TRIPS compliance of national patent regimes and Domestic Innovative Activity

The Indian Experience

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India's patent regime was made TRIPS compliant in 2005 after a series of three amendments to the oroginal Patent Act of 1970. TRIPS compliance meant recognition of product patents in pharmaceuticals, agrochemicals and food products, raising the patent term to twenty years from the date of application and reversing the burden of proof from the patentee to the infringer. The paper undetakes a detailed survey of the processes through which the national patent regime in India was made TRIPS compliant and then analyses the more proximate effects of these changes on a number of dimensions of innovation activity in general and those in pharmaceutical industry in particular. The resulting analysis presents a mixed picture. Some of the more positive and negatuve effects expected have not happened.

Keywords: TRIPS, patents, pharmaceutical industry, traditional knowledge, licensing of technology, neglected tropical diseases, exclusive marketing rights, patent cooperation treaty.

JEL Classification: O34;O38;N75

Introuction: An important aspect of changes in international governance rules with respect to Intellectual Property Regimes is the passage of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement has been in force since 1995 and is to date the most comprehensive multilateral agreement on intellectual property. The Agreement introduced global minimum standards for protecting and enforcing nearly all forms of intellectual property rights (IPR), including those for patents. International conventions prior to TRIPS did not specify minimum standards for patents. At the time that negotiations began, over 40 countries in the world did not grant patent protection for pharmaceutical products. The TRIPS Agreement now requires all WTO members, with few exceptions, to adapt their laws to the minimum standards of IPR protection. In addition, the TRIPS Agreement also introduced detailed obligations for the enforcement of intellectual property rights. However, TRIPS also contains provisions that allow a degree of flexibility and sufficient room for countries to accommodate their own patent and intellectual property systems and developmental needs. This means countries have a certain amount of freedom in modifying their regulations and, various options exist for them in formulating their national legislation to ensure a proper balance between the goal of providing incentives for future inventions of new drugs and the goal of affordable access to existing medicines. The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Although the TRIPS came into being in 1995, developing countries were given time until 2005 to have their respective IPR regimes aligned to the varied provisions of TRIPS. After a series of three amendments, the Indian Patents Act 1970 was made TRIPS compliant wef January 1, 2005. In the context, the purpose of the present study is to analyse the potential and actual effects of the TRIPS compliant patent regime on innovative activity in the country

not only at the macro level but also on those industries such as pharnaceuticals and agrochemicals, the two industries that are most likely to be affected as a result of some major changes which the TRIPS compliance has brought about.

The study is structured into six sections. The first section traces the evolution of the patent regimes in India over time. The emphasis here is to distil in very specific terms the precise connotation of TRIPS compliance. The second section discusses the macro implications of TRIPS compliance in as much as it affects innovative activity. We divide these macro changes to proximate and distant changes. The third section maps out the increasing cases of patent litigation which TRIPS compliance seems to have precipitated. The fourth section analyses its effects on the R&D strategies of the domestic pharmaceutical industry and the fifth one on the agrochemicals industry. The sixth and final section sums the main findings of our study.

I. The long road to TRIPS compliance of India's Patent regime[1]

The Indian patent system, dating as far back as 1856, has undergone several modifications at different times that have strengthened or relaxed patent rights. The Patents Act, 1970 that came into force in April 20, 1972 was a response to the growing national debate on how to best strike a balance between patent rights as incentives to innovation and the need to protect the public interest and to boost industrial development. Up until the 1960s foreign multinational pharmaceutical companies supplied almost 85 percent of medicines in India, and prices were among the highest in the world. To redress this problem and with a view to make the patent law compatible with Indian developmental objectives, in the post independence period from 1947 to 1970, the Indian Parliament vehemently debated amendments to the Patents Act. One of the main changes of the Patents Act, 1970 was that it allowed process patents in pharmaceutical and agrochemical based products, but not product patents. This allowed the national pharmaceutical industry to develop technical expertise the manufacturing process – and thus to become an efficient producer of generic medicines (Chaudhuri, 2005; Sampat, 2010).

- The establishment of ***IPR in India commenced in 1856*** with the enactment of an Act of Protection of Inventions, based on the British Patent Law of 1852 when certain privileges were granted to the inventor for new methods of manufacture.
- The ***Patent Act of India 1911*** was fairly liberal as patenting of products related to foods, pharmaceutical, chemicals, etc. was available with a full term of 16 years.This was directly in line with the British Patent Act of 1907. India follows the ''first-to-file'' system as in most countries.
- The ***Indian Patent 1970*** brought in significant changes with restrictions related to patenting of inventions, in the area of *chemicals, pharmaceuticals, agro chemicals, foods,* in which product patents had been discontinued and patenting of processes with a restricted life of seven years from the date of filing of the complete specification (or five years from the date of sealing the patent, whichever is shorter) was introduced.

[1] For a history of India's patent laws, see Ganguly (2003), Kankanala, Narasani and Radhakrishnan (2010) and Sampat (2010)

The three amendments

India did not come out with a new Patent Act in 2005, but merely amended its Patent Act 1970 three times in 1999, 2002 and finally in 2005 to make it TRIPS compliant. In the following we undertake a quick survey of these three amendments with a view to understanding the specific changes that were made.

The amendment in 1999: Being a developing country India was given a 10 year transition time from 1995 through 2005 to make its 1970 IPR regime TRIPS compliant. The most important requirement for TRIPS compliance is the granting of both product and process patents for all inventions including those in pharmaceutical, agrochemicals and food which the 1970 Act had a different position[2]. There are two important substantive obligations that have been effective from the entry into force of the TRIPS Agreement on 1 January 1995. One is the so-called "non-backsliding" clause in Article 65.5 which concerns changes made during the transitional period, and the other the so-called "mail-box" provision in Article 70.8 for filing patent applications for pharmaceutical and agricultural chemical products during the transitional period. So the 1999 amendment also put in place this mailbox provision under which from January 1, 1995 till January 1, 2005, an application can be filed for a product patent (in pharmaceuticals and agrochemicals) under the provision of this mailbox clause and after January 1, 2005 the applications will get examined and only those that comply are granted product patents.

However the applicants in the mailbox could apply to be granted exclusive marketing rights to pharmaceutical products as an alternative to product patent protection during this period. This lead to the amendment in 1999, which introduced Chapter IVA in the 1970 Act: under Chapter IVA Exclusive Marketing Rights (EMRs) to sell and distribute a pharmaceutical product was granted to applicants on satisfaction of a set of five conditions:

1. A patent application covering the new drug or agrochemical should have been filed in any of the WTO member countries after 1 January, 1995;
2. A patent on the product should have been obtained in any of the member countries (which provides for product patents in drugs and agrochemical) after 1 January 1995;
3. Marketing approvals for the product should have been obtained in any of the member countries;
4. A patent application covering the product should have been filed after 1 January 1995 in the country where the EMR is sought;
5. The applicant should apply seeking an EMR by making use of the prescribed form and paying requisite fee.

Once granted these exclusive marketing rights were valid for a period of five years and would come to an end earlier on grant or rejection of the patent. Although about 8500 applications were received under this facility, only about 12 were actually granted. See Table 1. It is seen that of the 12, four were from domestic companies (although one of these,

[2] Only process patents were granted and not product.

namely Ranbaxy has become an affiliate of a Japanese MNC since 2008). The important point is that these numbers show that the worst fears expressed by a variety of commenters that a large number of EMRs are going to be awarded has been proved wrong.

An analysis of the mailbox applications in 2005 showed that majority of them referred to minor changes to the structure of molecules and not for patenting new chemical entities. Thus according to Abbott, Kapczynski and Srinivasan (2005), MNCs which accounted for majority of these applications were actually using the mailbox provision for erecting a barrier of sorts to the Indian generic manufacturers who were manufacturing drugs which were invented before 1995. The fear of a protracted and costly patent litigation would have loomed large on them.

Table 1: Profile of applicants who were granted Exclusive Marketing Rights in India: Post 1999 amendment

EMR No	EMR Applicant Name	Title	Nature of Ownership
1. EMR/1/2000	Hoffman-La Roche Inc.	Pharmaceutical composition (Details not available)	MNC
2. EMR/2/2000	Schering-Plough Corporation of USA	Formulation for protection of PEG-Interferon Alpha Conjugate	MNC
3. EMR/4/2001	Ranbaxy Laboratories Limited	Pharmaceutical composition in the form of oral controlled release tablets or capsules	Domestic
4. EMR/2/2001	United Phosphorus Limited	A synergistic composition of Carbendazim and Mancozeb	Domestic
5. EMR/3/2003	Novartis AG of Schwarzwaldallee	Crystal modification of a N pheny1-2-pheny1-2-pyrimidineamine derivative, process for its manufacture and its use	MNC
6. EMR/3/2003	Eli Lilly & Co	On Teteractadic Derivative Process	MNC
7. EMR/1/2003	Nichola Piramal India Limited	Combination of Kit for Malaria	Domestic
8. EMR/2/2003	United Phosphorus Limited	Insecticidal composition of Carbendazim and Mancozeb	Domestic
9. EMR/3/2003	Eli Lilly & Co	Tetracyclic derivative preparation and use	MNC
10.EMR/3/2004	Panacea Bio Tec. Limited	Pharmaceutical composition (Details not available)	Domestic
11. EMR/2/2004	Eli Lilly & Co	Tadalafil and its dosage forms	MNC

12. EMR/1/2004	Hoffman-La Roche Inc.	Interferon conjugates	MNC

Source: Adapted from Kankanala, Narasani and Radhakrishnan (2010), p.3

The amendment of 2002

The amendment effected in 2002 was a major step towards aligning the Patents Act of 1970 more closely with all the provisions of TRIPS. Further it incorporated safeguards for protection of public interest, national security, biodiversity, traditional knowledge, etc. Patent granting procedures were harmonised with international practices so that the system become more user friendly. Some of the important changes made are as follows:

- The definition of the term "invention" has been modified in consonance with international practices and consistent with TRIPS Agreement.

- Section 3 of the 1970 Act has been modified to include exclusions permitted by TRIPS Agreement and also subject matters like discovery of any living or non-living substances occurring in nature in the list of exclusions which in general do not constitute patentable inventions and also to specifically exclude the inventions which in effect are traditional knowledge.

- The rights of patentee have been aligned as per Article 28 of the TRIPS Agreement.

- A provision for reversal of burden of poof in case of infringement, suit on process patent, in accordance with Article 34 of the TRIPS Agreement, has been added.

- Uniform term of patent protection of 20 years for all categories of invention as per Article 33 of the TRIPS Agreement has been prescribed.

- Three flexibilities are provided for: (i) The provisions relating to *compulsory licensing* have been modified to suit the public interest requirements and also to comply with TRIPS Agreement; (ii) A provision has been incorporated for enabling *parallel import* of patented products at lowest international prices; (iii) To ensure smooth transition of a product from the monopoly status created by the patent to the public domain, a provision has been incorporated for obtaining marketing approval from the appropriate regulatory authorities before the expiration of the patent term. This *"Bolar" provision* then allows the generic producer to market and manufacture their goods as soon as the patent expires. Bolar Provisions have been upheld as conforming to the TRIPS agreement.

- The provisions relating to national security has been strengthened.

- A provision has been incorporated for hearing of appeals which at present, lie before High Court, by the Intellectual Property Appellate Board, for speedy disposal of such appeals

- A science background was made compulsory for a person seeking to be registered as a patent agent under the Act. Earlier lawers without scientic backgrounds could become patent agents.

In our view, the two most significant changes that the 2002 amendments have brought about was in lengthening the term of patent protection and in reversing the burden of proof. In terms of the former, the term has been raised to 20 years from the date of filing: the orginial Act allowed only 5 years for process patents in pharnaceuticals and that too from the date of grant (sealing) or 7 years from the date of application. For all the non pharmaceutical products and processes, the term was 14 years. In other words, TRIPS has increased, considerably, the monopoly protection for a new invention. In the case of pharmaceuticals this can mean very high prices being charged. Reversal of the burden of proof being the responsibility of patent infringers do impose considerable costs on those infringers of the small and medium category given the high costs of patent litigation.

The amendment of 2005

The last step in India's implementation of the changes required to make its patent law TRIPS compliant happened by way of the 2005 amendment. By this amendment Indian law for the first time since 1970, allowed product and process patent protection to substances capable of being used as pharmaceutical, food and agro-chemicals. The 2005 amendment was preceded by a presidential ordinance in 2004.[3] After its promulgation there were intense debates about the scope of various provisions and finally the Indian Parliament enacted the 2005 amendment after making certain changes in the ordinance.

The 2005 amendments contain many controversial features which have led to many disputes post 2005. They cover elaborate provisions mentioning what is and is not considered patentable subject matter, a new definition of the "inventive step" criterion of patentability, procedures governing both pre- and post-grant opposition, and a more liberal framework for compulsory licensing. Since most of the disputes that have arisen after 2005 involve interpreting various provisions of the said amendment it will be covered in detail in the section dealing with patent litigation.

These amendments have virtually closed the option of reverse engineering that largely contributed to the growth of the Indian pharmaceutical industry. It will now not be possible to produce the patented product by adopting a different process. Some safeguard measures and flexibilities contained in the TRIPS Agreement were introduced in the patent system to protect public health, such as the provision for compulsory licensing to support access to

[3] Patents (Amendment) Ordinance, 2004, full text available at http://lawmin.nic.in/Patents%20Amendment%20Ordinance%202004.pdf (last visited on July 22, 2012))

sources of generic medicines, restricting pharmaceutical patents to new chemical and medical entities, and the introduction of pre-grant opposition to patent applications.

In sum, TRIPS compliance means the following:

- Introduction of product patents in Chemicals, pharmaceuticals, agrochemicals and food products
- Harmonisation of patent term to 20 years irrespective of the field of technology.
- Publication of the patent application 18 months after filing.
- Further definition of non-patentable inventions.
- Definition of requirements for biological materials.
- Faster prosecution of patent application and transparency in the whole process.
- Reversal of the burden of proof of process when there is an infringement of process patents. As per the TRIPS requirement the alleged infringer will have to prove that he is not infringing the process patenent.
- Effective framework for enforcement.
- Conditions for ‘‘working of patents’’, ‘‘compulsory licensing’’, ‘‘opposition’’ and ‘‘revocation’’.
- Introduction of *Bolar provisions* This exemption allows generic manufacturers to prepare generic drugs in advance of the patent expirationm without any time restrictions.

India provides an example of the flexibilities under TRIPS which can effectively be used by the developing countries. Instead of rejecting TRIPS, India has engaged in creative acts of legal interpretation that take full advantage of known TRIPS flexibilities, and have also generated new grounds. As our brief survey has shown, India's new patents regime is at an evolutionary stage and the jury is still out on the issue whether India will be in a position to successfully exploit the TRIPS flexibilities. Undoubtedly India got a good beginning with its patent amendments, however it needs to be seen whether this can be converted into a successful model where the interests of all stakeholders can be safeguarded.

However of the three flexibilities priovided under TRIPS, hitherto the country has invoked only one of them dealing with compulsory licensing for the manufacturing of an anti cancer drug by an Indian pharmaceutical manufacturer (See Box 1 for details). The domestic generic manufacturer was able to make a generic version of a oatented anticancer drug at 3 per cent of the cost of the original drug. This decision of using TRIPS flexibility is likely send an

important signal that despite the rigidities under TRIPS, it is still possible to have beneficial rulings in favour of domestic manufacturers.

