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Faith is a bird that feels dawn breaking and sings while it is still dark! said Tagore. It is with that faith that we started on our journey alone ten years ago, with only our mission as company; to advance new ideas, encourage innovation, promote IP awareness and create a unique learning environment in India.

Building on our network of expert IP professionals we inched closer each day to the fulfillment of our dreams.

In our tenth year and having established our credentials as educators in classrooms and in corporate, legal corridors, a logical next step for us lay in carrying forward the information dissemination on a more interactive platform of publications, both in print and online media.

Came the idea to launch 'IPost- IIPS Intellectual Property Journal', as an annual magazine/journal for discussion of intellectual property issues along with new insights, analysis, news, and commentary about the law of patents, trademarks, copyright, trade secrets, and related subjects in the IP world.

The genesis of course lay in the 'IIPS Annual IP Essay Competition' that we organized this year and in our objective to encourage the winning authors by finding an avenue to publish their works. The Competition was a success and in that we are grateful to Krishna Saurashtri & Associates the well known law firm for sponsoring the essay awards and making it easier for us.

At the same time IPost hopes to be that window for many of the country's IP and industry experts to ventilate their thoughts and views on topical issues of intellectual property. For us, IPost will also provide our best students an opportunity to publish their work and consequently encourage them undertake and write issue based journal quality articles and papers.

The journal will carry a mixed bag of essays/articles and reviews on issues related to IP in the context of a global trade market on a bi-annual basis, which can be used as reference reading. We will also cover interesting IP news, new resources, new technologies and events in India and abroad and hope it will appeal to a broad range of readers - professionals and students and yet provide each with a meaningful perspective on an IP subject of relevance.

We thank our Editorial Board for their inputs and their support of our initiative, despite their professional commitments. Last but definitely not the least we thank L&T Infrastructure Finance for coming forward to use our advertising space and helping us make the journal a self sustaining exercise.

So we begin yet another journey with the wise words of Leo Burnett, "When we reach for the stars we may not quite get them, but we won't come up with a handful of mud either...."

Anuradha Maheshwari
Director, IIPS
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Policies for Better Protection for Intellectual Property in Indian Small and Medium Sized Enterprises

Winner One:
Mr. Konark Sharma

1Student, National Law School of India University, Bangalore
ABSTRACT
Small and medium enterprises (hereinafter referred to as SMEs) are the backbone of developing economies. SMEs represent over 90% of enterprises in these economies. The driving force behind these SMEs is the large number of innovations which has led to the growth of the national economy through employment creation, productive investments and value-added exports. Since this growth is innovation based therefore intellectual property rights (hereinafter referred to as IPRs) have assumed an unprecedented significance. In the knowledge-based society of our times IPRs have a profound influence on the social, economic and technological progress. New products, brands and creative designs appear almost daily on the market that are the result of continuous innovation and creativity in SMEs. Thus In order to improve the business environment and encourage innovation in this sector it is necessary to provide robust policy framework and formidable legal protection to the IPRs of SMEs especially against unauthorized exploitation.

However, little groundwork exists on the use of IP protection by businesses, especially in respect of SMEs, in fast developing countries such as India. Evidence indicates that SMEs in India do not use formal IP protection as a competitive strategy, and adapt to the threat of imitation by using informal methods such as trade secrets, maintaining product quality, and constant innovation. The essay advocates promoting IP as a tool for enhancing SME competitiveness. It requires an integrated approach involving awareness creation on the benefits of IP and ensuring effective enforcement of IP rights together with promotion of other competitive strategies. The essay also lays emphasis on the strong need for more research into the nature and characteristics at the enterprise level and how best to adapt formal IP registration systems so that SMEs can be encouraged to register their technological innovations and derive benefits from them. The impending question is does India have a policy for securing intellectual property of its SME sector from unauthorized exploitation?

• Introduction
“Knowledge Has Become The Primary Ingredient Of What We Make, Do, Buy, And Sell.”

- Thomas Stewart
Intellectual Capital (1997)

The phrase "Knowledge-based economy“ describes the new economic environment in which the generation and management of knowledge play a predominant part in wealth creation, as compared with the traditional factors of production, namely land, labor and capital. Intellectual property (IP) is a method for legally protecting this knowledge or intellectual activity. The system of Intellectual Property (IP) rights creates a mechanism to resolve the "Appropriability" problem, by creating property rights over knowledge. At the SMEs level, IP has been a significant source of comparative advantage of business enterprises and a major driver of their competitive strategies. Looking from the perspective of developing nations like India where SMEs represent over 90% of enterprises, IP protection cannot be overlooked anymore. SMEs are often the driving force behind a large number of innovations and contribute to the growth of the national economy through employment creation, productive investments and value-added exports. However, various ad hoc surveys and studies indicate that, despite the importance of SMEs for the vitality of the economy and the potential offered by the IP system for enhancing the competitiveness of SMEs, most of them do not use or do not get the best out of their use of the IP system. Their innovative and creative capacity is not always fully exploited as many are not aware of the intellectual property system nor the protection it can provide for their inventions, brands, and designs. To date there have been very few systematic research and publications on the nature and characteristics of IP creation as well as on the relationships between IPR systems and instruments and the IP-driven growth and competitiveness of business firms.

