Interest Groups and Patent Reform in India

Anitha Ramanna[•]

Abstract. India's patent reforms represent a shift in India's policy from one of enormous opposition to revising patent laws according to the WTO, to one of compliance with many aspects of TRIPs (Trade Related Intellectual Property Rights) Agreement. Industry and civil society had a strong interest in blocking reforms on IPRs (Intellectual Property Rights), and initially played an important role in preventing reforms of India's patent law. India has recently changed its patent regime, led by important industry groups who revised their positions, and new NGOs that promoted reform. The preferences of actors and their changing interests are important factors in the reform process. Perceived benefits from the new regime partly explain the rise of a pro-reform constituency among industry and NGOs. Yet preference formation is complex and depends on interpretation of strategies by various actors. The Indian pharmaceutical case reflects the imperatives both to forge ahead on patent reform, while protecting the generic market and restricting IPRs. NGOs that emerged to support patent reform also played a role in directing policy towards protecting traditional knowledge. The interests of actors do not always follow predictable paths, and are not fixed. Evaluating the preferences of actors rather than assuming them provides insights into the way policy processes are shaped.

Key Words: Intellectual Property Rights, industry groups, NGOs, reform, preferences.

India's reforms on Intellectual Property Rights reveal the complex dynamics of interest group behaviour in shaping policy. Industry and civil society had a strong interest in blocking reforms on IPRs, and initially played an important role in preventing reforms of India's patent law. Recently, however, India has revised its patent regime, led by important industry groups who revised their positions, and new NGOs that promoted reform. What led to these shifts, and what factors enabled these groups to dominate over existing lobbies that opposed reform? Although it is acknowledged that pressure groups play a role in influencing reform, it is assumed that their interests can be deduced from the existing structure. Many studies also don't take into account the changing nature of actors within the interest groups themselves. Such analysis misses a key component of the means by which reforms take place. As Haggard and Webb (1994) observe, "If interest groups determine policy, and interests in the period before reform tend to favor the status quo, how is reform ever possible? The answer to this paradox is that interests are not fixed but rather change in response to features of the program itself." This paper explores the changes in the definition actors' interests and the rise of new groups to support policy change by focusing on IPR reform in India.

Intellectual Property Rights (IPRs) are limited property rights over information resources. They come in various forms including patents, copyrights, trademarks, etc. Patents protect industrial innovations and grant the inventor a limited monopoly over his/her invention. India's patent reforms represent a shift in India's policy from one of enormous opposition to

[•] Visiting Research Associate, Indira Gandhi Institute of Development Research. E-mail: anithar@igidr.ac.in

revising patent laws according to the WTO, to one of compliance with many aspects of TRIPs Agreement. The preferences of actors and their changing interests played an important role in this policy shift.

The influence of pressure groups in shaping policy has largely been studied from the point of view that actors attempt to maximize their interests where the interests of actors are assumed as given. The interests of firms, for example, are taken as profit maximization, while those of other actors such as NGOs are viewed as being based on principles rather than on material interests. Such assumptions, however, ignore the complexities of preference formation and change. Actors' interests don't remain static and do change according to various factors. How actors define what is in their interest is itself a fluctuating phenomenon. New actors can also arise which redefine the interests of a particular group. The interests of NGOs and business groups also cannot be clearly delineated as material and value based. Pressure groups are viewed as homogenous entities, but in reality they are rarely so. Divisions within these groups can be important in analysing why changes in policy take place. What determines how actors define their interests? When and how do these interests change? How do new actors arise to redefine interests? These questions are explored in this study.

Preferences refer to the way an actor orders the possible outcome of an interaction. (Frieden, 1999). Some analysts have attempted to observe preferences or deduce them from existing theories and have also tried to explain or predict changes in policy preferences. In the case of industry preference changes, differences among groups in factor ownership, import and export competition, and scale economies coupled with the national economic setting are used to infer the economic preferences of groups (Frieden, 1999). In trade, domestic preferences have been deduced from theory to try to explain why some groups favour protectionism and others free trade. Relying on the Stopler-Samuelson theorem, analysts have deduced that scare factors will support protection, whereas abundant ones will oppose it (Milner, 1999). In contrast, sectoral and firm-based theories of trade preferences follow from the Ricardo-Viner model of trade in which because at least one factor is immobile, all factors attached to import-competing sectors lose from trade liberalization while those in export-oriented sectors gain (Milner, 1999). Others have focused on how particular characteristics of industries affect patterns of protection such as how low-skill, labour-intensive industries with high and rising import penetration are frequently associated with high protection. Preference changes then occur due to large changes in relative factor endowments, changes in the firms that are export or import competitive or in the particular characteristics of industries. Frieden and Rogowski (1996) offer another explanation by arguing that exogenous changes bring about changes in policy preferences. They assert that easing of international trade brings about a reduction in the costs of trade, creating new actors who prefer free trade thus shifting the balance. They state that exogenous change, often in the form of technological change, may have altered interest group politics of trade.

Preference formation and change in the case of NGOs is much less studied. Most studies assume that NGOs differ from corporations or other interest groups in that they are guided by shared values rather than material interests (Sell and Prakash, 2002). Keck and Sikkink (1988) argue that, "transnational advocacy networks are motivated by values rather than by material concerns or professional norms." This assumption ignores the fact that NGOs

operating in the same environment may adopt different stances on issues and may have different preferences. While some studies have attempted to analyse the role of NGOs in shaping policy (Bas, 1998) most of the literature does not account for motivations and differences in the interests of NGOs.

