS, since the majority of drugs required in India are off-patent, for which no increase in price is

[1] This is not to suggest that this list is strictly exhaustive in nature.

on the card (see, for instance, Lanjouw 1999). Thus, to put it succinctly, while, under TRIPS, the evils of delay and the lack of incentives for R&D would be reversed, poor people would not be hurt.

We critically examine the veracity of these arguments in the following section.

Impact of TRIPS on Indian's Health Care: Some Realities

I. Delay in launch of new drugs?

The first argument essentially tells us that weak patent regime discourages innovating firms to launch new drugs in India, and therefore causes loss of welfare to Indian patients by denying access to newer and better medical treatment. While this argument may hold some water for countries with low or no reverse engineering capabilities, it certainly is a far-fetched one in the context of India, where sound reverse engineering capabilities have enabled domestic firms to introduce novel innovations in the Indian market by developing non-infringing processes in the absence of foreign innovators. In fact, the delay in the launch of new drugs has considerably declined over the past few decades, much due to strong reverse engineering R&D capabilities of Indian firms (see, for instance Watal 2000). Indeed, for some recent important blockbuster drugs, Bhaduri and Ray (2006) provide evidence of a very short or no delay in their launch in India. A drug is qualified for the Blockbuster status when its annual global sale is more than $1 Billion (Landau et al 1999). Blockbuster drugs can, therefore, safely be assumed to derive much of their popularity among physicians due to some "major therapeutic gains"[2].

We illustrate this point taking a few examples from Bhaduri and Ray (2006).[3] The rheumatic analgesic blockbuster drugs, *Celecoxib* and *Refecoxib* were globally launched in the year 1999. Both drugs were launched in India in 2000 by leading domestic firms, with a delay of less than two years. The pattern is also very similar for another blockbuster drug *Sildenafil Citrate* (popularly known

[2] Surprisingly indeed, major therapeutic gains are rare qualities among newly discovered drugs! According to US Food and Drug Administration only a minor fraction of new drugs (around 40%) are considered to bring about critical improvement in medical treatment! All other new drugs only provide marginal gains over existing drugs, their higher prices notwithstanding.

[3] The data on their global and Indian launch were collected from various domestic and international sources and company databases.

as Viagra) for erectile dysfunction, globally launched by Pfizer in 1998. It was introduced in India by some domestic firms in the year 2001, within three years of its global launch (launch was presumably delayed due to legal battle between Pfizer and some Indian firms). Likewise, cardiovascular blockbuster drug *Atorvastatin*, globally launched by Pfizer in 1997, was also introduced in India by a few domestic firms within three years. More striking is the example of the anti-diabetic drug *Rosiglitazone Maleate* that was imitated and launched by leading domestic firms within the first year of its global launch in 2000. The story of weak patent regime delaying launch of new drugs in India, therefore, seems to be in want of more justification.

Indeed, Bhaduri and Ray (2006) offer an altogether new argument for the delay in drug launch. They argue that weak patent regime, per se, has no role to play in determining the delay. Rather, it is the therapeutic type of a drug, which determines the length of delay. Short delays in the launch of new drugs in specialised disease segments (like cardiovascular, rheumatic diseases and diabetes) lie on high first mover advantages in these markets.[4] These diseases often require a long-term treatment, and are only controllable (not curable) in nature. The patients also predominantly come from rich enlightened segments of the population with high level of quality awareness. As a result, the physicians rarely experiment with new cheaper brands, unless proved to be decidedly superior in quality, rendering it difficult for a latecomer to seize the market through a price cut. Thus, imposition of a strong patent regime would serve very little objective in shortening the delay of launch in these segments, which has more than 99% share in the total number of drugs discovered during the last three decades (Trouiller and Olliaro 1999).