Even if for a second, we forgo competition oriented arguments and adopt a larger social perspective as set forth in the Millennium Development Goals by the world leaders in 2000 for reducing poverty and hunger, improving health and
education, we find that our capacity to achieve these objectives would be seriously compromised if adequate protection to IPRs is not provided. The impasses and the collapse of the WTO Ministerial Meeting over consensus on access to essential (but patented) drugs in the context of paragraph 6 of the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and Public Health brought home closer the intimate relationship between (IPRs) and achievement of these objectives.

Therefore if we leave, a good invention or creation unprotected, it may not only be lost to larger competitors that are in a better position to commercialize the product but we also put ourselves several steps backward in our fight against hunger and poverty. To help SMEs more fully utilize their IP assets in their business activities, India will have to establish a comprehensive policy framework to assist entrepreneurs, SME-support institutions in increasing awareness and use of the IP system among SMEs.

• **IP across SME spectrum**

  IP affects SMEs in almost every aspect of business development and competitive strategy: from product development to product design, from service delivery to marketing, and from raising financial resources to exporting or expanding businesses abroad through licensing or franchising. IP offers many opportunities for SMEs:

  a) **Enhancement of market value and the competitiveness of SMEs:**

      The value of IP is often not adequately appreciated and its potential for providing opportunities for future profit is widely underestimated by SMEs. However, when IP is legally protected and there is demand for the IP-protected products and/or services in the marketplace, IP can become a valuable business asset.

      • IP may generate an income for SME through the licensing, sale, or commercialization of the IP-protected products or services that may significantly improve an enterprise’s market share or raise its profit margins.

      • IP rights enhance the value or worth of SME in the eyes of investors and financing institutions.

      • In the event of a sale, merger or acquisition, IP assets may significantly raise the value of enterprise, and at times may be the primary or only true assets of value.

  The strategic utilization of IP assets can, therefore, substantially enhance the competitiveness of SMEs. SMEs should make sure that they are ready to face the challenge and take measures to exploit their IP and protect it wherever possible.

  b) **IP as a business assets:**

      An enterprise's assets may be broadly divided into two categories: **physical assets** - including buildings, machinery, financial assets and infrastructure - and **intangible assets** - ranging from human capital and know-how to ideas, brands, designs and other intangible fruits of a company's creative and innovative capacity. Traditionally, physical assets have been responsible for the bulk of the value of a company, and were considered to be largely responsible for determining the competitiveness of an enterprise in the market place. Increasingly, and largely as a result of the information technologies revolution and the growth of the service economy, companies are realizing that intangible assets are often becoming more valuable than their physical assets. In short, large warehouses and factories are increasingly being replaced by powerful software and innovative ideas as the main source of income for a large and growing proportion of enterprises worldwide. And even in sectors where traditional production techniques remain
dominant, continuous innovation and endless creativity are becoming the keys to greater competitiveness in fiercely competitive markets, be it domestic or international.

c) **IP as an investment:**
Making the right investments is crucial for enhancing the market value of SMEs. Investing in equipment, property, product development, marketing and research can strongly enhance company's financial situation by expanding its asset base and increasing future productivity. Acquiring intellectual property may have a similar effect. Markets will value company on the basis of its assets, its current business operations and expectations of future profits. There are numerous examples of SMEs that have seen their market value increase overnight as a result of their acquisition of important patents in key technologies. Similarly, a good trademark with a good reputation among consumers may also enhance company's current value and may decisively contribute to making company's products and services more attractive to consumers. Investment in developing a good IP portfolio is, therefore, much more than a defensive act against potential competitors.

d) **The value of IP assets:**
A crucial point about legal protection of intellectual property is that it turns intangible assets into exclusive property rights, albeit for a limited period of time. It enables SMEs to claim ownership over its intangible assets and exploit them to their maximum potential. In short, IP protection makes intangible assets “a bit more tangible” by turning them into valuable exclusive assets that can often be traded in the market place.

Increasingly, investors, stock market brokers and financial advisors are becoming aware of this reality and have begun to value IP assets highly. Enterprises worldwide are also more and more acknowledging the value of their IP assets, and, on occasions, have included them in their balance sheets. Many enterprises, including SMEs, have begun to undertake regular technology and IP audits. In a number of cases, enterprises have realized that their IP assets are in fact worth more than their physical assets. This is often the case for companies operating in knowledge-intensive and highly innovative sectors, or companies with a well-known brand name.