This study focuses on the way different groups within industry and NGOs frame their interests in the IPR debate in India and attempts to explain the differences. We analyse the reasons for business shifting its preference on patent policy and the variations in NGOs interests on IPR policy, and point out how these changes led to reform in India. We challenge the view that the preferences of industry and NGOs can be assumed and focus on the way preference formations and changes shape reform. Extending the framework utilized by Sell and Prakash (2002), NGOs and industry are not defined as groups with specified interests (NGOs as value based and industry as material) but both actors are viewed as pressure groups seeking to influence policy. A pressure group can be defined as, "a group that tries to influence government policy or public opinion in the interest of a particular cause."[1] Broadly defined, we focus here on two pressure groups, industry and NGOs. The latter can be thought of as "non-profit pressure groups"[2]. The first part of the paper describes India's policy reforms on patents. The second part of the paper focuses on the changes in the interests of industry and the different interests of NGOs that influenced policy formation. The final part of the paper provides the conclusions.

INDIA'S POLICY SHIFT FROM OPPOSITION TO REFORM

India established a patent system that sought to balance the need for public interest with encouraging innovation. This was in tune with the science and technology mission of developing indigenous technology and fostering R&D activities in areas of national significance. The main aim in India was to ensure that patents did not lead to monopoly by foreign companies nor lead to high prices for medicines and food items. The patent law of 1970 restricts the field of patentability, only grants process and not product patents in food, pharmaceutical and chemical fields, restricts the term of patents and has an elaborate system of licenses to ensure that patents are worked in India. The Patent Act of 1970 was based on the recommendations of two expert committees that were established to provide advice on the type of patent system India should set up. The reports concluded that foreigners held 80-90% of the patents in India and were exploiting the system to achieve monopolistic control of the market. The Ayyangar Committee (1957-59) noted that foreign patentees were acquiring patents not "in the interests of the economy of the country granting the patent or with a view to manufacture there but with the object of protecting an export market from competition from rival manufacturers particularly those in other parts of the world". Thus India, "is deprived of getting, in many cases, goods…at cheaper prices from alternative sources because of the patent protection granted in India." The committees therefore suggested that a patent system that focused on access to resources at lower prices would be beneficial to India.

The Paris Convention acts as an international umbrella for national patent systems and was concluded in 1883. India refused to join this treaty due to the wide definition of industrial property and the restrictions on promoting public interest in the Convention. In the area of patents, India and other countries also attempted to reform existing laws to incorporate views

on the free flow of information. India and other developing nations under the NIEO (New International Economic Order) attempted to put forward the view that technological information should flow to all since it is jointly owned as part of the common heritage (Braithwaite and Drahos, 2000).

India was one of the most vociferous opponents of revising its patent laws according to the TRIPs Agreement of the WTO, and refused to comply with its provisions. To conform to TRIPs, India had to revise one of the main aspects of its patent policy that only process and not product patents would be granted in pharmaceuticals and agrochemicals. By 1995 India had to establish legislation that would allow for applications for agrochemical and pharmaceutical product patents and grant EMRs (exclusive marketing rights), a transition to product patents that gives the firm the exclusive right to sell the product for five years. Domestically and internationally India resisted conforming to TRIPs. The government's attempt to pass an Ordinance (an Ordinance did not require immediate assent by the legislature but had to be passed in six months) in 1994 on reforming India's law to conform to TRIPs, failed to be passed by the upper house of Parliament when it was introduced as a bill. The government was heavily criticized for issuing an Ordinance (Dasgupta, 1999). From 1995-1998, inspite of external pressure, India did not revise its patent laws as required by TRIPs. India's resistance to patent reform in the initial years following TRIPs was led by Industry and NGO groups who protested against change. While Industry stressed the losses and price rises in drugs that would occur if TRIPs was adhered to, NGOs pointed out the negative implications on farmers, access to medicines and the appropriation of traditional knowledge.

A marked shift in India's policy occurred around 1998-99. The policy shift in India was initiated when a bill to conform to TRIPs by allowing for exclusive marketing rights (EMRs) for drugs and agro-chemical products, was passed by the Parliament in March 1999. The bill was passed in the upper house of Parliament in December 1998 and in the lower house in March 1999. The parliament also passed a second amendment act in May 2002. The Patents (First Amendment) Act 1999 and the Patents (Second Amendment) Act of 2002 allowed for applications on product patents in pharmaceutical and agrochemical fields, increased the term of patents to 20 years, and restricted the system of licenses found in India's patent Act. Table 1 outlines the major changes resulting from the amendments. India also joined the Paris Convention and the PCT (Patent Cooperation Treaty) in 1998, marking a turnaround in India's earlier decades of refusal to be a member of these treaties. There was thus a clear shift in policy from opposition to patent reform towards a revision of India's patent policy. The changing nature of actors' interests was a major factor in promoting this policy shift.

INDUSTRY CHANGES

India's patent policy was largely supported by domestic industry and pharmaceutical companies particularly advocated India's Patent Act of 1970. India's Patent Act with a provision for granting only process and not product patents in pharmaceuticals enabled domestic companies to produce drugs through cheaper alternative processes. The gains that Indian pharmaceutical companies have been able to accrue due to this provision along with other measures have been documented (Das, 2002). Supported by this patent law and other regulatory provisions, in 1991 Indian firms accounted for 70% of the bulk drugs and 80% of

the formulations produced in the country. Some estimates state that production processes for about 80 drugs have been developed by Indian industry and research laboratories (Alam 1996). In 1996, out of the top ten companies in pharmaceutical sales, six were Indian firms. Indian companies resisted moves to amend India's laws according to TRIPs as this could harm their interests in generic manufacturing.

