

Harmonization of Patent Rules and Regulations and its Plausible Implications in Developing Countries: A Case Study of India

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Introduction

Historically it has been the privilege of each country to define rules and regulations of its patent system, scope of patenting, exceptions and enforcement mechanism. This had resulted in sharp differences in patenting provisions in different countries; particularly the differences were substantial between developed and developing countries. Majority of the developing countries like India had limited term of patenting, product patents were not allowed in some sectors (mainly 'pharmaceutical'), etc and enforcement mechanism was not so strong. This type of patent system was in force in developing primarily to enable industries in these countries to catch up with their counterparts in the industrialised economies. The multilateral trade agreement, the WTO (World Trade Organisation) enacted in 1994, enforced new rules and regulations for trade between countries. It was for the first time through the TRIPS (Trade Related Intellectual Property Rights) agreement in the WTO, protection and safeguard of intellectual property rights was introduced in trade between countries.

International trade is increasingly becoming technology driven. Share of high technology goods in export is becoming important component of international trade particularly by developed countries. In this technology driven market, creation and successful translation of proprietary knowledge allow firms to be competitive. Firms have increasingly complained that there are widespread infringements of their protected technologies particularly in developing countries due to weak patent laws and inadequate enforcement mechanism. This has been the major argument for inclusion of IPR provisions in international trade agreement i.e. the Agreement establishing the World Trade Organisation (the WTO Agreement) (*However, this argument has also come in for criticism as it has been argued by developing countries as well as international agencies such as the WHO, that inclusion of stringent IPR provisions can retard the growth of countries which are in different stages of development*).

TRIPS agreement has three broad components: (A) Goals, objectives and standards of IPR, (B) Mechanism for enforcement, (C) Specific needs of developing countries. This agreement, explicitly defined through various articles, specifies the patent provisions that member countries would have to provide in their patent law. Thus in other words it essentially leads to the creation of a harmonised patent system i.e. to a large extent creating similar patent rules and regulations in member countries.

The present article by taking the case of India, a country in transition and a member of the WTO, examines the changes that were undertaken by it in its patent provisions to comply with the TRIPS agreement. The article also underscores the plausible

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implications of these changes. In a broad sense the situation in India i.e. the patent system in the country and the effect of TRIPS agreement would be similar to other developing economies. The paper is articulated in five main sections. Section 2 looks at Indian Patent System) for patenting in India and the major deviations from the TRIPS agreement. Section 3 covers changes that were required in the Indian Patent Act to comply with the TRIPS agreement. Section 4 discusses the plausible implications of the amendments. Section 5 examines India's preparedness by examining patenting trends of Indian firms. This section also covers impact of India joining Patent Cooperation Treaty (PCT) by observing patent filing by Indian firms through the PCT route as well as foreign patents that are entering India through this route. Section 6 highlights the main findings that emerge from this study and their implications.

Indian Patent System

The patent system was first introduced in India in 1856 through the Exclusive Privileges Act, 1856. This act provided exclusive right to the patent holder for a period of 14 years. The Indian Patents & Design Act, 1911, replaced the previous act, although the main clauses remained the same. The patent right was provided for 16 year. The Indian Patent Act of 1970 that came into force from 1971 made significant changes. This act limited the scope of patent by defining inventions that can be patented and introduced a number of exclusions. A major exclusion was discontinuing product patents in pharmaceuticals, food and agrochemicals. Patenting of process was restricted to seven years (or five years from the date of sealing the patent, whichever was shorter).

The 1970 Act also defined the provisions that residents had to follow for patenting outside India (apart from the patent rules in the country of patenting). It can be concluded that the Indian Patent Act of 1970 was enunciated to help Indian industry in technology substitution (creating alternate products of patented technologies) by restricting the scope and terms of patenting. This act was instrumental in creating opportunities for Indian pharmaceutical firms to create generic drugs. There were other provisions in this Act that helped Indian industry in general to overcome barriers of patented technology.