**• Bottlenecks or Roadblocks? The SME Story**
It would be preferable to understand at the outset as to which enterprises fulfill the eligibility criteria for being an SME and need preferential protection. There exist several definitions of the term small and medium enterprises (SMEs), varying from country to country and varying between the sources reporting SME statistics. The commonly used criteria at the international level to define SMEs are the number of employees, total net assets, sales and investment level. If employment is the criterion to define, then there exists variation in defining the upper and lower size limit of a SME. The European Union makes a general distinction between self-employment, micro, small and medium sized businesses based on the following criteria:

### Number of employees

<table>
<thead>
<tr>
<th>Number of employees</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Self-employed</td>
</tr>
<tr>
<td>2-9</td>
<td>Micro business</td>
</tr>
<tr>
<td>10-49</td>
<td>Small business</td>
</tr>
<tr>
<td>50-249</td>
<td>Medium-size business</td>
</tr>
</tbody>
</table>

In the Indian context, micro, small and medium enterprises as per the MSME Development Act, 2006 are defined based on their investment in plant and machinery (for manufacturing enterprise) and on equipments for enterprises providing or rendering services. A medium enterprise is where the investment in plant and machinery is more than five crore rupees but does not exceed ten crore rupees. A small enterprise is where the investment in plant and machinery is more than twenty five lakh rupees but does not exceed five crore rupees. In the case of the enterprises engaged in providing or rendering of services, as

- A small enterprise is where the investment in equipment is more than ten lakh rupees but does not exceed two crore rupees.
- A medium enterprise is where the investment in equipment is more than two crore rupees but does not exceed five crore rupees.

According to the Ministry of Micro, Small and Medium Enterprises, recent ceilings on investment for enterprises to be classified as micro, small and medium enterprises are as follows:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Manufacturing Enterprises*</th>
<th>Service Enterprises**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small</td>
<td>Rs. 50 million/ Rs. 5 crore (US$ 1 million)</td>
<td>Rs. 20 million/ Rs. 2 crore (US$ 40,00,000)</td>
</tr>
<tr>
<td>Medium</td>
<td>Rs. 100 million/ Rs. 10 crore (US$ 2 mn)</td>
<td>Rs. 50 million/ Rs. 5 crore (US$ 1 million)</td>
</tr>
</tbody>
</table>

*Investment limit in Plant & Machinery  • Investment limit in equipments  • Rs 50 = 1 USD

But irrespective of the definitional differences, there exists operational similarities among the enterprises in this sector. The contribution of SMEs sector to manufacturing output, employment and exports of the country is quite significant. According to estimates, in terms of value, the sector accounts for about 45 per cent of the manufacturing output and 40 percent of the total exports of India. The SME sector employs about 42 million persons in over 13 million units throughout the country. There are more than 6000 products, ranging from traditional to high-tech items, which are being manufactured by the Indian MSMEs.

Graph 1 shows that the SME sector observed better growth rates vis-à-vis the overall industrial sector in India.

Graph 1: Comparison of the growth rates in micro and small enterprises and the overall industrial sector

It can be witnessed from the graph 2 the contribution of the SME sector to the gross domestic product (GDP) has increased from 5.86% in 1999-2000 to 5.94% in 2006-07.

**Graph 2: Contribution of SME (%) at 1999-2000 prices in total industrial production and GDP**

Against the backdrop of appreciable economic contribution it is expected that IP creation and protection must have taken off in big way for better enterprise management in SME sector. But the statics seems to suggest otherwise and SMEs face a number of constraints. The volume of the formally registered IP assets do not mirror the enterprise development over the past three decades in India. It is no wonder that the report by the World Bank, *Doing Business 2010: Reforming Through Difficult Times* ranks India at 133 out of 183 economies in the Ease of Doing Business and ranked 169 overall for Starting a Business. To count a few, some of the key constraints that are being faced by the Indian SMEs are:

- a) Accessing adequate and timely financing on competitive terms, particularly longer tenure loans.
- b) Accessing credit on easy terms has become difficult in the backdrop of current global financial crisis and the resultant liquidity constraints in the Indian financial sector, which has held back the growth of SMEs and impeded overall growth and development.
- c) The financing constraints faced by Indian SMEs are attributable to a combination of factors that include policy, legal/regulatory framework (in terms of recovery, bankruptcy and contract enforcement), and institutional weaknesses.
- d) It has become difficult for lenders to be able to assess risk premiums properly, creating differences in the perceived versus real risk profiles of SMEs.
- e) Access to skilled manpower, R&D facilities and marketing channels is limited.

These factors are further compounded by the lack of detailed information on the sources or composition of industrial property assets in India. The paradigms to convert creative ideas into assets are different in developing countries. Whereas in the developed world, IP is treated as an asset and a part of the company's portfolio, hence valuing goodwill, securitization of IPRs, licensing the patent protected technology/assigning the copyright, outright sale of the IP etc., are common practices, none of these are of much importance in developing countries because of the level of their development and very meager IP portfolio in general. This is predominantly true in the field of patents but less so for trademarks and copyright, which are, compared to patents, quite widely used in India. Most of the IP assets generated by Indian firms are not formally registered as IPRs, patents in particular. This is due to the complexity and high transaction costs of IPR regimes. All these factors have great significance on the financing of IP, which requires a number of essential variables, including creation, maintenance and proper valuation to raise money and use IP portfolio as collateral.
It is also notable that with the opening up of trade in goods and services under the WTO, IPRs have become more susceptible to infringement without adequate return to the creators of knowledge. There has been a quantum jump in R&D costs with an associated jump in investments required for putting new technology in the market place. The stakes of the developers of technology have become very high and hence the need to protect the knowledge from unlawful use through IPRs has become expedient, at least for a period that would ensure recovery of the R&D. In view of the multi-sided constraints and bottlenecks reviewed earlier there is urgent need for a systematic, staged approach in IP protection.