As strong proponents of India's patent Act, industry groups resisted any attempts to join international treaties that would lead to changes in the existing policy. In 1986 India debated the option of joining the Paris Convention. At this time reportedly a major pharmaceutical lobby in India, IDMA (Indian Drug Manufacturers Association) played an important role in pointing out the negative impact of the Convention on India (Anand 1998). In 1988 a reference to India joining the Paris Convention provoked reactions in Parliament on the negative implications for industrial development if India became a party to the treaty.[3] The stance of industry bodies was also made clear in Parliament when the Minister of State for Industrial Development pointed out that FICCI (Federation of India Chambers of Commerce and Industry), the most influential representative of Indian industry at the time, had taken the position in 1986 that India should not join the Paris Convention.[4] ASSOCHAM (Associated Chambers of Commerce and Industry), another industry body in India, however, took the view in 1986 that India should join the Paris Convention reflecting internal changes that took place within ASSOCHAM. In 1986, ASSOCHAM underwent enormous transformations from being a representative not only of industry but also trade interests and opened itself up for the first time to overseas membership.[5] At this time however, ASSOCHAM was in the minority and most industry favored the Patent Act of 1970.

When initially faced with pressure for reforming India's patent law, domestic industry in India began to mobilize to counter TRIPs. Pharmaceutical companies and other interests established an organization to lobby the government against changing patent laws. In 1988, the National Working Group on Patent Laws was established in India. Composed of experts from science, law and health industries, the lobby was supported by certain industry groups and was influential at the governmental level in fostering resistance against change. It effectively pointed out the implications of raising patent standards on drug prices, health care and domestic industrial development. Industry groups at this time played a role in ensuring that the bill to amend India's patent laws could not be passed. Industry groups that supported the National Working Group on Patent Laws (NWGPL) including Cipla (a large pharmaceutical firm) and the Indian Drug Manufacturers Association (IDMA) were opposed to the change. The NWGPL played an extremely significant role at this time not only in terms of organizing conferences and issuing publications but also in mobilizing political opposition against changing patent laws. It established the Forum of Parliamentarians (a group of legislators from various parties) that was the crucial factor in defeating the patent bill in 1994-95 and stood firmly against change on patent laws.

The opposition to patent reforms underwent a change within industry. Industry bodies and various groups shifted their position and became vocal on the need to grant product patents prior to the introduction of bill to amend patent laws in Parliament in 1998-99. The CII (Confederation of Indian Industry) took the position in its statements before the Gujral Committee (a committee established by the Indian Parliament to solicit views and prepare a

report on the impact of the WTO Agreement on India) that India was not able to get relevant technology due to the absence of product patents.[6] The CII emphasized that India needs to raise patent standards. ASSOCHAM also took a pro-patent view before the Gujral Committee. ASSOCHAM stressed before the Gujral Committee that India needed to strengthen patent laws in order to attract foreign direct investment.[7] The CII placed on its 'wish list' for the government the passing of the patent bill to conform to TRIPs.[8] FICCI, the older industry body also began to openly promote change at this time. In 1997 FICCI established the International Institute of Intellectual Property Development (IIPD). This institute 'aims at promoting the patenting culture amongst the scientific and technical community and use IPR as a strategic tool in forwarding business interests. It loudly promotes the slogan "Patent or Perish".[9] FICCI has organized a number of conferences and training programs across India. Along with WIPO (World Intellectual Property Organization) the IIPD and the Ministry of Industry have organized various conferences on intellectual property management, the PCT, and interactive sessions between Indian and foreign firms on intellectual property. India's joining of the Paris Convention and PCT appeared to have broad support by industry, media and lawyers.[10]

EXPLAINING INDUSTRY SHIFTS

Why did certain industry groups shift their position on patent reform? What led to changes in policy preferences on the part of these firms? External trade pressure can be seen as one factor that may have promoted changes in the strategy of firms. The United States exerted both bilateral and multilateral pressure on India to change its patent laws. One form of trade pressure came with the Special 301 legislation of US trade act. The United States had filed a case with the Dispute Settlement Body for India's failure to implement TRIPs and the WTO had ruled that India must reform its laws by April 1999. In 1992, the US also placed a sanction on India for not changing its IPR policy. In 1992, the US suspended GSP (Generalised System of Preferences) benefits to India on pharmaceutical and chemical products. The action meant that duty-free treatment of $ 60 million worth of imports from India was suspended. This certainly was a major impediment to the functioning of pharmaceutical companies. In addition, the US effectively utilized the 'piracy' argument against Indian industries. Domestic firms in India found it difficult to refute US accusations that Indian companies were not innovators but were copying US technology and ideas. Phrma, the association that represents US based pharmaceutical companies points out, "Based on the refusal of the Government to provide pharmaceutical patent protection, India has become a haven for bulk pharmaceutical manufacturers who pirate the intellectual property of the world's research- based pharmaceutical industry."[11]

However, external pressure provides only a partial explanation. What we witness in the case of India is that industry groups started become votaries of reform and began focusing on the gains that could accrue from the new regime. The policy debates shifted from that of the negative implications of patents to the benefits that Indian industry could achieve through Intellectual Property. External trade pressure was inadequate to ensure compliance in 1995 but was successful in 1998-99 because domestic actors had become mobilized towards change. Some firms in India shifted their position as they saw benefits from the new regime rather than just as a reaction to coercion. Industry heads from Ranbaxy, a major pharmaceutical firm expressed that, "India currently has a deficient system as far as providing intellectual

protection goes, therefore we see the need for a radical change….It is a myopic view that multinationals will dominate the industry, as players are emerging at all levels".[12] Interviews with several Indian and MNC subsidiary firms and two industry associations conducted by Lanjouw (2001) revealed a shift in the debate on patents in India around 1997-98. Compared to just a year before she notes, "No one any longer expressed doubt that India would, in fact, be in compliance with WTO intellectual property requirements when deadlines were reached…….", and that, "recent interviews indicated that there was an entirely new debate underway in the country on whether India should voluntarily skip the end of the period under EMR and go straight for product patents."