TRIPS and the Indian Patent System

The WTO is essentially a rule based multilateral trading system and the member countries have to necessarily comply with all the Agreements. The WTO agreement is an umbrella agreement². Annexed to it are various agreements covering trade in services, goods, intellectual property, dispute settlement, etc. Agreement on intellectual property is governed by the TRIPS agreement. TRIPS agreement has far reaching implications as it brings in protection of intellectual property rights in trade between countries. TRIPS agreement contains general provisions and basic principles

² On 1 January 1995, the WTO replaced GATT, which had been in existence since 1947, as the organization overseeing the multilateral trading system. India became member of GATT on 8th July, 1948. India was signatory to WTO when it was established in April 15, 1994 and came into force from 1st January, 1995. Upon signing the new WTO agreements (which include the updated GATT, known as GATT 1994), signatories officially became known as "WTO members".

that are to be followed for IPR protection of all types (Watal, 2000). The subsequent sections cover specific guidelines for each type of IPR, rules for enforcement, acquisition and maintenance, dispute prevention and settlement, and transitional agreement.

From 1971 onwards, Indian Patent Act of 1970 governed the patent system in the country. This act was not in compliance with TRIPS provisions. India being a member of the WTO it was obligatory for India to change its patent act to conform with the TRIPS Agreement. In principle there were three major changes that were required in the above act. The first deadline was to be adhered on the day the WTO agreement came into force (1st January, 1995): (a) to introduce 'Mailbox' protection (providing a means by which product patents in pharmaceutical and agriculture can be filed) and (b) provision of exclusive marketing rights (EMRs) to a pharmaceutical product that has been granted patent in any WTO member country after 1995. These changes had to be made in patent laws of country such as India that did not provide product patents in pharmaceuticals and agro-chemicals. The second major change required was to increase the duration for patent protection to 20 years from the date of filing of a patent by 2000. The third major requirement was to introduce product patents in pharmaceuticals, food and agro-chemicals by 2005. In principle by 2005, Indian Patent Act had to be made compliant with TRIPS requirements.

Apart from meeting the three deadlines, other important changes were required to be incorporated in Indian patent Act by 2005. TRIPS include a number of provisions from other major treaties covering IPR. In framing its rules/guidelines in patents, it has included articles from Paris Convention. Additionally India has also signed PCT (Patent Cooperation Treaty) and Budapest Treaty and thus it was imperative for India to include all the major clauses in its Patent Act that were required by these treaties.

Amendments in the Indian Patent Act

Amendments in the Indian Patent Act of 1970 were thus required keeping in view the deadlines imposed. In other words by 2005 Indian Patent Act had to meet the entire obligatory clauses covered by TRIPS. India's accession to PCT and Budapest Treaty also required additional changes or provisions in patent filing (PCT) and providing designated centres for deposition of micro-organism (Budapest Treaty).

The Indian Government drafted the Patent Amendment Bill in 1995 but this bill could not be passed by Parliament. Only in 1999, the first amendment was made in the Patent Act of 1970. This amendment was consequent to a WTO ruling following a complaint filed by the European Union and the US against India at the WTO citing India's failure to comply with Article 70.8 i.e. 'Mailbox' provision) and Article 70.9 (provision of Exclusive Marketing Rights i.e. EMRs). The WTO ruled that India was in default of its obligations and also India was obligated to have a transitional system in place immediately. Keeping this ruling in view, amendment was made in 1999, to allow EMRs and Mailbox facility. It was also notified that this act would come into force from 1995.

The Patents (Amendment) Act, 1999 specified four pre-conditions to be met by an EMR applicant: (a) The applicant must hold a valid patent on pharmaceutical product granted after January 1, 1995 in any of the WTO member countries (countries who are also WTO members); (b) The applicant should have marketing rights in the

member countries; (c) A product patent application should already have been made in India, and (d) Marketing approval of the same product should have been granted in India. The first three conditions were as per the stipulation of TRIPS agreement. The fourth clause was incorporated to meet the Indian drug regulatory approval. The EMRs were to be given for a period of 5 years as per TRIPS requirement. The other important change made was the removal of restriction on residents to apply for patents outside India. In the Patent Act (1970) it was obligatory for residents (section 39) to seek prior permission before applying for patents outside India.