Box 1 : Compulsory Licensing: Case of Bayer vs Natco Pharma

Department of Industrial Policy and Promotion (Government of India) has informed that so far one Compulsory license has been granted by the Controller General of Patents, Designs and Trade Marks to a drug manufacturing company since the amendment of the Patents Act in 2005 for an application filed under Section 84 of the Patents Act (as amended in 2005). The details are given as under;

- The Compulsory license has been granted by the Controller General of Patents, Designs and Trade Marks for the anti-cancer drug in which the compound is `Sorafenib Tosylate` (Patent No. 215758). The patent was granted to M/s Bayer Corporation, USA on 03.03.2008 by Indian Patent Office, consequent to their filing a national phase application in India.

- Bayer Corporation, USA developed the drug under trade name `NEXAVAR` and received regulatory approval for importing and marketing the drug in India and launched it in India in the year 2008.

- The Compulsory license for the drug has been granted to Natco Pharma Ltd., Hyderabad, Andhra Pradesh.

- As per the orders of the Controller of Patents, Mumbai compulsory license has been granted to Natco for manufacture of `NEXAVAR`. Natco Pharma Ltd, are required to sell this drug at a price not exceeding Rs. 8880/- for a pack of 120 tablets, required for a month`s treatment which was earlier being sold by M/s Bayer Corporation at Rs. 2,80,428/- for one month treatment.

- The patent office stipulated that Natco pay 6% of net sales as royalty to Bayer.

Source: Lok Sabha Unstarred Question No: 6851 answered on 17/05/2012 , http://164.100.47.132/LssNew/psearch/QResult15.aspx?qref=124620 (last accessed on July 24, 2012)

II. Macro implications of TRIPS compliance

The entire process of TRIPS compliance of India's patent regime spread over a period of over ten years or so have had many potential and actual effects on innovative activity in the country. It must, however, be stated at the beginning that it is not at all easy to separate out the TRIPS effects from the effects of economic liberalization in general which was also happening during exactly the same period. In fact one may argue that TRIPS compliance itself was part of the larger liberalization efforts that had gripped world's economy. Given the inexorable link between the two, one has to be cautious in attributing some of the changes that we observe merely to TRIPS compliance.

Proximate and distant implications of TRIPS compliance

Notwithstanding this caveat, the larger atmospheric changes brought about by TRIPS compliance may broadly be divided into proximate and distant changes. Under the former, we may add the following: (i)increased emphasis placed on the need for importance of patenting by various national and sub national authorities (defining work done in government research institutes in terms of number of patents granted, setting up of patent facilitation centres, becoming a contracting party in the UN Patent Cooperation Treaty etc are tangible manifestations of this); (ii) as a corollary of this, attempts made by those national IPR regimes that did not hitherto recognise 'utility models" to have it included as a way of recognising incremental innovations in especially SMEs; (iii) more research on neglected tropical diseases; (iv) more clarity on patenting of medicinal plants and traditional knowledge; (v) reforms of national patent offices etc and facilitating patents by domestic inventors; (vi) relationship between TRIPS compliance and licensing of disembodies technologies. This is beccause it was generally argued that a tighter IPR regime will encourage MNCs to transfer technologies to local firms in an easy manner as technologiy suppliers need not any longer worry too much on the possibility of licencees trying to learn the technology and developing local capabilities through reverse engineering.

Under distant changes we may list all those changes to instruments and institutions that support local development of technology (introduction or elaboration of tax incentives of various types, introduction of research grants, establishment of new technology funding institutions etc, schemes for improving the quality and quantity of science and engineering workforce). The very first initiative of the government was to come out with an explicit policy on innovation, the Science and Technology Poicy, 2003[4]. Incidently it was the first time that in twenty years that a new policy on onnovation was stated and above all it was the very first that a policy on science and technology had some explicit references to the term 'innovation". It had also some specific pronouncements on strengthening the IPR regime. This will be seen in more detail when we discuss the proximate changes. Further these measures include successive increase in plan allocations for scientific departments, setting up

[4] See Department of Science and Technology, Government of India, http://www.dst.gov.in/stsysindia/stp2003.htm (last accessed on July 24, 2012)

of new institutions for science education and research, creation of centres of excellence and facilities in emerging and frontline areas in academic and national institutes, induction of new and attractive fellowships, strengthening infrastructure for Research and Development (R&D), encouraging public-private R&D partnerships etc. Launching of programmes like *Innovation in Science Pursuit for Inspired Research* (INSPIRE), Nano Mission, Mega Facilities, Open Source Drug Discovery, Network Projects, National Biotechnology Development Strategy etc. The Government has established a Science and Engineering Research Board (SERB) in the country as an autonomous body through an Act of Parliament. The creation of SERB, apart from significantly enhancing the level of basic research funding, shall also impart the necessary autonomy, flexibility and speed in shaping the research programmes and delivery of funds to researchers. For experimenting and opening new areas of research and entering into novel territories, programmes such as Encouraging and Motivating Pursuit of World Class Exploratory Research (EMPOWER), Research Initiative to Scale New Knowledge (RISK) and CSIR.WWW have been launched. The outlay proposed for the 12th Plan for Science and Technology is Rs. 1700 billion. Apart from expanding the scope of investigator centric extra mural research support programmes in terms of quantity and quality, multifaceted programmes like Start-up Research grant for Indian Diaspora undertaking faculty assignments in Indian academia, overseas doctoral scholarships and post-doctoral fellowships, Building Educators for Science Teaching, PAN India Mission, Public Private Partnerships for R&D, Disha Programme for Women in Science, Platforms for Technology Solution, Challenge Award for Global Positioning etc. are proposed for the 12th five year plan to take R&D to higher levels. To this one may also add a number of new institutions such as the National Knowledge Commission and its successor the National Innovation Council. Further a number of technology policies have been announced in areas such as telecommunications, information technology, automotive, semiconductor, electronics. The policies have several instruments to promote innovations in these specific areas.

Proximate Changes

As argued earlier, it is not easy to attribute the distant changes to TRIPS compliance per se as some of these changes have been precipitated by lberalization policies. On the contrary the proximate changes are more the result of TRIPS compliance and we begin piecing together the proximate changes. According to us there are six of these changes that merit our attention. They are:

(i) **Increased emphasis on patenting:** Till TRIPS compliance of the IPR regime, Indian scientists and inventors whether based in industry, academia or research institutes barely patented their inventions. But with so much discussion on the need for and importance of taking ownership of intellectual property rights on new inventions, one could see a see change in the attutude towards patenting inventions. A clearer articulation of this new emphasis on patenting could be seen in the then new Science and Technology Policy, 2003 (See Box 2). Three indicators of this increased propensity to patenting are considered: (a)

increase in the number of patents secured by Indians in the India Patent Office[5] and at the US PTO (Figures 1 and 2); (b) emergence of the CSIR, the government research institute as a major patenter of its inventions. CSIR accounts for a large proprtion of domestic patents; and (c) participation of India as a contracting party in Patent Cooperation Treaty (PCT).

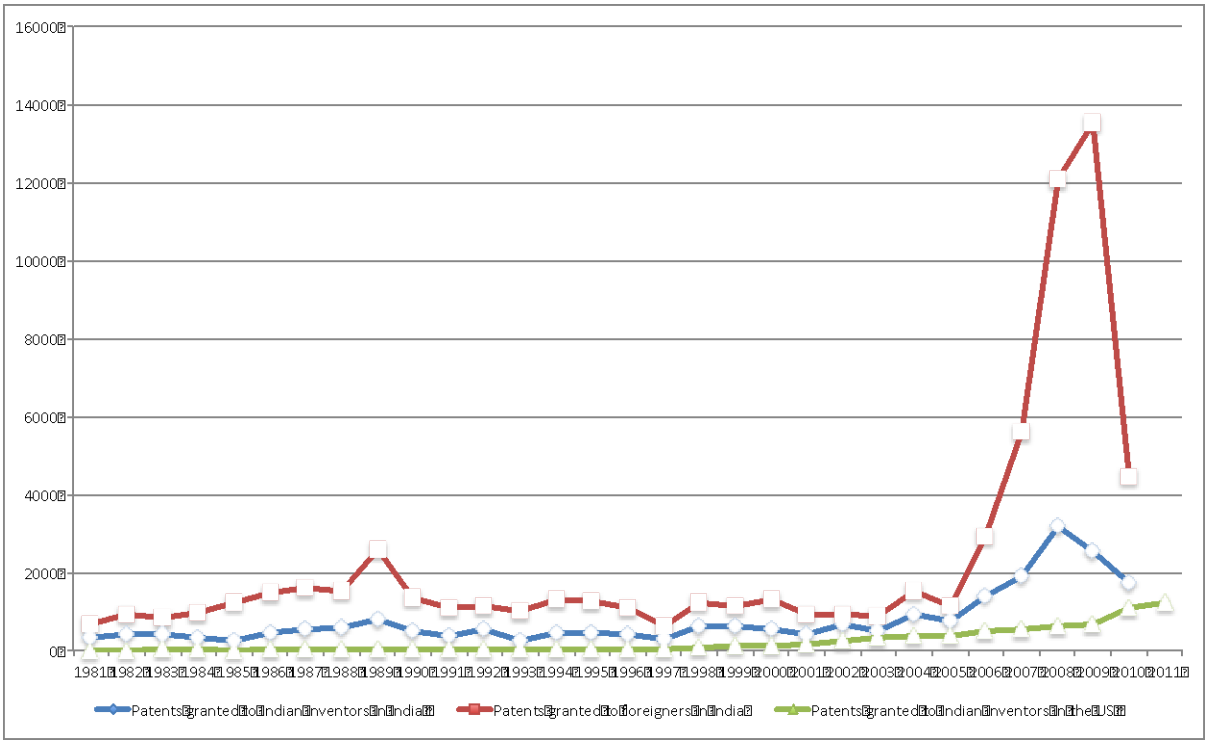

Figure 1: Trends in the number of patents granted to Indian and Foreign Inventors by the India Patent Office and by the USPTO

Source: Office Controller General of Patents, Designs and Trade Marks and Geographical Indications (Various issues)

Traditionally most of the patents granted by the India Patent Office have been secured by MNCs. This continue to be so although one can see that there has been a disntict upturn in patenting by both Indian and foreign inventors since 2005 or so. Figure 1 also shows that the number of US patents granted to Indian inventors and that too is showing an increasing trend especially after TRIPS compliance. But Mani (2010) had shown that over two-thirds of the US patents are secured by foreign firms located in India. This implies that with the tightening up of the patent regime in India has led to a number of MNCs locating at least a portion of their R&D activities to India. In otherwords, the period of TRIPS compliance is also accompanied by an increase in R&D outsourcing to India[6].

[5] The official name of the India Patent Office is Controller General of Patents Designs and Trademarks.

[6] See Basant and Mani (2012) for the details.

Another issue to be examined is the technology-wide distribution of patenting. We did an exercise with the data on patenting in India by both Indian and foreign inventors[7]. See Figure 2. The results shows us an interesting result namely that the share of pharmaceuticals in total patents granted after a reaching its zenith in 2003 has started declining and cuurently accounts for just about 9 per cent of the total number of patents granted. This shows that although TRIPS compliance has led to an increase in the number of patents intially, the growth was not sustained. Both the number of patents granted for pharmaceuticals and food items have been showing considerable year to year variations (Figure 2). It is interesting to note that the number patents granted in bpth have spiked since TRIPS compliance in 2005, but has since decline in 2010 for pharmaceuticals and since 2008 in the case of food.

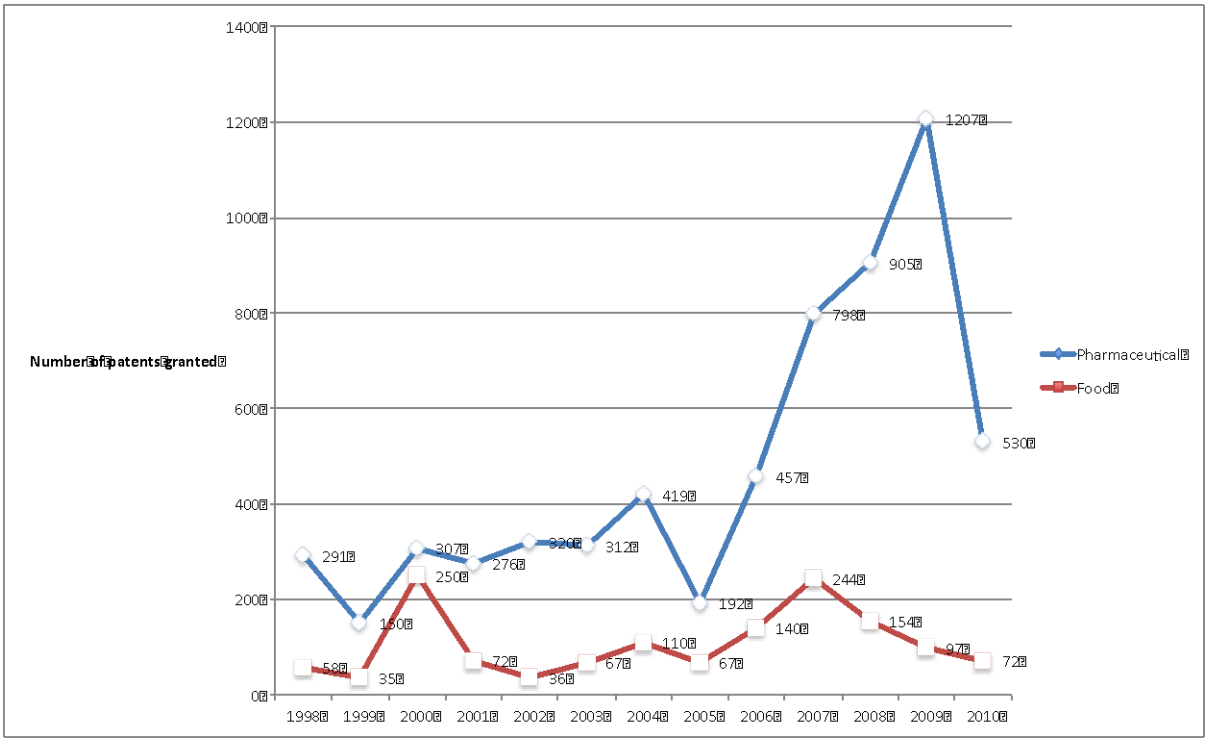

Figure 2: Trends in the number of patent grants for pharmaceuticals and food at the India Patent Office

Source: Office Controller General of Patents, Designs and Trade Marks and Geographical Indications (Various issues)

The India Patent Office does not provide us with a break up of industry-wide patents applied for and ganted. So we are unable to find out the break up between Indian and foreign patentees in this case although given the overall distribution between foreigners and domestic patentees, it is highly probable that even in the case of pharmaceuticals most of the patentees are foreign companies. One thing that is clear is that TRIPS compliance has led to a sort of

[7] If one repeats this with the USPTO data on patent grants one gets exactly the same type of results.

surge in patenting in India, although most of the patentees are foreign companies rather than Indian ones.

For a brief period in 2004-2005, software patents were allowed in India for embedded software. According to press reports[8] about 150 patents on technical effects of software was granted by the Indian patent Office in areas such as video imaging systems in mobile handsets, data transmission systems as well as methods for controlling speeds of devices. However software patents are allowed by the USPTO. Given India's expertise in software, a number of MNCs have established software development centres in India and these have been, increasingly securing a number of patents granted at the USPTO. See Figure 3. What is important is software patents now account for about a quarter of all patents granted to Indian inventors at the USPTO. Of late, Indian IT companies too have been securing software patents at the USPTO: their share has increased from just about 2 per cent of software patents from India to about 5 per cent in 2011. Indian IT companies have been a bit slow in patenting their inventions, but with growing awareness of patenting they too have following the pharma firms in taking IPRs over their new inventions.

