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**Breaking the Fence:**

**Patent Rights and Biomedical Innovation in “Technology  
Followers”**

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## **Breaking the Fence:**

### **Patent Rights and Biomedical Innovation in “Technology Followers”\***

By

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#### **Abstract**

The impact of patent protection on biomedical innovation has been a controversial issue. Although a “medical anti-commons” has been predicted due to a proliferation of patents on upstream technologies, evidence to test these concerns is only now emerging. However, most industrial surveys that shed light on this issue are mainly from developed countries, making it very difficult to predict the impact of patenting on biomedical innovation in developing and least developed countries. This paper develops a framework of analysis for the impact of patent rights on biomedical innovation in “technology follower” developing countries. Based on the framework developed in the paper, empirical data collected in an industry-level survey of the Indian pharmaceutical industry between November 2004 and January 2005 is used to analyze the impact of patent rights as recognized under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) on biomedical innovation in technology followers.

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## 1. INTRODUCTION

Firms rely on a variety of appropriability mechanisms to protect their innovations, such as secrecy and first mover advantages, sometimes even much more than on patents (see Cohen et al, 2000; Arundel, 2001). But the choice of appropriability mechanisms depends very much on the industry in question. Within the pharmaceutical industry, patents have always been a very important instrument for the protection of innovations (Mansfield, 1986; Cohen et al, 2002).<sup>1</sup> Over time, stronger patent regimes, newer technologies such as biotechnology and changing industrial structures have contributed to an increased proliferation of patents in the biomedical sector.<sup>2</sup>

Therefore, not surprisingly, the issue how intellectual property protection as contained in the Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement) will impact biomedical research is a controversial one, with claims in either direction. A medical “anti-commons” was predicted following a dramatic increase in patenting activity especially in the pharmaceutical and biotechnological sectors in the early 1990s (Heller and Eisenberg, 1998; Heller, 1998).<sup>3</sup> It has been argued that present levels of intellectual property protection lead to too many patent rights on upstream discoveries in biomedical research and has the potential to stifle downstream discoveries and product development by increasing transaction costs and magnifying the risk of failures (Heller and Eisenberg, 1998; Heller, 1998; Eisenberg, 2001). According to scholars, this problem is worsened by patent scope issues that grant too broad claims to early innovators, thereby making it incumbent on subsequent innovators to procure licenses on research tools or earlier innovations to conduct R&D, or even limit them from fully capturing the gains of their innovations (Scotchmer, 1991; Green and Scotchmer, 1995). These detrimental impacts of patents on access to research tools in the biomedical sector can be classified into three major categories: increasing the costs of available

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<sup>1</sup> Propensity of firms to patent differs across industries. A comparative survey that assessed the importance of patents in different industries showed that patents were most important for the development and introduction of products in two industries – the pharmaceutical and chemical industries – where they accounted for over 30% of development activities (Mansfield, 1998, p. 174).

<sup>2</sup> According to the OECD (2004, p.22), there has been a rapid rise in patent grants in biotechnology. In the time period 1990 to 2000, the number of patents granted in biotechnology rose by 15% a year at the USPTO, and by 10.5% at the EPO, compared with a 5% increase in overall patents.

<sup>3</sup> An “anti-commons” is the opposite situation to a commons, where “...multiple owners are each endowed with the right to exclude others from using a scarce resource, and no one has an effective privilege of use” (Heller, 1998, p. 622).

services, imposing transaction costs and inconveniences on R&D and impeding the transfer of existing tools and technologies (WHO, 2005, p. 37).

Whether intellectual property rights (hereafter, IPRs) create an anti-commons or lead to restricted access to research tools is a highly complex question. This not only involves considerations of broader patent scope and its impact on innovation, but also, effects of IPRs (as we have them now) on stimulating R&D, bargaining anomalies that may result from monopolistic positions, information issues and transaction costs (see Heller, 1998), and most importantly, social costs imposed by grant of such a patents regime - that is, whether there are research projects under this regime that were not undertaken due to IPR issues under a TRIPS-compliant regime, and if so, do the other benefits of granting such IPRs offset these costs/losses? Many of these issues have been dealt with in the literature on the topic, but mainly from a developed country perspective and in a framework that predominantly considers the needs and characteristics of biomedical innovation in developed countries. The evidence to test the relationship between patents and biomedical innovation, although scanty, is available only from select developed countries.

But this topic assumes at least as much importance if not more, in technology follower developing countries that are trying to/have been able to develop significant local innovative capacity in the biomedical sector. The impacts of IPRs on hindering access to useful research tools in biomedical innovation may vary significantly in countries with different income levels and pharmaceutical industries at different stages of development. Specifically, what may look like a benign hindrance in the case of developed countries with significantly advanced biomedical sectors may in fact turn out to be a major deterrent in the case of a technology follower country where firms routinely experience difficulties in building technological capabilities in biomedical sciences. Other differences in the local systems of innovation may also have an impact on how IPRs on biomedical products affect innovation trends.

Three main issues are of utmost importance for technology follower countries: (a) Can accumulated IPR positions by firms in developed countries that have a lead technological advantage be used to prevent serious competition from industries in developing countries in innovative activities at the frontier? (b) What sort of bargaining anomalies could result from monopolistic positions, information issues and transaction costs when one talks of licensing arrangements between firms across the globe? (c) How important are the restrictions placed by such IPRs when compared to other factors that affect firm-level decisions on taking up new R&D projects?

This paper seeks to make a contribution towards analysing the impact of patent protection on biomedical innovation in developing countries in two ways – by developing a framework for assessing the impact of intellectual property rights on biomedical innovation in these countries, and by presenting evidence from the Indian pharmaceutical industry on this issue. Based on empirical data that was collected in 2004-2005 as part of a firm level survey of the Indian pharmaceutical industry, the paper seeks to draw robust conclusions on the impact of patents when compared to other factors that impede/ facilitate innovative capabilities in the biomedical sector.