A few large firms in India revised their thinking on their capacity to benefit from the new patent system. Smith (2000) in a study of major pharmaceutical firms in India notes the strategy of companies like DRL, Ranbaxy, Wockhart and Dabur to use product patents to produce their own IP. He points out that their attempts to turn their existing capacity for reverse engineering into moves for new drug discovery. He notes that reverse engineering requires technicians to screen molecules, to use complex analytical equipment, and to create standardized test conditions, practices which all have direct applications in the discovery process. Dr. Reddy's laboratories, which has been preparing for the change in patent policy since 1984, believes that it has a competitive edge in new drug discovery which will lead to its growth under the revised policy.[13] The change in industry strategy is being reflected in their current activities. About six to eight Indian firms have established their own foreign subsidiaries overseas as of 1998 and Cipla, Ranbaxy, DRL and Lupin are already on the vanguard of the trend to export more to developed countries than to less emerging markets (Smith, 2000). Domestic firms in India also began to increase their patent applications and change their strategies (see Figure 1). Since 1994, patent applications in India have been growing at the rate of about 30% a year.[14] Although a large number of this represents applications by foreign companies, some Indian firms have been playing a major role in this increase in patent applications.

We can partly explain the rise of a pro-IPR stance among Indian industry by noting that firms with the ability to transform their potential into patents became votaries of reform. Those firms with greater sales, export competition and R & D investment are the firms that are in a position to transform their capacity into gains from patents and therefore shifted their interests towards promoting rather than opposing patent reform (See table 2). Differentiating firms based on these factors does enable us to understand why some firms shifted their strategies towards greater patent activity and explain the reasons for the rise of a pro-reform constituency. However, domestic pharmaceutical companies continue to be dependent on sales of generic drugs for their revenues leading to divergent interests.

Domestic firms, while supporting the patent reform, have also attempted to influence the policy process to promote their interests in generic manufacturing. The importance of the generics markets both in India and abroad continues for Indian pharmaceutical companies inspite of their push towards patents. Adiga (2003), points out "...India's copycat pharmaceutical firms are increasingly becoming a throbbing headache for Big Pharma. Not only are they expanding aggressively in the U.S. and Europe, they are also making inroads by challenging patents on some of the world's most profitable drugs so that inexpensive Indian alternatives become more widely available….. In all, Indian companies have received either judicial or administrative clearance to

sell 87 generic drugs in the U.S., and 68 more are awaiting approval.." According to B. K. Raizada of Ranbaxy, "The Indian pharma industry would continue to be predominantly generic in nature for the next few years. A robust and vibrant generic industry is, therefore, of vital importance for the overall development of the industry and to ensure abundant availability of reasonably priced, good quality medicines in India."[15] Domestic firms are also concerned with restricting IPRs to ensure that MNCs do not curtail their activities in generic manufacturing at home. In a recent case, Novartis has been granted an EMR for its drug Glivec. This is likely to affect many of the generic producers as this prohibits companies like Ranbaxy and Cipla from manufacturing generic versions of the drug[16]. One specific measure to promote the generic industry is a provision to enable generic producers to market their products as soon as the patent expires. This involves a clause that the use of a patent "related to the development and submission of information" for the purpose of getting regulatory approval before the expiry of the patent will not be considered as an infringement of patent rights also known as the 'Bolar' provision (Chaudhuri, 2002). Raizada points out, "The Indian patent law requres a "Bolar Type" provision so as to sustain the generic industry in India. Bolar Provisions, as they are now widely known, allow R&D and clinical testing of patented molecules other than by the patent holder during the life of the patent."[17] The Indian Patents Amendment Acts have incorporated this provision. Other measures promoted by the domestic firms include provisions on compulsory licensing i.e., government granted licenses to enable third parties to use a patented invention for public policy purposes that have also been incorporated into the Indian Patent Amendment Acts.

One large domestic firm has chosen a diametrically opposite route and focused on its capabilities in generic manufacturing utilizing international developments that have aimed at restricting patents. The international access to medicines campaign emerged to counter TRIPs with its emphasis on strictly enforcing patents on medicines. The access to medicines campaign was led by NGOs who pointed out that the HIV/AIDS crisis in South Africa demonstrated the negative implications of strong patent laws. They effectively argued that patent standards should be relaxed so that drugs for HIV/AIDS patients in South Africa should be priced to make them affordable. Cipla, a large pharmaceutical firm in India, utilized and promoted the access to medicines campaign. Dr. Hamied of Cipla presented data on the prices at which Cipla could manufacture the drugs for HIV/AIDS to an influential NGO in this campaign, Consumer Project on Technology (CPT) who urged Hamied to make a dramatic offer as a humanitarian donation (Sell and Prakash, 2002). Hamied agreed to sell the drug to the NGO MSF (Medicines Sans Frontiers) for about $ 1 a day per dose and following a joint statement by Cipla and MSF offering the discounted price, MSF was immediately swamped for requests for the drugs (Sell and Prakash, 2002). The World Health Organization (WHO) also listed Cipla as one of the companies who could supply good quality drugs internationally. Cipla stressed the need to restrict patents and reinterpret TRIPs. Y. K. Hamied, director of Cipla in 2002 stated, "The Government should critically examine and correctly interpret the provisions of trade related intellectual property rights (TRIPs)…We strongly believe that India should be granted a further extension of its transition period until 2019, as given to other LDCs for implementation of TRIPs."[18] In 2001, the Doha Declaration of TRIPs was issued which was to pave the way for companies like Cipla to supply drugs to countries like South Africa without violating legal patent standards. The Doha Declaration marked a shift in the interpretation of TRIPs towards allowing for restrictions on patents for health reasons. Cipla also has the capacity to file patents and ranks among the top four companies in terms of gross sales. Yet Cipla chose to utilize the international access to medicines

campaign to promote its interests in generic manufacturing. It ordered its preferences on the issue in a different manner than others who focused mainly on patent activity. Cipla's initiative led firms who had turned towards patents to also reframe their focus towards generic manufacturing.