### Start from Scratch: Need of Umbrella protection

There are certain problems, typical of developing countries, in IP financing. The whole exercise is to create and own an IPR at this juncture of their development is an arduous task. The whole journey from inventing, to obtain a patent, then to get venture capital to exploit the patent, build a business around it, grow it larger and then go public is riddled with problems. Once the product is developed or IP is at the stage of exploitation, the issue of financing of IP arises, i.e., securitization, licensing/franchising etc. In IP financing, the risk of infringement litigation is not uncommon when two companies are dealing in the same stream of technology. Small companies are usually not in a position to pursue infringement litigation. Financing companies have to take into account these risks while financing IP as security. Similarly, for management of IPR, a good support system is required, including legal, technical, financial and administrative functions. Let us discuss the policy areas where SMEs need prioritized protection:

#### a) Securitization of Intellectual Property Assets

Financial constraints and lack of infrastructure are hurdles creating and maintaining IP in developing countries like India. Capacity building for innovation is a very significant requirement in IP infrastructure. The industries in India need to appreciate that a good portfolio makes good business sense. The basic premise of financing intellectual property is – how to convert a creative idea into a financial asset.

Financial assets are the possession of an entity, which are held for purposes of producing revenues. Intellectual property rights (IPRs), like other financial assets, be they manufacturing plants, bonds, or goodwill, cost capital to produce or acquire, and are owned for purposes of generating a cash return. Many companies treat proprietary IPRs as patents, copyrights and trademarks as a discrete asset. In recent years, there has been a growing awareness that IP assets can be monetized. IP can be sold, licensed, used as collateral or security for debt finance, or it can provide an additional or alternative basis for seeking equity from private investors, venture capitalists, specialized banks and sometimes even from regular banks. IP assets may help a company to obtain business finance from investors/lenders.

The investor/lender, in undertaking an appraisal of the request for equity assistance or loan, will assess whether the new or innovative product or service offered by a company is protected by a patent, a trademark, an industrial design, or copyright or related rights. Such protection is often a good indicator of the potential of a company for doing well in the marketplace. IP ownership is thus important to convince investors/lenders of the market opportunities open to the enterprise for the commercialization of the product or service in question. For securitization, proper valuation of IP is very crucial. Valuation of IP is also important to secure loans or finances for business. So far, the valuation of IP has remained highly subjective for both lenders and borrowers and is generally not understood by most people. There still dearth of established norms for satisfactory evaluation on which uniform policy or guidance needs to be issued.

#### b) Significance of IP Infrastructure in Capacity Building for Innovation in SMEs

Before one may think of financing of IP, there has to be IP worthy of protection and leveraging. Most of the companies in
developing countries do not possess enough of that. Increasingly, it is being realized that the real innovation bottleneck is not the supply of new knowledge, but external factors surrounding the process, including lack of necessary infrastructure.

It has often been highlighted that in developing countries, a great gap exists between IPR and economic development policies, leading to low financial support for IPR institutions at all levels. IPR is not been mainstreamed in the national development policies nor into donor assistance programmes. India needs to prepare a national policy process that generates a national action plan with priorities. Since India is rich in traditional knowledge (TK), genetic resources and folklore, capacity building in IPR policymaking/administration should cover developing countries’ desire to establish protection and benefit-sharing arrangements for TK, folklore and biodiversity.

Policy-makers must carefully consider which type of protection is appropriate for each innovation whose needs are being served, and how to weigh expected costs and benefits. The development of indigenous technological capacity in is a key determinant to decide these issues. Capacity building in the technical field is very crucial to India. Bearing in mind the limited resources provided for IP technical assistance today, its effectiveness, its inclusiveness in terms of stakeholders, and its openness in addressing both strengths and weaknesses of current programmes, exploring ways to improve them are essential. Surprisingly though, very limited independent analytical work has been undertaken in this area and the literature is scarce.