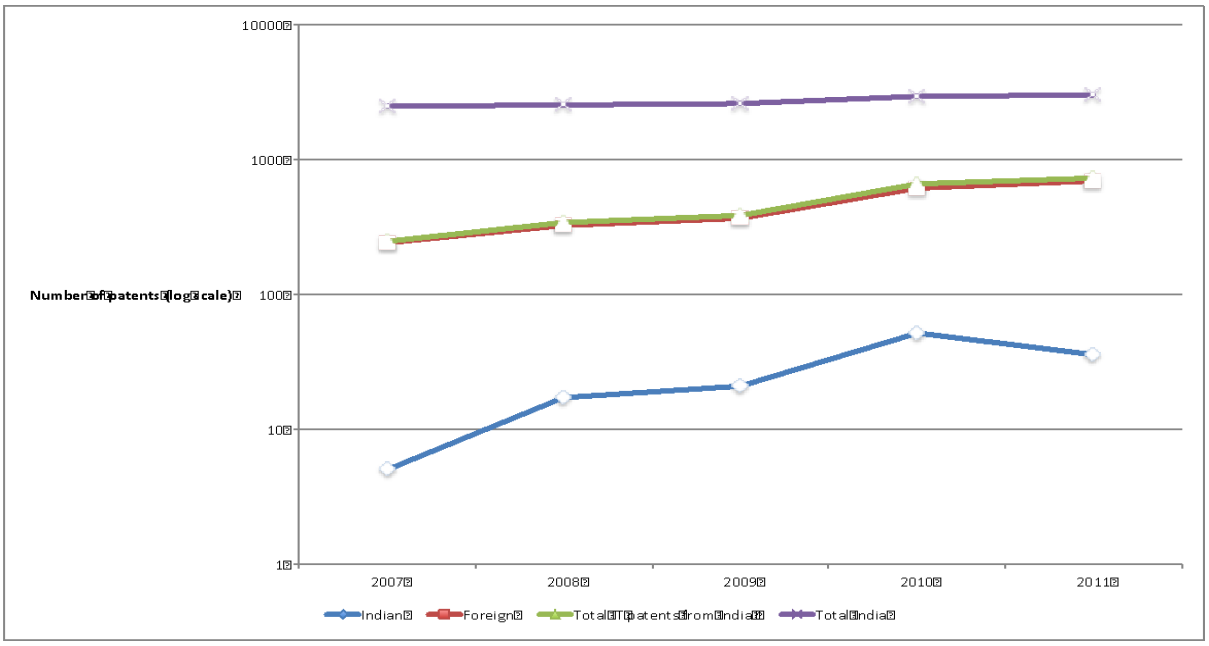

Figure 3: Trends in IT patenting from India at USPTO, 2007-2011

Source: Computed from USPTO.

Another interesting finding is that the number of Indian inventors patenting at USPTO has significantly in a number of high technology areas such as those in telecommunications ,medical devices and in semi conductor devices- two fast growing industries in India. See Figure 4.

[8] See the article, 'Software patents under ordinance face reversal', *Financial Express*, March 29, 2005, http://www.financialexpress.com/news/software-patents-under-ordinance-face-reversal/82155/ (last accessed on July 28, 2012).

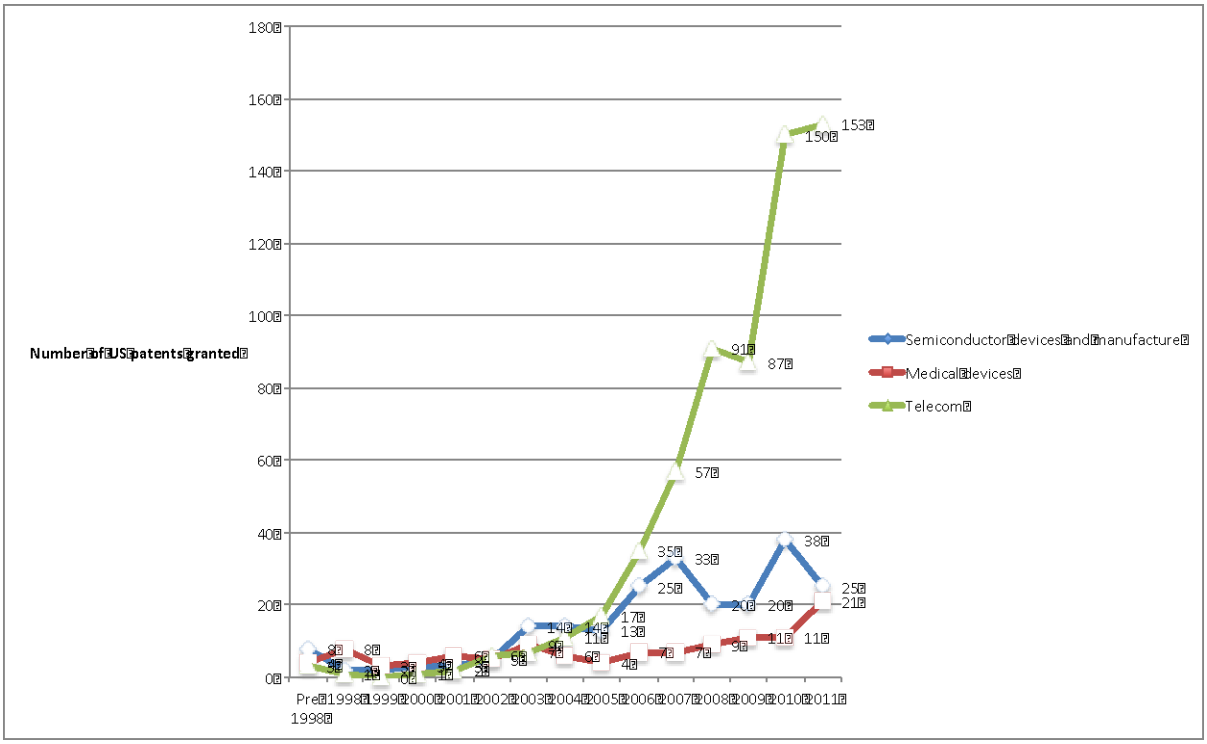

Figure 4: Trends in the number of patents granted in three high technology industries: Post TRIPS

Source: Computed from USPTO

The most prolific Indian inventor is of course the Council for Scientific and Industrial Research (CSIR)[9], an important civilian scientific research establishment in the country. The CSIR in 1996 had announced reform strategy[10] where in it targeted to hold a patent bank comprising of 50 Indian and 1000 foreign patents by 2001 as against 80 Indian and 436 foreign patents in its portfoio in 1996. So it actively encouraged its scientists to file patents, both in India and abroad (Figure 5).

[9] CSIR is a network of 37 laboratories spread throughout the country and focusing on a range of technologies from aerospace, biotechnology, chemicals, drugs& pharmaceuticals, energy, food & food processing, information dissemination, leather, metal, minerals, manufacturing etc.

[10] See the CSIR (1996), *CSIR 2000: Vision and Strategy*. In this document, it states: "The maximization of the benefits to CSIR from its intellectual property by stimulating higher levels of innovation through a judicious system of rewards, ensuring timely and effective legal protection for its IP and leveraging and forging strategies alliances for enhancing the value of its IP."

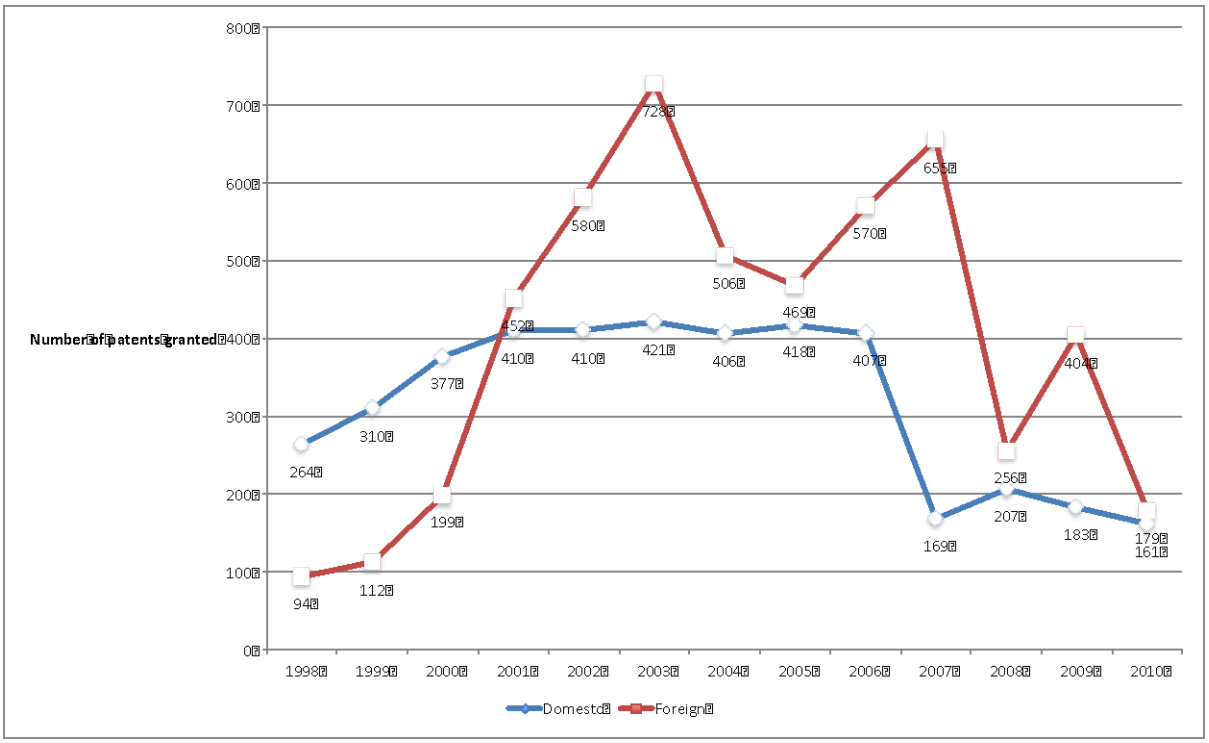

Figure 5: Trends in foreign and domestic patent applications by CSIR, 1998-2010

Source: Council of Scientific and Industrial Research (various issues)

As against this target, the CSIR, by March 31, 2010, has in its portfolio 2349 Indian patents and 3054 patents abroad[11]. This increased patenting has certainly improved its stature in the scientific landscape. It has now published a new vision document[12] which extends to the year 2022 and this has IP generation as an important measurement of work done. But there is very little information on whether these patents are yielding any royalties to the research network[13], although it apparently spent till todate a sum of Rs 742 million on securing these patents of which only a sum of Rs 18 million or so was spent in securing patents from the

[11] See CSIR, Annual Report 2009-10, http://www.csir.res.in/External/Utilities/Frames/aboutcsir/main_page.asp?a=topframe.htm&b=leftcon.htm&c=../../../Heads/aboutcsir/about_us.htm (last accessed on July 29, 2012)

[12] The document titled *CSIR@80: Vision and Strategy* could be found at, http://rdpp.csir.res.in/csir_acsir/PDF/CSIR80-final.pdf (last accessed on July 29, 2012)

[13] Although very important, data on royalties received through licensing of its patent portfolio is apparently not compiled and available centrally at the CSIR headquarters. Mr T Prashant Reddy has revealed this to us through an RTI inquiry by him. For details of this communication, see https://docs.google.com/file/d/0Bxi2TzVXul5ZVDQ5YzFYZzYtNTA/edit?pli=1(last accessed on July 29, 2012)

IPO[14]. The remaining Rs 724 million was spent on securing patents around the world including jurisdictions like the U.S., Japan and the E.U.

In order to encourage the generation of innovations in universities and government research institutes, the government has tabled the Protection and Utilisation of Public Funded Intellectual Property (PUPFIP) Bill, 2008 before the upper house of India's parliament, the Rajya Sabha[15]. The bill stresses the creation of intellectual property rights (IPR) as a form of accountability — inspired by the American Bayh-Dole Act of 1980. The Parliamentary Standing Committee[16] found that the PUPFIP bill is likely to take away creativity from universities and research institutions, and instead promote crass competition. This is also echoed in other writings on the bill that say it erroneously assumes that protection of intellectual property is the best and only way to promote creativity and innovation (Basheer, 2008, Kochupillai, 2010, Centre for Internet and Society[17]). However the bill itself is yet to be passed by the parliament and has therefore not come into being as a law.

An important development that merit mention here is that India became a contracting party to the Pate Cooperation Treaty (PCT) in 1999. This enabled Indian inventors to file applications in over 150 jurisdictions with one PCT application. Consequently the number of PCT applications has shown a steady increase (Mani, 2010) thereby allowing Indian inventors the chance of their inventions being protected in a larger number of jurisdictions.

The Patent Facilitating Centre (set up in 1995) at the Technology Information Forecasting and Assessment Council (TIFAC) also has been having various schemes of support (technical, legal, and financial) for enabling patenting of innovations emanating from research funded by Department of Science and Technology, any of the Indian universities or government research institutes. It will also aid private and public sector enterprises for a nominal fee. Further it has set up state-level Patent Information Centres across 17 states in the country. Together these centres have been attempting to raise the awareness on patenting among inventors and potential inventors. However to date there have not been any comprehensive evaluation of the activities of the PFC and therefore we are unable to draw any inferences about its efficacy in creating and sustaining a patent culture.

The private sector industry too have been emphasising the need for patenting new inventions. In order to sensitise its members, the major industry association in the country, the Confederation of Indian Industry (CII) in association with George Washington University Law School and US India

[14] This data on costs incurred for securing patents was obtained by Mr Prashant Reddy through a Right to Information application. For details see blog SPICY IP http://spicyipindia.blogspot.in/2012/03/csir-spends-whopping-rs-7424-crores-on.html (last accessed on July 27, 2012).

[15] See http://164.100.24.167/newcommittee/press_release/Bill/Committee%20on%20S%20and%20T,%20Env.%20and%20Forests/protection_utlisation.pdf (last accessed on July 29, 2012)

[16] See the report of the standing committee at: http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20S%20and%20T,%20Env.%20and%20Forests/211%20IPR%20Bill.pdf (last accessed on July 30, 2012)

[17] This could be found here, http://cis-india.org/a2k/publications/pupfip/why-no-pupfip/ (last accessed on July 29, 2012).

Business Council have been organizing a series of summits on intellectual property annually since 2004. According to CII, the objective of the summit was, inter-alia, to build partnerships between overseas and Indian industries for collaborative Research and Development (R&D) projects and to disseminate information about international best practices in Intellectual Property (IP) protection.

Box 2: References to generation and management of Intellectual Property as contained in Science and Technology Policy, 2003

- Intellectual Property Rights (IPR), have to be viewed, not as a self-contained and distinct domain, but rather as an effective policy instrument that would be relevant to wide ranging socio-economic, technological and political concepts. The generation and fullest protection of competitive intellectual property from Indian R&D programmes will be encouraged and promoted.
- The process of globalisation is leading to situations where the collective knowledge of societies normally used for common good is converted to proprietary knowledge for commercial profit of a few. Action will be taken to protect our indigenous knowledge systems, primarily through national policies, supplemented by supportive international action. For this purpose, IPR systems, which specially protect scientific discoveries and technological innovations arising out of such traditional knowledge, will be designed and effectively implemented.
- Our legislation with regard to Patents, Copyrights and other forms of Intellectual Property will ensure that maximum incentives are provided for individual inventors, and to our scientific and technological community, to undertake large scale and rapid commercialization, at home and abroad.
- The development of skills and competence to manage IPR and leveraging its influence will be given a major thrust. This is an area calling for significant technological insights and legal expertise and will be handled differently from the present, and with high priority.

Source: Department of Science and Technology (2003), http://www.dst.gov.in/stsysindia/stp2003.htm#c7 (last accessed on July 24, 2012).

