

# Factor Affecting Innovation Performance of Manufacturing Firms: Case Evidences

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## ABSTRACT

In the knowledge-based economy, creation, management, and dissemination of knowledge in an organized way will certainly enhance the innovative practices of companies in any country. This article has tried to explore the impact of various factors on innovation. Following a qualitative research methodology, the article has come up with 8 propositions and tried to build up the arguments in the real company's context in India by 3 case studies. The research has been able to provide necessary evidence of particular companies and tried to build arguments for the suggested propositions. The findings of the research article will certainly help academicians and practitioners to emphasize the intellectual property related laws of any country to enhance the innovation quotient of any country.

## KEYWORDS

Case Study, Innovation, Intellectual Property Rights, Manufacturing

## INTRODUCTION

In today's business landscape, innovation is being increasingly identified as a key driver for creating competitive advantage. According to Banerjee (2015) "Innovation is gaining prominence in all kinds of economic activity around the world. Not only advanced economies but also developing nations are finding that innovation is one of the main drivers of economic growth. This renewed understanding of the significance of innovation is having a growing impact on the course of policy formulation in many countries". Globally innovation has become a priority, innovating companies are now able to make many fold profits with their products and services. India has also awakened to the need of innovation post liberalization which can be attributed to exposure of global market forces. As a result of this, patentable innovations are on the rise in India.

The purpose of patents according to Olwan (2013) is to provide an inventor exclusive control over his invention for a certain period of time to help him derive an income from his invention. The two theories of patents have been discussed by Denicolo and Franzoni (2003), the reward theory says that the patent system is for rewarding innovation and support R&D, and the contract theory, says the purpose of patent is for dissemination of new knowledge (Denicolo

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& Franzoni 2003). According to the economic theory of patents for invention (Arnold Plant 1934), patents give an inventor the control for definite period to derive an income from it. The ultimate aim of intellectual property rights is to encourage invention, which has a potential of economic and technological development and for technological advances. In absence of this intervention, there would probably remain little incentive to innovate. In a report, PWC (2013) found that clear correlation exists between innovation and business success in terms of increase in revenues, especially in manufacturing companies. The report highlighted that over a period of 3 years there was a 38% increase in revenues of innovative companies, on the other hand least innovative companies showed a moderate growth of 10% over a similar time frame. Furthermore, in the developed market economies patent and trademark, related laws provide barriers to the companies to imitate and launch similar products or services and hence promotes innovation and facilitate the intellectual property rights (Helpman, 1993).

The problem being posed in India is that we have been seeing cases regarding patenting issues since we became Trade-Related Aspects of Intellectual Property Rights (TRIPS) compliant and adopted the new product patent regime. We have seen litigation regarding compulsory licensing in terms of Bayer v/s Natco Pharma. There are evidences regarding rejection of patent in India on issues as ever greening of patent, by means of article 3(d) in Indian Patent Act elucidated in case of Novartis V/s Union of India. Compulsory licensing issue and the patentability issues of known substance (article 3d) has resulted in eroding the confidence of multinational drug makers to enter Indian manufacturing stream. We have also recently seen a string of litigation between mobile phone manufacturers and Ericsson during 2013-2014. Some of the litigations are: Ericsson vs Micromax; Ericsson vs. Intex; Ericsson vs. Gionee; Ericsson vs. Xiaomi on infringement of its Adaptive Multi-Rate (AMR) patents (IN213723, IN203034, IN203686, IN203036 and IN234157) on which Ericsson had sued low cost mobile phone manufacturers in India. The suits that Ericsson filed against a few low-cost mobile manufacturers were for damages for the supposed infringement of eight of the SEPs owned by Ericsson. Also, with all this in background the competition commission of India has now alleged that Ericsson has violated its fair, reasonable, and non-discriminatory (FRAND) terms commitment by fixing excessive royalty rates and also that it is using non-disclosure agreements to get away with it. There are growing concerns on the issue of FRAND negotiations and royalty decisions between the SEP holder and the manufacturer.

Such lengthy litigation process not only puts a burden of litigation expenses which is exorbitant on the local manufacturer but sometimes, as in case of smartphone industry, also puts a pressure for the payment of higher royalty to the patentee. The present study will explore these aspects of business in terms of intellectual property rights as the factors affecting innovation relates their impact on the manufacturing industry in Indian context.

## **BACKGROUND**

### **Indian IP Regulation and Enforcement**

Tiwari et al. (2011) reviewed the aspects of Intellectual Property Rights in great detail, with their protection criteria available under Indian Patent Act. Furthermore, India along with most developing economies has weak Intellectual Property (IP) enforcement (Kumar, 2003). It fails to provide relief from the imitators, thereby becoming hurdle to trade, investment in research and development and also for the all-round growth of the country's economy. Dutta (2017) feels that the weak enforcement of IP rights in India is the causal factor for IP right holders' inability to enjoy their IP assets fully. Puri and Varma (2005) reviewed Indian Patent Act 2005 and found that the standards (TRIPS) were defined with reference to its domestic conditions. The real challenge according to Puri and Varma (2005) lies with future amendment.