At the national level, key factors that need to be addressed in innovation capacity building are technology and information infrastructures, legal framework, business support services, human resources and financial infrastructure. The help of international agencies can be taken to build this infrastructure. Commercialization of innovation into new processes and products that can benefit the economy requires infrastructure such as universal standards, policy and guidelines, venture capital, skilled labour, organized alliances and networks. Equal emphasis needs to be given to the provision of these infrastructures to ensure that world-class research and its commercialization can take place.

c) Building Information Infrastructure
Automated information systems are key requirements for efficient administration of IPR and an important indicator of institutional capacity. Although some larger, higher income developing countries have fully automated systems for searching and application processing to grant IPR, a large number of countries still have manual, paper-based systems. This not only hinders efficient processing of applications, but also greatly complicates collection of important statistical and management information.

d) Legal Framework
The legal awareness about IP rights is very low in developing countries and because of that most of inventors/innovators do not take advantage of the laws. The industry has yet to learn defensive as well as aggressive management of their IPRs, by protecting their own rights while at the same time not to infringe others’ in order to avoid any infringement suits. India faces arduous institutional challenges in implementing IP protection. The challenges include formulating appropriate legislation, administering IPRs in line with international obligations, and enforcing and regulating IPR in a pro-competitive manner appropriate to national levels of development. Most of these countries lack an effective implementation of IP laws.

Judicial delays are the order of the day, which means that cases can take years to see resolution and payment of damages on IPR violations. A specific enforcement mechanism may lead to an effective implementation of these rights. In Chennai, where there is a separate Deputy Police Commissioner who deals with copyright infringement, the industry has reported a steep decline in film and music piracy. This success could be repeated in other sectors provided government and industry cooperate in dedicating sufficient resources to strictly enforce IPRs.
e) Business Support Services

Another important plank of innovation facilitators is that of business support services through appropriate government agency or professional association that forges and maintains a link between the inventors/innovators, research organizations and SMEs with respect to sourcing of technologies, knowhow, equipment, workshops and test laboratories for quality assurance, and formulation of demand-driven research projects, and ready commercialization of inventions. In India, an extensive system of broad public consultation has evolved over the years, which includes public workshops on issues such as protection of biodiversity and traditional knowledge, use of compulsory licensing, and the need of high level expertise in the academic, business and legal communities. But the government should vigorously go ahead with policy on industrial location and incentives for the development of sub-sectoral clusters of SMEs. Such clusters would share facilities, with common pool of information network on markets, venture capital, databases, etc. Sustaining regional innovation clusters requires continuous interaction between research centres, universities and local business leaders in order to sustain cluster growth and the development of new knowledge-based industries. A prime example of such clusters and initiatives is the National Innovation Foundation (NIF). The Department of Science and Technology and the Government of India constituted the NIF with an aim to recognize and support the creative potential of innovators at the grassroots and harness their creativity to help make India self-reliant and a leader in sustainable technologies. Further, in this regard the Government of India through various ministries should set up nodal agencies that provide entrepreneurial assistance, investor facilitation, processing of all applications which require government approval, assisting entrepreneurs and investors in setting up projects and in monitoring the implementation of projects.

- Conclusion: Combatting counterfeiting & A few suggestions

Nam et ipsa scientia potestas est("Knowledge is Power")
- Sir Francis Bacon (1597)

In an increasingly international marketplace, many companies are finding that prosperity is best achieved from specialization, as opposed to diversification. Thus protection for intellectual property rights of the SMEs become all the more important. Counterfeiting and piracy harms commerce and the public well being, and undermines confidence in the quality of brand name products, resulting in billions of dollars of lost revenue, investment, future sales, and growth opportunities. It also harms legitimate businesses and workers who play pivotal roles in creating, manufacturing, distributing, and selling genuine products. In addition, because infringing products are often substandard in quality, they can harm consumers in a myriad of ways. Consumers are vulnerable to harm when infringing products penetrate the process between the manufacture and sale of goods - known as business supply chains.

Protecting supply chains from counterfeit and pirated goods requires close public-private sector collaboration. Both must work in concert to identify infringing goods and prevent them from entering the marketplace and international channels of commerce. In this interplay, SMEs should actively endeavor to ensure the security of their production and distribution chains. Indeed, close cooperation is required between government and enterprises for effectively securing protecting consumers and right holders.

It is also important to make the public aware that the manufacture and the trafficking of counterfeit and pirated products, including the importation and exportation of such products, is illegal and may result in severe civil and/or criminal penalties. To this end, the following measures should be taken:

- Undertaking campaigns to inform importers and exporters of the severity of penalties associated with the unlawful trafficking or distribution of counterfeit and pirated goods.
• Undertaking broad educational campaigns that address the harm counterfeiters cause to society and the economy.
• Developing educational programs for consumers and retailers on identifying and avoiding counterfeit and pirated products

But the onus is not on the government alone, SMEs must keep in mind the following measures to get best out of their IP rights:
• Registering IP assets at the earliest in order to take full advantage of IP rights while undertaking advertising and other promotional activities.
• Checking carefully to make sure that SME does not infringe the IP rights of others. In this respect, it is advisable to conduct trademarks and patent searches before commercializing products and services which may conflict with the IP rights protected by other persons or enterprises.
• Use, or make reference to, IP rights in advertisements and other promotional activities in order to make customers and potential customers aware of the IP protection of products and services.
• Monitoring the market and be ready to contact an IP lawyer or an official enforcement authority wherever infringement of IP rights is detected

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Does The Need For Access To Information Override The Protection Of Copyright & Other Property Rights, Especially in the Digital Media?