For purposes of this paper, the term “technology followers” refers to developing countries with newly industrializing sectors where the technological frontiers do not represent the “state-of-the-art” technology in the field (Amsden, 2001; Forbes and Wield, 2000).<sup>4</sup> But as against a static definition of “technology followers”, the definition considered in this paper is more dynamic and assumes that whereas the newly industrializing sector as a whole may not be involved in “state-of-the-art” innovation; individual firms therein are capable of offering competition in innovative activities at the global technological frontier. Biomedical innovation is defined as pharmaceutical innovation that has integrated modern biotechnological processes into its domain, whether for research or the development of products (Ramani, 2002, p. 381). Research tools are defined as “...[a]ny tangible or informational input into the process of discovering a drug or any other medical therapy or method of diagnosing a disease” (WHO, 2005, p.39). In the analysis, newer R&D projects are taken as opportunities of building innovative capabilities. From a dynamic perspective, the more a firm is compelled to abandon useful R&D projects due to IPR restrictions, the larger the probability that the expansion of its technological capabilities are restricted.

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<sup>4</sup> The intellectual origins of the term “technology followers” can be attributed to Akamatsu’s original flying geese hypothesis (1961). See Amsden (2001) and Forbes and Wield (2000) for discussions and applications.



## **2. INTELLECTUAL PROPERTY RIGHTS AND BIOMEDICAL INNOVATION IN DEVELOPING COUNTRIES: A FRAMEWORK FOR ANALYSIS**

In neoclassical economics, patents are a solution for the market failure caused by the non-excludability and non-rivalrous nature of information as a good (see Arrow, 1969). Traditionally, the dynamic effects of patents in terms of incentives to innovate are balanced by the static costs in terms of limitations on competition and diffusion of information. Hence, design of optimal patent regimes comprises an assessment of the links between patent characteristics (patent length and patent scope), firm profits, and incentives to innovate (see Nordhaus, 1969; Scherer, 1972, among others). Simply put, one can assume that the longer the patent life, the greater the expected rents and the broader the patent scope, the greater the market power conferred on the patent holder.<sup>5</sup> Patent breadth/ scope, on the other hand, is defined as “how similar other innovations can be without infringing the original patent”.<sup>6</sup> Patent scope determines the strength of protection granted, and therefore also the extent of power vested in the patent holder to limit competition. Restricting the scope of protection has therefore been seen as a way of balancing the static costs of intellectual property protection as against the dynamic gains of encouraging innovative activity (Glasgow, 2001, p. 230).<sup>7</sup> Similarly, diffusion of useful information that forms the basis of the patent is to be achieved by placing certain limitations on patent height (level of disclosure required in a patent application for the grant of a patent) within patent regimes.

### **2.1. Motives for Patenting: A Survey of Recent Evidence**

Recent evidence generated by industry surveys reveals that as against the market failure argument postulated by neoclassical economics for grant of patents, a variety of strategic motives prompt the use of patents as an appropriability mechanism by firms today. These “strategic motives” include the use of patents as negotiating levers, as tools for prevention of infringement suits, blocking innovations from competitors, capturing extra value for innovative

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<sup>5</sup> A caveat in the case of patent length is that longer life of a patent does not always translate into higher expected rents, since expected rents is also determined by how long it takes for a more superior technology to find its way into the market (Scotchmer and Green, 1990, p. 131).

<sup>6</sup> cf. Gallini and Trebilcock, 1998, p. 19.

<sup>7</sup> Gallini and Trebilcock (1998, p. 20) note in this context that mainly due to this, economic models on this topic view patent scope and competition policy as perfect substitutes for one another.

efforts, among others. Excess market power accumulated through patents is used by firms to control diffusion of inventions and research results (Gallini and Trebilcock, 1998) and/or to cover entire areas of research or preserve market shares by accumulating 'sleeping patents' that help capture extra value for innovative efforts (Barton, 1998; Kanwar and Evenson, 2001; Dumont and Holmes, 2002). Not surprisingly, in a comparative survey of the manufacturing sectors in USA and Japan, Cohen et al (2002) found strategic uses of patents to be common in the manufacturing sectors in both countries, with a higher prevalence of the same in Japan (Cohen et al, 2002, p. 1358). The electronics industry is also a fertile example of strategic patenting (OECD, 2004).

In biomedical innovation too, patents are used for a variety of strategic reasons. Thumm (2004) notes from the results of a survey of the Swiss biotechnology industry that apart from protecting one's own technology from imitation, the second most prominent motive of firms to apply for a patent was to prevent competitors' patenting and application activities (Thumm, 2004, p. 278). The survey also found that the fourth most prominent motive to patent was to improve the firm's situation in R&D cooperation (ibid). Strategic use of patenting by firms are encouraged by patent policies that lay an emphasis on enhanced patenting activity in the biomedical sector and also grant increased patent scope (and encourage broader claims), thereby leading to a situation where there are more patents per products/ technology. This creates scope for proliferation of patents on upstream discoveries that can stifle newer innovations. In one of the first papers on this topic, Heller and Eisenberg made the point that the greater the number of patent holders who need to be brought into agreement for any downstream discovery to proceed, the greater the risk that bargaining anomalies due to transaction cost issues will prevent this from happening, thereby causing a "tragedy of the anti-commons" (see Heller, 1998; Heller and Eisenberg, 1998).