## LITERATURE REVIEW

According to a report by Kamphausen (2015) in the National Bureau of Asian Research, many sectors in India are facing the challenges of IP protection and enforcement. Weak IP law enforcement in India is acting as a deterrent to innovation in Indian industry (Kumar, 2003). According to Cockburn (WIPO, 2009) in countries where the generic competition is strong, the processes for challenging or enforcing patents are extremely important. On the other hand, stronger IP protection is linked to technology transfer in developing world. Yang and Maskus (2008) find that the consequence of greater protection of IPR in a developing country would be increased technology transfer through licensing. Lee et al. (2006) also find that improvements in IPR protection would lead to increase in technology transfer within multinational companies. According to Prabhu et al. (2012), the society gets four benefits from a strong IP regulation: innovation by private agent, use of new knowledge, greater dissemination of new knowledge and stimulation of innovation in other enterprises (Gollin, 2009). Hence, we come up with our first proposition that:

**Proposition 1:** Indian IP regulation and enforcement is not strong and has negative impact on innovation in Indian manufacturing industry.

### Patents (Pharma/SEPS etc.)

The investment in R&D for a Pharmaceutical company can be as high as US \$802 million (DiMassi et al., 2003). Global Alliance for Tuberculosis Drug Development (2003) has estimated the total cost for a new tuberculosis drug development, taking into account the cost of failure, somewhere between US\$115 million to US\$240 million. The patents of the drug developed from these R&D efforts are also very high. More than 95% of essential drugs on WHO list are not patent protected. However, WHO acknowledges that patent protection encourages innovation in Pharmaceutical sector. It is similar in Information and Communication technology (ICT) sector.

Various studies (Blind et al., 2006; Blind and Thumm, 2004) indicate that growing technical sophistication of standards is due to more aggressive patenting strategies that the firms adopt to seek better income from their standard essential patents. Empirical evidence from Rysman and Simcoe (2008) undeniably suggests that Standard Essential Patents (SEP) are more important than other patents and firms which have a large share of essential patents have a strong market position. Beckers et al. (2005) and Pohlmann et al. (2014) also state that SEPs may directly increase a company's profits. SEP may give market power to the holder of the technology over technology manufacturers who would need the technology input so as to make their products compatible with each other (Gingsburg et al., 2014). The SEP owner enjoys the monopoly power gained due to 'locked in' network over entire network of manufacturers. Hence, we propose that:

**Proposition 2:** Patents in Pharmaceutical sectors and inclusion of patents in SEP in ICT will provide incentive for innovation in Indian manufacturing industry.

### Infringement Suits/Litigation

Koren and Wong-Ervin (2014) find investigations and litigation involving SEPs have begun to emerge across the globe. Koren and Wong-Ervin (2014) further find that in US and Europe the litigation is primarily focused on injunction relief on FRAND-encumbered SEPs. In China and India, most important issues revolve around the royalty rates and non-disclosure agreements, and litigation revolves around these issues. According to Cockburn (WIPO, 2009) litigations in infringement are important factors which influence the return on R&D in pharmaceutical sector. The court decision on litigation also has serious impact on the company's strategy to operate in the country or not (Anand et al., 2013).

The fact cannot be denied that the company which owns the patent, whether pharma or standard, is in dominant position. This has also been endorsed by Pohlmann and Blind (2014) but the standard adopter has a right to get license on the FRAND terms and these issues become point of defence for infringements leading to litigation. A series of infringement suits were filed in India by Ericsson against Micromax, Intex, Gionee, Xiomi, Lava, etc., for infringement of SEPs relating to technologies of GSM, AMR and EDGE. Most of these cases are still under litigation with some interim relief to Ericsson on royalty payments by the infringing companies. However, all this infringements and litigation is diverting attention from innovation in the manufacturing sector. The decisions of courts in favor of generic companies for issues of compulsory license or FRAND terms are proving detrimental for innovation in Indian manufacturing companies. As it is easy for them to get license on nominal rates, hence they don't want to invest in in-house R&D to develop proprietary technology. Hence, we propose that:

**Proposition 3:** The litigation regarding patenting (protection / infringement) is leading to reduction in innovation in Indian manufacturing industry.

### **Competition/Antitrust Regulation**

Competition Commission of India was established in 2009, under the Competition Act 2002 which provided for scraping of restrictive trade practices and monopolies. The Commission was established with an aim of promotion of fair play in market and a function to keep an eye on anti-competitive practices of companies which may distort or stifle competition. However, CCI has not been very effective in implementing any of the aims with which it was established. Chaudhary (2015) talks about the competition laws of India in context of standards. The non-disclosure of essential IP by enterprises can give market power to firms by unfair means (Lemley, 2002). Such abuse of standard setting process amounts to anti-competitive behavior. To deal with anti-competitive activities effectively, competition authority can become an institutional member of Global ICT Standardization Forum for India (GISFI). It will ensure precompetitive standard setting in India (Chaudhary, 2015). In the present setup, the CCI is not able to regulate the antitrust issues which is having a negative impact on investment in Research and Development (R&D) and thus on the innovation in Indian Manufacturing sector. Hence, we propose that:

**Proposition 4:** The competition/antitrust regulations are not able to resolve issues regarding licensing, which is having a negative effect on innovation in Indian manufacturing industry.