Thus our detailed survey has shown that one of the more proximate implication of TRIPS has been to create a great awareness of the need for importance of patenting their new inventions aong researchers of various hues. But foreign companies operating from India seem to have better taken advatage of this emphasis rather than Indian inventors and have vastly improved their patent portfolios especially in the field of IT.

(ii) **Patenting of incremental innovations especially by small and medium enterprises**

India's patent lawas does not provide for utility models. Utlity models are are ideal IPRs for incremental innovations. India's industrial structure is charecterised by a large number of small and medium firms. These firms do not make new inventions but incremental changes in known products and processes for which an utility model is the most appropriate form of IPR. TRIPS does not specifically mention utility models. However Part I of this Agreement

(Article 2,3 and 4) refers to the provisions of Paris Convention. Further, Article 1 mentions "Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement."Given this, policy makers in India are favourably disposed to including utility models in India's IPR regime. Towards this end, the Department of Industrial Policy and Performance (DIPP) has floated a discussion paper on utility models[18]. Several reactions from a varirty of stakeholders to the inclusion of utility odels has been received[19].

(iii) **More research on Neglected Tropical Diseases**

India is home to a number of Neglected Tropical Diseases (NTD), the incidence of which has been growing (Table 2). It is often the very poor whom these diseases afflict. Given that the market for the drugs for these diseases is small even the domestic companies were not interested in R&D to find out new drugs for its recent treatment. TRIPS compliance with product and process patent protection was expected to improve the investment climate for R&D in these NTD. A recently released report (Thomson Reuters, 2012) measured NTD coverage in scientific publications across the world between 1992 and 2011, using data from *Web of Science*, an online database that covers 11,500 journals worldwide. During the time period (1992-2011) analysed, more than 73,000 papers on NTDs were published. Most of these focused on a single disease, and articles covered diverse aspects of NTDs, ranging from the biology of disease vectors to healthcare solutions. The number of papers doubled from around 2,500 in 1992 to more than 5,000 in 2011, the report states. As a share of world research output, the papers on these diseases accounted for around 0.4 per cent of total global articles and reviews for much of the period, but that share began to rise in 2005, around the time that the general term for this disease group also started to come into use. Most papers included at least one author from developed countries, but the presence of authors from Brazil and India is particularly noteworthy. In 2011, more papers on NTD had an author or co-author from Brazil than from the United Kingdom, and India's participation is higher than Germany's, for example.

In terms of R&D investments too the public resources devoted to research on NTD in India though rising is still only a paltry sum compared to what is invested in pharamaceutical R&D in general by both domestic and foreign enterprises (Figures 6 and 7). According to G-Finder[20], the government (through either the Indian Council of Medical Research or the Department of Biotechnology) funded $ 57 million worth of R&D projects in 5 NTDs during the period 2008 through 2010.All these R&D projects were performed by either the government research institutes or the universities and not a single project was funded with any of the numerous pharmaceutical enterprises either in the public or private sectors.

[18] The discussion paper could be found at: http://dipp.nic.in/english/Discuss_paper/Utility_Models_13May2011.pdf (last accessed on July 29, 2012)

[19] These reactions could be seen at, http://dipp.nic.in/English/Discuss_paper/FeedBack_UtilityModels.htm (last accessed on July 30, 2012)

[20] http://g-finder.policycures.org/gfinder_report/search.jsp (last accessed on August 13, 2012)

Domestic pharmaceutical firms are continuing to concentrate their research on products for the export market and are therefore not spending much on the R&D for NTD. This will be discussed in detail in the section on R&D strategies.

Table 2: Incidence of Neglected Tropical Diseases in India (Number of Cases)

	Dengue	Rabies	Leprosy	Kala-Azhar	Active trachoma	Trichiasis	Lymphatic Filarisis
2008	12581	259		33598			1130016
2009	15535	263	134184	24212			1179051
2010	28292	162	133717	28941			1210108
2011	10344		126800		15289	3436	

Source: Compiled from Lok Sabha, Annexure referred to in reply to unstarred question no: 813, http://164.100.47.132/Annexure/Isq15/9/au813.htm (last accessed on July 30, 2012)

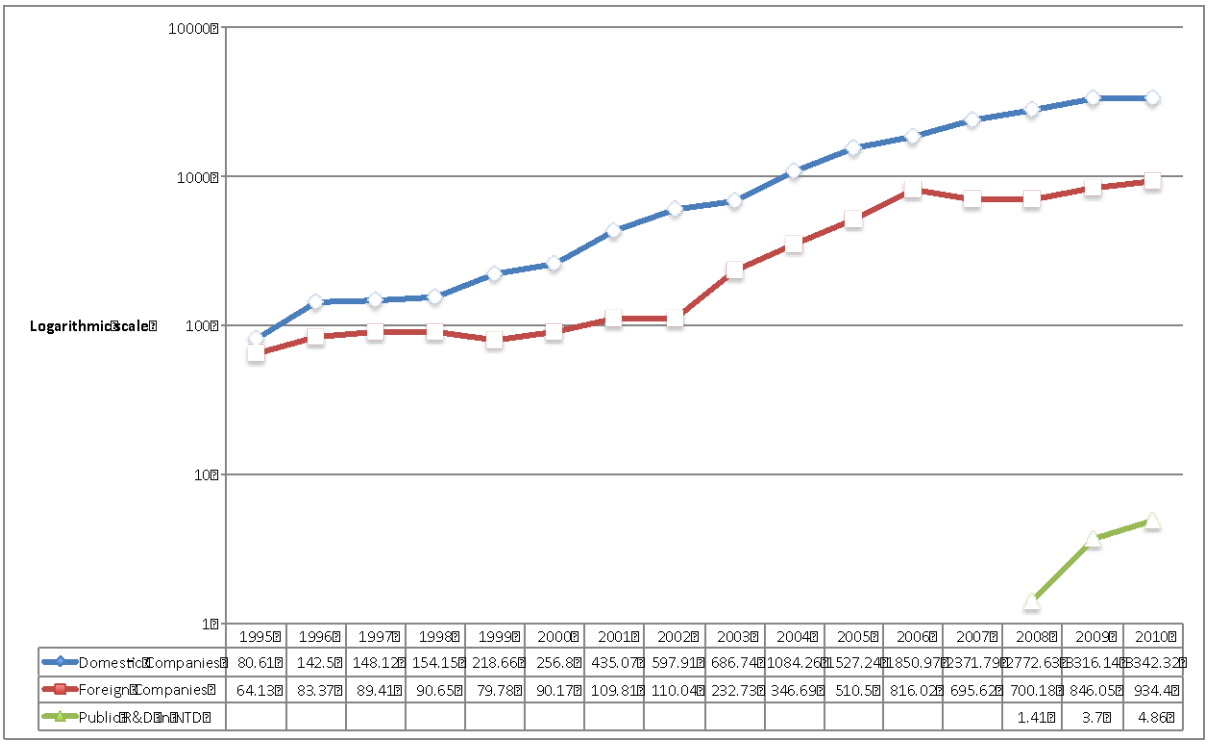

Figure 6: Public R&D investments in NTD compared to R&D investments by domestic and foreign pharmaceutical firms

Sources: Department of Pharmaceuticals (2012); Lok Sabha Unstarred Question No: 815

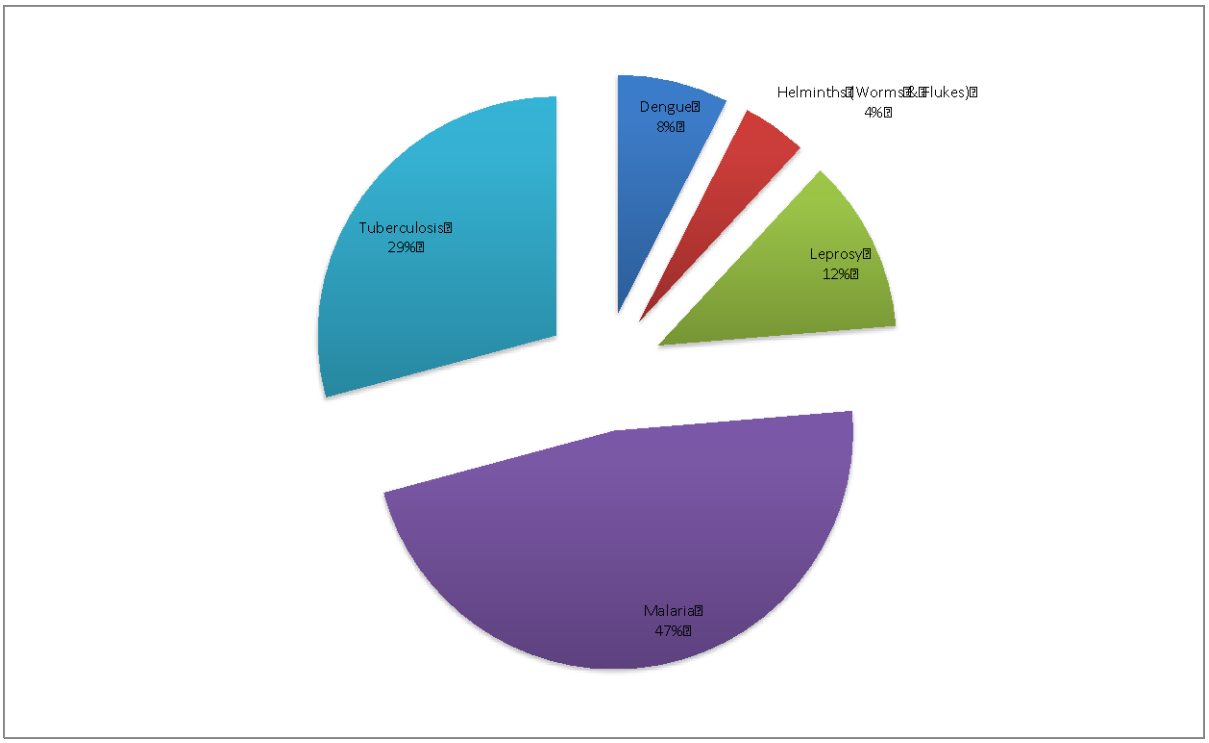

Figure 7: Disease-wide distribution of public R&D on Neglected Tropical Diseases, 2008-2010

Source: Computed from data provided in G-Finder (Global Funding of Innovation for Neglected Tropical Diseases), http://g-finder.policycures.org/gfinder_report/search.jsp (last accessed on August 13, 2012)

(iv) **Clarity in patenting of traditional knowledge, medicinal plants and microorganisms**

India is the only country in the world to have set up in 2001 an institutional mechanism - the Traditional Knowledge Library (TKDKL)[21]- to protect its Traditional Knowledge (TK). The TKDL enables prompt and almost cost-free cancellation or withdrawal of patent applications

[21] The CSIR and the Department of Indian Systems of Medicine (AYUSH) maintain the TDKL. The idea to establish a TKDL came to the fore amid India's efforts to revoke the patent granted by the United States Patent and Trademark Office (USPTO) on the wound healing properties of turmeric, and the patent granted by the European Patent Office (EPO) on the antifungal properties of neem. These endeavors, while successful, proved extremely costly and time-consuming. For a patent to be granted, an applicant must satisfy certain criteria as defined by national patent law, in particular, an applicant must prove that a claimed invention is novel and not previously known. Why then had patents been granted for so many applications relating to Indian medicinal systems? When patent examiners assessed these applications for patentability, the claimed inventions did not feature in the prior art searches carried out. They were, therefore, deemed patentable. At that time, however, much of India's traditional medicinal knowledge only existed in Sanskrit, Hindi, Arabic, Urdu and Tamil. These languages were neither accessible to nor understood by patent examiners working in the major patent offices to which the applications had been submitted.

relating to India's TK. The TKDL is a unique, proprietary database that integrates diverse knowledge systems and languages. It is based on 148 books of prior art relating to Indian systems of medicine. The TKDL connects patent examiners around the world with these books of knowledge and it is available to all patent offices that have signed a TKDL Access Agreement which has built-in, non-disclosure mechanisms to safeguard India's interests and counter any possible misuse. Under such an agreement, patent examiners may use the TKDL for search and examination purposes only and its contents may only be revealed to third parties for the purposes of citation. So far, India has signed TKDL Access Agreements with the EPO and the patent offices of Australia, Canada, Germany, the United Kingdom and the United States. Negotiations are also ongoing with the patent offices of New Zealand and Japan where agreement in principle has already been reached.

Around the time the TKDL was established, the TKDL expert group estimated that, annually, some 2,000 patents relating to Indian medicinal systems were being erroneously granted by patent offices around the world. Hitherto the TKDL has enabled the cancellation or withdrawal of a large number of patent applications attempting to claim rights over the use of various medicinal plants. It is generally opined that India's TKDL is a unique tool that plays a critical role in protecting the country's traditional knowledge.

The establishment of the TKDL has helped India to resolve patents that were issued abroad for technologies that were based on traditional knowledge. The case of patent for a method of treatment or management of stress is a good illustration of this. See Box 3.

Box 3: Patent for *Ashwagandha* extract

Natreon Inc., a US pharmaceutical company specialising in developing novel compounds extracted from the traditional botanicals of Ayurvedic medicine, had filed a patent application titled 'Method of Treatment or Management of Stress' on July 27, 2006 through a composition comprising Withania somnifera plant extract; and a pharmaceutically, veterinary or nutritionally acceptable carrier(s) before the European Patent Office (EPO). The TDKL has submitted evidences to EPO along with references of various texts of the three Indian system of medicine, namely Ayurveda, Siddha and Unani. These evidences established that *Ashwagandha* (Withania somnifera) is frequently and effectively used through oral administration in the treatment of depression, insomnia, gastritis, gastric ulcer and convulsions which are defined as the causative factors of stress in the patent application. TKDL evidences also mention the use of *Ashwagandha* in the treatment of palpitation, excessive perspiration, diabetes mellitus and anemia which have been stated as conditions resulting from stress by the applicant. After examination of the evidence presented before it, the EPO has observed that, in the light of this document, the subject-matter of claims cannot be considered as novel. Accordingly, the applicant Natreon Inc withdrew its application on March 25, 2010.

Source: Lok Sabha Unstarred Question no: 6818 http://164.100.47.132/LssNew/psearch/QResult15.aspx?qref=87568 (last accessed on July 31, 2012

Medicinal plants as well as the products derived from these which is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components are not patentable under Section 3(j) and Section 3(p) of the Patents Act, 1970 respectively. However, substantial improvement in products derived from medicinal plants, which fulfils the criteria prescribed for patentability in the Patent Act, 1970, can be granted patents. So far, 18 such patents have been granted to foreign companies. Of these, five are derived from medicinal plants which are indigenous to India. See Table 3 for details of patents granted for medicinal plants. As far as ayurvedic medicines are concerned since 1995, the Indian Patent Office has granted 4 such patents to foreign companies, while Indian companies and institutions have secured 117 patents[22].

The Biodiversity Act, 2002 takes into account the impact of awarding an intellectual property to a product derived from medicinal plants, on the conservation of the medicinal plant. This process is carried out in consultation with state level biodiversity authorities. Section 6 (i) of the *Biological Diversity Act* states that "No person shall apply for any intellectual property right by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application". However, this provision is subject to Section 40 of the Biodiversity Act, 2002, which states that the Central Government may, in consultation with the National Biodiversity Authority, by notification in the Official Gazette, declare that the provisions of this Act shall not apply to any items, including biological resources normally traded as commodities. Ministry of Environment and Forests vide their Notification dated 26th October 2009, has declared that the provisions of the Act would not apply to 190 biological resources which are normally traded as commodities.