Ranbaxy also announced that it would manufacture the anti-AIDS retrivorals[19] and ensured that its name was also placed on the WHO's list. The emergence of a new association of pharmaceutical firms in India in 1999 consisting of firms such as Cipla, Dr. Reddy's, Ranbaxy and Lupin Labs marks their focus on generic manufacturing. The Indian Pharmaceutical Alliance (IPA) represents the interests of firms that want to utilize their patent potential but also capitalize on their generic manufacturing capability. The Alliance, working closely with government on policy related matters, aims to imbibe the experiences of the generic pharmaceutical industry internationally and it is reported that it will seek affiliation with the International Generic Pharmaceutical Association (IGPA)[20]. The IPA emerges as a third important industry lobby among pharmaceutical companies alongside the Indian Drug Manufacturers Association (IDMA) representing small-scale firms with not much capacity for patents and who oppose patent reform, and OPPI (Organization of Pharmaceutical Producers of India) representing mostly MNCs that are strongly in favour of patent reform. The formation of the IPA signals a middle ground between these two associations. As the Commission on Intellectual Property (2001) concluded on its visit to India, "…the IPA…is perhaps a little schizophrenic about where its members' interests lie. On the one hand many of them such as Ranbaxy, wish to develop as research based companies and see the value of strong patent protection to achieve that. On the other hand the overwhelming majority of their revenues remain derived from generic production, and accordingly they share many of the concerns of IDMA".

The preference formation and strategy choice of firms is thus complex and in the Indian pharmaceutical case reflects the imperatives both to forge ahead on patent reform, while protecting the generic market and restricting IPRs. Frameworks that attempt to deduce preferences from existing theory do not provide adequate explanations of these dimensions. Attempting to differentiate among firms based on factor ownership, export competition or R & D capacity provides some insights into the rise of pro-reform lobby. However, it would not have accounted for different strategies of firms such as Cipla and the impact of the international access to medicines campaign on the activities of domestic firms. As the Cipla case illustrates, not all firms with the greater export competition or other indicators chose to utilize the patent route but rather strategically opted for focusing on generics. The new opportunities opened up by initiatives taken by Cipla and the international NGOs enabled some shift in preference formations. The emergence of a new alliance among these firms to focus on generic drug interests demonstrates the way firm preferences are revised based on new strategy options. The complex interaction between international developments and the shifting nature of preference formation illustrates that it is not only the firm structure or orientation that can shape interests. How firms view and interpret their strategic advantages in a changing international context is important in determining their preferences and this plays an important role in determining the shape and continuity of reform.

NGOs OPPOSITION TO REFORM

Enormous protest against implementing TRIPs, arose from non-governmental organizations in India. Their most effective and forceful argument was that the IPR system as

outlined in TRIPs recognizes only innovations of corporations, but ignores informal innovations of farmers and communities, especially in developing countries. These NGOs not only pointed out the negative impact of patents on industry, health and prices but also highlighted the issue of bio-piracy. Bio-piracy refers to the utilization of traditional knowledge or resources by industrialized nations to create profitable products without compensation. NGOs effectively raised public opinion in India that changing patent laws would affect local knowledge. Their campaign was launched not only in India but globally with the neem issue. Neem is a common tree in India that yields a variety of pesticidal, medicinal and other uses. W.R. Grace, a company based in the United States, acquired a patent in 1992 covering the method of extracting the active ingredient in neem and stabilizing it for longer shelf life in the US Patent Office. In 1995 over 200 organizations led by various activists including Vandana Shiva (a prominent activist in India against IPRs) and the leader of a farmer's lobby in India filed a petition in the USPTO requesting a withdrawal of the patent.[21] This petition was dismissed but led to an enormous public outburst both in India and other countries on the implications of patents on traditional knowledge/genetic resources. It enabled the NGOs to effectively turnaround the accusation by multinational firms against Indian 'piracy' by claiming that the real pirates were the MNCs. The most prominent NGO is the Research Foundation for Science, Technology and Natural Resource Policy, founded by Dr. Vandana Shiva. Gene Campaign, established by Dr. Suman Sahai in 1992, is another NGO that is "dedicated to protecting the genetic resources of the IIIrd world and the rights of IIIrd world farmers".

NGOs in India were able to effectively promote their view through events at the international level. Within TRIPs, the relevant article that dealt with agriculture became the subject of an intense debate. The conclusion of the Convention on Biological Diversity (CBD) at the Earth Summit in Rio de Janeiro in 1992 also provided momentum to their protest[22]. The issue of farmers' rights within the FAO (Food and Agriculture Organization) and other forums was another factor in shaping the debate. NGOs in India used these developments to protest against patent reform in India.

