COLLOQUIUM

includes debate by practitioners and academicians on a contemporary topic

Emerging IPR Consciousness in India: Strengthening IP and Open Source Systems of Technological Innovations

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INTRODUCTION

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India has always believed in the middle path. It can be traced to the tendency in our cultural milieu to avoid extremes in any thought process. Intellectual property rights (IPR) management is no exception. We have tried to bring parity with international norms as required under WTO but have also introduced specific variations to suit our conditions.

However, while the law is evolving, the practices are changing even faster. Indian companies have started suing each other; in the recent years, there have been several cases filed by Indian companies against other Indian companies demonstrating increasing awareness among the inventors of their rights. As if this is not enough, the unschooled and untrained grassroot technologists and innovative farmers and artisans show surprising enthusiasm to file patents in the US to protect their intellectual property rights —all of this in the last few years. At the same time, there is an increasing concern about the transaction costs involved in accessing or acquiring third party IP by smaller companies or other economic entities. Thus, the case for open source technologies has also become quite strong in the recent times. Indian filings in India are increasing though still not in sizeable terms. On the other hand, the open source movement/free software movement is also becoming stronger. Public policy support for it, of course, is very weak. Unlike many other countries, where government has provided a massive support for open source software and technology movement, Indian policy support is rather muted. It is not just in softwares that one ought to be concerned about open source technologies, but even in hard technologies, government can incentivise innovators to bring their technologies in public domain. One can hybridize both IP and open source system – protection among corporations and other organized sector entities but freedom to copy, improve, and learn from each other at the community level.

KEY WORDS

Intellectual Property Rights
Open Source Technologies
Tata Steel
Technology Commons
Patent System
Trade-marks
TRIPS
Patent Pooling

The 'creative commons' license for literary activities has taken off in the country though much more remains to be done. The geographical indications (GI) have been filed for many traditional knowledge-based products. Their effect on safeguarding the markets is yet to be assessed.

Thanks to the Turmeric and Basmati case fought by CSIR, patent literacy, as Dr R A Mashelkar puts it, has increased a great deal. But then the real change among public and private institutions is rather slow to come about. Opportunities in expired or abandoned patents have also not been explored enough by small scale industries in different sectors. Lot of innovations take place at all levels in firms but these are seldom tracked systematically. This is one area that must get more attention in times to come. Similarly, the user-driven innovations have not received the attention that they deserve. Should companies give credit to lead users and other users and should IPs that might arise from their feedback be shared with users, are the questions, still to be asked in the Indian context.

The support for traditional knowledge holders to obtain IP and assert it or enforce it is still rudimentary. The Traditional Knowledge Digital Library (TKDL) contrary to popular conception, does not provide any support to TK holders at the community level. It merely helps in preventing foreign patent offices in issuing improper patents on the Indian codified classical Ayurvedic and other herbal and mineral-based healing knowledge systems. Ironically, while patent offices abroad have access to TKDL, Indian organizations including various universities and research and action organizations like the National Innovation Foundation (NIF) do not have access to TKDL.

We are very keen to get the experience of organizations which have licensed in or out, various IPs to generate better economic opportunities. We are also keen to learn about the experience of companies which have reorganized their internal IP tracking systems and have thus achieved spectacular breakthroughs.

It is realized that while inventors must get incentives for their efforts in R&D, from among the consumers of their products, poor and disadvantaged social groups should not be excluded, particulary in the case of drugs.

This Colloquium aims to look at different trends in the IP situation in India drawing upon both conceptual and empirical experiences. The invited contributions are meant to generate a better understanding among the readers of *Vikalpa*. Some of the recommendations, we believe, could lead to policy or procedural action.

Strengthening IP and Open Source Systems of Technological Innovations: The Tata Experience

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With globalization and increasing competition, technological self-reliance has become a necessity. The companies which traditionally held our hands on technology and supplied us know-how (at a price), have started to see us as a competitor. Additionally, with WTO's insistence, technology leaders have hardened their positions on intellectual property (IP). One of the results of this is the non-availability of technology and know-how even at a price.

Anticipating the need to become self-reliant in technology, Tata Steel took three steps during 2000-2005 that would help establish itself as a leader in chosen technologies:

- formalized the continuous improvement and innovation process under the powerful programme of Aspire.
- identified seven thrust areas of strategic technology development which have now grown to ten for the Tata Steel Group.
- established a sound mechanism for capturing new developments and filing them as intellectual property.

In order to energize the process of creation, protection, and leveraging of IP assets, two committees were formed, i.e., IP Executive Committee and Team IP.

GOVERNANCE

The formation of a Team IP with an IP Champion in 2005 was the second major organizational step after the creation of the Patent Cell (in 2001). Team IP comprised the business heads of profit centres and the operational heads of a number of departments. This effectively positioned IP not as an isolated, stand-alone department but as an activity that had the buy-in of the larger organization. With the help of the members of Team IP, awareness programmes were held on all the departments of Tata Steel and also in a number of Tata Group companies during 2006 and 2007. IP workshops and symposia have been held every year since 2003.

Commercialization not only unlocks the value of the IP portfolio, but equally importantly, provides publicity and thus acts as a deterrent to deliberate or inadvertent misuse of our IP by others.

COMMUNICATION VEHICLES

In 2003, the first one-day symposium on IP was organized in Jamshedpur. The purpose of this symposium was to create large scale awareness within Tata Steel and also among the Indian steel industry. A software was developed in-house during the last six months of 2002 that would enable all employees of the company to file new developments easily on the intranet. These filings were to be considered and processed by the Patent Cell. This "Electronic IP Filing System" was inaugurated by the then Deputy Managing Director (Steel) at the IP symposium. With this system, the inventor was given a single window to file information about the new developments; the flow of information about new developments became systematic; and the subsequent dealings with attorneys were automatically taken up by the Patent Cell.