Table 3: Number of patents granted to medical plants by the IPO: Post TRIPS

	Patent No	Title	Patentee	Nationality	Indian Medical plant
1	248562	An antioxidant-promoting composition	Lifeline Nutraceuticals Corporation	U.S.A	This medical composition contains plant extract of turmeric plant, which is of Indian origin
2	231692	Compositions for preventing or treating pollenosis, allergic nephritis, atopic dermatitis, asthma or urticaria	Matsuura Yankugyo Co., Ltd	Japan	The first plant used in this composition is Cucurbita moschata is basically originating from either Central America or northern South America, but is also widely cultivated in India. The second plant used in the composition is Carthamus tinctorius, which is grown/cultivated in India.

[22] During the period 79 applications were received from foreign companies. See Lok Sabha starred question, http://164.100.47.132/LssNew/psearch/QResult15.aspx?qref=115211(last accessed on August 14, 2012)

3	213308	Nutritional supplement	The Quigley Corporation	U.S.A	This composition contains extract of turmeric plant, which if of Indian origins.
4	190850	Process for the preparation of herbal pharmaceutical composition for the management of menopausal syndrome	United Global Ventures Limited	Hong Kong (China)	The medical plant used in this composition is Tinospora cordifolia, which is known by the common name Guduchi, is an herbaceous vine of the family Menispermaceae indigenous to the tropical areas of India.
5	243564	Process for the preparation of a herbal composition for the treatment of viral infections	Sage R&D	U.S.A	Composition derived from Chinese herbal medicines. Aeginetia indica is the active ingredient found in India too.
6	211690	Process for preparation of a composition for both human and veterinary application	Ropapharm B.V.	Netherlands	The first plant material used in the claimed composition is Origanum vulgare, which is a common species of Origanum, a genus of the mint family (Lamiaceae). It is native to warm-temperate western and southwestern Eurasia and the Mediterranean region.
7	242831	An anti-microbial composition	The Quigley Corporation	U.S.A	The first ingredient used in this composition is ginger powder extract, which consumed as a delicacy, medicine, or spice. Ginger cultivation began in South Asia and has since spread to East Africa and the Caribbean
8	219874	Composition useful for the treatment of viral infections in an animal	Sage R&D	U.S.A	This composition is derived from Chinese herbal medicines, medical plants and extracts thereof. Aeginetia indica is the active ingredient found in India too.
9	221614	Herbal injection and a method to produce the same	Maoxiang Wang	China	The plant material used in this composition is from genus Ixeris, which is flowering plants in the daisy family. The active ingredient of this plant is used Chinese traditional medicine. Ixeris Sonchifolia found in India too.
10	200879	Composition for heart disease, method	Tianjin Tasly Pharmaceutical	China	The plant material used in this composition is Salvia

		to prepare same	Co., Ltd.		miltiorrhiza, which is also known as red sage, Chinese, tan shen, or danshen. It is a perennial plant in the genus Salvia, highly valued for its roots in traditional Chinese medicine. Native to China and Japan.
11	209391	Negatively charged polysaccharide derivable from aloe vera and a process for preparing the same	2Qr Research Bv	Netherlands	The medical plant used in this product is aloe vera. The large scale agricultural production of Aloe vera is undertaken in Pakistan, Australia, Bangladesh, Cuba, the Dominican Republic, China, Mexico, India, Jamaica, Kenya, South Africa and USA.
12	214166	Herbal composition for angina pectoris, method to prepare same and uses thereof	Tianjin Tasly Pharmaceutical Co., Ltd.	China	The medical plant used in the said compositions is negative to Japan and China.
13	219566	Nutraceutical for the prevention and treatment of cancers and diseases affecting the liver	Bui, Cuong, Q.	U.S.A	The product contains the compositions from the medical plants Aloe Vera and Brassica oleracea, which are grown in other countries alongwith India widely.
14	238006	Pharmaceutical composition for the treatment of prostatic hyperplasia and prostatitis	Bright Future Pharmaceutical Laboratories Limited	Hong Kong	The medical plants used in the said composition are endemic to southern China, with further outposts in Europe, and central, southern and eastern Asia.
15	221711	Process for preparing a novel medicament mixture	Suleiman Dado	Austria	The process involves mixing honey, olive oil and optionally one or more of: beeswax, propolis, chamomile, sage, Aloe vera, thyme, lavender and/or various oils.
16	244699	An improved composition of a drug	Malireddy S. Reddy	U.S.A	The drug is selected from the group consisting of herbal drugs, allopathic drugs, periodontal drugs, and combinations thereof.
17	206049	Method of producing a herbal composition for angina pectoris method to prepare same and uses thereof	Tianjin Tasly Pharmaceutical Co., Ltd.	China	The medical plant used in the said compositions is negative to Japan and China.
18	216577	Herbal composition	Tianjin Tasly	China	The medical plant used in the

		for angina pectoris	Pharmaceutical Co., Ltd.		said compositions is negative to Japan and China.

Source: Annexure to Starred Question No: 248 answered on December 12, 2011 at: http://164.100.47.132/Annexture/Isq15/9/as248.htm (last accessed on July 31, 2012)

Another related but important issue that has been brought to the fore is the pateting of microorganisms. Under Section 3(j) of the Patents Act, 1970 (as amended in 2005), a patent cannot be granted to plants and animals in whole or any part thereof other than micro organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals. During the debate on TRIPS compliance in the Indian parliament (which took place in 2005), patentability of micro-organisms were raised. In order to have clarity on this issue, the government established a committee under the chairmanship of Dr R A Mashelkar, known as the *Technical Expert Group on Patent Law Issues*. The final report[23] of the committee submitted in 2009, concluded that excluding micro-organisms *per se* from patent protection would be violative of TRIPS Agreement. However it is not immediately clear if patenting of microrganisms is allowed in India.

(iv) Relationship between TRIPS compliance and technology licensing

One of the most important statements that were made during the discussions on TRIPS compliance was that with it the IPR regimes in developing countries such as India would have tightened up to an extant that reverse engineering is virtually impossible. This state of affairs would prompt MNCs to transfer technology to unaffiliated companies located in developing countries much more freely than before. Now that with TRIPS compliance, the IPR regimes are tightened one should see an increase in the number of technical collaboration agreements signed between MNCs and unaffiliated Indian companies. The period of TRIPS compliance coincides with a period of economic liberalization where in the government had already relaxed the conditions under which technical collaboration agreements are contracted between foreign and Indian forms. Soecifically unlike before these collaboration agreements do not go through a fornal apprival process. Further, the upperlimit that was fixed on royalty payments and technical knowhow fees was considerably raised. All these would have a contributed to a large number of lkicensing agreenents- the traditional mode adopted by Indian companies towards technology importantion from developed country firms. In order to check this we have compiled data on two different ways of looking at the colume of licensing contracts signed between MNCs and Indian companies. At the aggregarte level, we have first put together the fragmentary data that afe now available in the total number of collaboration agreements and the share of those collaboration agrrements in the totak that does not iunvolve any equity payments. See Table 4. The share of pure technical collaboration agreements has been steadily coming down over time.

[23] This report could be found at the website of Department of Industrial Policy and Performance, http://dipp.nic.in/English/Publications/Report.aspx (last accessed on July 31, 2012)

Table 4: Declining share of foreign technology licensing agreement in total foreign collaborations

Year	FDI Cases	Foreign technology licensing agreement	Ratio of licensing agreements to FDI
1991	289	661	2.29
1992	692	828	1.20
1993	785	691	0.88
1994	1062	792	0.75
1995	1355	982	0.72
1996	1559	744	0.48
1997	1655	660	0.40
1998	1191	595	0.50
1999	1726	498	0.29
2000	1726	418	0.24
2001	1982	288	0.15
2002	1986	307	0.16
2003			
2004			
2005		90	
2006		86	
2007		81	

Source: Department of Industrial Policy and Performance, Government of India

This shows that MNCs are willing to transfer technologies to companies in India only if their own affiliates are allowed in India. In fact this data from India can be counter checked with the source of royalty receipts received by US MNCs from abroad: over two thirds of it emanate from their own affiliates abroad (National Science Board, 2012).

The argument here is that while the total number of collaboration agrrements may have increased (and so do royalty payments per unit of GDP), an overwhelming majority of these transactions are itra firm transfers, namely between MNCs and their affiliates in India and not between MNCs and unaffiliated companies.

The number of cases of collaboration agreements may not sometimes give us the full picture as agreements may differ in scope. So in order to overcome this limitation and also to have a disaggregated picture we analysed the diret cost of technology importation (as revealed through a sum of royalty and technical know-how fees) by firms in two of the fast growing industries in india which are most likely to have been affected by TRIPS compliance. These are the chemicals (including pharmaceuticals) and the automotive industries. See Figure 8

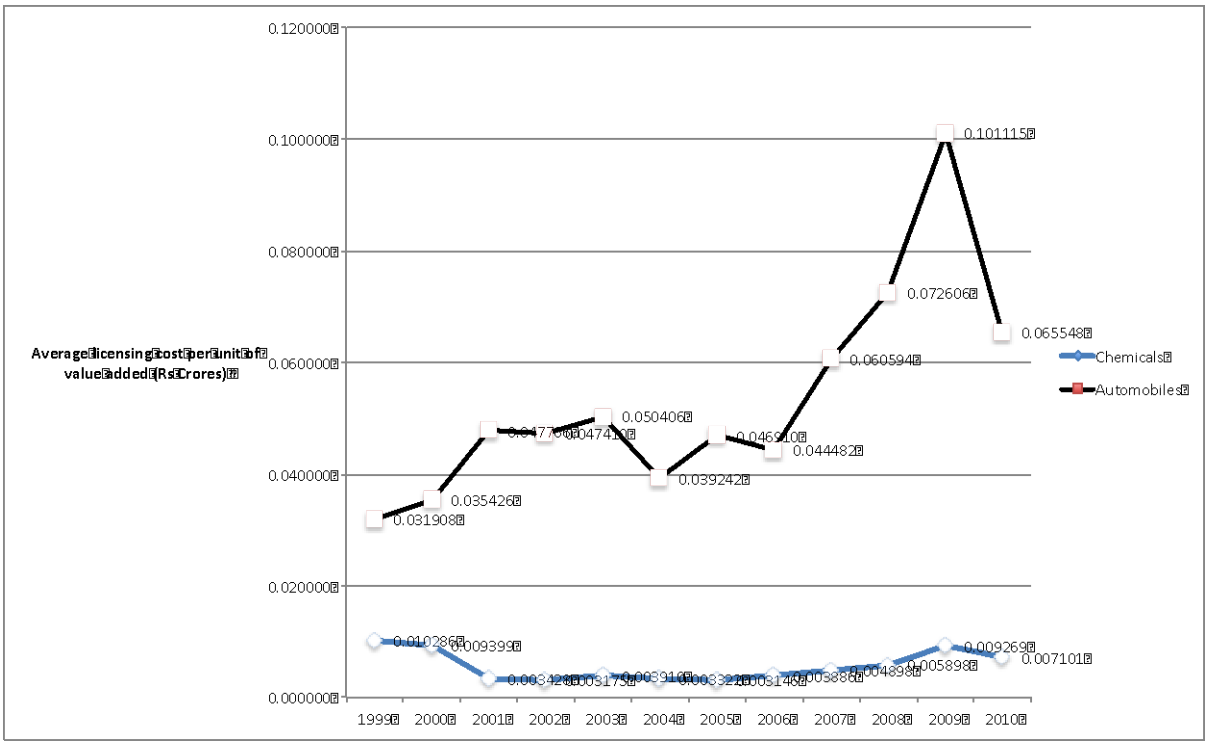

Figure 8: Trends in average cost of licensing foreign technology: Automotive vs Chemicals

Source: Computed from Prowess Dataset

One caveat is in order. The data on direct costs contained in Figure 6 referes to both types of transactions, namely those between MNCs and their own affiliates in India and those between MNCs and unaffiliated companies. Ideally speaking we should have had the two series. Neverthless majority of the firms in the chemicals industry are Indian ones while in the case of the automotive industry, the industry is divided (in terms of share in sales turnover) more or less equally between the two. It is interesting to note (from Figure 6) that the technology importantion of the chemicals industry has increased very slowly, while that of the automotive industry has shot up during the TRIPS compliance period. These two sets of evidence, given its limitations, show us that TRIPS compliance does not appear to have increased technology transfer agreements on a large scale as was predicted. This state of affairs could be attributed to the imperfections in the market for disembodied technology: the market is highly oligopolistic (Mani, 2002).

(v) Reform of the patent office

The Indian Patent Offie has undergone considerable modernisation since TRIPS compliance: a sum of Rs 1.5 billion was spent during 1998-2007 period. In very specific terms this

resulted in the commissioning of state-of-the-art offices in Delhi, Kolkata, Chennai and Mumbai, creation of additional posts in the Patent Office,and E-filing of patent applications were also started during this period. Further an Intellectual Property Training Institute (IPTI) was set up to impart training to patent examiners. As a result of these initiatives, timelines for patent and trade mark processing have come down considerably and backlog of over 44,000 patent applications and 3,75,000 trade mark applications was done way with in the three years ending 2006-07. The initiatives for creation of awareness have triggered IP activity in the country in terms of increased filing of the applications for grant of intellectual property rights (IPRs). The impact of these initiatives is as follows:

(a) The filing of patent applications increased six-times from 4,824 in 1999-2000 to 34, 287 in 2009-10 and the patents granted during the period increased four-fold from 1881 to 6168;
(b) Average time taken for grant of patents reduced from about 6-10 years earlier to about 2-3 years; and
(c) An institute for training fresh examiners as well as contollers and regisrtars in the IPOs was established.

However even now (March 31, 2010), India has only a total of 80 patent examiners to deal with around 34000 applications that were received during the time implying thereby that each examiner had to potentially examine 425 applications although only about 75 applications were actually examined during that year (2009-10). Compare this figure with what an average USPTO examiner does: it is only 88 applications per examiner (Kapczynki, 2010).

III. Trends in opposition and patent litigation

The amended Patent Act 1970 does allow for pre and post grant opposition of patents. Pre-grant opposition can be filed by any person by representation in the IPO within six months from the date of publication of the patent application or in case the six months duration is not available then the representation can be filed till the grant of the patent whichever expires later. The grounds of opposition are provided under section 25 (1) of the Indian Patent Act 1970 as amended in 2005. Some of important grounds of the are wrongful obtainment, anticipation by prior publication or used or already claim in any other patent, obviousness, the subject matter of the invention falls into non-patentable category under section 3 of the said Act. The applicant or any party considers pre-grant opposition only after the filing of an examination. On receiving of the pre-grant opposition the controller issue a notice to the patentee. The patentee is to submit her statement and evidence against the opposition within three months from the date of notification by the controller of patent. The controller may offer a hearing on request by the patentee as well as by the opponent to settle down the pre-grant opposition. A pre-grant opposition has to be disposed off by the Controller within one month by rejecting the opposition and granting the patent or by accepting the opposition and rejecting the application or amending the application and granting the patent. As can be seen from Figure 9, the number of pre grant opposition has always been very small of the total number of published cases and it too has decreased over time.

Post-grant opposition can be filed by any interested persons who are engaged in or promoting research in the field of technology. Post grant opposition can be filed within a period twelve months after the grant of a patent. The grounds of opposition are provided under section 25 (2) of the Patent Act 1970. Some of the grounds are wrongful obtaining of the invention by the inventor, anticipation by prior publications, use, traditional knowledge, the invention is obvious to a person in the art, non-patentable inventions, disclosure of false information to patent office, non-disclosure or wrongful disclosure of the biological source etc. An opposition board is formed by the controller consisting of three members. The examiner who has dealt with the patent application during the prosecution for grant is not eligible to become a board member. The opposition board is given the time three months to conduct examination and submit recommendation with reasons on each ground of opposition. The Controller can fix for a date of hearing by giving at least ten days to the parties on receiving the recommendation from the opposition board. After hearing the parties and analyzing the recommendation of the board the controller decide the matter and inform the parties about her decision giving reasons thereof. Controller can order to either maintain or amend or revoke the patent. As Figure 10 indicates, the post grants oppositions although small in number of cases, but as a share of total number of patents granted has been increasing.