Winner Two:
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Abstract
The dawn of digital technologies in the latter half of the twentieth century has worried the copyright enthusiasts, mainly because of the ease with which information can flow through such technologies, including a vast world of copyrighted materials. Legislations are being enacted and technological mechanisms are being used to control such free flow of information. In the author’s opinion, excessively regulating the digital media can impede creativity and innovation. As will be shown in the essay with the help of examples from the past, creativity has flourished only in a culture reasonably balanced in the favour of public, as opposed to the copyright owners. The author has suggested that digital media should not be treated as a threat to the copyright owners, but should be used by the authors as well as by the lawmakers to promote reasonable flow of information to inspire creativity and inventiveness.

Introduction
The inherent conflict between the need for a robust public domain for free access to information on one hand, and that of protecting the copyright of the content creators on the other, has been dynamic, yet centuries old. The need for striking a balance between the two has been recognized by the Courts and the lawmakers alike. This balance, however, is threatened by the recent technological changes which started with the advent of personal computer (PC) in the late 1970s and early 1980s, and followed by rapid succession in the late 1980s and 1990s by pre-recorded compact discs, digital audio recording media, digital multimedia technology, the internet, high quality recording tools etc. The threat posed by these networks and digital technology to the ownership and control of information has led industries to obtain increasingly absolute protection over their “property”. However, rapid changes in regulating digital content undermine the need for access to knowledge and information, and stand a chance of adversely affecting the crucial public domain.

Free access to information is perhaps the main requirement of the emerging digital economy, and it is commonplace to say that information is the new petroleum of our societies. Excessive regulation through extreme copyright and other intellectual property law regime threatens to deprive the society of its petroleum, by bringing more and more works within the ambit of copyright and taking it away from the public domain.

The copyright law of any country is based on a charming notion that authors create something from nothing, that works owe their origin to the authors who produce them. However, this is not true. Composers recombine sounds that they have heard before; playwrights base their characters on bits and pieces draws from other human beings and other playwrights’ characters; novelists draw their plots from lives and other plots within their experience; lawyers transform old arguments to fit new facts etc. One can safely say that nobody has ever been able to create anything out of nothing.

The need for a stronger public domain is as important as the air we breathe. It is the fuel to enrich creativity; it acts as a fodder for artists and scientists alike. The digital revolution could be an unprecedented contribution to this ideal. Sadly, even in the present ‘information society’, it is this public domain which is threatened the most due to an overtly strong intellectual property regime, which in turn is obstructing access to valuable information.

The Need (and Necessity) for Free Access to information
“If you have an apple and I have an apple and we exchange apples, then you and I will still each have one apple. But if you have an idea and I have one idea and we exchange these ideas, then each of us will have two ideas.”
- George Bernard Shaw

Information does not possess the same characteristic as the classical real property. For instance, unlike real property, the
dissemination of ideas does not reduce their use value. Information is considered a ‘non-rival’ good, in the sense that usage of a particular piece of information cannot impair the utility of that information to another user. It has also been characterised as ‘non-excludable’ in the sense that use of a certain piece of information does not exclude other users from utilising the same information. The sharing of information goods, especially in the digital context, does not diminish in any manner the quality of the good that is shared. The best example of this is software. The use of software by any other person except for the owner does not affect the utility of the software itself, nor does it prevent the usage of that software by the original owner. The only way a person can prevent the copying of software is by preventing third persons from accessing it. Once access is granted, it can be copied for almost no cost.

Access to information is essential for a democratic society. Free access facilitates public health, public policy and the economy as a whole. It helps scientists in finding new cures for diseases or better options to the existing cures. It has been argued that it may be cheaper to regulate some forms of property by providing free access to it, rather than restricting access through regulations.³

Further, copyright was intended to serve the public interest by encouraging the advancement of knowledge while protecting the rights of authors and copyright owners. It is meant to balance the competing interests of creators, publishers, and users, not stifle the free flow of information.

From Shakespeare to Mickey Mouse to Doujinshi: A History of Free Access

Any culture develops with significant reference to the past. The importance of this interaction with the past for future cultural development makes copying of earlier works a culturally valuable activity. The information from the past serves as a vehicle, through which apprentice, students and experts hone their skills to develop new technology and products for the ultimate betterment of the society, thus distinguishing the present from the past.