During 2003 and 2004, two new publications were initiated to create greater awareness among employees. One of them was an IP Ready Reckoner, which was a pocket-sized booklet containing essential information about how to file, what to file, and who to contact in case of doubts. The second publication was an IP newsletter that gave a broader coverage about recent international developments.

An IP search facility was established in 2005. This facility gave access to extensive collection of worldwide information sources including patent databases, millions of documents, scientific journals, and patent office information from Europe, US, and Japan. It was made compulsory for researchers to carry out patent search along with literature search at the start of a project. Project notebooks were introduced as compulsory research documentation medium. This project notebook was designed in accordance with the IP documentation rules.

Tata Steel is a manufacturing industry. This year the company is celebrating hundred years of its existence. During this hundred years' journey, a number of new products and processes and also modification in the existing equipments have been developed, and IPRs filed for protection. Today, there are 520 IPRs filed and 143 IPRs granted. There is a sound process of the system capturing the new developments but commercialization of IPs has not been actively pursued so far.

CHALLENGES BEYOND 2008

There are two main challenges that will be addressed in the years ahead:

The first challenge is the commercialization of IP. This involves marketing of granted IPs, finding prospective customers, and negotiating licensing conditions. Commercialization not only unlocks the value of the IP portfolio, but equally importantly, provides publicity and thus acts as a deterrent to deliberate or inadvertent misuse of our IP by others. This is a specialized activity in which there is very little prior experience within the Company. Effort is currently on to benchmark with international best practices and to take professional help from agencies (government and private) that provide IP licensing and commercialization services. Currently, one patent and twelve copyrights have been identified for commercialization as pilot cases. Seven companies world-wide have shown interest for the patent on our on-line property prediction in a hot strip mill. Seventy Eight companies have so far shown interest in our copyrights on e-learning packages.

As Tata Steel's indigenous, new technologies are growing from small scale to large pilot scale and commercial scale, it has become necessary to partner with suppliers and other industries.

The second challenge that will be addressed is dealing with IP sharing in the case of collaboration with big manufacturing partners. As Tata Steel's indigenous, new technologies are growing from small scale to large pilot scale and commercial scale, it has become necessary to partner with suppliers and other industries. Maintaining claim on one's own IP and yet sharing the developmental knowledge with others is a fine balance that needs as much understanding of technology as of legal negotiation skills. Again, effort is on to benchmark against international best practices on this front.

The vision of the future in IP is to continue to grow the IP portfolio of Tata Steel and to continuously unlock the value through licensing and commercialization.

Harnessing IP Awareness for Global Business Dominance: A Tale of Two Indian Companies

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The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement is generally considered as the cornerstone of global Intellectual Property Laws as it lays down the minimum standards for all World Trade Organization (WTO) member countries. More importantly, TRIPS is often talked about as a package deal whereby developing countries agreed to the TRIPS standards in exchange for the other carrots associated with WTO membership, which definitely included increased access to foreign markets. India, which is also a member of the WTO, is in the process of acclimatizing itself with the new international trade regime. This acclimatization process included a lot of changes in its laws and notably Intellectual Property Laws.

The period starting from 1995 saw some major amendments in the Indian Patents Act.[1] 1st January 2005 was an important day in the history of Indian pharma companies. From 1970-2004, India had by design excluded pharmaceutical products from patent protection and had thus become a global leader in the top-end generic drug manufacturing. But as India joined the WTO, it was compelled to once again award patents on drugs.[2] Since 2005, there has been a significant increase in pharma patent litigations both inside and outside the country that involved Indian companies.[3] The major pharma litigations which are hogging the limelight are the Glivec case involving Novartis and Roche's case against Cipla.[4] Apart from the battles going on inside the country, the leading Indian pharmaceutical companies are taking the battle to the opposition camps in many jurisdictions.

THE CHANGING FACE OF INDIAN COMPANIES

Unlike earlier days, the Indian companies are well aware of the global developments taking place in the field of law and business. The best example of such a changed outlook is the way in which Lupin, an Indian company, won its case last year and Cipla, another Indian pharma major, lost its case after a valiant fight. The most important feature of the former case was that Lupin took full advantage of a 2007 US Supreme Court decision which dealt with the concept of non-obviousness under the law of patents.[5] This write-up will be focusing upon the two cases which were fought by the Indian companies and the lesson it holds for the other Indian companies.

[1] The present Indian statute was amended three times, i.e., in 1999, 2002, and 2005 and now provides for a product patent regime in drugs, food, and chemicals. It should be noted that the other branches of IP Laws like Copyright and Trade Marks even before 1995 was more or less in tune with the global legislations.

[2] Mueller, Janice M (2007). *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and The Rise of Indian Pharmaceutical Innovation*, 68 (Spring), U Pitt. L Rev. 491 p 495.

[3] Even in areas other than pharma, patent litigations are on the rise, e.g., Bajaj Auto has sued TVS Motors for patent infringement.

[4] In this case, Cipla started making the generic version of the anti-cancer drug, Erlotinib, in spite of Roche having a patent. At the interim stage, the Delhi High Court refused to prevent CIPLA from producing the said drug.

[5] KSR International Co *vs.* Teleflex Inc, 127 S.Ct. 1727 (2007).