NGOs, NEW IDEAS AND CHANGE

The emergence of pro-reform NGOs enabled a shift in the view on the negative implications of patents on traditional knowledge. Non-governmental organizations who took the position that IPRs were not necessarily harmful if India protects its genetic resources provided an important counter- argument against those who spoke of bio-piracy. Until this time, NGOs mainly focused on the harmful impact of patents on genetic resources/traditional knowledge and were able to raise enormous pressure against reforming patent laws. The rise of NGOs that took an alternative view paved the way for changes in India. The pro-reform NGOs pointed out that a more strategic means of securing gains from intellectual property was to extend it to traditional knowledge rather than to protest against patents per se. These NGOs utilized the same international debates used by anti-IPR NGOs but reframed these arguments to call for IPR reform. They applied the debates at the Convention on Biological Diversity (CBD), and on farmers' rights to argue that rather than oppose IPR reform, with the vast knowledge of traditional innovations, India could benefit from the regime as long as grassroots innovations were also recognized.

Professor Anil Gupta head of SRISTI (Society for Research and Initiatives for Sustainable Technologies and Institutions) stated that "there is a genuine case for reforms of patent regime" and what is needed is a system requiring full disclosure regarding the origin of patents based on local knowledge or resources involving prior informed consent and benefit sharing.[23] He states, "SRISTI has been campaigning to defend the intellectual property rights of Third World farmers. True, the present property right arrangements do not leave much scope for improvement, but we cannot defend the rights of individual farmers or communities on moral grounds unless we also respect the rights of scientists and inventors in developing and developed countries."[24] Speaking of the neem patent case he argues, ". . .in this case the neem tree grows in many countries including India and knowledge about its uses is also widely shared. Therefore no contribution can accrue to any one community or country. It can only be put in an international fund to support conservation of neem germplasm as well as R & D by local communities and entrepreneurs for developing various products. It must however be understood that this contribution can arise only if profits are made. And profits can only be made if and entrepreneur has efficient technology, consumer demand and some protection from others not imitating or copying his/her formulation. Therefore, patents on products per se do not preclude the possibilities of communities benefiting from the managerial support to local innovators in order to protect their IPRs and ensure their ability to generate returns for their knowledge, inventions and value additions." Madhav Gadgil (1997) of the Indian Institute of Science states, "It is necessary that India accepts the broad framework of IPRs prevalent in the industrial countries to function efficiently in the emerging global framework….they (industrial countries) can impose on us an intellectual property rights regime of their own design. It is best to accept this reality and then actively work towards modifying the IPR regime to serve our interests better."[25]

These NGOs have played a role in shaping reform to extend private property type rights to protect traditional knowledge. Several NGOs are documenting the traditional knowledge found in India rather than focusing only on opposing patent reform. The FRLHT (Foundation for Revitalization of Local Health Traditions) along with the Center for Ecological Sciences at the Indian Institute of Sciences, for example, launched the "People's Biodiversity Register" in Bangalore in April 1995. It is a program aimed at organizing information on the status, uses and management of living resources. The aim is to create a network of decentralized databases, ultimately linking them to a consolidated national database which would give full credit to the origin of information at the level of individual, community or village panchayat. These initiatives have also influenced the Indian government to create such databases. Indian government bodies are taking active steps to document traditional knowledge and to find means to reward grassroots innovations. India is also taking the lead internationally in attempting to devise mechanisms to protect traditional knowledge. The Amended Indian Patent Acts have a provision that patents cannot be granted on an invention which is traditional knowledge.

The pro-reform NGOs differed from the anti-IPR NGOs in their ability to benefit from a reformed IPR structure. Table 2 compares two NGOs, Research Foundation and Sriti's Honeybee Network. NGOs such as SRISTI had more of a connection with industry and policy networks that would enable these organizations to commercialize traditional innovations.

These organizations could more easily negotiate deals with industry for selling valuable information found among local people. They could also apply science and technology to local information and scale-up these inventions to make them patentable. Organizations such as Sristi housed within an academic institute or the Swaminathan Foundation with its own laboratories for biotechnology research can utilize the infrastructural facilities to transform grassroots innovations into IPR protectable products and processes. These NGOs therefore have more of an interest in promoting IPR reform than those who opposed it.

The differences between the pro-reform and anti-reform NGOs in India demonstrate that preferences among non-governmental actors are not uniform. Even among NGOs that are involved in similar issue areas, operating in similar environments and catering to similar groups, there are variations in how these actors define and promote their interests. The preference formation of NGOs also cannot be assumed to be value based rather than material interests. This is not make any normative judgments regarding the superiority of value based interests over the material or to assert that strategies pursued by anti-reform NGOs are better than pro-reform NGOs. Rather, it is to point out that we cannot assume one set of preferences and assign them to NGOs. A careful examination of the interests of NGOs is also required to evaluate their role in shaping policy.

CONCLUSIONS

This paper explored the role of two important lobbies in promoting policy change in India. It illustrated that policy preferences cannot always be deduced from existing structures. In the case of industry, analysis based on industry structure would have led to the view that those with a capacity in reverse engineering and an interest in generic drugs would have opposed the patent reforms and would have formed coalitions to lobby against reform. While this did occur, some firms also changed their strategies and positions by attempting to turn their capacity for reverse engineering into new drug discovery. These firms then became a prominent force for reform. The complex nature of preference formation is clear from the fact that Indian firms are still interested in maintaining their revenues from the generics market while focusing on patents and new drug discovery. Firms also adopt various positions to take advantage of external changes and these cannot be easily predicted. The activities of NGOs also illustrate that preferences are not fixed and that strategy options are formulated by interpreting the international developments. Rather than continued opposition to reform, we find the rise of new NGOs who reversed the IP arguments and supported reform. Different types of NGOs also interpret developments in different ways. The framework of assuming preferences or attempting to deduce preferences would not have enabled us to explain these complex dimensions of interest formation and change.