But up until now, concerns raised in the IPRs-biomedical innovation nexus have mainly been prompted by several characteristics of biomedical innovation in developed countries. Legislative initiatives such as the American Bayh-Dole Act of 1980 meant to encourage patenting in academic research have not only expanded the kinds of institutions that claim patent rights on biomedical innovations, but also encouraged the patenting of early-stage discoveries that result from publicly-funded research and are considerably removed from final product development (Eisenberg, 2001, p. 226).<sup>8</sup> The emergence of biotechnology start-ups have blurred the boundaries between academic research and commercial entrepreneurship, and at the same time, expanded the limits of patenting in biomedical research even further. The

predominance of private research over public-funded research in biosciences is yet another factor that has led to a larger amount of research results being covered by proprietary claims.<sup>9</sup> All these developments have led to the widespread feeling that not only firm-firm interactions are hindered by IPRs, but also firm-academia or even academia-academia interactions are likely to be held-up in biomedical research (Eisenberg, 2001, p. 230).

## **2.2. Bargaining and Transaction Cost Issues**

Bargaining for patented research tools is more often than not unsuccessful due to transaction costs that result from institutional heterogeneity, conflicting agendas of different agents, difficulties in valuation and increased litigation in public research organizations (Eisenberg, 2001; OECD, 2002).<sup>10</sup> Biomedical innovation is characterized by the flow of ideas, skills and research tools between universities, research institutes and the private sector and these institutions may be heterogenous in terms of business demands, practices and work ethics that hinder meaningful cooperation. Information asymmetries on the value of patented tools as research inputs cause difficulties in evaluation and lead to undue expectation of rents from the transaction (see for example, Merges, 1994). More generally, research tool users feel that the provider is asking for too much in return for access to a patented product based on an over-valuation of the contribution of the tool relative to other inputs for future valuable discoveries. Such factors create situations that do not necessarily foster meaningful exchange. As Cohen et al (2000) appropriately note: “Patents become weapons in mutually reinforcing, non-cooperative strategic interactions where firms feel increasingly compelled to patent either because they need to protect themselves from suits or from being blocked, or they want to block rivals or use patents as bargaining chips in negotiations.”

Apart from bargaining and transaction cost issues, patents on research tools can also create commercialization hurdles (OECD, 2002). Patent thickets and royalty stacking discourage subsequent innovators - the larger number of licenses that have clauses on royalty sharing on the final product, the lesser the revenue for the inventor.<sup>11</sup>

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<sup>8</sup> See Rai (1999) and So et al (2005) in this context.

<sup>9</sup> Eisenberg (2001, p. 227) notes that in the 1990s, despite heavy investment by the US government, private research expenditure in biomedical sciences was much more than public funded research.

<sup>10</sup> Eisenberg summarises these as the main issues that were significant during the investigation of the Working Group on Research Tools, National Institute of Health, USA, 1998, which investigated difficulties encountered by researchers in obtaining access to proprietary research tools in biomedical research.

<sup>11</sup> Royalty stacking refers to a situation where each earlier innovator grants access to his/her

Major cases where patents have blocked subsequent innovation and attracted public attention have up until now not been from the biomedical sector.<sup>12</sup> But is the lack of a “block buster” case pointing out to the absence of such behaviour in the biomedical sector? Up until now, limited evidence that tests these concerns is available from USA, Switzerland and Germany. Walsh et al (2003) conducted a survey of the biomedical sector in the USA, an interview method supplemented mainly by archival data, which tried to test whether an “anti-commons” can really be observed in the USA, and whether patent rights in the biomedical sector hinder innovation.<sup>13</sup> The study concludes that although problems of transaction costs, restricted access to research tools and royalty stacking exist, there is no real “anti-commons” in biomedical research since parties are able to deal with these issues and “...IP on research tools, although sometimes impeding marginal projects, rarely precludes the pursuit of more promising ones”. The study underscores the importance of working solutions - like infringement, research exemptions, inventing around and invalidating patents in courts – in reducing the risks associated with the creation of an “anti-commons” due to intellectual property protection on research tools. A German survey conducted on the issue (Straus et al, 2004) also uses a similar interview method.<sup>14</sup> This survey concluded that although royalty stacking is a real problem, research agreements are not usually hampered by the presence of intellectual property in the German biopharmaceutical sector, and working solutions and court resolution of disputes are common (Straus et al, 2004). Another common conclusion in both these studies was that firms in both countries admitted to avoiding taking on research projects where there are too many patents on research tools (OECD, 2002, p. 51).

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product in return for a royalty on the new innovation. The greater number of earlier patents that need to be licensed to proceed with innovation, the larger the number of royalty agreements that get “stacked” on to the yet-to-be-discovered product.

<sup>12</sup> See for example the case of the digital video compression standard MPEG 2, where patent pools have been successful in solving problems of patent thickets and ‘stacking’ licenses, or the case of “golden rice” in agricultural biotechnology.

<sup>13</sup> The sample is a mix of universities and firms. 70 interviews were conducted with IP attorneys, business managers and scientists from 10 pharmaceutical firms, 15 biotechnology firms as well as university researchers and technology transfer officers from 6 universities and finally, patent lawyers, government and trade association personnel.

<sup>14</sup> The sample size was 25, and consisted of four large pharmaceutical companies, nine small and medium-sized specialized biotechnology companies, seven public research institutes and five genetic research testing centres.

### **2.3. Assessing the Impact of Intellectual Property on Biomedical Innovation in Developing Countries: The Overwhelming Considerations**

I suggest a framework that analyses the impact of intellectual property on biomedical innovation in technology follower developing countries. This framework primarily considers four main issues, and requires that an analysis on the impact of IPRs on biomedical innovation be necessarily conducted from an *ex-ante* decision-making perspective.

Can accumulated IPR positions by firms in developed countries that have a lead technological advantage be used to prevent serious competition from industries in technology follower countries in innovative activities at the frontier? The implications of patents on research tools may be much more drastic in technology follower countries: in addition to imposing transaction costs on research (of the kinds that can be resolved through “working solutions” of various kinds), they can completely impede the transfer of existing tools and technologies completely (WHO, 2005). Such an impediment to the transfer of existing tools and technologies to technology follower countries can prevent the development of innovative capabilities including knowledge-bases in the biomedical sector (CIPR, 2002). This problem is in many ways synonymous to the access to medicines problem that Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health is seeking to resolve (WHO, 2005, p. 42). Only, the impact of this issue is being felt only recently and may take sometime until it mobilizes attention.