### **Licensing (Compulsory/FRAND) or Royalty Rates**

As stated by Andrew Updegrave (2013), the definition of FRAND is always word for word the same. Investigations and litigation involving SEPs have begun to emerge across the globe (Koren and Wong, 2014). FRAND terms are usually followed by SSO while declaring SEP so that the SEP holder will not try to make unfair gains just because of holding a patent which has been accepted as part of SEP (Rysman and Simcoe, 2008). Standard setting is understood as part of a joint innovation effort combining competition and collaboration (Besen and Farrell, 1994). Case studies on recent standardization projects (Bekkers, 2001; DeLacey et al., 2006) discuss into details the strategies induced by the inclusion of essential patents. Lemley (2002) provides a detailed overview of the rules on essential patents in various SSOs. Accordingly, one school of thought is that a FRAND declaration constitutes acceptance of a third-party beneficiary contract between the standards, essential patentee and the standardization organization, so that when a user of a technical standard indicates its intention to request the right to use the standards-essential patent under FRAND terms, a license agreement is automatically concluded between the user and the patentee (Lemley 2002). In the United States, a 2012 judgment held that a FRAND declaration constituted a third-party beneficiary contract

(Microsoft Corp v Motorola Inc., 864 F Supp 2d 1023, WD Washington 2012). Another opinion is that a FRAND declaration is only a manifestation of the intention of the standards-essential patentee, and no contract between the user and the patentee is concluded unless some other form of agreement is executed between them.

The introduction of a compulsory licensing in Canada during 1970s resulted in a remarkable fall in the amount of pharmaceutical research in Canada. This trend reversed and a remarkable increase in R&D was observed when it was scrapped in 1990s (Padznerka, 1999). In India also, compulsory licensing is having a negative impact on innovation in manufacturing sector. Hence, we propose that:

**Proposition 5:** The licensing terms compulsory/FRAND are proving to be detrimental for innovation in Indian manufacturing companies.

### **Internal R&D Capacity of Manufacturing Companies**

World Intellectual Property Organisation (WIPO) comes out with Global Innovation Index (GII) every year. In the recent report (2015) which includes 141 economies from all over the world and use 79 indicators (WIPO 2015), India has fallen to 81<sup>st</sup> position in 2015 from 76<sup>th</sup> in 2014. In 2013 it was at 66<sup>th</sup> position, 64<sup>th</sup> in 2012 and 62<sup>nd</sup> rank in 2011. The trend is downhill. In India, annual science and technology expenditure is around 0.9% of GDP (Kumar 2014). R&D expenditure in India remains at about 0.9% of GDP — compared to some of the other BRICS countries with 1.12% in Russia (down from 1.25% in 2009), 1.25% in Brazil and 1.84% in China. In India, the declining importance of R&D activity is a matter of grave concern where knowledge acquisition is mostly through import of technology by local enterprises (Kumar and Agarwal, 2000). One of the reasons for this may be that the imported technology is more attractive over the locally-developed technologies as these technologies have been proven and therefore the uncertainty of availability of financing from suppliers is less. Also, there is an added advantage related to use of known brands and trademarks. Such association gives incentive of market power (Kumar, 1990). Katrak (1985), Kumar (1987), Deolalikar and Evenson (1989), Siddharthan (1988) and Aggarwal (2000) among others have also reported that technology imports in India takes place more frequently and are followed up by adaptation and absorption of imported technology. Hence, we propose that:

**Proposition 6:** The internal R&D capacity of Indian manufacturing sector is low which is having a detrimental effect on Innovation in Indian manufacturing sector.

### **Technology Transfer (Licensing, Joint Ventures, FDI)**

In the manufacturing setup especially in the R&D intensive sectors, where IP protection is an important factor for return on investment on the R&D technology transfer happens either through licensing, joint venture or FDI. An example of this is the non-exclusive licensing agreement that Gilead Sciences Inc. had with seven India based generic companies for “Sofosbuvir (Sovaldi™) for distribution in 91 developing countries. (Gilead press release 2014). Joint Ventures are also a source of technology transfer. An example to this effect in Indian context may be quoted from Automobile manufacturing sector - of Renault and Mahindra and Mahindra, Hero and Honda and so on. However joint ventures are very fragile ecosystem and riddled with difficulties. Dhir and Mittal (2013) have carried out some studies on characteristics and asymmetric motives of partners in Joint ventures of developing nation (Dhir et al, 2019, Parmeswar et al, 2017). There are three sources to achieve technological advancement: technology transfer, domestic R&D, and foreign direct investment (Hu et al. (2003). Yang and Maskus (2008) find that greater Intellectual Property Rights (IPR) protection in a developing country would result in increased technology transfer through licensing. Lee et al. (2006) find that improvements in IPR result in real increase in technology transfer within multinational companies. Increase in IP will lead to increase in technology transfer (Lee et al., 2004). Hence, we propose that:

**Proposition 7:** An increase in technology transfer in the form of Licensing, JV's or FDI can improve innovation in Indian manufacturing sector.

### **Indian Representation in Policy-Making Bodies (SSO)**

Many Standard Setting Organizations (SSOs) have subcommittees for a particular set of standards also. The private organizations formed by congregating dozens of member companies form SSO (ETSI, IEEE etc.) which agree on formation and/or adoption of standard often supported by public bodies (Lemley 2002). The standards thus formed are the most significant as they raise the most important issues in the industry. Most companies would like to participate in standard setting process, as they get to discuss technical merits of standard and get to include their patents in standards, as even if the royalty rate per unit is miniscule – the number of units sold decide on the profitability – which could be huge – inclusive of all licensees.