The study also reveals how industry and NGOs should not be assumed to be homogenous groups. The divisions that took place within these groups were a crucial factor in evolving a pro-IPR constituency in India. Much of the literature on the role of interest groups emphasize stability and continuity, whereas in reality there is instability and interest groups have learned to exploit the opportunities presented by a policy process which in increasingly characterized by multiple opportunity structures (Richardson, 2000).

Ideas play an important role in the change in interests. The emergence of new ideas or new interpretations of strategy affect the preferences of existing groups. In the case of industry, the idea that the international access to medicines campaign provides an entry for generic drugs affected the strategy of firms who had adopted the patent route. In the case of NGOs, new ideas by pro-IPR NGOs completely transformed the debate leaving the anti-IPR NGOs with a need reinterpret their positions. The NGOs who opposed reform had to also talk of documenting traditional knowledge and devising mechanisms for protecting traditional knowledge. In this process some of them moved closer to accepting IPRs. Richardson (2000) points out that "New ideas have a virus-like quality and have an ability to disrupt existing policy systems, power relationships and policies."

Evaluating the preferences of actors rather than assuming them provides insights into the way policy processes are shaped. Policy change can occur through shifts in interests and the rise of new lobbies that are more articulate than existing groups. International developments are interpreted in various ways by domestic actors and this has significant implications for the pace and direction of reform. The interests of actors do not always follow predictable paths, and cannot be assumed to be static. Analysis of economic reform cannot ignore the dynamics of preference formation and change.

Table 1: Major Changes to India's Patent Law

India's Patent Act of 1970	**Amendments to Patent Act, 1999 and 2002**
Only process and not product patents allowed on medicines, food, agrochemicals	Applications allowed for product patents in medicines, food, agrochemicals and Exclusive Marketing Rights introduced
Term of patents 14 years; 5-7 in chemicals, drugs	Term of patents 20 years
Compulsory licensing and license of right (these provisions allow governments to issue licenses to allow other companies to make a patented product or use a patented process without the consent of the patent owner under certain circumstances)	No licenses of right; Compulsory licensing allowed but more restricted
Government allowed to use patented invention to prevent scarcity and included "right to sell goods" Government had to notify the patentee of use "unless it appears to the Government that it would be contrary to the public interest to do so" Royalty payment not to exceed four percent of price	Right of government restricted to "right to sell on non-commercial basis" Government must notify patentee of use "except in the case of national emergency or other circumstances of extreme emergency or for non-commercial use" Not more than adequate renumeration taking into account economic value of patent

Source: Indian Patent Act 1970, Patent (Amendment) Act 2002, Patent (Amendment) Act 1999, Chaudhuri (2002), Cullet (2002).

Figure 1: Indian Patent Applications 1970-1999*

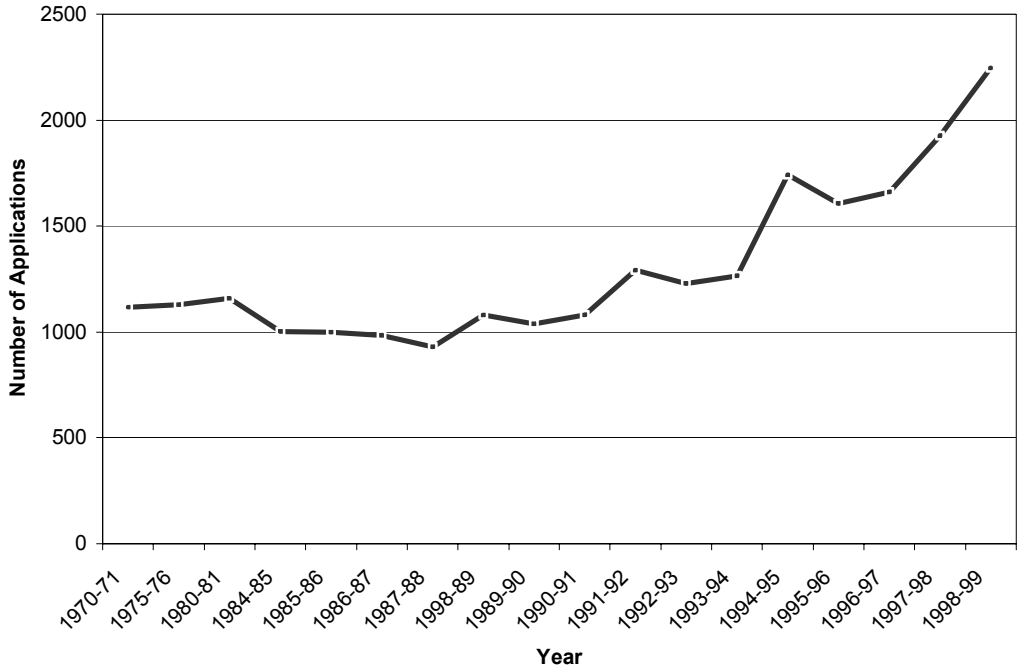

*Table depicts patent applications by Indian individuals and firms filed in India. Source: Compiled from Controller General of Patents, Designs and Trademarks, (various years), *Annual Reports* and A. R. Rajeshwari, *Indian Patent Statistics—An Analysis*, Scientometrics, vol. 36, no.1, 1996, p. 110

Table 2: Indicators of Major Domestic Pharmaceutical Firms in India (2002)