US PATENT LAW

Like most of the jurisdictions, even under the US patent law, a patent will not be issued if "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the said subject matter pertains.[6]

Although the first US Patent Statute was drafted in 1790, a formal requirement of non-obviousness first entered the statutory patent law with the Patent Act of 1952.[7] Meanwhile, the US Supreme Court in the famous case of Graham V John Deere Co. laid down the framework for an objective, factor-based test for obviousness.[8] Three essential points are involved here: (1) the scope and content of the prior art are to be determined; (2) the differences between the prior art and the claims at issue are to be ascertained; and (3) the level of ordinary skill in the pertinent art resolved. Against this, the obviousness of the subject matter has to be judged. Other factors like commercial success, long felt but unsolved needs, failure of others, etc., might be of some help to show that the circumstances surrounding the origin of the subject matter sought to be patented.[9]

> TRIPS is often talked about as a package deal whereby developing countries agreed to the TRIPS standards in exchange for the other carrots associated with WTO membership, which definitely included increased access to foreign markets.

The United States Court of Appeals for the Federal Circuit (CAFC) to handle patent law cases was set up in 1982. The CAFC independently developed the TSM (Teaching, Suggestion, Motivation) test as a third approach to non-obviousness and this test requires the person who seeks to invalidate a patent to demonstrate a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious. In other words, the party seeking to prove invalidity must establish some suggestion, teaching, or motivation that would lead a person of ordinary skill in the art to combine the relevant prior art teachings in the manner claimed.[10] However, in 2007, while dealing with the landmark case of KSR *vs* Teleflex, the US Supreme court unanimously rejected the CAFC's rigid application of the TSM test for obviousness and reaffirmed the current applicability of its broader approach to obviousness.[11]

The US Supreme Court's broad non-obviousness standard is likely to have many consequences and the KSR decision will alter patent jurisprudence by decreasing the overall number of patents issued. This will also invalidate some of the weak patents which were upheld earlier by relying upon the TSM test. This write-up will focus upon two cases which have been decided post-KSR involving Indian companies. In the case of Aventis *vs* Lupin[12], Lupin was successful in invalidating the patent of Aventis on the ground of non-obviousness. However, Cipla, a co-party, lost the case as it was not able to invalidate the patent of Forest Laboratories.[13]

AVENTIS *VS* LUPIN

This is a patent infringement action concerning the pharmaceutical compound, Ramipril.[14] Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") appealed against a final judgement entered by the District Court in favour of King and Aventis.[15] The District Court concluded that the claims of Aventis' US Patent No. 5,061,722[16] was not invalid and Lupin appealed be-

[6] In the US Patent Law, the requirement of non-obviousness is provided under 35 USC. and 103 (a). It states: A patent may not be obtained though the invention is not identically disclosed or described as set forth in Section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the said subject matter pertains. The Indian Law also has such a requirement though the Patents Act 1970 uses the term 'inventive step.'

[7] However, the requirement regarding non-obviousness had existed as judge-made law for many years, from the famous case of Hotchkiss *vs.* Greenwood 52 US 248 (1851).

[8] 383 US 1 (1966).

[9] Ibid. 17.

[10] Pro-Mold and Tool Co. *vs.* Great Lakes Plastics, Inc., 75 F.3d 1568 (Fed.Cir.1996).

[11] Supra note 5, 1739-41.

[12] Aventis *vs.* Lupin, (CAFC Decided on 11th September 2007) available at http://www.cafc.uscourts.gov/opinions/06-1530.pdf

[13] Forest laboratories *vs.* Ivax Pharmaceuticals, Inc. as a blood pressure medication under the name Altace.

[14] which is marketed by King Pharmaceuticals, Inc. as a blood pressure medication under the name Altace.

[15] No.2:05-CV-421 (E.D. Va. July 18, 2006).

[16] Hereinafter 722 patent

fore the CAFC against the decision of the District Court.

The patent at issue in this appeal was directed to the pharmaceutical compound, Ramipril, in a formulation, "substantially free of other isomers." Ramipril, like many complex organic molecules, is one of a family of sterioisomers.[17] Ramipril is a family member of drugs known as "Angiotensin-converting enzyme inhibitors," or "ACE inhibitors." ACE inhibitors inhibit a biochemical pathway that constricts blood vessels and therefore are useful for treating high blood pressure. The earliest ACE inhibitors, dating back to the late 1960s, were based on the venom of the Brazilian Viper, which was known to reduce blood pressure. Ramipril's immediate predecessor is an ACE inhibitor known as Enalapril that was introduced by Merck in 1980. Enalapril has three stereocentres. In a published article, Merck scientists explained that the all-S (SSS) stereoisomer of Enalapril was found to have 700 times the potency of the SSR stereoisomer.[18] The Merck article taught how to separate the all-S isomer using standard chromatography techniques.[19]

Both Aventis and its competitor, Schering, sought to create new ACE inhibitors based on Enalapril. Soon after Enalapril's introduction, in 1981, Dr. Elizabeth Smith, a chemist, at Schering, conceived of the structure of Ramipril and recorded it in her laboratory notebooks. Ramipril had the same overall structure as Enalapril, with one distinction: where Ramipril had linked five-sided carbon rings (a "5,5 fused ring system"), depicted, in the chemical diagrams above, on the left side of the molecule, Enalapril had only a single ring.[20] Thus the key question was whether the 5(S) stereoisomer of Ramipril, in a form substantially free of other isomers, would have been obvious over the prior art to one of ordinary skill in the art at the time of the '722 patent's priority date.

This question arose because Dr. Smith, working at Schering, had synthesized a mixture[21] of 5(S)-configuration of Ramipril and its stereoisomer. Secondly, another patent—the 944 patent—which was before the 722 patent, specifically taught that stereoisomers of Ramipril could be separated by conventional chromatographic crystallization methods. When the case came up before the District Court, it held that Lupin failed to meet its burden of proof by clear and convincing evidence that a person of ordinary skill in the art would have been motivated to purify 5(S) Ramipril into a composition substantially free of other isomers.[22] Since the date of the District Court decision, however, the Supreme Court decided the KSR *vs* Teleflex case which essentially counseled against applying the "teaching, suggestion, or motivation" ("TSM") test as a rigid and mandatory formula.