India does not have an umbrella body focusing on telecom standards. All other countries with sizeable telecom market have their own national standards development organisations (SDO) and participate in the global standards process. However, there is no common interface to represent context specific industry and its specific requirements in global standards. In India, most of the technological innovations have been imported instead of developing them. The need of the hour is to impel IPR and promote standards participation in order to catalyse technology development and manufacturing in India. The government needs to immediately form an Indian telecom SDO with active participation from all stakeholders. The Bureau of Indian Standards (BIS) is India's national SSO. In the ICT (Information and Communications Technologies) sector the Telecom Engineering Centre (TEC) is the only formally recognized telecom standards/specification/type approval body in India. Global ICT Standardization Forum for India (GISFI) and Telecommunications Standards Development Society, India (TSDSI) and Development Organization of Standards for Telecommunications in India (DOSTI) are private SSOs in the Indian ICT sector. Also, competition authority in India can become an institutional member of GISFI. It will ensure precompetitive standard setting in India (Chaudhary, 2015). Hence, we propose that:

**Proposition 8:** An Indian representation in Policy making bodies (SSO) will lead to increase in innovation in Indian manufacturing sector.

### **Conceptual Framework**

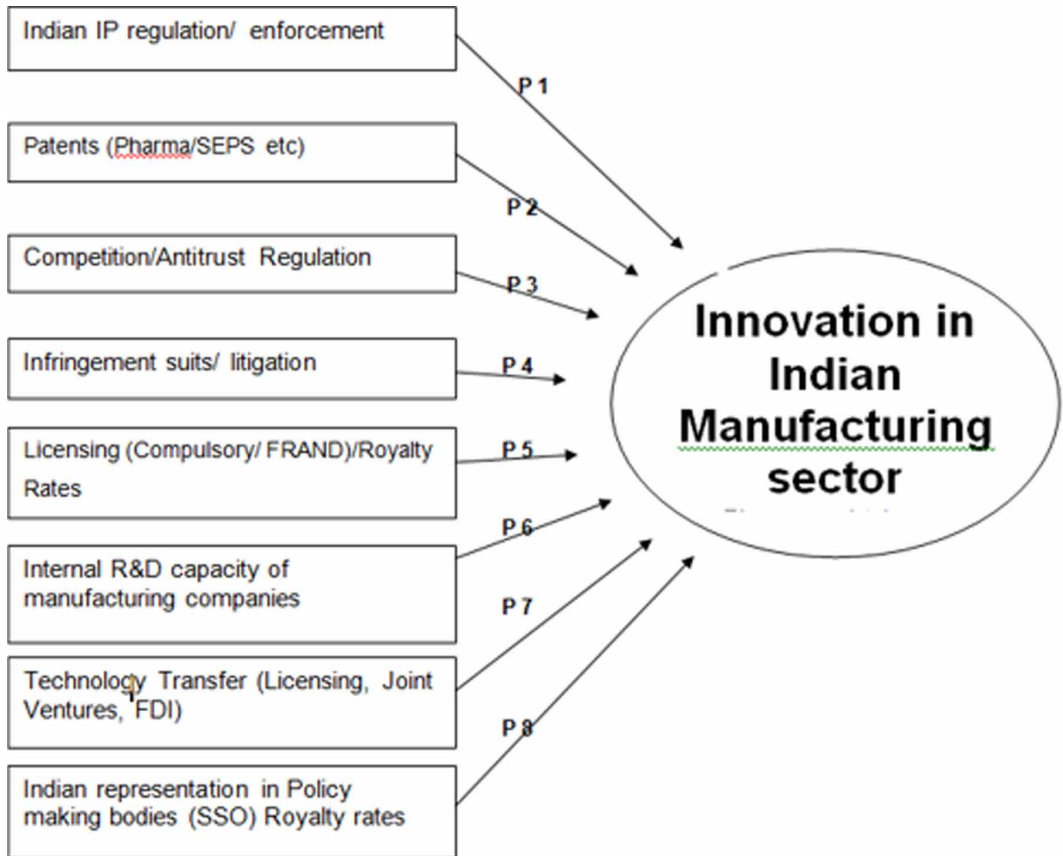
Figure 1 gives the conceptual framework developed.

### **METHODOLOGY**

We have used a qualitative case study method for elucidating on the topic at hand as the topic is very contemporary and the issue at hand is very complex in nature. Qualitative case study method provides tools for researchers to study complex phenomena within their contexts (Baxter and Jack, 2008). Case study method, according to Rowley (2002), has proved to be useful for preliminary exploratory stage of a research project, as a basis for the development of the more structured tool that are necessary in surveys and experiments (Eisenhardt, 1989).

This methodology is being adopted in the present study as the cases taken are real life situations, with many variables and the boundaries between the phenomenon and its context not being very distinct. This methodology is adopted from another perspective; which is for the purpose of generalising the theoretical proposition as we are not having any statistical data on the current research topic. We shall be reporting the evidence in a systematic manner so as to derive at the proposition being tested against the evidence available in the cases discussed. The cases which are discussed are all available in public domain.

Figure 1. Conceptual framework of factors affecting Innovation in Indian manufacturing industry with special reference to Pharma and Telecom Industry



## RESULTS AND ANALYSIS

Three cases which throw light on different aspects of issues related to patenting, patent infringement and patent licensing in India including compulsory licensing are chosen for the present context. Two of the cases thus taken are from Pharma industry and one from ICT industry. We will test our propositions based on these cases which are described in very brief.