Patents Amendment Act 2002 incorporated the 20 years period of protection for granted patents from the date of filing of patents in India. Some other important changes made were: (a) Redefining the scope of invention. Of particular significance were (i) allowing patents for treatment of plants (medicinal, surgical, curative and prophylactic process) to render them free of diseases or to increase their economic value or that of their products, and (ii) allowing patents covering micro-organisms; (b) The source of geographical origin of biological material used in invention was made mandatory to be disclosed in the invention. A list of Authorized Depository Institutions were notified in the gazette of India, Part II, Section 3 for depositing the biological materials mentioned in the specification at the time of filing a patent application. This change was made as per compliance with Budapest Treaty; (c) Request for examination introduced implying all patent application in which First Examination Report have not been issued on or before 19th May 2003 were to be examined in serial order in which the request for examination is filed. ;(d) Reversal of burden of proof in case of process patent infringement from patent holder to the infringer (this was a requirement under TRIPS). The defendant has to prove that process used by him/her to obtain a product (identical to the product obtained by a patented process) is different from the patented process. The patentee is only required to prove that the product is identical to the product obtained by the patented process. (e) Provisions were made for filing as well as receiving patent application through PCT.

Additionally new grounds of opposition were introduced covering: (a) Non-disclosure or wrongly mentioning the source of geographical origin of biological material used in invention.;(b) Anticipation having regard to the knowledge oral or otherwise available within the local indigenous community in India or elsewhere. As per TRIPS agreement, patent or some form of protection had to provided for protecting plant varieties. Government introduced “protection of plant varieties and farmer’s rights act” (PPVFR 2001) for providing protection to various plant related/derived products (plant extracts, various compositions derived from plant products).

The present Act, The Patents (Amendment) Act 2005 has incorporated a major change in the Patent Act of 1970 by allowing product patents in all fields of technology. Thus it has removed the restriction on product patents in pharmaceuticals, food and agro-chemicals. Another important provision has been made regarding provision of compulsory license to countries which have insufficient or no manufacturing capacity to meet public health situations.

Like most countries, priority is established strictly by filing date in India. This confirms to TRIPS agreement. TRIPS require WTO member countries to comply with most of the important articles of Paris Convention. This includes the clause of

National Treatment and Right of Priority (Ganguli, 2001). National treatment implies member states must grant the same protection to nationals of the other members as it grants to its own nationals. Right of Priority implies application made within one year from the first application in any member state will have the same priority if they file application within 12 months in another member country. Further, applicant will have freedom to exploit his invention in any member country without losing novelty due to disclosure. These provisions are now applicable for patenting in India.

Table 1 illustrates the major changes that were made in the Indian Patent Act of 1970.

Table 1
Major Amendments Incorporated in Indian Patent Act 1970 to comply with the TRIPS Agreement

Indian Patent Act of 1970	TRIP'S	Patent Amendments
Only process not product patents in food, medicines, chemicals	Process and product patents in almost all fields of technology	To be fully implemented as per TRIPS in 2005. (Patent Amendment Act 2005)
Term of patents 14 years; 5-7 years chemicals, drugs	Term of patent 20 years	Now confirms to TRIPS requirement (Patent Act 1999)
Several areas excluded from patents (method of agriculture, any process for medicinal, surgical or other treatment of humans, or similar treatment of animals or plants to render them free of disease or increase economic value of products)	Almost all fields of technology patentable. Plant varieties excluded from patent protection, but confusion exists on protection in some areas of agriculture and biotechnology	Uses the exception allowed by TRIP's. Rules out the patenting of living things or non-leaving substances occurring in nature, and further rejects the patenting of animal and plants.
Patent holder to prove that the patented process has been infringed in creating a product.	Reversal of burden of proof in case of process patent infringement from patent holder to the infringer	Now confirms to TRIPS requirement
Government allowed to use patented invention to prevent scarcity	Very limited scope for governments to use patented inventions	Now confirms to TRIPS requirement

Source: Indian Patent Act 1970 and Rules 1991, GATT Agreements: results of the Uruguay Round, World Trade Centre, January 1995, Patent Act 1999, Patent Bill, 2002, Patent Rules 2003, Patent Ordinance 2004 and The Patents Amendment Act, 2005.