The second issue for technology follower countries relates to the kinds of bargaining anomalies that could result from monopolistic positions, information issues and transaction costs when one talks of licensing arrangements between firms/ research institutes and universities across the globe? Specifically, are institutions in developing countries in a position to conclude such arrangements? What are the transaction costs faced by firms in developing countries where “working solutions” such as infringements and invalidating patents in courts is not common?<sup>15</sup> How are these affected when firms on both sides do not have IP assets to trade that interest them mutually, in *quid pro quo* relationships?

Thirdly, what are the social costs of such an IPRs regime? Will a project be undertaken *ex-ante* even under the present IPRs regime? If patenting is excessive under this regime, then are the

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<sup>15</sup> In India, as the discussion in the next section of the paper shows, one could suppose that the research exemption applies for commercial research as well and this is a good working solution, but there seems to be a need for clarification on this, either through a legislative amendment or a court ruling on the topic.

social costs of offset by the diffusion of information through patents or through reduced incentives to litigate (Cohen et al, 2002)? How would negotiation proceed without intellectual property protection and how does IPR protection change bargaining thresholds of parties? That is, do we have more or less the same number of projects under alternate IPR regimes, all other things being constant? If not, how important are IPRs restrictions, when compared to other factors that affect firm-level decisions on taking up new R&D projects?

Another more general but important set of issues are raised by the nuanced relationship between patent policies and institutions, and the diffusion of knowledge and competition in different environments (Granstrand, 2000). Not only is it widely acknowledged now that the impact of patents on diffusion of information, inhibiting competition and promoting innovation is sector and context-specific but also that habits and practices of actors in a system of innovation can hinder/ help leverage these effects.<sup>16</sup>

Several observations made in the American and German surveys support the need for such a framework for technology follower countries that looks deeper into these questions. The US survey itself, in several places, infers that the problems of royalty stacking, costs and delays in licensing due to IP protection and upstream discover patents may be much more acute and even prohibitive for smaller firms with limited budgets, it is very likely that firms in other countries, especially developing countries, are more affected (see Walsh et al, 2003). The authors also conclude that the problem of intellectual property holders being able to limit access to upstream discoveries and promising research targets was generally considered to be manageable because if research tool was critical, the interviewed firms would buy access to it (p. 322-323). Even if one would accept this observation, the extent to which this will hold for firms/ research institutes in technology follower developing countries will depend on their ability to “buy” access to important research tools. The emphasis on “working solutions” to deal with these problems in the American and German surveys also calls for a more rigorous assessment of this issue on a larger scale, once again with a special emphasis on technology follower countries. Specifically, what will happen when a particular national legal regime does not provide for the same or similar “working solutions” to be negotiated between parties in an efficient way? A final point that stands out is – what will be the implications for building innovative capabilities

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<sup>16</sup> Cohen et al (2002) found in a comparison of R&D labs in the manufacturing sectors between Japan and USA that appropriability conditions depend on cross-national differences in policy and institutional environments. Hence, patents played a larger role in diffusion of information across rivals in the Japanese industry than in the USA and this was found to be due to their respective patent systems (Cohen et al, 2002).

in firms in technology follower countries cannot pursue research projects in areas where there are already too many patents on research tools?

### 3. BIOMEDICAL INNOVATION IN INDIA: THE CASE OF A TECHNOLOGY FOLLOWER

India is often cited as a prime example of an “innovative developing country” (Morel et al, 2005, p. 2; Mashelkar, 2005).<sup>17</sup> The Indian pharmaceutical industry is a good case to analyse the impact of stronger patent rights on biomedical innovation due to several reasons. India has a thriving pharmaceutical industry with an increasingly expanding biotechnological sector, and is presently transitioning from a weaker IPR regime that promoted incremental and imitative innovation to a TRIPS compliant IPR regime.<sup>18</sup> With the full-scale implementation of the TRIPS Agreement and associated questions of access to medicines, biomedical innovation in India has attracted much attention as an example of success by scholars and donor agencies aiming at building local capacities in other developing countries.

The remaining sections of this paper use empirical data to test the impact of patents on biomedical innovation in India. To answer the question: will a project be undertaken *ex-ante* even under the present IPRs regime? This paper considers the earlier Indian IPR regime as a weaker alternative to the one presently prescribed by the TRIPS Agreement, in order to assess the impact of the TRIPS-compliant IPRs regime on choices of firms to pursue specific R&D portfolios, and its resulting impact on building innovative capabilities in biomedical sciences.

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<sup>17</sup> These authors define the term “innovative developing countries” as developing countries that have demonstrated a significant promise in carrying out activities in health innovation.

<sup>18</sup> A variety of reasons promoted the Indian pharmaceutical sector in the last fifty years, main ones being: the presence of a weak patent regime, the initiation of government-held pharmaceutical companies for local production, price control of drugs and other sectoral factors, such as the lack of data protection. For a detailed discussion, see Gehl Sampath (2005).



### **3.1. Innovation in Indian Pharma Biotech and the Impact of Patent Compliance**

The Indian pharmaceutical industry is amongst one of the largest industries within developing countries and accounted for 8% of the global output in terms of the volume and ranked 13<sup>th</sup> in terms of value in 2004 (IBEF and Ernst and Young, 2004, p. 8). On the domestic front, the sale of retail formulations in the domestic market reached an estimated US\$ 4.3 billion in the fiscal year 2003, and was dominated by Indian companies which held a market share of 75% (IBEF and Ernst and Young, 2004, p 8). Its major strengths include: a cost-competitive manufacturing base that extends to clinical studies, extensive skills in chemistry and process development, ability to manufacture over 50% of the bulk drugs needed for its pharmaceutical production activities locally, the emergence of a promising biotechnology industry, availability of local scientists and R&D personnel of a high scientific quality and a wide network of R&D (CII, 1999; IBEF and Ernst and Young, 2004, p. 2; Grace, 2004, p. 18).