- Case 1:** Ericsson had gone in for infringement regarding litigation for its patented technology which was part of SEPs between 2011 and 2016. Some of the infringement suits are still in progress in the court of law regarding the FRAND issues.
- Case 2:** Novartis had got entangled in a legal battle against Union of India for its Patent claim in Indian Patent Office for its cancer drug Glivec. This patent was rejected by the IPO under section 3 (d) of Indian Patent Act.
- Case 3:** A compulsory license for Bayer's cancer-treatment drug 'Nexavar' (sold at Rs 2.8 Lakhs) was given to Natco pharma to manufacture and sell at a price of Rs 8800/- with a royalty of 6% to be paid to Bayer. The grounds of compulsory license as per Indian patent act were (a) reasonable requirements of the public with respect to the patented invention have not been satisfied; or (b) it is not available to the public at a reasonably affordable price; and (c) the patent is not being worked.

## Ericsson v/s Micromax Informatics Limited

In March 2013, Ericsson filed a case against Micromax Informatics Limited, claiming that Micromax had infringed eight of its SEPs on AMR, 3G and EDGE technologies, and was selling mobile devices compliant with these standards and that Micromax had avoided obtaining licenses FRAND terms from Ericsson. It had also sought Rs 100 crores in damages and asked Micromax to provide its sales accounts of mobile devices with the said technology for years 2008-2012.

Delhi High Court granted interim relief to Ericsson and directed Micromax to make interim royalty payments. Ericsson was also allowed to inspect every consignment for Micromax that arrived at customs with an instruction to reach FRAND licensing terms. Micromax filed a complaint before the Competition Commission of India (CCI) in November 2013 claiming that Ericsson had abused its dominant position in the market by imposing exorbitant royalty rates for licensing its GSM technology under FRAND terms. Micromax's claim was found to be valid by CCI and an investigation was ordered. Ericsson went to Delhi High Court questioning the CCI authority. The Court directed that CCI should not interfere with Ericsson's negotiations with third parties and subsequently fixed new royalty rates as interim arrangements pending trial of the suit.

With reference to the case mentioned above, Ericsson v/s Micromax Informatics Limited, we find that though IP regulation is not the issue in this case but enforcement is weak in India, since Ericsson was given relief only when it approached Delhi high court for the infringement of eight of its SEPs on AMR, 3G and EDGE technologies by Micromax Informatics Limited. Delhi High Court granted interim relief to Ericsson and directed Micromax to make interim royalty payments. Also, Ericsson has a policy of signing non-disclosure agreements from different licensees while deciding on royalty rates being charged. It is thus able to charge differently from different licensees as there is no regulation against signing NDA in India.

Thus, the case elucidates that IP regulation and enforcement in India is not at par with the standards in developed world. Also as discussed earlier, when the IP regulation is weak there is no incentive to innovate. Thus, the proposition that Indian IP regulation and enforcement is not strong and has negative impact on innovation in Indian manufacturing industry holds true and we support proposition 1.

It is evident from the case that Ericsson gained dominance in market because of its patents which are included in SEP. Thus, the proposition that patents in Pharmaceutical sectors and inclusion of patents in SEP in ICT will provide incentive for innovation in Indian manufacturing industry holds good and we support proposition 2.

It is evident from the case that Ericsson had gone in for filing infringement suits not only against Micromax but against all low-cost manufacturers in Indian subcontinent and had not made agreements on FRAND rates before the Indian manufacturers started supplying the handset. One reason for the same may be to attain higher royalty than the FRAND terms. This is resulting in Indian Manufacturing sector spending more in royalty payments and also in fighting infringement suits, effecting their profitability and subsequently ability to innovate. Thus, the proposition 3 that the litigation regarding patenting (protection/infringement) is leading to reduction in innovation in Indian manufacturing industry holds good.

With reference to the case mentioned above, Ericsson v/s Micromax Informatics Limited, it was observed that though Micromax filed a complaint before the Competition Commission of India (CCI) against Ericsson for abusing its dominant position by imposing exorbitant royalty rates for licensing its GSM technology under FRAND terms and CCI ordered an enquiry against Ericsson, Delhi High Court gave a ruling that CCI should not interfere with Ericsson's negotiations with third parties and decided the interim royalty as a measure of relief to Ericsson. The proposition 4 that the competition/antitrust regulation are not able to resolve issues regarding licensing, which is having a negative effect on innovation in manufacturing industry in India thus holds true.

It is evident from the case that Ericsson had not made agreements on FRAND rates before the Indian manufacturers started supplying the handset. The reason for the same may be to attain higher



royalty then the FRAND terms and that the company is signing non-disclosure agreements from different licensees while deciding on royalty rates; thus being able to charge differently from different licensees. The case has unfolded the fact that Ericsson had failed to sign agreements on FRAND rates and had chosen to file infringement suits not only against Micromax but also against all low-cost manufacturers. One reason for the same may be to attain higher royalty than the FRAND terms. Thus, the proposition 5 that the compulsory licensing terms/FRAND are proving to be detrimental for innovation in Indian Manufacturing companies, holds good.