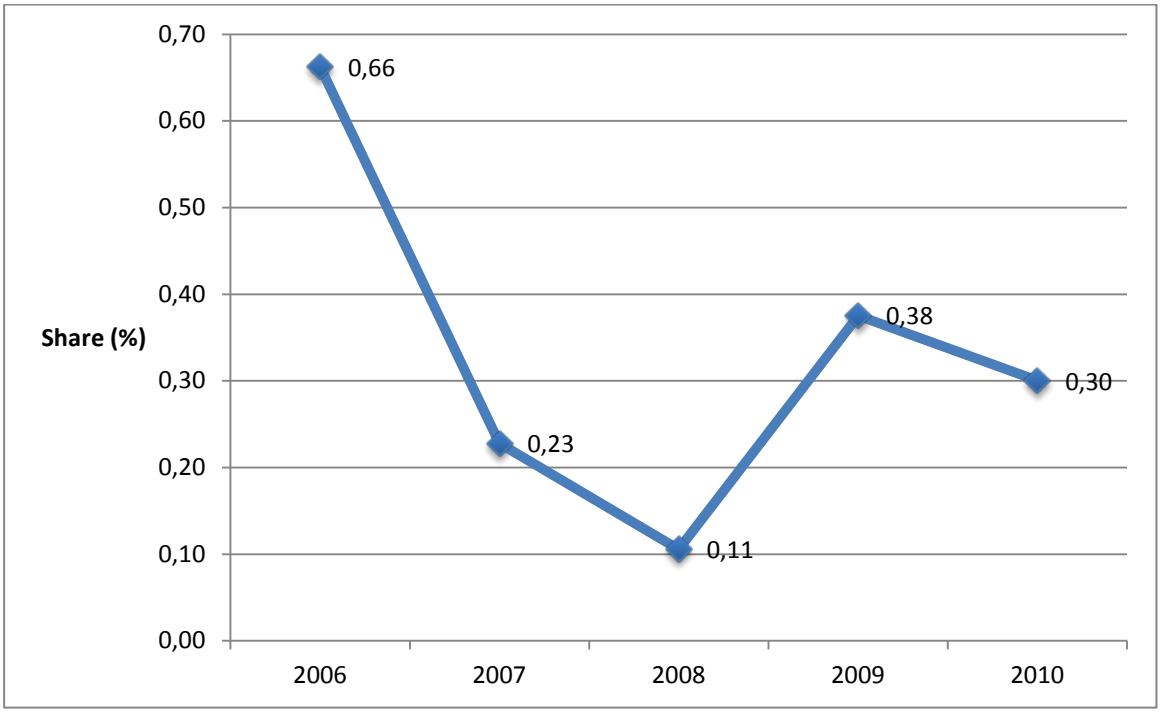

Figure 9: Trends in the share of pre grant cases in total number of published cases

Source: Computed from The Office of the Controller General of Patents, Designs, Trade Marks and Geographical Indications (2010), p.12

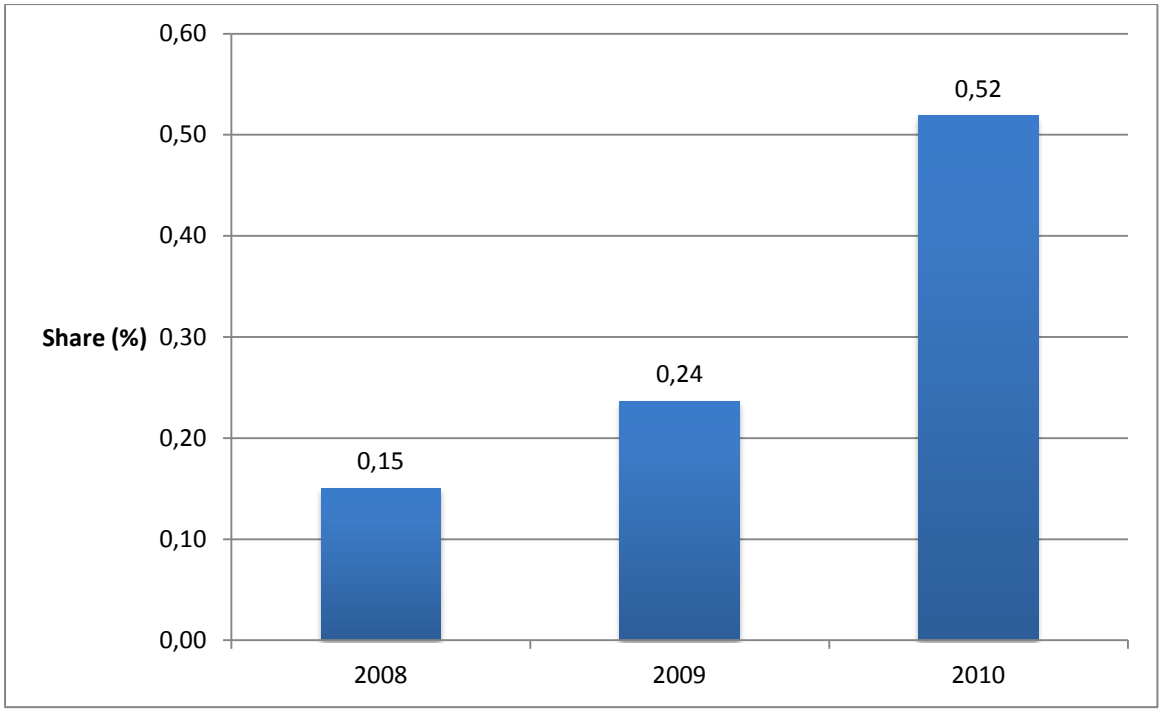

Figure 10: Post grant opposition intensity as a per cent of total number of patents granted

Source: Data on post grant opposition are compiled from Lok Sabha Unstarred Question 5018, http://164.100.47.132/LssNew/psearch/QResult15.aspx?qref=86005 (last accessed on August 2, 2012).

Further to these, there has been also increase in the number of patent litigation in India. Although traditionally these litigations have been between MNC patent holders and domestic companies which have infringed these patents, in the post TRIPS period, one also see increasing cases of litigation between rival Indian companies as well. There are no reliable data on patent litigations. However we have been able to piece together some data from a private source (Bhola, 2012) and we have not been able to verify whether these are reliable figures. See Figure 11. It indicates a significant increase un the number of cases from just 7 in 2006 to 29 cases in 2011. There have been a numbrer of high profile cases, the most discussed being the Bajaj Vs TVS (See Box 4) and the 'Novartis Glivec cases'.

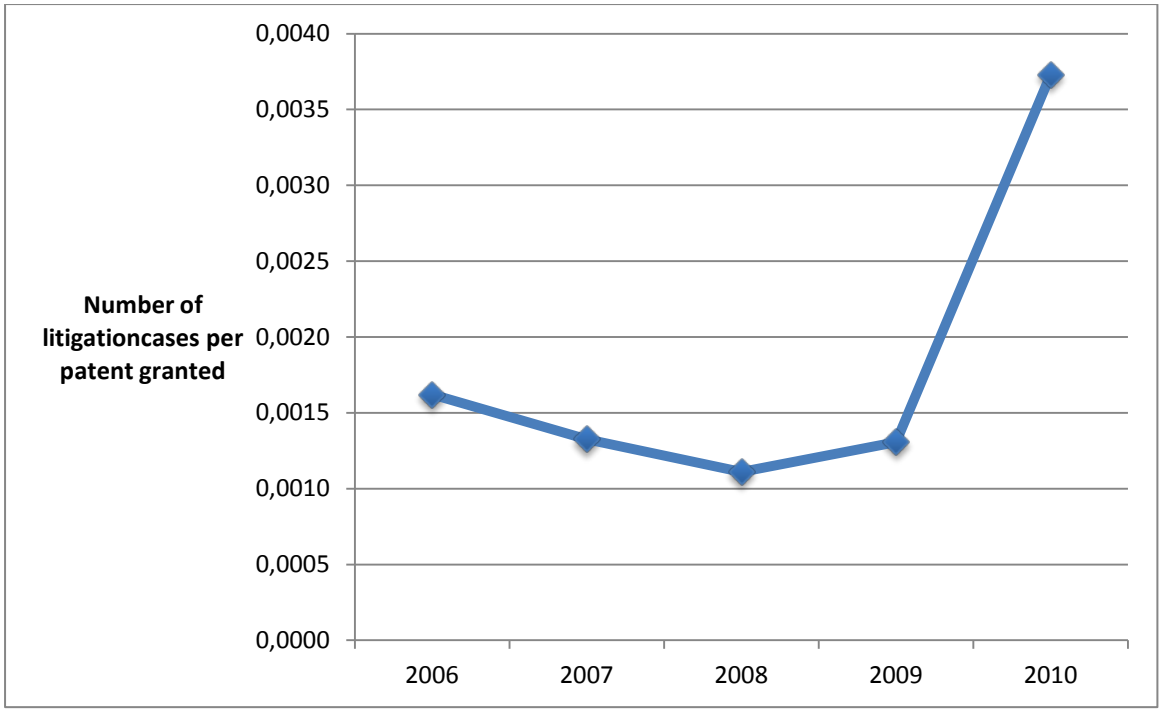

Figure 11: Number of cases of patent litigation per patent granted by IPO: Post TRIPS phase

Source: Based on estimated number of litigation cases filed from Bhola, R (2012)

The 'Novartis Glivec' case[24] also brings to our attention a very contentious section in India's IPR regime, namely the section 3 (d): under this flexibility certain inventions are not patentable in India. The basic rationale behind the section is to prevent or limit 'ever greening' of existing molecules and patent portfolios as variants of existing compounds hat do not show enhanced efficacy are not considered to satisfy the first criterion of patenting, namely novelty. Invoking this provision, the Indian patent office has rejected the patent application of Novartis and the matter is now before the supreme court. Sampat, Schadlen and Amin (2012) discusses the implications of this case for patent policy in an emerging ecomomy in the post TRIPS phase.

[24] For a succinct write up on the implications of the case, see Sampat, Shadlen and Amin (2012). For a more detailed discussion on the issue, see James (2009).

Box 4: Bajaj Vs. TVS Patent Litigation Case

In 2005, Bajaj was granted a patent related to twin spark plug and it was called*DTS-Itechnology*. In 2007, TVS announced the launch of its motorbike *Flame*. Bajaj alleged infringement suit at Madras High Court and TVS initiated revocation proceedings against Baja's patent. According to TVS Baja's invention was prior art and the concept of twin spark plugs was in public knowledge through an expired US patent of Honda. It thus deceptively obtained an Indian Patent. But Bajas has contested this argment and claimed that its invention was directed to improve the combustion of lean fuel mixture in the small bore engine for improved fuel efficiency. The court granted an interim injunction against TVS, but the company filed an appeal against the injunction order. After hearing both the parties, the injunction was vacated by a division bench of the high court and the appeal is still pending in the Supreme Court of India.

Source: Bhola (2012) and other sources.

IV. R&D Strategies in pharmaceutical industry in India

In this section our focus is on the impact of re-introduction of product patent protection in pharmaceuticals on R&D for innovation. The other important impact of product patent relates to competition and market prices. As Chaudhuri (2012) finds, the days of product monopolies and high prices are back in India. The MNCs have started marketing new patented drugs at exorbitant prices particularly for life threatening diseases such as cancer. A 50 ml injection of Roche's anti cancer drug Herceptin (generic name: trastumuzab) costs Rs 135200. Among the other high priced drugs are Merck's Erbitux (cetuximab) (Rs 87920), Bristol-Myers-Squibb's Ixempra (ixabepilone) (Rs 66430), Pfizer's Macugen (pegaptanib) (Rs 45350), Sanofi-Aventis' Fasturtec (rasburicase) (Rs 45000) Roche's Avastin (bevicizumab) (Rs 37180). It is important to note that these prices are for a single injection/tablet etc. The cost of treatment per person per year would be much higher. For example, for Dasatinib used for the treatment of chronic myeloid leukaemia, the price of a 70 mg dasatinib tablet is Rs 3905. But the cost of treatment per person per year exceeds Rs 2 million.

In the underdeveloped Indian pharmaceutical industry before 1972, the capacity to conduct R&D was limited. But has the situation changed following the rapid growth of the industry since the 1970s to justify stronger patent protection in India? Is it that product patent

protection may have adverse impact on access by making prices dearer but can be good for the R&D based pharmaceutical industry in India? What has been the nature of R&D activities and innovation in the Indian pharmaceutical industry? Does India's experience support the claims of MNCs and their supporters that strong patent protection is needed in India for R&D and innovation?

Traditionally, the Indian pharmaceutical industry spent very little on R&D. In the early 1990s, its R&D expenditure amounted to only about 1.5 per cent of sales (Grace 2004, p.37). Even larger companies such as Ranbaxy and Dr Reddys Laboratories spent only 2-3 per cent of their sales on R&D in 1992-93.[25] Since then, however, and particularly since the early 2000s, there has been a substantial increase in research spending in a segment of the industry. While most of the Indian companies continue to be minor R&D spenders, for 38 companies each with R&D expenditure of more than Rs 100 million in 2010-11, R&D expenditure has increased steadily from 1.7 per cent of sales in 1992-93 to 4.3 per cent in 2001-02, and then sharply to 8.1 per cent in 2004-05 and 9.1 per cent in 2005-06. Thereafter however a decline is observed to 7.2 in 2010-11.[26] Here we focus on the more dynamic segment of the Indian pharmaceutical industry for which R&D expenditures have substantially increased (Table 5).

Table 5 R&D expenditure of major Indian pharmaceutical companies, 2010-11

Company	R&D Expenditure Rs million	Research Intensity (%)	R&D Expenditure US $ million
Dr. Reddy'S Laboratories Ltd.	6247	11.1	138.85
Lupin Ltd.	5475.6	12.3	121.7
Ranbaxy Laboratories Ltd.	4978.9	9.3	110.26
Cadila Healthcare Ltd.	3017	13.0	67.06
Matrix Laboratories Ltd.	2936.9	10.3	65.28
Cipla Ltd.	2848.5	4.5	63.31
Aurobindo Pharma Ltd.	1732.4	4.2	38.51
Sun Pharmaceutical Inds. Ltd.	1592	8.2	35.38
Torrent Pharmaceuticals Ltd.	1336.5	7.6	29.71

[25] Calculated from the CMIE Prowess database.

[26] Calculated from the CMIE Prowess database.

Wockhardt Ltd.	1102.2	6.3	24.5
Ind-Swift Laboratories Ltd.	973.5	9.5	21.64
Fresenius Kabi Oncology Ltd.	850.7	20.7	18.91
Panacea Biotec Ltd.	849.7	7.4	18.89
Ipca Laboratories Ltd.	712.7	3.7	15.84
Sun Pharma Advanced Research Co. Ltd.	701.3	120.3	15.59
Parabolic Drugs Ltd.	689.7	10.9	15.33
Venus Remedies Ltd.	685.6	19.2	15.24
Unichem Laboratories Ltd.	663.5	8.7	14.75
Glenmark Pharmaceuticals Ltd.	659.2	5.7	14.65
Biocon Ltd.	520.1	3.4	11.56
Agila Specialties Pvt. Ltd.	504.7	17.3	11.18
Alembic Pharmaceuticals Ltd.	489.8	4.3	10.89
Ajanta Pharma Ltd.	478.8	10.5	10.64
Piramal Healthcare Ltd.	413.2	2.6	9.18
Orchid Chemicals & Pharmaceuticals Ltd.	397	2.4	8.82
Suven Life Sciences Ltd.	333.8	22.2	7.42
Arch Pharmalabs Ltd.	314.6	2.5	6.99
Divi'S Laboratories Ltd.	216.6	1.7	4.81
F D C Ltd.	208.1	3.0	4.63
Surya Pharmaceutical Ltd.	158	1.0	3.51
Strides Arcolab Ltd.	152.5	3.1	3.38
Shasun Pharmaceuticals Ltd.	142.7	2.5	3.17
Plethico Pharmaceuticals Ltd.	134.8	3.0	2.99
Vivimed Labs Ltd.	132.3	4.3	2.94
Neuland Laboratories Ltd.	118.8	3.0	2.64
J B Chemicals & Pharmaceuticals Ltd.	113.6	1.4	2.52
Indoco Remedies Ltd.	113.3	2.3	2.52

Natco Pharma Ltd.	110.5	3.2	2.46
Total 38 companies above	43106.1	7.2	957.65
Total 13 NCE R&D companies	26032.5	9.4	578.21

Source: Calculated from CMIE Prowess data base.