Indian compliance with the TRIPS Agreement has proceeded in several stages up until now. The Patents (Amendment) Act, 1999 introduced the mail box system and set up a system of exclusive market rights (hereafter, EMRs) to be retrospective from 01 January 1995 in conformity with the TRIPS Agreement. The Patent (Amendment) Act, 2002 introduced 64 changes to the Patent Act of 1970, the most important ones of these being the extension of patent term from 14 to 20 years, and the reversal of burden of proof from patent holder to alleged infringer (see People's Commission, 2003). The final set of changes to make India's patent regime comply with the TRIPS Agreement *in toto* were first contained in the Indian Patent Ordinance of 2004, that has now been replaced by the Indian Patent (Amendments) Act of 2005. The Indian Patent (Amendments) Act, 2005 seeks to complete India's full-scale compliance with the TRIPS Agreement. The Act has the effect of invalidating Section 5 of the Indian Patent Act, which granted only process patents for food, medicines and other drug substances, in order to make product patent protection of pharmaceuticals possible under Indian law. As a result, reverse engineering possibilities available to the pharmaceutical industry will only be limited to those drugs that are off-patent.

Section 47 of the original Patents Act of 1970 contains a research exemption for patented inventions (see Section 47 (3)). This section, which can be interpreted as applicable for both academic and commercial research, has been left unmodified by all subsequent amendments to the patent regime. But two major changes introduced in the Amendments of 2002 affect the patenting of research tools for biomedical and biotechnological inventions in India. The Patent

Act has extended the scope of patentable inventions to a method or process of testing during the process of manufacture, including those in biochemical, biotechnological and microbiological areas.<sup>19</sup> Section 3 of the Patent Act that deals with inventions that are not patentable was amended in 2002 to include any process for the diagnostic or therapeutic treatment of human beings or for a similar treatment of animals or plants (See Section 3(i)).

As a result of these provisions, biomedical research tools are patentable under Indian patent law. There are two exceptions to this. Firstly, there is a research exemption for patented inventions (Section 47 (3) of the original Act), which can be interpreted to be applicable for both academic and commercial research. Secondly, medical, diagnostic and therapeutic kits/ tools are not patentable *only when* they are for the treatment of human beings or animals or plants.

### **3.2 Methodology and Variables**

The data used for the analysis was collected in an industry survey of 103 pharmaceutical firms in India between October 2004 and January 2005, complemented with insights from case study interviews conducted to supplement information gathered in the survey. One major result achieved using the country-level data was the classification of Indian pharmaceutical companies into three main categories, based on both their structural characteristics and emerging R&D and business strategies. In order to achieve this, several databases of the Indian pharmaceutical and biotechnological industry were considered, such as the *India Infoline* and *Pharmabiz*. Using a background report on the state of the industry that was prepared to aid the survey and the databases, firms were ranked on the basis of their export potential, ability to invest in R&D activities and annual turnover, since these factors determine their ability to invest into R&D, devise marketing and R&D strategies and access other markets. The first group of firms (hereafter, group 1) comprises large-scale pharmaceutical firms that are both subsidiaries of MNCs in India or wholly-owned Indian firms. The second group of firms (hereafter, group 2) comprises pure generic manufacturers whose ability to do product development is very limited. These companies supply predominantly to the Indian market as well as to other semi-regulated and unregulated markets. The third and final group of companies (hereafter, group 3) are those that mainly perform contract research and manufacturing (CRAM) for bigger Indian companies, both local and MNCs.<sup>20</sup>

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<sup>19</sup> See “Salient Fratures of the Patents (Amendment) Act, 2002 and the Patent Rules, 2003”, downloadable from: [www.patentoffice.nic.in/ipr/patent/salient\\_f.htm](http://www.patentoffice.nic.in/ipr/patent/salient_f.htm)

The 103 firms that participated in the country-level empirical survey were chosen through a purposive probability sampling technique.<sup>21</sup> Of these 31 belonged to Group 1, 27 to Group 2 and 44 to Group 3. Data was collected for a time period of 2000 to 2004, in order to be able to assess emerging constraints, firm strategies and the impact of patenting over time. In addition to interviewing a cross-section of firms that participated in the survey, several other firms that were not part of the questionnaire survey were also interviewed during field work especially in the biotechnology sector to understand their main concerns and experiences on patent issues. A range of organisations within the pharmaceutical and biotechnological industry in India were consulted for the field work and also as sources of primary information. These included the Confederation of Indian Industries (CII), Federation of Indian Chambers of Commerce and Industry (FICCI), the Organisation of Pharmaceutical Producers of India (OPPI), the Indian Drug Manufacturers Association (IDMA) and the Indian Pharmaceutical Alliance (IPA). The key informants consulted during field work were the Heads of Marketing and the Heads of R&D in each firm. Wherever the firms had their own intellectual property divisions, the heads of the intellectual property division were also interviewed.

Apart from primary data, a variety of other data sources were employed, including secondary sources and case studies that rely considerably on scientific expertise perception of scientists. Secondary research consisted of a detailed review of existing literature including general documents on access to medicines and international developments related to the TRIPS Agreement and policy documents and papers on the impact of product patent protection on the Indian pharmaceutical industry.