Though the case does not directly link to the R&D capacity of Indian Manufacturing sector, however with the oblique reference that the case provides about the fact that Micromax was importing the goods which infringed several SEPs on AMR, 3G and EDGE technologies owned by Ericsson, it is clear that Indian ICT manufacturing firms do not have internal R&D capacity. The proposition 6 that the internal R&D capacity of Indian manufacturing sector is low which has a detrimental effect on innovation in Indian manufacturing sector holds good.

The case does not directly link to technology transfer, the low R&D capacity of Indian Manufacturing sector and as a result the need for the sector to depend on technology transfer. The technology transfer in this case is happening with licensing but this does not affect the innovation in the Indian manufacturing sector. Thus, the proposition 7 that an increase in technology transfer in form of Licensing, JV's or FDI can improve innovation in Indian manufacturing sector does not hold true.

Ericsson is a large MNC and being part of the most SSOs, it is participating in standard development and SEP declaration also. This puts Ericsson in a position of advantage vis-à-vis development and adoption of its patents in SEP. Thus, the proposition 8 that Indian representation in Policy making bodies (SSO) will lead to increase in innovation in the Indian manufacturing sector holds good.

### **Novartis v/s Union of India**

This case was a litigation suit which was fought up to the Supreme Court of India, between Novartis and the Union of India. The case started when Novartis applied for a patent in 2005 (under new patent regime of product patent) for its blood cancer drug Glivec, and was denied patent in 2007 by the Indian Patent Office under Section 3(d) which intended to prevent incremental/trivial changes in existing compounds leading to ever greening of patents. The appeal filed by Novartis in Intellectual Property Appellate Board (IPAB), India was rejected as the pricing of the drug made it unaffordable to Indian patients. However, the IPAB did say that the process had novelty. Novartis subsequently approached the Supreme Court of India challenging the legality of Section 3(d) of Indian Patents Act. The article 3(d) of Indian Patent Act provides that mere discovery of a new form of a known substance without any enhancement of the known efficacy of that substance, or mere discovery of new property, or new use for a known substance, or of the mere use of a known process etc. are not patentable.

The judgement of Supreme Court of India on the grounds of modification of known drug wherein no enhancement in efficacy of the said drug was demonstrated, was made on sound foundation under the provision of Indian Patent Act. Also, as the patent was for a drug so the increase in efficacy had to be in terms of "therapeutic efficacy", as the use of the drug was towards treatment of disease. It is also to be kept in mind that while the patent for Glivec was accepted in 40 different patent jurisdictions, it is not necessary to make it acceptable in India also. It has to stand the test of Indian Patent Act to be granted a patent in India.

This decision however goes against incremental innovation and adversely impacts innovation on the whole, especially in Pharma industry where de novo discovery of new chemical entities is very few and most new drugs come under the ambit of derivatives. As a result of this, profitability is also decreasing and creating disincentive among pharma manufacturers for improvement of drugs. While this is true for MNC, the clause 3(d) also holds good for Indian Pharma manufacturers - with the absence of patent protection for incremental improvements, there is no motivation for Indian manufacturers to invest in R&D.

Incidentally, US Patent Act has a similar clause of “threshold limit” which checks patenting on frivolous ground and eliminates repetitive patenting. A similar judgement was given by US Federal Court in the matter of Appeals in Pfizer vs Apotex case in 2007. The court had agreed with Apotex that Pfizer’s patent on the compound Besylate (a salt form of amlodipine) lacked the “unexpected superior results” from the base compound (amlodipine), and hence could not be patented. (Pfizer Inc. v. Apotex Inc. 2007 United States Court of Appeals, Federal Circuit).

With reference to the case mentioned above, Novartis v/s Union of India, it can be safely concluded that IP regulation and enforcement in India is not at par with the standards adopted by the developed world. While we do say so, the fact that it cannot be called weak by any standards adopted also holds true. The enforcement problem does appear at certain instances and there are cases of a delay in judgement due to long drawn judicial matters. The IP regulation in fact appears to be more stringent as can be seen from the section 3(d) of Indian Patent Act. The proposition 1 that the Indian IP regulation and enforcement is not strong and has negative impact on innovation in Indian manufacturing industry does not hold good as the regulation in India is stronger than in US and EU vis-a-vis article 3(d) of Indian Patent act. However, the judgement in the case of Novartis v/s Union of India is on lines of similar judgement in US in case of Pfizer v/s Apotex (2007).

The case deals with high commercial value patent in Pharmaceutical sector which would have given company competitive advantage in Indian markets also had it been granted in India. Novartis still has been able to enforce its patents across 40 countries giving the company market power, providing incentive to innovate. Thus the proposition 2 that Patents in Pharmaceutical sectors and inclusion of patents in SEP in ICT will provide incentive for innovation in Indian manufacturing industry hold good in this case.

The case shows direct linkages that the litigation process consumes the profitability of a new product launched on the basis of Patented technology. It may also be kept in mind that lack of patent protection for incremental improvements is resulting in lack of incentive for Indian manufacturers to invest in R&D. Thus the proposition 3 that the litigation regarding patenting (protection / infringement) is leading to reduction in Innovation in Indian manufacturing industry stands good.

With reference to the case mentioned above Novartis v/s Union of India, it is can be safely concluded that, as the Competition Commission of India was not referred to in this case and its role never was identified. The proposition 4 that Competition / antitrust regulation are not able to resolve issues regarding licensing, which is having a negative effect on Innovation in manufacturing industry in India does not hold good vis-a-vis case facts of the case being discussed.