Plausible Implications of the Amendments

The stronger patent protection provided by the Patent (Amendment) Act 2005 would have impact across all the technological sectors. In complex technology areas that

have multiple applications (such as information and communication technology, biotechnology), patented technologies would increasingly dominate the market. A substantial amount would have to be spent by Indian firms towards royalties and license fees. Foreign Direct Investment (FDI) in these sectors would include a major share in technology transfer comprising of patented technology. Thus increasingly Indian market would become technology driven market.

However, the main impact would be in the pharmaceuticals industry as product patent in pharmaceutical sector is possible by the Patent (Amendment) Act 2005. Post 1995 generic versions of patented drugs would have to be withdrawn from the market. The criteria of patentability, compulsory license and other provisions would mainly affect patenting in this sector.

Presently, Indian firms dominate the market accounting for 75% of the drugs that are sold. The domestic firms meet 90% of the country's pharmaceutical demand including almost all of the 300 essential drugs. The present situation was largely due to the Patent Act of 1970. Prior to 1970, Indian drug industry accounted for only about 25 % of the bulk drugs. The absence of product patent protection for pharmaceuticals and agrochemicals led many multinationals to limit their portfolios to patent expired products or a few selected patented products. This resulted in an erosion of their market share because local manufacturers introduced advanced medicines through reverse engineering (simple change in the process). *However, sometimes to develop a new process (non-infringing) in itself requires considerable skill. Drugs, particularly those that are block-buster have a large number of patented process to prevent the entry of generics. For example, Eli Lilly protected the production of cefaclor through thirty-two processes. In spite of the large number of patented process, Ranbaxy could develop a new and superior non-infringing process (Chudhuri, 2005).*

Foreign firms were required to pay royalties for international drugs, while Indian companies could access the newest molecules from all over the world and reformulate them for sale in the domestic market. This thus resulted in the systematic weakening of patent rights for pharmaceutical products in India and helped domestic firms to overcome the patent barriers. This situation also put India in an enviable position among developing countries in generic drug formulation.

The direct implications of TRIPS would be that products that have been on the market before the signing of products patent will remain free of product patent; companies that produce any of these products will be able to continue as before. On the other hand products patented post-1995 will be protected thereafter (Bhattacharya, 2004). Companies that produce products that fall under patent protection will have to stop manufacturing them or negotiate a licensing agreement with the (foreign) patent holder. The transition will cause move towards a monopoly market. Chemically identical products that were there in the market would cease to be available. Non-identical products that perform the same function i.e. substitutes would remain. These substitutes can be patent protected or can be off patent generic drugs. Thus the future market would be of three kinds (a) patent drug (b) generic versions of drugs that are off patent, and (c) non-bio equivalent drugs.

Another major impact would be in filing patents. Accession to PCT in 1998 has opened another route for Indian institutions/individuals for filing patents in different

countries. The PCT provisions helps in filing patent as an international patent through the Indian Patent Office. The countries that the applicant wishes to protect his/her invention is marked as designated country(ies) in the patent document. PCT route allows cost saving, not going through the trouble of filing the patent in each country as well as it maintains priority for at-least 12 months. Similarly, foreign applications can file patents in India through the PCT route by designate India in their PCT patent.

Some Indications from Indian patenting Trends

The main implications of the new patent act would be in the pharmaceutical sector as discussed above. Patents play a primary role in the pharmaceutical industry as investments are huge as well as risky but where product imitation requires minimal investment and capability. It would be imperative for Indian firms to develop proprietary products (products that do not infringe upon other patented product) in the new patent regime. The products can be chemically non-identical or new-patented product. Additionally multiple patented process will have to be developed making the product difficult to infringe upon others.