> Since the Indian pharma companies make use of the Drug Price Competition and Patent Term Restoration Act of 1984, popularly known as the Hatch-Waxman Act, to launch their drugs in the US market, they also need to keep abreast with the latest changes in the US Patent Law.

Thus when the case came in appeal before the CAFC in September 2007, i.e., after the KSR decision, CAFC noted that there was no evidence to show that the separating 5(S) and Ramipril was outside the capability of an ordinarily skilled artisan. It also noted that Aventis had failed to show unexpected results that would tend to rebut a *prima facie* case of obviousness. Thus, CAFC finally held that the 722 patent, which covered the 5(S) stereoisomer of Ramipril in a composition substantially free of other isomers, were invalid under 35 USC and 103 over the mixture prepared by Dr. Smith, the 944 patent, and some other references in the prior art on Enalapril published by Merck scientists. In simple words, CAFC invalidated the 722 patent on grounds of obviousness.

FOREST LABORATORIES *VS* IVAX PHARMACEUTICALS AND CIPLA

This was a dispute involving a patent that claimed compounds including an anti-depressant, Citalopram. The

[17] A stereoisomer is an isomer in which the same atoms are bonded to the same other atoms, but where the configuration of those atoms in three dimensions differs.

[18] Patchett, A A ,*et. al.*(1980). "A New Class of Angiotensin-Converting Enzyme Inhibitors," *Nature* 280 (November 20), 288.

[19] Supra note 12

[20] The addition of the second ring gives rise to two more stereocentres than are present in Enalapril; thus, Ramipril has the same three stereocentres as Enalapril, plus two new ones that span the fused ring system.

[21] The mixture came to be known as SCH 31925.

[22] It should be noted that the decision of District Court came in 2006 much before the 2007 judgment of the KSR which considerably diluted the TSM test.

patent in issue, 712 patent, issued on August 30, 1994 related *inter alia*, to a substantially pure enantiomer of Citalopram and non-toxic acid additional salts thereof.[23] Forest also owned the now expired US Patent 4,136,193 on the racemic form of Citalopram.[24] Upon sued for infringement, the defendants[25] raised the counter claim that the patent was invalid for anticipation and obviousness. Defendants contended that Citalopram was obvious in light of racemic Citalopram and descriptions of techniques available to separate enatiomers from their racemates. According to them, a person of ordinary skill in the art would have a reasonable expectation that one could separate the enantiomers of Citalopram.[26]

However, the Court rejected their contentions and held that *prima facie* obviousness, based on racemic Citalopram, was rebutted by the evidence demonstrating the difficulty of separating the enantiomers and the unexpected properties of Citalopram. According to the Court, a person having ordinary skill in the art at the time of the invention would generally have been motivated to develop new compounds rather than undertake the difficult and unpredictable task of resolving a known racemate. Such a person attempting to resolve racemic Citalopram would have no reasonable expectation of success because many medicinal chemistry experts for many years had tried to resolve the said compound without any success, the court noted.[27] Thus Cipla was unable to invalidate the patent on the grounds of non-obviousness.

The judgement delivered by the US Supreme Court in the KSR *vs* Teleflex case has in effect raised the bar regarding patentability and has brought a lot of cheer to generic companies which want to oppose patents which might have been granted on an obvious subject matter. The manner in which Indian companies have tried to capitalize upon the KSR decision is really commendable.

CONCLUSION

The decisions in both the cases are very important for the Indian pharmaceutical companies who intend to play a major role in the global generics market.[28] Since the Indian pharma companies make use of the Drug Price Competition and Patent Term Restoration Act of 1984, popularly known as the Hatch-Waxman Act, to launch their drugs in the US market, they also need to keep abreast with the latest changes in the US Patent Law.[29] Under the Hatch Waxman Act, there is a lot of regulatory interface with the Law of Patents and it is quite common for generic companies to be dragged to a court that deals with issues concerning patent infringement.

The judgement delivered by the US Supreme Court in the KSR *vs* Teleflex case has in effect raised the bar regarding patentability and has brought a lot of cheer to generic companies which want to oppose patents which might have been granted on an obvious subject matter. The manner in which Indian companies have tried to capitalize upon the KSR decision is really commendable. This clearly demonstrates the ability of Indian companies to keep abreast of the changes happening globally and frame effective strategies in the light of those changes. In the process, some may win and some may lose. Cipla may have lost the battle but Indian companies who are in the process of updating their business strategies by keeping abreast of the global changes will be in a position to win the war very soon.

[23] Isomers are compounds with the same chemical formula and often with the same kinds of chemical bonds between atoms, but in which the atoms are arranged differently. Stereoisomers are compounds that contain the same constituent atoms and the same bonding between those atoms but have different spatial arrangements. Enantiomers are stereoisomers that are non-superimposable mirror images of one another.

[24] A mixture of equal amounts of two enantiomers is called a racemic mixture or a racemate and separating the two enantiomers from a racemate is referred to as resolving the compound.

[25] Ivax and Cipla

[26] Supra note 13

[27] Ibid.

[28] Indian Companies have won major pharma patent litigations even in other markets like that of U K. In 2004 Ranbaxy, which may soon be taken over by Daiichi Sankyo of Japan, won a case against Abbott, see Abbott Labs *v s* Ranbaxy Europe Ltd. (2004) EWHC 2723 (Pat)

[29] Under Hatch-Waxman Act, generic manufacturers may now seek FDA approval to market the generic drug before the expiration of the patent of the branded product, via the Abbreviated New Drug Application (ANDA) route. For a detailed analysis regarding Hatch-Waxman Act, see Kelleher, Kathleen R (2007). "FDA Approval of Generic Biologics: Finding a Regulatory Pathway," *Mich. Telecomm.Tech. L.Rev*, 14 (Fall), 245.