The case does not directly link to the licensing terms followed by the Patentee and that the companies are charging differently from different licensees. The case also does not have any links to Royalty rates for SEP in ICT sector or in Pharma sector and for that matter does not talk about any royalty issues. Thus, the proposition 5 that licensing terms compulsory / FRAND are proving to be detrimental for innovation in Indian Manufacturing companies is not being proved with reference to the case.

Though the case does not directly links to the R&D capacity of Indian Manufacturing sector, however with the oblique reference that in the case Novartis v/s Union of India provides reference to the Indian Generic sector and that Natco Pharma had launched a generic product called “Veenat” at the fraction of the price of Glivec in India. However, Veenat was a generic product and not an original patented formulation. It is therefore clear that lack of patent protection for incremental improvements is resulting in lack of incentive for Pharma manufacturers to invest in R&D and that is why Indian firms have relatively low internal R&D capacity. The proposition 6 that the internal R&D capacity of Indian manufacturing sector is low which is having a detrimental effect on Innovation in Indian manufacturing sector holds true.

The case does not directly link to the dependence of the Indian Manufacturing sector, on technology transfer. However, we see that the Indian companies largely depend on technology transfer.

Thus, the proposition 7 that the increase in technology transfer in form of Licensing, JV's or FDI can improve innovation in Indian manufacturing sector holds true.

This case covers the lengthy litigation process which Novartis was able to take up due to its strong financial backing, as it is a large MNC conglomerate. The company was able to secure patent protection in 40 countries for its Glivec drug, however in spite of its superior market position it was not able to get a patent for its drug Glivec in India. The case however does not talk about policy level issues. Thus the proposition 8 that the Indian representation in Policy making bodies (SSO) will lead to increase in innovation in Indian manufacturing sector does not hold good.

### **Natco Pharma Ltd v/s Bayer AG's (Compulsory Licensing of "Sorafenib" Cancer Drug)**

Natco Pharma Ltd had applied for Compulsory License for making the generic version of the drug Nexavar, and in a rare criterion to promote competition, Indian patent office issued compulsory license in March 2012 to Natco Pharma, after Natco's request for a commercial license to manufacture Nexavar was rejected by Bayer. The Indian Patent Act (2005) provides provision of compulsory licensing under article 84 whereby any person may seek the compulsory license on the following grounds:

1. The public requirements with respect to the patented invention has not been met; or
2. The patented invention is not available to the public at an affordable price; and
3. The patent is not being worked in India.

Natco was given the license to make and sell 'Nexavar' a cancer-treatment drug at Rs 8800/- . The license fee that Natco was to pay to Bayer was fixed at 6% of net sales. The drug was a patented drug of Bayer (2008) and was sold under the name of "Sorafenib" at a price of INR 2.8 Lakhs. Other than the price being exorbitantly high, Bayer was not manufacturing the drug in India and was marketing it after imports in India and hence was able to meet the requirement only in 2% of cases. The in-affect price reduction post the grant of compulsory license was of the tune of 97%. Bayer approached the Intellectual Property Appellate Board (IPAB) by filing an appeal against the grant of compulsory license to Natco, which was dismissed by the IPAB. It then went to court and challenged the decision of IPAB, however High court upheld the decision of IPAB in this matter, thus Bayer did not get any respite.

This case brought in focus the weakness of the Intellectual Property Regime in India. This move on part of Indian Patent office was taken to take the innovation to the largest number of people and to maintain a balance between the rights and obligation of patent holder. However, in terms of incentive for innovation for the patentee the MNC Pharma companies which were involved in serious R&D had high sunk R&D costs as they would be unable to recoup their R&D investment. This step had a negative impact on R&D of domestic Pharma companies as this move was seen as killing the domestic pipeline of research, and making the domestic pharma companies prone to acquisition by MNC as they are better equipped to deal with pricing and revenue strains.

With reference to the case mentioned above Natco v/s Bayer regarding the compulsory license granted to Natco for Bayer AG's patented drug "Sorafenib". It can be concluded that, the IP regulation and enforcement in India is not at par with the standards adopted by developed world. While there was no instance of extreme urgency or national emergency the plea adopted by the Indian Patent Office was to promote competition and built domestic manufacturing capability. This in itself points towards the weakness in regulation and enforcement in India. A weak IP system is detrimental for innovation. The proposition 1 that the Indian IP regulation and enforcement is not strong and has negative impact on Innovation in Indian manufacturing industry hold good.

The case deals with high commercial value patent in Pharmaceutical sector which would have given the company a competitive advantage in Indian markets, also envisaged by Bayer. Moreover, Bayer had received 50% of the amount spent on R&D from US government as the disease was declared

‘Orphan’. Bayer’s patent was of high commercial value and it did provide the company market power, providing incentive to innovate. Thus, the proposition 2 of patents in Pharmaceutical sectors and inclusion of patents in SEP in ICT providing incentive for innovation in Indian manufacturing industry holds true in this case.

The case does mention the litigation process that Bayer first went to IPAB and then to High Court, spending time effort and money and eating into the profitability of the patented technology. However, its appeal was rejected on both courts. Thus, the proposition 3 that litigation regarding patenting (protection/infringement) is leading to reduction in innovation in Indian manufacturing industry holds true.