Patenting activity in pharmaceuticals is very high worldwide. For example in the ten-year period (1990-2000), almost Fifty-Three thousand patents were granted to this sector by the USPTO (United States Patent and Trademark Office). There has been doubling in the patents being granted from 1997 onwards with respect to the number of patents in 1990. In comparison Indian patenting activity in pharmaceuticals is insignificant. However, as Table 2 and Table 3 indicates, in the overall Indian patenting activity pharmaceutical was the dominant area in which patents were granted to Indian entities (NISTADS, 2005). This was true for both the USPTO and the IPO.

Table2
Patenting Activity in Major Sectors during Pre/Post WTO, and Current period by Indian entities in USPTO* (1990-2002)

Sectors	Pre-WTO 1990-94	Post- WTO 1995-98	Current Period1999- 2002	1990-2002 (% of total)
Pharmaceuticals	9	48	227	284 (42%)
Chemical	24	42	166	232 (35%)
Miscellaneous	8	15	42	65
Biotechnology**	0	7	46	53
Machinery	7	6	15	28
Instruments	-	5	13	18
Electronics	-	2	7	9
Transport	-	-	6	6
Electrical Equipment	-	-	1	1

Source: Indian Patenting Activity in International and Domestic Patent System: Contemporary Scenario (NISTADS, 2005)

*USPTO (United States Patents and Trademark Office). In this period, 669 patents were granted to Indian institutions.

** *patents in biotechnology were culled out from other sectors (mainly they were in pharmaceutical sector).*

Table 3
Patenting Activity in Major Sectors during Pre/Post WTO, and Current period by Indian entities in IPO* (1990-2002)

Sectors	Pre-WTO (90-94)	Post-WTO (95-98)	Current Period (99-02)	(1990-2002) (% of total)
Chemical	419	492	668	1579 (33%)
Pharmaceuticals	221	305	547	1073 (22%)
Miscellaneous	234	333	352	919 (19%)
Machinery	201	267	223	691 (14%)
Instruments	48	71	81	200 (4%)
Biotechnology	32	38	60	130 (3%)
Transport	38	41	43	122 (2%)
Electrical Equipment	39	30	30	99 (2%)
Electronics	15	17	42	74 (2%)

Source: Indian Patenting Activity in International and Domestic Patent System: Contemporary Scenario (NISTADS, 2005)

*IPO (Indian Patent Office). In this period, 4848 patents of Indian institutions were accepted by the patent office.

USPTO allows for product patents in pharmaceuticals, food and agro-chemical. Patents granted in pharmaceuticals, food and agro-chemicals by USPTO to Indian entities, were distinguished further in terms of protection they had obtained (process, product or both). Table 4 exhibits this distinction.

Table 4
Product/Process Patents in Pharmaceutical, Food & Beverages, and Agrochemicals (1990-2002)

Sector	Process	Product	Process & Product
Pharmaceuticals	133	73	80
Pesticides, Agrochemical products	9	4	11

Sector	Process	Product	Process & Product
Food & beverages	3	2	1

Source: Indian Patenting Activity in International and Domestic Patent System: Contemporary Scenario (NISTADS, 2005)

Above table shows that Indian firms have been able to obtain product patents in the three areas (pharmaceuticals, food and agro-chemicals) that were not allowed by the Indian Patent Act of 1970. This provides an indirect indication of the capability of Indian firms in undertaking innovation activity that can lead to product patents filing that the new Indian Patent Act (2005) allows. *However, this also includes patents granted to Incrementally Modified Drugs (IMD). These can be new formulation, new combinations of existing NCE (New molecular entity), and new salts and esters of existing NCEs. The Indian Patent Amendment Act (2005) does not allow patenting for IMD (also sometimes called as secondary patents).*