The objectives of R&D conducted by Indian companies can be broadly classified as follows:

- Development of new chemical entities (NCEs)
- Modifications of existing chemical entities to develop new formulations, compositions, combinations (also known as incrementally modified drugs)
- Development of generics (that is, development of processes for manufacturing active pharmaceutical ingredients (APIs) and development of formulations to satisfy quality and regulatory requirements for marketing patent-expired drugs).

The development of NCEs is not yet a significant part of the R&D activities of Indian companies constituting less than a quarter of the total R&D expenditure by the major companies (Chaudhuri 2010, p. 47). Nor are all the large R&D spenders involved in NCE development; Cipla, for example is the third largest spender on R&D but has no NCE portfolio.

The Indian pharmaceutical industry is highly now export oriented. The growth in exports has been one of the most outstanding features of the pharmaceutical industry in India. Exports were negligible in the product patent regime before the 1970s. Exports started picking up in the 1970s after the amendment of the Patents Act. Initially the growth was modest. It accelerated in the 1980s. Exports have grown particularly rapid since the mid-1990s. Exports have been increasing annually at more than 20% in most of the recent years.[27] The export market is larger than the domestic market not only for large companies such as Ranbaxy (63% of net sales in 2010-11), Dr Reddys (65.1%), Cipla (53.2%), but also for smaller companies such as Granules (77.8%), Shilpa Medicare (76.7%), Kopran (58.6%).[28]

Significant R&D efforts are directed towards developing processes and products to get regulatory approvals for entry and growth in patent–expired generic markets in developed

[27] Calculated from DGCI&S data obtained from CMIE India Trades database.

[28] CMIE Prowess database.

countries. Development of processes for manufacturing APIs and product development of formulations, process validation, bio-equivalence testing and generation of other data required for getting international regulatory approvals are specifically highlighted as areas where R&D is undertaken by companies active in the regulated markets.[29] Thus much of R&D by Indian pharmaceutical companies has nothing to do with TRIPS. It is the result of increasing export orientation of Indian pharmaceutical companies and diversification to the regulated markets, particularly to the US.

R&D for new chemical entities

But a remarkable feature of pharmaceutical R&D in India is that, though relatively smaller, the Indian private sector has started investing in R&D for new chemical entities. This began around the time TRIPS came into effect in the mid-1990s.[30] R&D investments were initiated by Dr Reddy's Laboratories followed by Ranbaxy Laboratories. Since then eleven other companies - Sun, Cadila Healthcare, Lupin, Nicholas Piramal, Dabur Pharma, Torrent, Wockhardt, Orchid, Glenmark, Biocon and Seven Lifesciences have also joined in. These companies are among the major pharmaceutical R&D spenders. Together they invested Rs 26032.5 million ($ 578.2 million) (9.4 per cent of net sales) on R&D in 2010-11 (Table 1).

It is important to note that none of these companies is engaged in the entire process of drug development. The reason is simple: Indian pharmaceutical companies are not yet ready for a start-to-finish model in NCE research because of the lack of the skills and funds necessary to develop a drug and put it to the market.[31] Whereas the 13 Indian companies together spent $578.2 million in 2010-11, Pfizer, the largest MNC, alone spent $ 7.8 billion in 2009 (Pharmaceutical Executive, May, 2010). The model that the Indian companies have adopted, rather, is to develop new molecules up to a certain stage and then license them out to partners from developed countries, primarily MNCs. There has been a marriage of interests. It is the development of biotechnology companies which has encouraged specialization according to stages of the drug development process. The MNCs seek and contract out specific activities. As the NCE pipeline of the MNCs started drying up, they in fact have intensified efforts to license promising compounds developed by others and most of the major MNCs have opened compound acquisition departments in their companies. There are also specialized companies, which keep track of promising compounds, maintain libraries, catalogue them and offer them for sale to prospective clients.

[29] See, for example, Dr Reddys Laboratories, *Annual Report, 2005-06*, p. 85; Ranbaxy, *Annual Report, 2005*, p. 46.

[30] In the Indian private sector, Sarabhai Research Centre was the first one to be set up in the 1960s for developing new drugs. But it was wound up in the 1980s.

[31] See, Chaudhuri (2005), chapter 5.

Even at the pre-clinical stage, Indian companies are not engaged with all the elements of the R&D process. Indian companies are not involved in basic research of target identification for new drugs. They rely on the basic research of others and adopt an approach called 'analogue research.' This entails working on certain pre-identified targets for specific diseases to develop molecules that alter the target's mechanism in the diseased person.[32] But even this requires medicinal chemistry and biology skills that are still scarce in the Indian pharmaceutical industry. In the pre-TRIPS era, Indian pharmaceutical industry scientists primarily acquired and developed organic chemistry skills required for process development. Indian companies are now filling up this gap primarily by hiring Indian scientists who worked in MNC laboratories in India and abroad and in the Indian public sector laboratories.[33]

The entry of Indian companies into new drug R&D was associated with tremendous optimism. The licensing deals of Dr Reddys, Ranbaxy and others became major news and aroused the expectation that Indian companies will be recognized not only as successful manufacturers but also as successful innovators of new drugs. About 30 NCEs developed by Indian companies are at various stages of clinical trials. But drug development did not progress as anticipated and the prospect of huge licensing revenue through milestone and other payments have failed to materialize.[34] Indian companies, particularly Ranbaxy and Dr Reddys, the two Indian companies that have invested most heavily in R&D (Table 1) and served as prime advocates for new drug R&D in India, have each suffered several setbacks. MNCs such as Novo Nordisk and Novartis discontinued further development of the compounds in-licensed from them.

What the Indian companies initially did not understand is that while their objectives are to earn license fees and royalties from successful commercialization, the MNCs do not necessarily aim to develop the in-licensed compounds for commercialization. In fact where the compound may compete with the MNC's existing or planned products, the MNC's objective may actually be to "kill" the compound.

Indian companies are now aware of this potential conflict. In some cases they are attempting to develop drugs further despite the lack of interest on the part of the MNCs who initially licensed them. Torrent, for example entered into an agreement with Novartis in 2002 for the

[32] Glenmark Pharmaceuticals Ltd, *Annual Report, 2003-04*.

[33] In the pre-TRIPS regime too some R&D for new drug development were undertaken in India primarily by Central Drug Research Institute (CDRI) (public sector), Ciba Geigy, Hoechst and Boots (all MNCs). As a result of these efforts not many drugs have come to the market. But it generated specialized skills – see Chaudhuri 2005.

[34] There are exceptions: Glenmark earned a total of $ 117 million as licensing revenue during 2004-07. But Glenmark too has been facing problems (Corporate presentation, August, 2009, www.glenmarkpharma.com).

development of the Advanced Glycation Endproduct or AGE breaker compound for the treatment of heart disease and diabetes. In 2004 the compound was out-licensed to Novartis. The agreement was terminated in 2005 when Novartis decided not to proceed further with the compound. Torrent is now trying to develop it on its own and explore other options. Torrent received only $0.5 million initially and then $3 million from Novartis.[35]This was too small an amount for a large MNC such as Novartis to have any stake in the project. Dr Reddys has suffered several similar setbacks.

The later the stage at which a compound is licensed out, the higher the license revenues. The licensor is also in a better position to select a licensee who is actually interested in developing the drug for commercializing and may therefore provide a genuine possibility of earning royalties. But Indian companies face the predicament that the unilateral development of a drug to such a later stage entails considerable cost and risk.

The rising R&D expenditure but lack of adequate returns has put strains on the profitability of these companies. Several companies – Ranbaxy, Dr Reddys, Sun Pharmaceuticals, Piramal Healthcare – cut their R&D budget around 2005-06/2006-07. Ranbaxy, Sun and Piramal have de-merged their NCE business. Such de-risking and reduction of R&D expenditure is an indirect admittance that NCE R&D has not been working as expected. Significantly enough, Ranbaxy and the domestic formulations business of Piramal have been taken over by MNCs as noted above. Dr Reddys has also changed its R&D strategy. It is experimenting with alternative business models including setting up a separate drug development company to reduce the risk and the dependence on MNCs.

No NCE developed by Indian companies have yet been approved for marketing in any country. But as Table 6 shows, 30 NCEs developed by Indian companies are at various stages of clinical trials. Dr Reddys and Ranbaxy the largest R&D spenders and which have been very active in NCE R&D have only 2 NCEs each under clinical trials. Some smaller companies have a larger NCE pipeline. Glenmark and Cadila Healthcare have 5 molecules under clinical trials followed by Lupin and Piramal Healthcare with four each. As Table 6further shows, the NCEs being developed by the Indian companies are related primarily to "global diseases" such as diabetes, cancer, heart diseases, asthma, and obesity. These are the diseases that offer much larger and more lucrative market in developed countries (though they are also prevalent in developing countries). The "neglected diseases" which primarily or exclusively effect the developing countries and promise much less financial returns are absent from the list except for malaria and TB. In both these cases, public sector or philanthropic funding is involved. Ranbaxy is participating in an international project sponsored and funded by the Medicines for Malaria Venture (MMV), a public-private partnership to develop a synthetic anti-malarial drug. Lupin is involved in developing an anti-TB drug in partnership

[35] "Novartis Acquires Rights in Torrent's AGE Compound", Press Release, October 31, 2002 and "Torrent Licenses AGE Compound to Novartis**,** **"** Press Release, July 29, 2004, Torrent Pharmaceuticals Ltd (accessed from website: www.torrent-india.com).

with some publicly funded research institutions in India (Commission on Intellectual Property Rights, Innovation and Public Health, 2006)

Table 6 New Chemical Entities under Clinical Trials, Indian Pharmaceutical Companies

Company	NCE	Indication	Development stage
Cadila Healthcare	ZY11	Pain	Phase II
Cadila Healthcare	ZYH2	Diabetes	Phase I
Cadila Healthcare	ZYH1	Dyslipidemia	Phase II
Cadila Healthcare	ZYH7	Dyslipidemia	Phase I
Cadila Healthcare	ZYO1	Obesity/diabetes	Phase I
Dabur	DRF 7295	Anti-cancer	Phase II
Dr Reddys Labs	DRF2593	Diabetes	Phase III (partner Rheoscience, Denmark)
Dr Reddys Labs	DRF1042	Anti-cancer	Phase I (partner Clintec International. UK)
Glenmark	GRC8200	Diabetes	Phase II
Glenmark	GRC6211	Osteoarthritis, pain	Phase II
Glenmark	GRC3886	Asthma/COPD	Phase II
Glenmark	GRC10693	Neuropathic pain	Phase I completed
Glenmark	GRC 4039	Rheumatoid Arthritis	Phase I
Lupin	LL3348	Anti-psoriasis	Phase II
Lupin	LL3858	Anti-TB	Phase I
Lupin	LL2011	Anti-migraine	Phase III
Lupin	LL4218	Anti-psoriasis	Phase II
Nicholas Piramal	P276	Anti-cancer	Phase II
Nicholas Piramal	P 1448	Anti-cancer	Phase I

Nicholas Piramal	P 1736	Diabetes	Phase I
Nicholas Piramal	P 1201	Diabetes	Phase I
Orchid	BLX1002	Diabetes	Phase II
Ranbaxy Labs (jointly with MMV)	RBx11160	Antimalarial	Phase II
Ranbaxy	RBx10558	Statin	Phase I
Sun Pharmaceutical Industries	SUN 1334H	Anti-allergy	Phase II
Wockhardt	WCK771	MRSA, resistant infection	Phase II
Wockhardt	WCK1152	Respiratory infections	Phase I
Biocon	IN-105	Diabetes (oral insulin)	Phase II
Biocon	T1h	Oncology inflammation	Phase II
Suven	SUVN 502	Neurodegenerative	Phase I

Source: Company annual reports and websites, accessed April, 2009.

Production of generic drugs:

It is generally held that the earlier Indian Patents Act of 1970 which did not recognise product patents was instrumental in the Indian pharmaceutical industry developing a fair amount of technological capability in designing and indeed manufacturing generic versions of already known drugs but which were off patents. With TRIPS compliance and along with it the regnition of product patents may have placed the industry in a difficult position . So it will be instructive to analyse the performance of the industry, post TRIPSn is attempted in terms of four sets of indicators : (i) employment in the pharmaceutical industry; (ii) exports; and two indicators of the technological capability (iii) trends in Abbreviated New Drug Applications (ANDAs)[36] issued by the US Food and Drug Administration (FDA) and (iv) India's share in Drug Master File (DMF)[37] by the USFDA. See Table 7.

[36] An Abbreviated New Drug Application (ANDA) contains data which when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public.

Table 7: Indicators of growth of India's generic drug industry

Year	Employment (in numbers)	Exports (Millions of US $)	Number of ANDAs approved by USFDA	Percentage of Indian DMF to total
1995	181497	724.2		
1996	204609	814		
1997	211614	947.2		
1998	189295	933.7		
1999	213999	1068.2		
2000	243410	1147	9	
2001	233704	1322.4	21	
2002	226416	1608.7	23	
2003	223556	1971.9	17	
2004	240791	2271.6	33	
2005	265396	2761.8	52	40
2006	290021	3416.1	77	46
2007	336211	4476.7	135	43
2008	353692	5822.7	155	45
2009		5921.5	152	62
2010			139	50
2011			162	

Source: Department of Pharmaceuticals (2012); Joseph (2012); Kuhrt (2011); Bakhru and Kerai (2011)

All the four indicators show an improvement. Of particular interest is the number of ANDA apprivals and India's share in DMFs. Thie improvements in these wo since TRIPS shows that the Indian generics industry has continued to maintain its capability in the production and marketing of generic drugs in the all important US market but also has managed to improve its share. This sows that India's technological capability in the manufacture and marketing of generics has been unaffected by the TRIPS regime.

V: R&D in the agrochemicals industry

India's patent laws since 1972 excluded chemicals and all foods from eligibility for utility patents. However, it did allow process patents for 7 years after filing or 5 year after granting the patent on chemicals. There was no legal protection for plant varieties. All this

[37] DMFs are essentially approvals to supply complex raw materials to all generic manufacturers servicing the US market,

changed to bring the law in compliance with TRIPS. Chemical, food, and agricultural products and processes and novel microorganisms could be patented for 20 years starting in 2005. A *sui generis* system of plant breeder's rights was passed and started accepting applications in 2007. Plant varieties and seed are protected by the plant variety protection law and are excluded from coverage in the patent act.

Who Uses Strengthened IPRs?