With reference to the case mentioned above, Natco v/s Bayer, it may be noted that the compulsory license was given to Natco with the purpose of promoting competition. As Bayer was not giving voluntary license and was unable to meet the demand, the pricing of drug also was exorbitant. However, the case does not talk about resolving issues regarding licensing through the antitrust regulation. The proposition 4 that competition/antitrust regulations are not able to resolve issues regarding licensing, which is having a negative effect on innovation in manufacturing industry in India, does not hold good vis-a-vis case facts.

The case talks about the licensing rate which is being fixed by the Indian Patent office in the case of compulsory licensing, and this rate is not under control of the grantee of the license. The case does reflect that Bayer was not satisfied with the grant of compulsory license to Natco and a 6% rate of license fee to be paid to Bayer. Natco may have got a compulsory license but a grant of compulsory license at such low license fee is hampering innovation in Indian manufacturing sectors. Thus, the proposition 5 that the compulsory licensing terms/FRAND are proving to be detrimental for innovation in Indian Manufacturing companies stands good in this case.

Though the case does not directly link to the R&D capacity of Indian Manufacturing sector, it however makes oblique reference that whatever internal capacity Indian Pharma manufacturing sector may have had was also adversely affected by the decision of Indian Patent Office to grant Compulsory license to Natco. It is therefore clear that this is resulting in lack of incentive for Pharma manufacturers to invest in R&D and as a result Indian firms have low internal R&D capacity. The proposition 6 that internal R&D capacity of Indian manufacturing sector is low which is having a detrimental effect on innovation in Indian manufacturing sector thus holds true.

The case brings to light the dependence of Indian Pharmaceutical manufacturing sector on technology transfer and licensing from multinational companies, as when Natco did not get license from Bayer it applied for compulsory license under article 84 of Indian Patent Act which provides provision for the same. Thus, the proposition 7 that increase in technology transfer in the form of Licensing, JV’s or FDI can improve innovation in Indian manufacturing sector does not hold true in this case.

This case does not hold any inclination towards representation in policy making bodies such as SSO. Thus, the proposition 8 that the Indian representation in policy making bodies (SSO) will lead to increase in innovation in Indian manufacturing sector does not hold true in this case.

## **IMPLICATION AND BROADER PERSPECTIVE FOR THE MANAGERS**

The subject matter under consideration is of great importance for the future of manufacturing setup in the country. The question that one needs to ask while we are trying to analyse each of these cases threadbare is that do we want the benefits of invention to reach those who need it or those who can pay for it. From business perspective, it depends on the stand one is taking. There might be a possibility that the innovating company is trying to get maximum royalty/price for their product while on the other hand there might be a possibility that licensee is trying to survive in competitive Red Ocean by betting on lower price. While trying to force morality on business perspective, one must never lose sight of the core business premise – make profit.

However, from a policy perspective we must realise that the policy makers have to take a holistic view, and keep into consideration the need of masses along with the profitability of innovator, as the system of patent is meant for providing incentives for innovation. While today we may need the developed world to make FDI in India which will result in some technology transfer and absorption, one must not lose sight of the fact that this is definitely not a one way process, developed nations are also going to have access to our markets and it is not a small opportunity for them. As the markets in developed world are getting mature and on the urge of saturation, they find great potential in Asian countries. Emerging markets must therefore be careful while negotiating, to not lose sight of local needs before opening up for the MNC players.

The paper has tried to build consensus through various case studies that Indian IP regulation and enforcement is not strong and hence has negative impact on innovation in Indian manufacturing industry. Also, patents in Pharmaceutical sectors and inclusion of patents in SEP in ICT will provide incentive for innovation in Indian manufacturing industry. If there are any litigation regarding patenting (protection / infringement), it certainly discourages the new innovation to happen. However, in India the competition/antitrust regulations are not able to resolve issues regarding licensing, which is having a negative effect on innovation in Indian manufacturing industry. Also, the licensing terms compulsory/FRAND are proving to be detrimental for innovation in Indian manufacturing companies.

Moreover, companies don't want to spend much money on the internal R&D capacity manufacturing sector, which brings a detrimental effect on Innovation. However, an increase in technology transfer in the form of Licensing, JV's or FDI will certainly improve innovation in Indian manufacturing sector. Hence, an Indian representation in Policy making bodies (SSO) will lead to increase in innovation in Indian manufacturing sector.

## **LIMITATIONS AND FUTURE SCOPE**

The issues dealt with in the present study broadly included issues related to innovation, its protection and exploitation for maximising returns for the innovator. The study was conducted with the help of 3 cases which were briefly discussed, especially in context of some common factors which were seen in all the cases. Though we were able to represent some common factors, the scope of some of the factors however is very vast. Some factors in real world intertwine and make the process complicated, especially when we are dealing with Law, whether in terms of the Patent Act, or the Competition act or still more when it is related to the civil and corporate law defining the company's act etc. The jurisdiction of each act and its redressal system, e.g. IPAB or CCI, at times appear to be overlapping. There will always be scope for interpretation. Also, while the factors identified may change, the alignment of intent with that of Government and all participating agencies/stakeholders may or may not happen and the scope of such study will change. Another limitation of present study was that we carried out qualitative analysis; a quantitative study of these aspects can be taken up in future.

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