Challenges faced by the Indian IPR System

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The modern IPR system in India, in the real sense, is a post-WTO phenomenon which has many new dimensions such as protection of IC layout design, geographical indications, and new plant varieties which were not part of the earlier Indian system. Earlier there were only four forms of IPR prevalent in India namely, patents, copyrights, trademarks, and registered design. It would be safe to state that most contested disputes in the country fell in the categories of copyrights and trademarks. The Indian patent laws were comparable to those of many countries except that product patents in the area of drugs, chemicals, and food items were excluded from patentability. Now, however, the laws are fully TRIPS-compatible and also allow product patents in all areas of technology. However, there are some provisions in the law, mandated by the social and political thought process, which do not allow certain types of invention to be patentable. Patents were not used as a competitive tool in the pre-WTO days because we had a centralized economy with very little competition. Globalization and opening up of the economy have increased competition and it will continue to rise at a rate not witnessed in the past. Obviously, each cubic centimeter of space in the world of trade will be strongly contested by many players. IPR will play a very important role in the competitive world and it would be in the interest of every one that there is a legal framework which is sensitive to the social, cultural, and political needs of the country but still provides enough incentives for innovators and the process of innovation.

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What we see today in terms of increasing IP issues was anticipated by many when it was decided to modify our IPR laws. It may be difficult to go back to the old system. Property always causes conflicts and disputes. This has now started happening in India in the IPR area as well and can be considered normal. When brothers can fight with each other on property matters, fight between two companies on IPR matters should not be a cause of disturbance and alarm. What perhaps would be required in disposing such disputes is judicial maturity, understanding of technological issues, and a balanced interpretation of patentable inventions to meet social goals. One will have to depend on the case laws within our country for developing a robust system for resolving IPR disputes. Indian courts had, for example, earlier disallowed the use of word 'scotch' for Indian whiskies. Yet, in another case, the Supreme Court has recently allowed the use of the word in respect of Peter Scotch.

The IP system of a country is now heavily influenced and governed by the IP systems of other countries, especially the developed ones. Patent practices in respect of biotechnological inventions were revolutionized in 1980 in USA; many similar events have been occurring since then. We must learn to develop a foresight to anticipate what is likely to happen. For example, inventiveness or non-obviousness of inventions will occupy the attention of many law-

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making authorities, international agencies, and judiciary. Indian inventors and their employers (if applicable) will have to pay serious attention to this aspect if they wish to have a right which can be defended in a court of law. The success will depend on critical scientific enquiry of each invention. Similarly, novelty determination is very crucial in light of expensive litigation and risk of losing market position. Therefore, awareness and training continue to be important elements for tilting the IPR system to our advantage.

New challenges are likely to emerge with the introduction of a system for protecting the new plant variety. One of the most important ones would be to register farmers' varieties because no nationwide system is in place to undertake this massive task. It may be reckoned that one will have to take farmers in confidence and educate them about the new laws which are farmer-friendly. There should be systems to identify such varieties, generate adequate scientific data to establish their reproducibility, stability, and the unique traits before going in for registration. This may become handy to address food security problems in the rainy days. Geographical indications are becoming popular. As the social and political ramifications could be serious in some cases where more than one state could be the interested parties, it would be a good idea to have government intervention right at the beginning.

One of the important principles to be adopted for ensuring that wrongs are not done is to examine whether unfair trade practices are being encouraged by the use of IPR. There are many dimensions to this aspect including transaction of IP. The Competition Commission of India has brought out some guidelines to avoid unfair trade practices which are quite similar to what are being followed elsewhere in the world. It may be reckoned that TRIPS also endorses that unfair trade practices in IP-related contracts should be avoided.

Open source system for collating and utilizing innovations is in the nascent stage and is yet to generate enough evidence for its candidature as an effective tool for generation and sharing of IPR. It may perhaps make an impact if suitable models for benefit sharing is evolved which could provide enough remuneration to inventors. In the present form, it seems to lack equitable sharing of IPR. Perhaps patent pooling in the specific areas regulated by standards may be a better candidate to be pursued provided a proper legal framework is worked out.

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There are many issues which need to be studied and researched in the Indian context to work towards a balanced practical state for our IPR system. In the absence of data, it is not possible to establish the advantage or disadvantage of the existing system. The research should be interdisciplinary in nature involving laws, science, engineering, business, economics, commerce, and social sciences.

Note: The views expressed above are that of the author.)

Growth of IPRs in India: Slow but Steady

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A quick search of the decided cases in the Supreme Court and the High Courts in India with reference to Section 64 (revocation of patents) of the Patents Act, 1970 gives 22 results. Only one case is from the Supreme Court of India, ten from the Delhi High Court, five from the Calcutta High Court, three from the Madras High Court, two from the Gujarat High Court, and one from the Bombay High Court. Revocation of patents is a very contentious issue and such a small number of patent cases on this issue in the last

four decades in India speaks volumes about the awareness about patents and the importance given to patents as a tool to protect the intellectual property by businesses. Out of these twenty two cases, twelve have been decided post-2000, i.e., in the last eight years. Only ten were decided prior to the year 2000. Five cases have been decided in the last three years. This number is surely going to increase and as the awareness grows, the number is expected to increase dramatically. Historically, patent litigation (legal action relating to patent infringement and revocation) in India has never been a very well-defined profession, as there were not enough number of cases for the lawyers to specialize in this field. The primary work of the patent lawyers in India has been patent prosecution, which describes the interaction between an applicant and the patent office. Since the year 2000, more and more applications are being filed in the patent office and many disputes are also arising. Cases like that of Bajaj-TVS[1] and Novartis are reaching the High Courts and more and more businesses are challenging the decisions of the Patent Office.