Mailbox' provision that allowed for product patent filing in pharmaceuticals in the Indian Patent Office during the transition period (in principle from 1999 to 31st December 2004) show the heightened activity of foreign companies. There are already around 5,000 product patent applications in the mailbox, which will now, to be taken up for examination. Most of these were filed by MNC's. This gives an indication of the monopolistic market that may emerge after 2005. Foreign firms however did not actively pursue EMR route during the transition period. The stringent conditions for granting EMRs may be responsible for this. The Indian Patent Office granted only three EMRs. These EMRs were Nadoxin (Nadifloxacin), anti-infective of Wockardt and Cialis (tadalafil, anti-impotency drug of Eli Lilly. An EMR granted to Glivec (for treatment of cancer) of Novartis has been challenged and is under litigation (ICAR, 2002).

Examination of Indian patenting activity in PCT revealed that Indian organisations were beginning to take advantage of PCT route for filing international patents. At the same time foreign organisations were also observed to be shifting to this route for patent filing in India. India is the leading country among the developing countries in terms of patent filing through PCT. One notable feature of the WIPO (World Intellectual Property Organisations) data on PCT patent filings by Indian firms is the dominant presence of pharmaceutical and biotechnology firms that had taken this route for international filing. Except one, all the Indian firms that filed for five or more patents under PCT during 1999-02 was either a pharma or a biotech company (NISTADS Report, 2005). Table 5 shows patents filed by Indian entities using PCT route.

Table 5
Indian Patenting Activity in the PCT: 1999-2002

Year	No. of Patents	Assignee
1999	7	Individuals-4, Dr. Reddy's Research Foundation, Nile Limited, Varma Trafag Limited
2000	54	Dr. Reddy's Research Foundation-7, Dabur

		Research Foundation-2, Lakshmi Machine Works Limited-2,
2001	122	CSIR-12, Biocon India Limited-5, Panacea Biotec Limited-5, Cipla Ltd.-3, Dabur Research Foundation-3, Nagarjuna Holdings Private Limited-3,
2002	216	CSIR-66, Carborundum Universal Limited-7, Biocon India Limited-6, Orchid Chemicals And Pharmaceuticals Limited-6, Dr. Reddy's Research Foundation-4, Aurobindo Pharma Limited-3, Blue Cross Laboratories Limited-3, Lupin Laboratories Limited-3, Neuland Laboratories Limited-3,

Source: Indian Patenting Activity in International and Domestic Patent System: Contemporary Scenario (NISTADS, 2005)

India's international patenting activity is mainly in the US patent office. Earlier study has shown that there are 8 organisations that account for almost 80% of the patenting in US. Organisations that had prolific patenting activity in US patent office are again the major players in using patent filing through PCT. However, there are also some new entrants such as Sahajanand Biotech Private Limited, Tejas Networks India Pvt. Ltd, Blue Cross Laboratories Limited, Neuland Laboratories Limited. Aggregate activity in the overall period 1999-2002 is depicted in Table 6.

Table 6
Aggregate Activity in the PCT:1999-02

Total Patents	Assignee
399	CSIR-78, Dr. Reddy's Research Foundation-12, Biocon India Limited-11, Carborundum Universal Limited-7, Orchid Chemicals And Pharmaceuticals Limited-6, Panacea Biotec Limited-5, Dabur Research Foundation-5, Aurobindo Pharma Limited-3, Blue Cross Laboratories Limited-3, Lupin Laboratories Limited-3, Neuland Laboratories Limited-3, Cipla Ltd.-3, Nagarjuna Holdings Private Limited-3, Lakshmi Machine Works Limited-2, Nile Limited-1, Varma Trafag Limited -1

Source: Indian Patenting Activity in International and Domestic Patent System: Contemporary Scenario (NISTADS, 2005)

The above Tables 5 and 6 underscore the importance of India joining PCT. Organisations are taking advantage of this new route to file patents in multiple countries. CSIR is among the top three organisations in the developing world in filing patents through the PCT route. Foreign firms are also increasingly using this route for patent filing in India. Around 17833 applications have entered national phase from 1998 onwards (i.e. in the Indian patent office) through this route in India and are being examined.