Table 8 provides data by major agricultural input industries on number of patents granted and applications for patents that are published by not yet granted as of 2011. The public sector plays virtually no role in patenting pesticides, biotechnology, food products or agricultural machinery. Data are not available from before 2000 in most agriculture-related industries because product patents were not allowed. The largest numbers of patents granted and of published applications are in the pesticide industry, followed by plant biotechnology. Agricultural machinery has the third-largest amount of patenting. MNCs dominate patenting in most industries except agricultural machinery. This may be due to the fact that much of the intellectual property in the agricultural machinery could already be protected as components of cars, trucks or construction equipment. However, patenting by Indian enterises is also growing (compare granted with published patents), especially in pesticides, fertilizers, and agricultural machinery. Patents by MNCs primarily reflect research conducted outside of India and brought in through local subsidiaries and partners.

Impact on R&D

Although pesticide research worldwide has declined since the 1990s (Fuglie 2012), pesticide research in India has grown—particularly in the last decade. Growth of Indian private sector R&D on food and agriculture by industry is shown in Table 9. It contains our best estimates of the levels of private R&D expenditure in 2008-09 plus data from two previous studies of R&D that were conducted in the mid 1980s and the mid 1990s. Total agribusiness R&D almost doubled between the 1980s and 1990s and then more than tripled in real dollars from the mid 1990s to 2008. The seed/biotech industry registered the most rapid growth – R&D expenditure went up almost 4 times between 1985 and 1995 and then grew more the 10 times from the mid 1990s to the present. Pesticide R&D grew rapidly - doubling in the first period and then doubling again in the latest period. Relative to agribusiness as a whole, seeds grew more rapidly and pesticides less rapidly.

Interviews with multinationals suggest that stronger IPRs have been influential in their decisions to increase their R&D in biotech, seed, and pesticides in India. The location of major pesticide discovery labs in India by Syngenta was due to a combination of factors one of which was stronger IPRs. However, they still take precautions against losing control over new technology by spreading out the different components of the research process around the globe so that no one group in India or China would have all the parts to be able to copy a product that was in the pipeline[38] The other factors which were also extremely important were relatively low costs of highly skilled scientists both in India and in the India community abroad who were interested in returning to India. Other agribusiness multinationals that have made major investments in basic biological and chemical research in India are Monsanto and DuPont.

Pesticide R&D of MNCs listed on the Indian stock exchange (Bayer Crop Science, Monsanto India, Syngenta, and BASF) tripled their R&D expenditures between 2003 and 2008.[39] Increases in sales, which doubled during this period, account for much research increases. However, research intensity also increased which is consistent with the argument that IPRs may also have influenced their decision to conduct R&D. In the 1990s, most pesticide companies were spending about 0.8 percent or 0.9 percent of sales annually on R&D. This increased to 1.5 percent in 2009 (Pray and Nagarajan 2012).

For Indian companies' biotech and pesticide research, stronger IPRs seem to have had some limited impact on R&D. As shown in Table 8 Indian pesticide firms and seed firms are just starting to patent pesticides or genes and are far behind their multinational competitors in using these IPR tools. R&D data for large Indian pesticide firms listed on stock markets show a different pattern than the data for MNCs, with slower and less uniform growth among firms. Rallis, the clear leader in 2000, declined in research investment from Rs 179 million rupees in 2000 to Rs 23 million in 2008. Gharda, on the other hand, continued to spend about the same amount each year on research and its research intensity is high. In contrast, UPL R&D has increased from about Rs 100 million in 2000 to Rs 6.7 billion in

[38] This is based on personal communication Syngenta officials , Mumbai , January 2009.

[39] The increase would have been even greater if data from Dow and DuPont had been available because both of them are making substantial investments in pesticide research, but they do not make data on their R&D expenditures in India public.

2008,[40] and it has become the leading Indian pesticide research firm. Research intensity of domestic firms, which account for about two-thirds of pesticide industry research, has increased somewhat—from just less than 1 percent of sales to slightly more than 1 percent (Pray and Nagarajan 2012).

Table 8: Private-sector patenting in India, 2000-2010

Sector	Firm type	Granted (2000-2010)	Published (2004-2010)
Plant biotechnology	Indian	1	8
	MNC	78	245
Pesticides	Indian	58	89
	MNC	373[a]	1,199[a]
Fertilizers	Indian	5	46
	MNC	16	25
Agricultural machinery	Indian	31	39
	MNC	52	109
Total	Indian	95	182
	MNC	519	1,573

Source: Compiled from Intellectual Property India, 2011. This table is from Pray and Nagarajan 2012
Note: [a] These numbers may include some chemicals that are not used for agricultural pest control

Indian companies tend to focus research on process innovation, such as finding inexpensive ways of making active ingredients (AIs) developed elsewhere, and on developing new formulations and combinations of AIs. In addition, firms are developing crop management practices to enable farmers to use pesticides more safely, more efficiently, and with less environmental impact. Excel and Rallis focus research on the manufacturing process to develop efficient processes to produce off-patent AIs that have available regulatory dossiers containing efficacy, toxicity, and environmental impact data and therefore can easily move through the Indian regulatory approval process. United Phosphorus reports research activities extending from more efficient manufacturing processes to developing safer, easier, and more effective spraying methods. Some firms are also involved in extension demonstrations, regulatory affairs, and product stewardship. Gharda Chemicals pioneered pesticide manufacturing technology.

Multinationals are also improving pesticide production and formulation as well as the safety, efficacy, and environmental impact of pesticides in India, but they are investing in

[40] A large share of this growth appears to be due to the acquisition of foreign pesticide firms and Advanta.

basic research as well to develop new molecules for pesticides in India. Syngenta established a research and technology center in Goa in 2006 that has grown to more than 100 scientists working on new chemical products for crop protection (Syngenta, 2010). Bayer is also developing active ingredients in India, where it is working specifically on developing new synthetic pyrethroids through its joint venture with Mitsui called Bilag. Isagro (an Italian firm) has an Indian division with a large research program to developing pesticide production processes. Its new AIs are identified in Italy, and then the India branch develops the least expensive production process. In 2007, DuPont built a basic sciences center for chemical and biological research in Hyderabad, and BASF announced in 2010 that it will establish a research center in India to develop new agricultural chemicals.

Both Indian and foreign firms in India conduct significant research on biopesticides. These include the Indian firms TERI, Coromandel, and Excel Industries, which together have been granted 25 patents on biopesticides between 1991 and 2009. Camson Bio Technologies entered the biopesticides market in 2001 and spends 20 percent of its revenues annually on research, having developed 22 biopesticides and 7 biofertilizers, and capturing 20 percent of the Indian bioproducts market (Camson Bio Technologies 2010). Research investment in this area totals about Rs 68.7 million ($1.4 million), nearly 3 percent of sales, and investment is increasing as new firms enter the market (Pray and Nagarajan 2012).

Impact on Innovation

While the previous section shows that the impacts of TRIPs compliance on R&D seem to have been positive but limited, what we are really interested in is innovations. They can come from local R&D but also may come into India through licensing, trade and foreign investment. The seed, biotech, and pesticide industries have data on innovation in addition to the data on patents and PVPs which are used in many studies as measures of innovation. Because the introduction of new technology in all of these industries is regulated, regulators have information on new plant varieties, new pesticides and new genetically engineered genes and plants. The fact that companies or research organizations took the time and invested money to move these products through the regulatory system means that they are expected to be commercially successful and valuable to society.

The numbers and trends of new Indian pesticide registrations (active ingredients not different formulations) are shown in Figure 12. The decline is pesticide registrations took

place in the 1970s when the product patents were eliminated. There has been a clear upward trend in the number of registrations since the 1980s. However, this acceleration of registrations took place in the 1990s before product patents were put back in place. Part of this could have been in anticipation of TRIPs. Registrations continued to grow in the first decade of the 21st Century when product patents were implemented again. Careful modeling and more interviews with the industry would be required to show that TRIPS had an important impact.

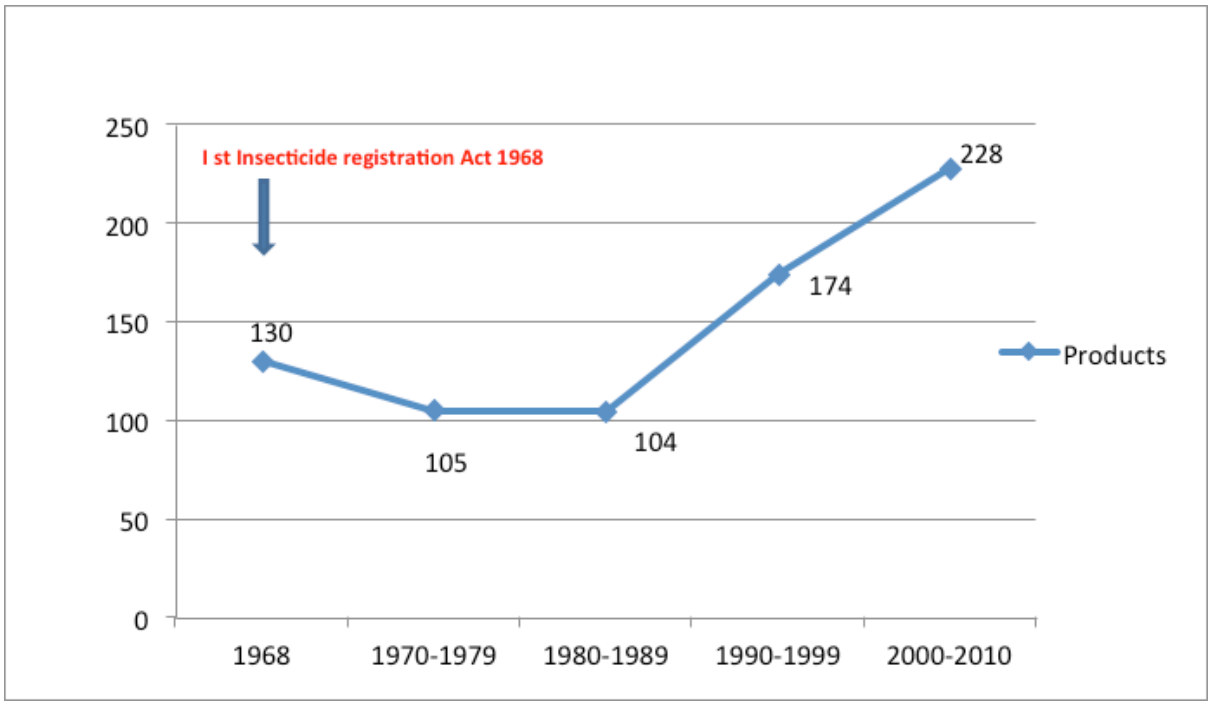

Figure 12. Pesticide Registration in India (1968-2010)

Source: Compiled from Central Insecticide Board and Registration Committee, Ministry of Agriculture, Government of India, New Delhi. http://www.cibrc.nic.in/cibrc.htm

Our evidence suggests that compliance with TRIPS has had some positive impact on R&D and innovation in the pesticide industries. Some growth in these indicators would have taken place anyway, driven by liberalization of industrial policy, increased demand for pesticides in India and the increase in pesticide exports, but discussions with industry leaders and the evidence on IPRs, R&D and innovation indicate that stronger IPRs have also had an impact. The impact seems to have been greatest on the MNCs which have made the most use of pesticide and biotech patents. These companies are investing in major laboratories that are parts of their global R&D networks but they are also building their R&D programmess to

develop innovations for the Indian market. The changes in patenting and the investments by multinationals also appear to have stimulated more research and innovation by Indian pesticide companies.

Table 9: Sectoral private agricultural investment in R&D, in millions of 2005 US dollars

Industry	1984/85[a]	1994/95[a]	2008/09[b]		
			Total	Indian firms	MNCs
	Millions of 2005 US$				
Seed and biotechnology	1.3	4.9	88.6	49.3	39.3
Pesticides	9	17	35.7	24.4	11.3
Fertilizers[a]	6.8	6.7	7.9	4.9	0.0
Agricultural machinery	3.7	6.5	40.5	20.5	20.0
Biofertilizers and biopesticides	0	0	1.3	1.3	0.0
Poultry and feeds	-	3.5	7.8	7.8	0.0
Animal health	0.9	2.7	18.6	3.7	14.9
Sugar	0.9	2.5	10.8	10.8	0.0
Biofuels	0	0	13.1	13.1	0.0
Food, beverage, and plantations	1.3	10.3	27	16.2	10.7
Total	23.9	54.1	251.3	155.0	96.2

Source: Pray and Nagarajan (2012)

VI. Conclusions:

India's patent regime has been made TRIPS compliant in 2005 after a series of three amedments and an intense debate which involved a number of stakeholders. The major facet of the TRIPS compliant patent regime is the recognition of product patents in pharnaceuticals, agrochemicals and food industries. In this stidy we analysed in depth the implications of this change in governance rule for innovative activity in India as a whole and the pharmaceutical industry in partuicular. Of the three flexibitlities provided in the TRIPS, India has invoked only one it, namely the one on, compulasory licensing and that too in the very recent A major implication is that there is far greater We find that although patenting has increased from India most of these are secured by foreign firms located in the country. An interesting finding was that the leading IT firms have started filing for patents at the USPTO where software patenting is allowed. During this time India has becoming a contracting party to the PCT thus enabling Indian inventors to patent their inventions in a large number of jurisdictions. The government has also initiated steps to bring utility models within the ambit of its IPR regime so that incremental innovations by small medium enterprises can be protected. Creation of the Traditional Knowledge Library has enabled

India to successfully oppose the granting of patents to inventions based on India's traditional knowledge in other jurisdictions. The expert committee that was appointed to see if microrganism should be patented has reached the conclusion that it should be patented. There is also some limited evidence to show that research in neglected tropical diseases have increased in India although thi appears to be confined to public research institutes and the research is leading to more publications than any new drugs. Also it is less clear whether the domestic pharmaveutical industry is involving itself in this area. Tightening up of the patent regime through TRIPS compliance has not resulted in unaffiliated Indian firms being able to secure foreign technical collaboration agreements on a large scale. However continued reform of the patent office has made the whole process of patenting more transparent and less time consuming although the time taken for examination of applications are still high when compared to best practices. TRIPS has alloed pre and post grant oppositions and especially post grant oppositions and patent litigations have shown an increase. What is more striking are instances of domestic conpanies litigating against each other and that too in non pharnaceutical industries.

Our analysis of the post -TRIPS R&D strategies of domestic pharmaceutical firms shows that little has changed to dispute the conventional wisdom that the developing countries should not grant product patent protection. They are already paying the cost of high prices of patent protected products. But the technological benefits claimed have not yet taken place. While R&D activities have diversified, Indian pharmaceutical firms are yet to prove their competence in innovating new products. No NCE has yet been developed for marketing. There have been several setbacks and the partnership model has not always worked properly. What Indian companies have really demonstrated is the ability to develop generics – an ability which they acquired and improved during the pre-TRIPS period. Contrary to what was claimed during the TRIPS negotiations, the product patent regime has not prompted Indian companies to devote more resources to developing drugs for neglected diseases that exclusively or predominantly affect developing countries. There is of course some evidence to show that public agencies in India have started devoting more attention to research on drugs for negelected tropical diseases. The large Indian pharmaceutical companies, who are the major R&D spenders in the country, have been focusing on the larger and the more lucrative developed-country markets, particularly that of the U.S. In that regard, the primary incentive to invest in R&D, whether for NCEs, for modifications, or for the development of generics, has not been the new TRIPS-compliant product patent regime in India but the product patent regime in developed countries that was in place well before TRIPS. TRIPS may have accelerated the trend toward such R&D because of the anticipated shrinkage of domestic opportunities. But in the absence of TRIPS, such R&D activities would still have been undertaken. With the larger domestic operations, Indian companies, in fact, would have had access to larger resources and would have been better placed to undertake such R&D.

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Finally, we see that most of alleged positive benefits of TRIPS are exaggerated while at the same time its negative effects on some fronts too are also equally exaggerated. The truth lies in between the two.

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