The survey focused on several aspects of access to technologies for biomedical innovation in India. Amongst these, it addressed the question whether access to new technologies has become more difficult for firms since India began its phased out compliance with the TRIPS Agreement in 2002. Firms were asked to rank reasons for the increasing difficulties to access new technologies. Firms were also asked whether they have abandoned R&D projects due to IPR restrictions; and those that abandoned R&D projects were asked to provide details. In the analysis, newer R&D projects represent opportunities for building innovative capabilities in the

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<sup>20</sup> See Gehl Sampath (2005); also see Sridharan (2005).

<sup>21</sup> Simply put, the purposive probability sampling (PPS) technique refers to a method of choosing firms in such a way that the key representatives of the industry are taken into account in the survey completely (purposive) and the rest of the population is chosen at random. In this survey, since group 1 firms are key representatives of the Indian pharmaceutical industry, the effort has been to cover them to the fullest extent possible. Firms from groups 2 and 3 have been chosen at random from the ranking list created for the study based on export potential, total sales and R&D investments.

biomedical sector. Therefore, from a dynamic perspective, the larger number of useful R&D projects a firm has to abandon due to IPR restrictions, the larger the probability that the expansion of its technological capabilities is restricted.

### 3.3. The Model

As a result of the binary nature of the problem analysed, logit technique has been used in the analysis to estimate the impact (both positive and negative) of various variables on the likelihood that a firm will abandon R&D due to intellectual property restrictions.

The logit model can be specified as follows:

$$\text{Ln} \frac{P}{1-p} = B_0 + \sum_{i=1}^n B_i X_i$$

Where P = the probability that a firm abandons R&D due to IPR restrictions on products/processes required for its innovation activities.  $X_i$ 's represents the independent variables.

#### *Dependent Variable*

Abanrd = 1 if a firm had abandoned R&D  
 = 0 otherwise (if a firm did not abandon R&D)

#### *Independent Variables*

Hiringmsk = 1 if a firm rates hiring managers and skilled personnel as a strong source of new technology  
 = 0 otherwise

Total sales = the natural logarithm of firm's total sales

Firm size = the natural logarithm of firm's total employment

Joint R&D = 1 if a firm rates joint venture R&D as a strong source of new technology  
 = 0 otherwise

Restricted access = 1 if a firm's has high restricted access to upstream technology due to IPRs  
= 0 otherwise

The model was estimated using stepwise maximum likelihood procedure. Thirteen variables were considered important to examine determinants of abandoning R&D in the Indian industry. This included factors that could hinder biomedical innovation, such as restricted access, royalty stacking, high licensing fees, financial constraints and too many patents on upstream technologies were taken. The other variables were those that could potentially improve access to tools for biomedical innovation – joint R&D, technology licensing, export orientation of firms, R&D expenditure of firms, improved sales, improved employment, foreign investment and hiring of skilled personnel.

The results obtained are presented in Table 3 but only for the variables that were retained by the stepwise procedure adopted. However, comments have been made thereafter where necessary for the variables rejected by this method. In order to be able to predict what the relative impact of each one of these variables is on a firm's likelihood to abandon R&D, the marginal effects of each one of the variables have been computed in Table 5.

## 4. MAIN FINDINGS

Descriptive analysis was conducted on a range of issues using the data collected, in order to corroborate and shed more light on the results of the model.

### 4.1 Descriptive Results

Will India's full-scale TRIPS compliance result in restricted access to technologies to the local pharmaceutical industry? To test this proposition, the survey posed the question whether firms face increased difficulties in accessing new technologies that are required for their activities after India started its phased compliance with the TRIPS Agreement over the past few years. A total of 43 firms felt that access to new technologies have become more difficult after India started implementing its compliance with the TRIPS Agreement. Of these, 12 belonged to group 1, 11 belonged to group 2 and 20 to group 3. But of the 43 firms that did face difficulties in accessing new technologies after India began complying with the TRIPS Agreement, only 28 firms admitted to having abandoned R&D projects due to patent protection. Of these, 11 belonged to group 1, 7 to group 2 and 10 to group 3 (see Table 1). Interviews with firm executives revealed that projects were abandoned mainly because (a) firms faced difficulties in terms of high costs for licensing and (b) firms realized ex-post that the results of their R&D would infringe patents filed for by competitors on the same compounds/ processes (interviews).

**Table 1: Impact of TRIPS agreement on access to technologies**

Firm group/Issue	More difficult access to technologies because of TRIPS	Abandoned R&D projects due to IPR restrictions
1	12	11
2	11	7
3	20	10
Total	N = 43	N=28

*Source: WHO-INTECH survey conducted by author, 2005*

The survey also asked the firms to identify factors responsible for difficulties in accessing new technologies. The respondents were asked to rank each one of the reasons contained in Table 2 from 1 (weakest) to 5 (strongest). As Table 2 shows, all reasons ranked from significant to very significant (above 2.5), with royalty stacking being a reason that is relatively less important than multiple patents, restricted access due to contractual difficulties and high licensing fees.

Furthermore, the survey response to this question also shows that group 2 firms are much more sensitive to the increasing number of patents, restricted access and the high licensing fees involved in carrying out incremental innovations as a result of India's TRIPS compliance.

**Table 2: Reasons for difficulties in accessing new technologies after India's TRIPS compliance**

Firm group/Effect	Too many patents on research inputs needed for R&D	Restricted access due to contractual difficulties	Royalty stacking in licensing contracts	High licensing fees
1	3.17 (12)	3.33 (12)	2.33 (12)	3.33 (12)
2	3.91 (11)	3.64 (11)	2.55 (11)	3.91 (11)
3	3.35 (20)	3.55 (20)	2.79 (19)	3.58 (19)
Average mean/ Firm total	3.44 (43)	3.51 (43)	2.60 (42)	3.60 (42)

Source: WHO-INTECH field survey conducted by author, 2005

## 4.2 Empirical Results

The results of the logit model are shown in Table 3 below. The overall goodness of fit statistics – Log likelihood, Likelihood ratio LR-Test and Pseudo R<sup>2</sup> indicate a relatively well fitted model. There were no problems of multicollinearity or heteroscedasticity. The model retained five of the thirteen variables originally chosen for the logit analysis.