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To handle the increasing number of prosecution and litigation matters, there is an urgent need of qualified and competent patent examiners, lawyers, judges, and court staff. We must make the necessary changes in the curriculum of business schools, law schools, and other schools to have graduates specializing in patent law. Most of the patents are highly technical in nature and require blending of legal knowledge with technical knowledge. More and more institutions on the lines of Rajiv Gandhi School of Intellectual Property Law at IIT Kharagpur are needed. There is also an urgent need to pay realistic salaries to the patent examiners. As of now, the patent office is being used by patent examiners as a platform for launching their careers with private pharmaceutical and biotechnology companies. The Indian law does not allow *per se* software and business method patents. The day, these patents are allowed, the position will become worse as it would be next to impossible to somehow retain the patent examiners in the patent office. We also need more number of law graduates with specialization in intellectual property to act as lawyers and later as judges.

It will not be an exaggeration to say that the American story of economic development and prosperity is the story of strong protection of patents in particular and other branches of intellectual property in general. The matters pertaining to the patent of telephone[2] (Graham Bell) or electric bulb[3] (Edison) were finally settled in the American Supreme Court. Similarly, Henry Ford had to fight a long legal battle against Selden[4] to manufacture the mass-produced car, which revolutionized the automobile industry.

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Today, the dispute between Bajaj and TVS in India gives a slight hint of the things to expect. Trademarks are becoming a gold mine for filing as well as litigation. Every business should have as many trademarks as possible for their products – not only for the device (the logo, etc.), but also for the sound (Harley-Davidson engine), colour (Qualitex), shape (Coke bottle), scent, etc. — the primary reason being the perpetuity of trademarks as compared to other branches of intellectual property, which always has a fixed term. Patents last for twenty years, whereas trademarks are forever. The American courts even recognize the concept

[1] Bajaj Auto Limited *vs.* TVS Motor Company Limited, Madras High Court, February 16, 2008.

[2] U S *vs.* American Bell Telephone Company, 167 U S 224 (1897).

[3] Consolidated Electric *vs.* McKeesport Light, U S Supreme Court, 1895.

[4] 'Will Fight Selden Patent', *The New York Times,* February 13, 1910.

of trade dress, which was learnt bitterly by ITC's restaurant 'Bukhara.'

So much protection already in place is making it very difficult for any new business to get proper protection from the law. It costs a lot of money and time to file for patents or trademark or design as the case may be. The same is true about offices dealing with different branches of intellectual property in India. Small innovators find it very difficult to file their applications for intellectual property protection. We may like to follow the petty-patents model used by Australia. There is also a need to protect the traditional knowledge and build electronic data banks for this purpose. A lot of work is being done in this regard; however, in a country like India with continental dimensions, it will take a pretty long time.

One area of concern for India is the weak enforcement of IP laws. Pirated software and printed material can be bought from any roadside seller. Training to police to nab the culprits, particularly for copyright violation, is far from adequate. There is a need to have stronger intellectual property laws with equally strong enforcement in India.

Intellectual Property Systems in India: Progressing towards Greater Maturity and Diversity

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India's IP systems and mechanisms are evolving in the direction of a greater richness and diversity that is necessary for spurring and supporting technology innovation for both economic and social/strategic benefits.

India today is seeing rapid development in every sphere of activity; IP rights and associated systems are no exception. Indian IP law and mechanisms are changing to accept global best practices. The patent filings are increasing rapidly with Indian companies also beginning to file and actively litigate patents. A new cadre of IP professionals and organizations is emerging. The increased level of activity is clearly challenging our existing systems and forcing them to improve in efficiency, richness, and diversity. On one hand, mechanisms are getting better to create and protect IP rights as private property for individuals and organizations investing in creating them while on the other hand, mechanisms to create intellectual property that will be held in trust for public use towards pursuing social and strategic goals are also coming up. Are these two approaches in conflict or are they complementary? We believe the latter is true. We explain why in what follows.

> The patent system provides a strong incentive for private initiatives whereas the open source programmes provide a platform for public initiatives in technology innovation.

It is undisputed that technology innovation and creation of intellectual property are critical to India's march towards economic success and the achievement of social and strategic goals. It is important to clarify here that if at all something is disputed, it is how the intellectual property should be utilized and what price should be extracted for it by the innovators. There is a clear need that India continuously increases its technology innovation and intellectual property activity and output. How can India achieve that? The answer lies in increased investment by the country in research and technology development, and in the people who drive technology innovation – the technology developers and the technology entrepreneurs. This investment needs to be pumped in continuously in a sustained manner into a variety of initiatives by private investors, industry, government, and the not-for-profit sector. India has to leverage every possible source of investment to accelerate technology innovation.

Amongst the various types of innovators and sources of investment in technology innovation, two broad

approaches exist: The first approach ("private initiatives") deploys funds (often, private investors, venture finance, corporate funds) and efforts (say, "private" entrepreneurs) with economic goals as the primary driver often realizing that coincidentally they shall help achieve social and strategic goals, while the second approach ("public initiatives") deploys funds (often government, not-for-profit sector) and efforts (social entrepreneurs) with social and strategic goals as the primary driver while relegating economic goals to second position. Both the above-mentioned approaches are important for any society and play useful roles in mature societies in promoting technology innovation and delivering the fruits of technology innovation to the people. It is therefore important that India creates mechanisms and systems to promote both private and public initiatives in technology innovation. In our view, the evolving intellectual property (such as, patent) systems of the country and initiatives such as the open source approaches to technology development are both mechanisms that spur and support technology innovation – in particular, the patent system provides a strong incentive for private initiatives whereas the open source programmes provide a platform for public initiatives in technology innovation.

