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***Breaking the Fence: Can Patent Rights Deter Biomedical
Innovation in “Technology Followers”?****

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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).¹ 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.²

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, 1996; Heller, 1998). 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, 1996; 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

¹ 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).

² 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.

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 hindered access to research tools is a highly complex question that 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 analyzing 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).³ The definition of biomedical innovation is taken to mean 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.

³ The intellectual origins of the term “technology followers” can be attributed to the flying geese hypothesis by Aerschenkron, Akamazu and Hirschman. 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 comprised of 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.⁴ Patent breadth/ scope, on the other hand, is defined as “how similar other innovations can be without infringing the original patent”.⁵ Patent scope determines the strength of protection granted, and therefore also the extent of power vested in the patent holder to limit competition. Restricting 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).⁶ 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

⁴ 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).

⁵ cf. Gallini and Trebilcock, 1998, p. 19.

⁶ 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.

infringement suits, blocking innovations from competitors, capturing extra value for innovative 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). (Cohen et al, 2002, p. 1357; Granstrand, 2000) Enhanced patenting activity in the biomedical sector and patent policies that increase patent scope (and encourage broader claims) lead 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).⁷

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

⁷ 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).

product development (Eisenberg, 2001, p. 226).⁸ 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.⁹ 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 help-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 reasons of transaction costs posed by factors such as institutional heterogeneity, conflicting agendas of different agents, difficulties in valuation and increased litigation in public research organizations (Eisenberg, 2001; OECD, 2002).¹⁰ 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 have very different demands 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.”

⁸ See Rai (1999) and So et al (2005) in this context.

⁹ 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.

¹⁰ 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.

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.¹¹

Although cases where patents have blocked subsequent innovation have in fact occurred, these are not in the biomedical sector.¹² For the biomedical sector, 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.¹³ 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”. It 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.¹⁴ 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 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).

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

¹² 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.

¹³ 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.

¹⁴ 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

A framework that seeks to analyze the impact of intellectual property on biomedical innovation in technology follower developing countries has to primarily consider four main issues, and such an analysis has to be 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 inconveniencing research (of the kinds that can be resolved through “working solutions” of various kinds), they can 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 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?¹⁵ 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 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

¹⁵ In India, 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,

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.¹⁶

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 concluded 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 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 in firms in

either through a legislative amendment or a court ruling on the topic.

¹⁶ 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).

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).¹⁷ The Indian pharmaceutical industry is a good case to analyze 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, which in turn led to a thriving local pharmaceutical industry.¹⁸ With the full-scale implementation of the TRIPS Agreement and associated questions of access to medicines, biomedical innovation in India has attracted much attention in the recent past 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 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.

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

¹⁸ 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 13th in terms of value in 2004 (IBEF and Ernst and Young, 2004a, 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, 2004a, 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, 2004a, 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.¹⁹ 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. Two exceptions to this exist. 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 interesting 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. A key determinant of the classification was the annual sales turnover of firms, since that determines their export potential, 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 of large-scale pharmaceutical firms that are both subsidiaries of MNCs in India or wholly-owned Indian firms. The second group of companies (hereafter, group 2) comprises of 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.²⁰

¹⁹ 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

²⁰ See Gehl Sampath (2005); also see Sridharan (2005).

The 103 firms that participated in the country-level empirical survey were chosen through a purposive probability sampling technique.²¹ 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 especially in the biotechnology sector to gather the main concerns and experiences on patent issues.

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 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. The 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 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 analyzed, 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.

²¹ 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

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 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

sales and R&D investments.

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 restricting access to technologies to the local pharmaceutical industry? To test this, 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 that were abandoned were done so 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 R² 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 ²	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 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 collaboration 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 only area of product development where there seems to be 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.²² 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

²² 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

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 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.

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

Independent Variables	Coefficients	Std. Err.	P-Values
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

welfare losses associated with such a regime.

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 tools on hindering biomedical innovation in technology follower countries. This paper has shown that four sets of issues are very important in such a framework from a 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 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 analyzed 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 was calculated, 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 countries. This analysis revealed 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.

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 analyze the implications from an *ex-ante* decision-making perspective.²³ To study this problem and its impact systematically in developed as well as technology follower developing countries, more unified research methodologies may be required. Divergence of research methodologies may be one important reason for contrasting empirical evidence on this issue until now. Some of the surveys conducted on this issue until now are characterized by methodological constraints that do not allow for a detailed assessment of these tradeoffs and impacts.²⁴ At the same time, several of the results obtained on this issue 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 set 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 interrelationships 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. Such reviews should take into account the nuanced relationship between patent policies on creating widespread technological interdependence in the biomedical sector. Patent policies that allow for patents to be granted only on fewer claims and where the claims themselves are interpreted more narrowly, there is a possibility that this generates more patents per product/ technology

²³ Since several developing countries have only recently complied with the TRIPS Agreement (and LDCs are yet to comply), data that compares a pre-TRIPS scenario to a post-TRIPS one will be very useful.

²⁴ 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.

thereby leading to as much technological interdependence as patent policies that construe and grant broad patent claims.²⁵ Solutions such as extended patent height 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).

²⁵ 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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