II. The political economy of Increasingly higher R&D costs:

A high R&D cost of drug discovery research has been cited by the international pharmaceutical industry as a justification of enhanced global protection in the form of TRIPS. It is indeed true that cost of pharmaceutical R&D has gone up. Approximately, it costs around US$ 300mn to discover a new

[4] Note that a somewhat longer delay was observed with regard to anti-infective drugs. However, as argued in Bhaduri and Ray (2006) the reason for those delays was a lack of first mover advantage, and not insufficient IPR protection.

drug and bring it to market. The reason for such an increase lies in both increasing automation in discovery and enhanced legal complexity associated with approval of drugs (Cockburn 2004). To illustrate it further, drug discovery research can broadly be divided into two groups (a) research, and (b) development. While the research stage consists of *synthesis* and *screening* of chemical compounds, the development stage comprises *various clinical trials* and *approval of drugs* for marketing. The central objective of increasing automation in the research phase was to enhance the probability of finding a potent molecule faster by routinising the screening process. Earlier, firms used to rely on the so-called "scientific acumen" of their scientists. Instead, now firms buy machines that are capable of running random experiments with hundreds and thousands of molecules (called high throughput screening) in order to increase the possibility of getting a potent drug. But, ironically, the use of such highly automated machines have not had a matching increase in research output (DiMassi et al 2003, Cockburn 2004). A phenomenal rise in sunk and variable costs associated with such automation has, however, led to a decline in over all R&D productivity. It has been shown that after a rapid automation in the last decade, the share of screening and synthesis costs in total R&D costs has gone up from 4-5% to around 14%. In addition, Cockburn (2004) shows that the annual number of active substances approved in major markets declined by 50 percent during the 1990s, despite a three times increase in the private sector pharmaceutical R&D. While in the 1980s, the industry used to spend an average of $318 million for one new molecule; it paid around $806 million in the last half of the 1990s (DiMasi et al. 2003). A significant proportion of this increase in R&D spending is attributed to the so called "re-tooling in response to innovation in the method of invention" (Cockburn 2004).

In so far as firms maintain a very high level of secrecy with reference to the flow of information between firms, easy availability of such highly automated machine may, in fact, have led to a prisoner's dilemma case with all firms, for the fear of falling behind, investing increasingly high proportion of their R&D budget on increased automation. Often, such a process requires a change in the whole organisation, and further asset specific investments. Such costs, therefore, can be large and irreversible. As a result, the automation level is not likely to decrease in near future, even if proved to be unproductive. Rather, the organised interest

groups of large firms may lobby for amending the necessary legal framework of drug discover research, where high level of automation is made mandatory for some reasons or another. While this argument may appear to be speculative on its face, it will certainly not be when one looks at the way the drug quality norm has evolved over the years. At the beginning, firms opposed the move by regularity authorities to introduce stringent norms, mainly on the grounds of technological feasibility (Bodewitz et al 1987). But, once they were successful to integrate those advanced technologies into their production systems these same set of firms formed an interest group to lobby for amending rules to make the stringent quality norm a statutory requirement, which in effect strengthened the entry barriers in this industry. The birth of the International Conference on Harmonisation is a direct fallout of such organised lobbying (see, for instance, Ray and Bhaduri 2003 for detail).

Thus, while the R&D costs have gone up, the efficiency gain of the enhanced R&D expenditure is questionable, and needs further research. One has to, therefore, cautiously investigate the efficiency gain of increased R&D expenditure, before supporting greater incentives for the industry in terms of stronger patent protection.

III. How marginal would be the impact?

The justification of this argument lies in the much highlighted claim that around 97% of drugs used in India are not patented and, therefore, not going to be affected by the new patent regime (see for instance, e-pharmail, February 7, 2005)[5]. Ironically, it is interesting to note that this argument is in conflict with the first argument, which claimed that India's health care has suffered a lot during the era of weak patent regime, due to non-availability of new drugs. The argument that Indian patients are not going to be hurt by the monopoly prices of new drugs[6], on grounds that new drugs contribute only insignificantly to the total health care expenditure in India, whisks away much of the justification of the former claim. However, apart from being sketchy and arbitrary, such a claim tends to hide the fact that the share of patented drugs is destined to increase in near future.

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[5] Source: People's Democracy, February 13, 2005.

[6] For a comparison between Indian and the US prices of some of the new drugs, see Bhaduri and Kumar (2005).