Shakespeare, for instance, adopted many of his plays from pre-existing sources in the same way as dramatists, poets, novelists; film-makers etc., later on used his texts as the basis for their own adaptations.⁷ Similar is the case with the creation of arguably the most popular cartoon character ever, the Mickey Mouse. It was brought to life in a cartoon Steamboat Willie. This was the first ‘widely distributed’ cartoon synchronized with sound. However, little do people know that synchronized sound has been introduced a year earlier in the movie The Jazz Singer. The widespread success of this movie led Walt Disney to ‘copy’ the technique and mix sound with cartoons.⁸

Perhaps a more blatant form of ‘copying’ (as we may call it today) was that of Steamboat Willie from a silent film of the same year Steamboat Bill, Jr. Steamboat Willie is a direct cartoon parody of Steamboat Bill, Jr. and both are built upon a common song as source, namely “Steamboat Bill”.⁵

Such “borrowing” was not unique. Early cartoons are filled with knockoffs - slight variations on winning themes; retellings of ancient stories. The key to success was the brilliance of the differences.¹⁰

A more recent and even more surprising example of such a borrowing is that of doujinshi. Doujinshis are famous ‘copycat comics’ of Japan. Its creators take the mainstream comics and develop them differently. The changes may be trivial, or significant. The artist must make a contribution to the art he copies. The crucial part here is that such comics are allowed to exist in Japan, when in the language of copyright, they are plainly “derivative works”.¹¹

Such has been the significance of a free flow of information from generations to generations. Creativity has flourished only...
on the groundwork laid down in the past, and has been interpreted as how much one can contribute to this groundwork to make it more beneficial to the society. As Shen Zhou, a Chinese painter of Ming Dynasty, is reported to have said “if my poems and painting, which are only small efforts to me, should prove to be of some aid to forgers, what is there for me to grudge about”?

**Shrinking Public Domain and Impeded Access to Information**

The trend of going for excessive IP protection has grown more acute in the last few decades and presently threatens creativity and access to information. Copyright laws around the world were originally enacted to encourage creativity, science and democracy. Instead, the law now seems to protect the producers and taxes consumers. It rewards works already created and limits works yet to be created. As copyright historian Lyman Ray Patterson has articulated, “copyright law in twentieth century has really been about the rights of publishers first, authors second, and the public a distant third.” As commercial interests commodify the Internet, laws are passed and boundaries built to ensure their dominance in the electronic world. The prevailing trend is towards strengthening property protection online. In other words, the threat to the status quo by digital technology has led to new laws being designed to limit the circulation of ideas. The drift towards overzealously guarding technical secrets for ulterior corporate purposes started way back in 1970-80, when computers were still in their nascent stage. Software companies released the source code with their softwares so that programmers could alter and customize it to their needs. As software industry blossomed in the 1980s, they realized that there was commercial value in keeping the source code secret. Hackers who had been utilizing these products as a source of public innovation were transformed into criminals. While conveniently ignoring the importance of the free flow of information, software owners began to assert property boundaries that locked up codes into the hands of concentrated monopolies.

This shift of priorities of software industries was well supported by a strong cluster of developed countries. The TRIPS Agreement is the culmination of efforts of these countries. The genesis of TRIPS negotiations lies primarily in the concern of the US and other developed countries that without a redrafting of rules governing the relation of trade and intellectual property rights, they could not sufficiently protect their trade interests.

A blatant example of legislative recklessness resulting from TRIPS Agreement is Digital Millennium Copyright Act (DMCA) of 1998. The DMCA:

- Prohibits the circumvention of any effective technological protection measure installed to restrict access to copyrighted works.
- Prohibits the manufacture of any device, composition of any program, or offering of any service that is designed to defeat technological protection measures.
- Orders the Librarian of Congress to conduct rule-making hearings to judge the effects of law would have on non-infringing uses of copyrighted material.
- Makes no textual change to the fair use provisions of the Copyright Law, despite eliminating the possibility of unauthorized access to protected materials for fair use purposes.

DMCA also seems to allow for potential censorship by permitting copyright owners to force internet service providers (ISP) to remove any material from the internet if the copyright owner believes the material to be infringing in nature. This clearly has transnational consequences for political freedoms that the internet enables for people around the world living in countries where the copyright law allows such material to exist. Even more interesting is that such demands for removal occurs without an independent judgment of whether actual infringement is in fact occurring.
Sonny Bono Copyright Term Extension Act (CTEA) of 1998 is another much criticized legislation, by which all copyrighted works were given an additional twenty years of protection before they would enter the public domain. The copyright protection given to authors was increased from life of author plus fifty years to life plus seventy years. In what seems to be a conceptually flawed judgment of Eldred v. Ashcroft, in which the constitutionality of CTEA was challenged, the Court held that “the CTEA is a rational exercise of the legislative authority conferred by the Copyright Clause... The CTEA may also provide greater incentive for American and other authors to create and disseminate their work in the United States. Additionally, Congress passed the CTEA in light of demographic, economic, and technological changes, and rationally credited projections that longer terms would encourage copyright holders to invest in the restoration and public distribution of their works.

The state sanctioned balance between protection and openness can be undermined if greater focus gets placed on the former as opposed to the latter. Original creators of copyright legislation understood the potential threats posed by long years of exclusive monopoly rights and therefore restricted these rights to a minimal period. Extension of monopoly rights to an unnatural term defeats the whole purpose of “promoting progress” as the US Constitution envisages.