**Table 3: Logit Analysis with Abandon R&D as the Dependent Variable**

Independent Variables	Coefficients	Std. Err.	P-Values
Hiringmsk	-0.589	0.359	0.101
Total sales	1.361	0.544	0.012
Firm size	-1.526	0.652	0.019
JointR&D	0.746	0.393	0.058
Restricted access	1.975	0.717	0.005
Constant	1.414	2.656	0.594
No of Observations	72		
LR-Test	22.57 (0.0004)		
Log Likelihood	-29.20		
Pseudo R <sup>2</sup>	0.2788		

Source: Computed from WHO/ UNU-INTECH Survey conducted by author, 2005.

The interpretation of the variables retained in Table 3 is as follows. Three of the variables had a positive probability/influence on abandoning R&D in the Indian pharmaceutical industry (Total sales, Joint R&D and Restricted access) – in other words the probability to abandon R&D

increases with higher sales, need to conduct joint R&D and with restricted access to upstream technology due to contractual hurdles.

*Total sales* was significant at 5 % while *joint R&D* was significant at 10 % and *Restricted access* was significant at 1 %. That joint R&D or prospects thereof leads firms to abandon R&D is also confirmed by data collected by the survey on local collaborations. Indian firms demonstrate a lack of collaborative links with other firms, universities and research institutes, although this is normally high in other countries that have shown significant success in biomedical innovation. Out of the 103 firms surveyed, only 31 firms admitted to having local collaborators whereas 72 firms had no local collaborations of any form. But those firms which collaborate have very strong collaborative linkages with other institutions, both local and foreign. These results are shown in Table 4 which contains the average ranking of intensity of local and foreign collaborations by the firms (where 1 = weakest and 5= strongest).

**Table 4: Collaborative links: local and foreign**

Links/Firm Group	Group 1	Group 2	Group 3	Total
Local	4.07(14)	3.86(7)	3.70(10)	3.90(31)
Foreign	3.69(13)	3.38(8)	2.89(9)	3.37(30)

Note: Figures in parenthesis refer to the number of firms

Source: WHO-INTECH Survey conducted by author, 2005

Also notably, amongst the firms that admitted to having collaborations, most were in the area of research as opposed to product development. The reason for this seems to lie in the way firms are used to competing in the Indian industry historically – prior to patent protection, all products were mostly generic copies and firms thrived mainly on brand name competition to sell their products. Therefore, although there are clearly greater gains to collaborating in product development in the newer research-intensive environment, habits and practices of industry actors seem to pose major hurdles. This seems to be gradually undergoing a transition, and the only area of product development with a greater degree of collaboration is health biotechnology, but mainly between large pharma and smaller biotechnological start-ups.

The result on *Restricted access* is also supported by descriptive data gathered in the survey, contained in Table 2. Firms repeatedly iterated the problems of contractual difficulties that pointed to transaction cost issues that arise especially in transnational contexts (Indian firms need to license research tools from foreign firms). In addition to the problems posed by the transnational nature of the transaction, this also points attention to another potential issue: such license transactions may be failing because although they are important for the Indian firm, they



may be only of marginal importance to the foreign counterpart who holds the patent.<sup>22</sup> Firm executives also confirmed abandoning research projects where there were too many existing patents, a finding which is in line with both the US and German surveys. At the same time, executives also admitted to the difficulties in branching out to specific areas of research due to the problems in obtaining licenses or too many existing patents that discourage R&D plans, thus clearing pointing out to the issues for expanding innovative capabilities and knowledge bases in technology follower countries.

*Hiringmsk* and *Firm size* both had a negative probability implying that the probability to abandon R&D decreased with greater skilled personnel and bigger firm size. *Firm size* was significant at 5 % while *Hiringmsk* was (near) significant at 10 %. Two-thirds of R&D spend is on active pharmaceutical ingredients (API) and formulation work, whilst only one-third is on new chemical entity research, and of that, 80% is prior art or analogue research (Grace, 2005, p.9) – this explains the negative correlation between firm size and a firm's probability to abandon R&D to a large extent.

Table 5 below presents the results of marginal effects on abandoning R&D. The coefficients represent the mean values of marginal effects. Note that all the variables remained significant. *Total sales* and *Restricted access* were significant at 1 %. Therefore, if a firm increased its total sales by one unit, it was likely to increase its chance of abandoning R&D by 0.182 points. *JointR&D* was positive and significant at 5% - when a firm increased the possibility of conducting joint R&D for newer source of technology, it was more likely to abandon R&D than consider joint R&D as a source of newer technology. Similarly if a firm increased its chances of high restricted access to technology by one unit, it was likely to increase its chance of abandoning R&D by 0.320 points. Or, if a firm moved from high restricted access to technology to low restricted access technology, it was likely to reduce its chances of abandoning R&D by 0.32 points. Similarly, when a firm increased its intake of skilled personnel who could be the source of new technologies by one unit, it was likely to reduce its chance of abandoning R&D by 0.079 units (*Hiringmsk* is negative and significant at 10%). *Firm size* which was negative and significant at 1 % can be explained in the same manner.

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<sup>22</sup> Walsh et al (2003) note in their survey that whereas IPRs impacted negatively on the pursuit of marginal projects, they hardly ever hinder the more important projects. Yet, economic theory dictates that as long as there are projects at the margin that are being hindered, there will be welfare losses associated with such a regime.