Conclusions

The study brings out the major changes in the Indian Patent Act that were required to meet India's obligations to international agreements and treaties. The new patent act

(Patents Amendment Act 2005) has created a strong patent system in India. Overall the present act has increased the scope of patenting and provides stringent safeguards to the plaintiff i.e. patentee. Defendant has to prove that he has not infringed upon a process patent and this would have far reaching consequence. The new act would play a major role in creating a technology driven market. Firms would increasingly try to create monopoly based on their patented technology. Indian firms primarily those that are in high technology areas would face increasing pressure, as patented products would enter the market.

The pharmaceutical sector would face the maximum impact. On one hand newer drugs would enter the market, as earlier due to weak patent act foreign drug firms were reluctant to bring their high value drugs in India. On the other hand drug prices are expected to rise as generic drugs for drugs patented post 1995 would have to be withdrawn. A patented drug provides the firm holding the said patent on it a monopoly and thus it can demand a very high price for the drug. It would be difficult for Indian firms to control the market. Mailbox' filing already shows the intention of foreign firms to bring in patented products in pharmaceuticals in the Indian market.

One of the ways for Indian firms would be to increase their own R&D and innovation activity to create patented products in pharmaceuticals. Patent trends show Indian firms are trying to become innovative firms. Product patents in pharmaceuticals were also obtained in the USPTO. However, it should be noted that through incremental modification of their products, changing dosage intensity and including minor features such as inert ingredients and the form, colour etc. it is possible to get product patents in pharmaceuticals in the USPTO. This may not be possible in the IPO, as patents would be granted only for any 'new entity' involving one or more inventive steps.

Indian firms can also gain advantage through compulsory license. The amendment now gives the option of exporting drugs to a country, which makes a request for a generic drug. The only condition would be that the country where it can be exported should have no or insufficient manufacturing facility (this condition is imposed by TRIPS agreement).

Broadly our examination shows that major changes made in the Indian Patent Act would have significant impact. The market would increasingly become technology driven. Indian firms would have to compete in the new scenario. The new act provides little scope for firms to infringe upon products that are protected by patents. This act may spur Indian firms to invest more in R&D and translate it to patented product. The significant impact of this act would be in pharmaceutical sector. Indian patenting trends in this sector provides encouraging picture.

References

Watal, J. (2000). *Patent protection and exclusive marketing rights In: Intellectual Property Rights in the WTO and developing countries*. Oxford. University Press.

Agreement on Trade Related Aspects of Intellectual Property Rights. Annex 1C. World Trade Organisation.

Gopakumar, K.M.; Amin, T (2005). Patents (Amendment) bill 2005: A critique. *Economic and Political Weekly*, April 9.

The Patents (Amendment) Act 1999. Gazette of India, Part II-Section 1.

The Patents (Amendment) Act 2002. Gazette of India, Part II-Section 1.

The Patents (Amendment) Act 2005. Gazette of India, Part II-Section 1.

Ganguli, P. (2001). *Intellectual property rights: Unleashing the knowledge economy*. Tata McGraw-Hill Publishing Company Limited: New Delhi.

Bhattacharya, S. (2004). Implications for Indian pharmaceutical sector in the new World Trade Organisation (WTO) regime. *Medicinal Chemistry Research*, 13: 6/7, 369-389.

The Indian Pharmaceutical Industry (2002). *Industry Watch Series*. ICRA, 33-35.

Chouduri, Sudip (2005). *The WTO and India's Pharmaceutical Industry: Patent protection, TRIPS, and Developing Countries*. Oxford University Press

Bhattacharya, Sujit (Principal author), Garg, K.C., Sharma, S.C and Bharvi, D. (2005). *Indian Patenting Activity in International and Domestic Patent System: Contemporary Scenario*. Study by National Institute of Science, Technology and Development Studies for the Office of the Principal Scientific Advisor to the Government of India. ISBN 81-85121-34-6.