Technology innovation and generation of intellectual property often require sustained investments of a considerable amount of money and effort over long time periods under circumstances of uncertainty and risks relating to not only technology but also regulatory hurdles, acceptance by end-users and customers, etc. It is therefore not surprising that such investments are often made by either private investors and individuals seeking better returns (in tangible or intangible ways) on investments than what relatively safer investments might offer or public (government, not-for-profit) funds and entities for whom social objectives supersede financial goals.

Private investors and entrepreneurs often need sources of sustainable competitive advantage to justify taking the risks that they normally do and patents (and other formal IP) provide that much needed source of competitive advantage. It is therefore important that India continues to refine and broaden the scope of intellectual property mechanisms and make all its aspects efficient. The recent trends in India indicate that the IP system is evolving to facilitate higher levels of activity, accommodate greater diversity, and provide a wider scope to technology innovators. It is important that we continue to refine the IP laws to be able to handle the challenges posed by recent technology advances, automate and digitize much of the operations and databases of the IP offices, strengthen and speed up mechanisms for addressing IP disputes, and create an environment that gives confidence to investors and entrepreneurs that ownership rights of intellectual property shall be honoured in India.

We as a society need to nurture strong public initiatives in creating intellectual property and holding them in trust for public use directed at social or national strategic goals. Public action, philanthropy, and shaping of public policy are all necessary to ensure that the government and the not-for-profit sector earmark sufficient funds for the creation of intellectual property and technology innovation directed at social and strategic objectives.

On the other hand, we as a society need to nurture strong public initiatives in creating intellectual property and holding them in trust for public use directed at social or national strategic goals. Public action, philanthropy, and shaping of public policy are all necessary to ensure that the government and the not-for-profit sector earmark sufficient funds for the creation of intellectual property and technology innovation directed at social and strategic objectives. It is also important that the government and the not-for-profit sector initiate programmes and platforms to facilitate and coordinate activities and resources that can result in technology innovation. It is in this context that the recent Open Source Drug Discovery (OSDD) initiative of CSIR is an important development. We believe that India today needs many more such initiatives addressing the pressing problems of the day of social or strategic importance such as public health, energy security, food security, water, environment, natural resources, defence, etc.

The ability of our country to sustain economic growth while meeting social and strategic objectives through

next several decades rests strongly in its ability to prioritize and facilitate investment into technology innovation and the creation of intellectual property through both private and public initiatives, and it is such a balanced and well-reasoned approach that we would like to advocate.

Emerging Issues in Managing IPRs and Open Source Technologies

Anil K Gupta

Unless economic growth becomes inclusive and knowledge- and innovation-driven, the momentum cannot be sustained. India seems poised to get out of the low level of economic growth by becoming more efficient, competitive, and also collaborative. After the introduction of a stronger IP regime in the country, many small, medium, and large firms have become conscious about R&D, innovation, and protecting their IP. However, the pace and process of triggering innovations do not seem to be strong enough. Many organizations want to become innovative but have not put in place a process to harness the creative and innovative minds within and outside the organization. In the informal sector, the situation is even more grim. Barring around 170 patents filed by the National Innovation Foundation (NIF) and GIAN (Grassroots Innovation Augmentation Network), there are not many examples of protecting IP in the informal sector.

Many organizations want to become innovative but have not put in place a process to harness the creative and innovative minds within and outside the organization.

Given the high transaction costs of acquiring or developing IP in the small and medium sector, the need for open source technologies has been strongly felt. Incentives for people to share the outcomes of their own R&D evolve with the expectation of reciprocity from others. In this Colloquium, we invited several scholars, scientists, practitioners, and policy makers to reflect on the emerging consciousness in India.

Bhuyan from Tata Steel shares the experience of the Aspire programme under which continuous improvement and innovation process were put in place. In 2005, an IP champion was identified together with the formation of a patent cell and an IP team. By now more than 520 patents have been filed and 143 patents are already granted. While a system for harnessing IP has been put on sound footing, the process of commercialization has not yet been actively pursued. The team has identified certain patents for potential licensing. Seven companies around the world have shown interest in their patents on online property prediction system in a hot strip mill. What is even more interesting is that 78 companies have shown interest in their software on e-learning packages. Tata Steel has recognized the challenge of not only protecting its own IP but also balancing this process with the need to share its knowledge with partners, suppliers, and other industries.

Unni looks at the experience of two major pharma companies and their operations in the international technology arena. The victory of Lupin and loss of Cipla are discussed to draw lessons from. Lupin had appealed to the United States Court of Appeal for the Federal Circuit (CAFC) against an infringement action allowed by a District Court in favour of Aventis, holding Patent No.5061722. Aventis and its competitor, Schering, wanted to create new ACE Inhibitors for treating high blood pressure using Enalapril drug. The District Court had held that Lupin could not meet the burden of proof beyond doubt that a person of ordinary skill in this field could have purified a 5(s) Ramipril into a composition which was substantially free of other isomers. The CAFC upheld the contention of Lupin and noted the failure of Aventis to prove the argument against Lupin. Its patent was considered invalid on the ground of obviousness. In another case, Cipla failed to invalidate a patent of forest laboratories on the ground that its claim was obvious. The Court held that a person with ordinary skills in the art would not have separated a known racemate and would have instead tried to de-

velop new compounds. Many scientists have been striving to achieve that but in vain. Unni argues that Indian companies wanting to carry out business in the US have to keep abreast with the latest legal changes in the US Patent Law as well as various judgments of the courts. The generic companies have better chances today than before to challenge patents which had claimed minor modifications and thus prevented the introduction of generic companies to provide cheaper drugs in the market.

Barring around 170 patents filed by the National Innovation Foundation (NIF) and GIAN (Grassroots Innovation Augmentation Network), there are not many examples of protecting IP in the informal sector.