**Table 5: Marginal Effects on a Firm's Likelihood of Abandoning R&D due to IPR Restrictions**

<b>Independent Variables</b>	<b>Coefficients</b>	<b>Std. Err.</b>	<b>P-Values</b>
Hiringmsk	-0.079	0.048	0.101
Ltsales	0.182	0.066	0.006
Lempt	-0.204	0.080	0.011
Jointrd	0.100	0.051	0.052
Restaccess	0.320	0.120	0.008

Source: Computed from UNU-INTECH Survey conducted by author, 2005

## 5. CONCLUSIONS

There is clearly a need to develop more comprehensive frameworks as well as collect more systematic data to assess the impact of patents on biomedical innovation in technology follower countries. This paper has shown that four sets of issues are very important in such a framework from a technology follower developing country perspective: Can accumulated IPR positions result in impeding access to research tools for firms in technology follower countries? What are the kinds of bargaining anomalies that could result from monopolistic positions, information issues and transaction costs when one talks of licensing arrangements between firms/ research institutes and universities across the globe? Do we have more or less the same number of projects under alternate intellectual property rights regimes (that is, TRIPS compliant regime versus a different one)? And, how do patent policies and institutions affect knowledge flows, diffusion of innovation and habits and practices of actors in a system of innovation?

To assess whether we have more or less the same number of projects under alternate intellectual property rights regimes (that is, TRIPS compliant regime versus a different one), this paper considers the earlier Indian IPR regime as a weaker alternative to the one presently prescribed by the TRIPS Agreement, in order to assess the impact of the TRIPS-compliant IPRs regime on choices of firms to pursue specific R&D portfolios, and the resulting impact on building innovative capabilities in biomedical sciences. All other things being constant, the Indian case analysed in this paper seems to show that patent protection in the biomedical sector has a negative impact on the number of projects pursued under a TRIPS compliant regime. Newer R&D projects represent opportunities for building innovative capabilities in the biomedical sector. From a dynamic perspective, the larger number of useful R&D projects a firm has to abandon due to IPR restrictions, the larger the probability that the expansion of its technological capabilities is restricted. This requires a more detailed look and a more rigorous analysis in the coming years, as and when more information on the Indian industry becomes available.

The model developed in the paper using empirical data from the Indian pharmaceutical and biotechnology sector shows that amongst the five determinants of a firm's probability to abandon useful R&D projects, restricted access to upstream technology due to contractual difficulties is a factor that is highly significant (at 1%). The marginal effects of each one of these variables has been calculated in the analysis, in order to see how likely each variable is to

influence a firm's probability of abandoning R&D, and how important IPR restrictions are, when compared to other factors that affect the building of innovative capabilities in technology follower developing countries. This analysis reveals that whereas all variables remained significant, restricted access to upstream technologies due to contractual difficulties was the variable with that is likely to have maximum impact on a firm's decision to abandon R&D projects. If a firm increased its chances of high restricted access to technology by one unit, it was likely to increase its chance of abandoning R&D by 0.320 points – this was much more than the computed effect of other variables that affected a firm's likelihood of abandoning R&D projects in the Indian industry.

A good analysis of the issues raised by patents on research tools in biomedical innovation will require firm-level surveys that gather empirical data on the impact of TRIPS-compliant patent regimes and analyse the implications from an *ex-ante* decision-making perspective.<sup>23</sup> To study this problem and its impact systematically in developed as well as technology follower developing countries, more unified research methodologies may be required. When existing evidence from USA, Germany and Switzerland, and now, India, on the issue are consulted, the impact of IPRs on biomedical innovation seems to be divergent. It appears that differences in research methodologies are the main reason for contrasting empirical evidence on this issue until now. The American and German surveys are characterized by methodological constraints that do not allow for a detailed assessment of the tradeoffs and impacts in stronger patent protection on biomedical innovation.<sup>24</sup> At the same time, several of the results obtained from the Indian survey and presented in this paper are very similar to the Swiss survey of the biotechnology industry, which was also a firm level investigation.

The same/ similar sets of patent policies and institutions can have different impacts on knowledge flows, diffusion of innovation and habits and practices of actors in different systems of innovation. These inter-linkages need to be assessed in country-specific contexts. Taking the TRIPS level of intellectual property protection for granted, technology follower countries should look at reducing the problem of restricted access through appropriate design of patent regimes. Analysis of these inter-linkages should take into account the nuanced relationship

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<sup>23</sup> Since several developing countries have only recently complied with the TRIPS Agreement (and several LDCs are yet to comply due to the extension granted to them under the Doha Agreement on the TRIPS Declaration and Public Health until 2016), data that compares a pre-TRIPS scenario to a post TRIPS one will be very useful.

<sup>24</sup> It is debatable whether the sample considered in the US and German surveys is representative enough – the American sample is a mix of universities and firms, whereas the German survey consisted of 25 institutions in total both from the private and public sector. Furthermore, both surveys are descriptive; descriptive surveys usually need to be corroborated by firm-level evidence.

between patent policies on creating widespread technological interdependence in the biomedical sector. Such technological interdependence does not necessarily have to be the result of policies that dictate broad patent scope. Even in regimes where patent policy dictates that patents are granted only on fewer claims and the claims themselves are interpreted more narrowly, there is a possibility that this generates more patents per product/ technology thereby leading to as much technological interdependence as patent policies that construe and grant broad patent claims (Cohen et al, 2002, p. 1357; Granstrand, 2000).<sup>25</sup> This calls for a very sound assessment of patent scope issues within every system of innovation. Additionally, solutions such as extended disclosure requirements in patent laws and increased pre-grant procedures that have been successful in inducing technological spillovers between firms in other sectors should be considered (Cohen et al, 2002).

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<sup>25</sup> Cohen et al (2002) note this form of interdependence in the case of the Japanese manufacturing sector. They note that such technological interdependence may, in addition to inducing spillovers, also stimulate patenting activity: firms derive bargaining power from larger patent portfolios (see also, Cohen et al, 2000).

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