Companies	Net Sales	Net Profit /PAT	R&D on Capital A/C	R&D on Current A/C	Total Forex Earnings	Net Exports
Ranbaxy	2067.97	262.43	12.42	64.7	1085.52	551.74
Cipla	1284.97	207.63	10.03	36.73	496.75	290.9
Dr.Reddy's Lab	1628.24	459.65	3.73	98.03	976.2	783.48
Nicholas Piramal	807.17	48.23	7.54	12.87	10.11	-105.54
Wockhardt Ltd.	610.36	101.63	4.18	36.06	166.75	101.12
Lupin Chem	866.93	72.18	28.54	25.02	310.1	131.46
Cadila Healthcare	528	67.1	21.1	20.5	84.9	2.8
Sun Pharma	668.42	168.64	13.94	19.73	133.88	68.88
Alembic Ltd	557.5	23.82	6.58	7.83	115.86	41.36

*All figures in Rs. Crores Source: Compiled from Prowess, Center for Monitoring Indian Economy

Table 3: Patents Filed by Major Domestic Pharmaceutical Firms in India 2001*

Companies	Patents filed
Ranbaxy	44
Cipla	6
Dr.Reddy's Lab	14
Dr. Reddy's Research Foundation	32
Wockhardt Ltd.	4
Lupin Chem	7
Cadila Healthcare	17
Sun Pharma	45
Alembic Ltd	17
Nicholas Piramal	2

*Source: TIFAC, Database on Patent Applications Filed in India (1998 updated 2002)

Table 4: Comparison between NGOs*

	RFSTE	Honeybee Network
Established	1982	1993
Founder-Director	Dr. Vandana Shiva Physicist	Dr. Anil Gupta Professor, IIM Center for Management in Agriculture
Aims	Biodiversity conservation and protecting people's rights from threats to their livelihoods and environment by centralised systems of monoculture in forestry, agriculture and fisheries. Concerned with the impact of Intellectual Property Rights (IPRs) on life forms as extolled by TRIPs	Strengthen the capacity of grassroots inventors, innovators and ecopreneurs engaged in conserving biodiversity and developing eco-friendly solutions to local problems. Protecting the intellectual property rights of grassroots innovators, and generating models for recognizing, respecting and rewarding creativity;
Main Activities	Campaigns, activities and publications to promote awareness of the impact of TRIPs, Community seed banks to ensure agricultural diversity, various meetings and seminars	Documentation, experimentation and value addition to local innovations Seminars, research papers
Links	Farmer Lobbies, International NGOs	Institutes, Government

*RFSTE=Research Foundation for Science Technology and Ecology. Source: Compiled from www.vshiva.net and www.sristi.org

[1] Compact Oxford Reference Dictionary, 2001
[2] Bas Arts, 1998
[3] Government of India, Rajya Sabha Debates, Official Reports, Rajya Sabha Secretariat, New Delhi, 5 December 1988, p. 114.
[4] Ibid., p. 115.
[5] www.assocham.org, History, p. 9.
[6] Shri Subodh Bhargava of the CII deposing before the Committee stated, "Nobody gives us the right type of technology because of the fear of not getting product patent protection".
[7] ASSOCHAM gave a written submission to the Committee on the need for phased introduction of product patents in India and pointed out that it was of the view that in order to attract increasing flow of Foreign Direct Investment, it is important for India to strengthen the patent system. This will ensure higher interaction in R & D as well as flow of foreign capital.
[8] "CII's Wish List for the Government", www.cii.org
[9] www.iprindia.org
[10] "No More Stiff Upper Lip: India Finally Joins the Paris Convention", Economic Times, August 13, 1998, "Patently Correct", Hindu Business Line, August 19, 1998, "India Agrees to Sign Two Patent Treaties", Financial Express, October 15, 1998.
[11] http://www.phrma.org/issues/intl/india.html
[12] Quoted in Siddhartha Prakash (1998) Trade and Development Case Studies India Trade and Development Centre http://www.itd.org/issues/india5a.htm.
[13] See Smith (2000).
[14] Quoted in Rukmini Parthasarthy, "The CEO's Guide to The New Patents Regime", Business Today, September 22, 1998, p. 58.
[15] http://www.ranbaxy.com/newsroom_pharmaworld.htm
[16] www.patentmatics.com
[17] Ibid.
[18] Sixty-sixth Annual General Meeting– Wednesday, 4 September 2002
http://www.cipla.com/aboutus/cmspeech.htm
[19] Kamath, Gauri, "Ranbaxy to foray into anti-AIDS drugs market" Economic Times, February 21, 2001
[20] "Eight drug firms come together, float association", Indian Express, November 26, 1999.
[21] "Patents on Native Technology Challenged", Science, (Washington D.C.) vol. 269, September 15, 1995, p. 1506.
[22] The CBD represented the overt shift of developing nations from the common heritage to sovereign control over genetic resources. The conclusion of this treaty played a role in the domestic debates relating to IPRs in India pointing to the need for India to protect genetic resources in light of the demands of advanced nations. It was linked with the issue of bio-piracy that was significant in the debates in India on the impact of patents on local communities.
[23] Anil Gupta, "Rewarding Creativity for conserving diversity in third world: Can IPR regime Serve the Needs of Contemporary and Traditional Knowledge Experts and Communities in the Third World?",
http://csf.Colorado.edu/sristi/papers/cottier.html
[24] http://csf. Colorado.edu/sristi/papers/patentonneem.html "Patent on Neem: Will It Deprive Indian Farmers of Right to Use It?", p. 5
[25] Madhav Gadgil, "A Framework for Managing India's Biodiversity Resources in the Context of CBD and GATT", RIS Biotechnology and Development Review, October 1997, vol. 1, no. 1, pp. 9-10.

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