Saha looks at the Indian scenario in the light of changes taking place on the technological, legal, and societal fronts. He refers to the way Indian courts are adapting to the new realities. For instance, the use of the word, 'Scotch' was forbidden for Indian whisky by the Indian courts. In another case, the Supreme Court allowed the usage in the case of Peter Scotch. He feels that the IP system of India is heavily influenced and governed by similar systems of other countries. He believes that the issues of inventiveness or non-obviousness will become much more contentious in the times to come. While the Protection of Plant Variety and Farmers' Rights Authority have come into being, no nation-wide system has been put in place for protecting the farmers' varieties. The Competition Commission has evolved new guidelines to avoid unfair trade practices *vis-à-vis* IPs. The author feels that open source system for dealing with innovation is yet to prove its efficacy for generating and sharing IP. Perhaps with the evolution of a benefit sharing system, it might become relevant. He also feels that there was a case for patent pooling in the areas regulated by standards. He advocates inter-disciplinary research to face the emerging issues in a proper manner while bemoaning the lack of rigorous database search in the country.

Agarwal looks at the recent cases and observes a lack of too many cases on revocation of patents suggesting that patent protection has not picked up a great deal in the Indian conditions. In the recent past, many disputes such as Bajaj and TVS and Section 3D case of Novartis have drawn the attention of the society to the contentious nature of IPR. He advocates changes in the curriculum of business, technology, and law schools so that experts with inter-disciplinary knowledge could help in pursuing IP scholarship and practice. The trademarks are being obtained not only for device or logo but also for the sound, colour, shape, scent, etc. The concept of trade dress is recognized abroad so that imitators are deterred. He justifies the need for a petty patent model along with the strengthening of the enforcement mechanism for IP.

Premnath and Sivaram argue that the diversity of IP systems and mechanisms in India have been increasing which are quite conducive for technological and social development. They justify both the patent system as well as open source for providing incentives to private and public players. They recommend urgent automation and digitization of the operation and databases of IP office so that they can address the needs of inventors and innovators better. A recent initiative of CSIR in the area of Open Source Drug Discovery is mentioned as a very important landmark in the field of technology development and innovation. The authors feel that similar open source innovation discovery models need to be established in other areas.

It is quite understandable that a contentious field should trigger diverse responses and stimulate multiple perspectives for looking at the same problem. The case for open source technologies, databases, and platforms has been made. There are several other issues that need to be addressed:

Lateral learning among farmers, artisans, and other self-employed people at the grassroots level should not be restricted or inhibited. The local improvements play an important role in adaptiveness of innovation developed indigenously or exogenously.

- What is the capacity of small and medium industries to innovate and develop major breakthroughs in solving problems through innovations? Should they be enabled to come out with incremental innovations which may improve their competitiveness?
- Can open source technologies be encouraged through public policy

support so that the inability of the individual small firms to carry out R&D does not come in the way of their acquiring open source solutions?

- What lessons can be learnt from some of the developing countries which have encouraged IP as well as open source models for different problems?
- The relationship between IP and innovation is not linear. Not all IPs are intended to promote or protect innovations. It is to overcome the predatory practices of some of the large IP owners that the recent court judgments have raised the bar of novelty and non-obviousness. The scope for generic drugs is expanding even in the Western countries to make health care affordable. What lessons can India learn in this regard?
- How does one blend IP and open source? An experiment pursued by Honey Bee Network as a part of the Ph.D. research of Riya Sinha is worth exploring further. In a workshop of inventors, imitators, improvisers, and users held in Rajkot last month, considerable support was found for the concept of 'technology commons.' The idea is that lateral learning among farmers, artisans, and other self-employed people at the grassroots level should not be restricted or inhibited. The local improvements play an important role in adaptiveness of innovation developed indigenously or exogenously. These improvements around a local innovation could be pooled in a 'technology commons' so that there is no restriction on local imitation and innovation. However, if a commercial corporation wanted to license not only the main invention but also the various improvements, then it would have to license the technology pool from the managers of 'technology commons.' No single person can license a pool of innovations without the consent of others. It has to be seen as to how incentives for innovation can be matched with a need for social diffusion of some of the technologies at the grassroot level. The historical asymmetry in the rights of small innovators and large corporations also will get reduced through such a concept.
- The need for a faster track for providing protection to green innovations and also the innovation by small inventors and innovators have been felt. It remains to be seen as to how long it will take for systems to reform in the field of IP. At the same time, the incentives for open source technologies can be enhanced by establishing Technology Acquisition and Licensing Funds. NIF has recently proposed that it would acquire the rights to some of the innovations from the innovators after due compensation and then make them available to small enterprises at no or low fees. India must evolve variations in its policies so that the bias of the dominant actors to push a uniform solution worldwide is tempered.
- Unlike many other countries, the Indian patent office does not provide searchable content of indian patents abstracts and full texts in the online data bases. This is a deficiency which must be overcome soon to enable researchers and innovators to perform searches quickly and efficiently.
- The quality of patent issued is another area, which requires attention. Many frivolous claims are allowed for patenting by the Indian (and many other) patent office(s) and this is an issue that needs considerable improvement.
- The access to basic health through affordable drugs has been an important policy issue that has been debated in the country. Despite various kinds of criticism of the provision of IP system, many small drug companies are trying to improve the delivery system or the efficacy of patented as well as non-patented drugs, thus extracting entrepreneurial rent at economical rates.

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There are many other issues relating to traditional knowledge, rights of individuals *versus* communities, production of public goods and services by publicly funded institutions *vis-à-vis* the contradictory trends apparent today. The small scale entrepreneurs see the role of IP differently than the established large corporations. We have to evolve sufficient diversity and flexibility in our systems to encourage innovations and expansion of 'technology commons.' Many ideas have been thrown up here while many more remain to be articulated and addressed. We hope that the readers will join the discussion and share their experiences in both the arenas of IP— stronger protection, and at the same time, expansion of public domain/open source.