In particular, the replacement of older drugs by newer drugs would occur somewhat naturally in the markets for anti-infective drugs, where resistance to older drugs create a natural market for new drugs in a continuous manner[7]. Indian people are more prone to infective diseases compared to the westerners due to tropical climate as well as poor hygiene. Some casual observations suggest that while the first generation antibiotic drugs are sufficient to treat 90% people in the US, it can only cure a meagre 10% people in India, primarily because of a higher level of resistance to these old drugs. In such circumstances, giving monopoly rights of a new antibiotic drug to an innovator could prove to be disastrous. Since older drugs would not work, Indian patients will be compelled to buy the newest antibiotic paying the monopoly price[8].

Giving a monopoly power to the innovator would also put the patients subject to the whims and fancies of the commercial interest of the industry. It is suspected that the instances of abrupt curtailing of production and drastic price revision could occur more frequently under strong monopolies (e-pharmail, February 7, 2005). The fact that such pharmaceutical firms have high influence on the prescription pattern of medical practitioners tends to aggravate the problems. See Ray (2004) for a pioneering study on the political economy of medical practice in India. The study shows how the persuasion of medical representatives has important bearing on the prescription pattern of specialist physicians in India. A stronger monopoly power would only strengthen this process, as more funds could be allotted to "pursue" a physician for prescribing a "desired" (more

[7] It is interesting to note that Ray (2005) coined the term "vicious cycle of antibiotic" to refer to such phenomena, where resistance to existing antibiotics calls for the development of new antibiotics in a continuous manner. However, while drug resistance does lie in the core of the above argument of vicious cycle, the cause of drug resistance in his study is different from its usage by the World Health Organisation (WHO). While Ray (2005) views drug resistance, exclusively, as an outcome of unwarranted (and unethical) prescription bias towards antibiotic drugs (due to the nexus between firms and some medical practitioners) and poor patient compliance, WHO claims drug resistance to be a "natural response to the selective pressure of the drug", which can, however, be intensified by several factors including abuse and unwarranted prescription (see http://www.who.int/drugresistance/en/, last accessed on March 8, 2006). See Norgaard (1994, pp. 23-25) for a discussion on "selective pressure", and a historical account of how the pests and the pesticides co-evolved in the history of chemical fertilisers.

[8] See also Mrazek and Mossialos (2003) for further elaborations on the impact of TRIPS on health care in poor countries.

profitable new) drug without paying much attention to the issue of therapeutic gains.

Synthesis and Conclusion

This essay was intended to examine the justification of some of the arguments advanced to implement TRIPS in India. It is clear that a more careful analysis is required before we accept the logic of TRIPS and act upon it. Moreover, if one accepts the true spirit of capitalism as a continuous and restless process of change and creative destruction, a la Schumpeter, where new technologies and organisations are created only to get destroyed by something newer, then the logic of TRIPS, presumably, runs in the opposite direction, where existing innovations and profitable organizations are *made* to stay longer by designing monopoly creating institutions.[9] Extending monopoly rights up to 20 years can lead to a situation, where the *complacency effect* of a monopolist, arising out of a secure market, could become dominant leading to a decline in R&D expenditure[10]. Also, it will have less or no incentive to search for more efficient processes of the same product during the patent life. As a result, TRIPS can reverse our existing strength in reverse engineering and process innovation developed under a weak IPR regime, and may turn out to be a breeding ground for cost inefficient process technologies[11]. Historically, indeed, declining competitiveness of the US and British synthetic dye industries vis-à-vis the Germans in the early 20th century, and the US automobile industry in the hands of the Japanese in the mid-20th century have primarily been attributed to such a lack of attention towards cost efficiency, under a strong IPR regime, by the US firms (Rosenberg and Steinmuller 1988, Murrman 2003). The consumer may, therefore, have to pay higher prices for inefficient processes of novel drugs under the TRIPS- in sharp contrast with the stated objectives of the WTO, which propagates to raise global cost efficiency and, thereby, consumer welfare!

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[9] Stan Metcalfe in his inaugural lecture in the last year's DRUID conference (2005) describes this move as an attempt to revert back to feudalism (personal discussion).

[10] Gallini (2002), indeed, seems to indicate the setting off of a similar trend in the US economy after their recent modifications in the patent laws.

[11] Under a strong intellectual property rights regime, which grants patents to the whole product, there are no incentives for investing on R&D to find out more cost-efficient ways to prepare the same product.

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