In recent years, new objects and subjects have appeared in the area of intellectual property, such as the rights recognized as pertaining to producers of phonograms and video graphic recordings to the sui generis rights on databases. Article 10.2 of the TRIPS Agreement categorically provided for database protection. The WCT also affirmed this protection in Article 5. The European Union has developed database protection that extends to data and “provides a sui generis right that protects the contents of the database that may or may not exhibit such creative arrangement or selection.” Databases are also covered by the definition of literary works in the Indian Copyright Act. It has been argued that “since the standard of originality accepted by the Indian Courts for entitlement of copyright protection is a low one, almost all the compilations enjoy copyright protection. Expend ing labour and skill in the creation is the only criterion that is applied to judge the eligibility of a work for copyright protection and based on that computer databases enjoy protection in India.”

Database rights contradict the very foundation of intellectual property rights, which are designed to protect intellectual work and not mere compilations. Furthermore, it enables the holder to control and therefore prohibit access to information itself. The threat will be particularly real when the whole of the data can only take the shape that the producer of the database gives it. This will be true, for example, of public transport timetables, television programme schedules, tide charts, weather reports, etc. Accessing this data requires accessing the database proposed by those who collect the data, giving the latter a legal monopoly over the base amounts to giving them a de facto monopoly over its content.

Technological mechanisms are also used by corporations and software industries to supplement the legal protection provided by law to these industries. Serial Copy Management System (SCMS), cryptography, digital signatures and Digital Rights Management (DRMs) are in the forefront of these technologies. DRMs regulate what one can and cannot do with a digital file. Its conditions can include how many copies of the original file a user may make, whether a back-up or archive file can be created or whether a user can move the contents to another device. However, DRMs are completely oblivious to the specific circumstances of the user, as well as his rights. In some countries, fair dealing, or fair use might allow for ways of personal consumption of copyrighted material that the DRM withdraws, or the user might be a blind person, or a person working in a public library in a country whose national copyright law might specifically extend provisions to visually disabled people and libraries, thus resulting in a situation where the whims of a multinational industry render national law meaningless.
Technological measures like DRMs, coupled with legislative measures like DMCA or CTEA pose serious problems for access to information for the users in digital world. Will the future be the one where centralized content owners erect barriers to control the circulation of ideas? According to current industry trends, nothing will be free in the future.

**Digital Media: Are they (or Can They Be Made) a Blessing in Disguise?**

Digital technology has literally revolutionized the mode, quality and speed of transmission of information not only through internet but also in the conventional transmission mediums. The emergence of Internet as a powerful and reliable platform for communication facilitated the creation of new works in the form of multimedia. Today these works are used not only for educational purposes but also for business. As Lawrence Lessig puts it:

“Digital media has truly unleashed an extraordinary possibility for many to participate in the process of building and cultivating a culture that reaches for beyond local territories… It can produce vastly more competitive and vibrant market for building and cultivating culture; that market could include a much wider and more diverse range of creators; those creators could produce and distribute a much more vibrant range of creativity; and depending upon a few important factors, those creators could earn more on average from this system than creators do today.”

Under the digital technology, there are three principal developments that have dramatically altered the structure and accessibility of information. These are (a) zero marginal cost of copying, (b) zero cost of transmission especially over the internet and (c) almost negligible cost of producing/posting new information on the Internet. We are going through a significant mode of transition in terms of global access to information. It is important for countries to consider viable alternatives to the traditional copyright system, which will allow further replenishing of information rather than depleting it. Some of the promising innovations working for such replenishment deserve special consideration.

1) **Copyleft**

Copyleft is the term that is now commonly used to designate the free software or free art initiatives. Such initiatives have coined the term copyleft in opposition to copyright to emphasize that contrary to a traditional exercise of the copyright, the author in copyleft gives up her right in the work and leaves it to the public. Actually, the copyright is not properly given up or left to the public, but the author authorizes a broader right to use her work than what is traditionally granted. The term “Copyleft” was originally used by Free Software Foundation to describe its free software copyright license. According to its website: “Free software is a matter of liberty, not price”. To understand this concept, you should think of free as in free speech, not as in free beer.” General Public License (GPL) is another innovation which is a part of the Copyleft movement. Section 2(b) of the GPL license says:

“You must cause any work that you distribute or publish, that in whole or in part contains or is derived from the Program or any part thereof, to be licensed as a whole at no charge to all third parties under the terms of this License”

It clearly allows for free re-distribution of software without any royalties or licensing fees to the author. It is mandatory to distribute the source code with the software. It also allows anyone to modify the software, and to redistribute the modified software under the same terms. This encourages free flow of information, and will help the new creators who wish to access the source code of softwares to build up new softwares on already existing information.

2) **Peer-to-peer (P2P) open source collaboration**

The basic concept of P2P networks is to provide direct connectivity between end users, thus enabling them to easily share files with each other directly instead of going through a centralised server. P2P networking was made famous by Napster
and even more famous by the case which shut Napster down.\textsuperscript{37} Even after Napster, downloading of “illegal” music thrived. The music industry which was earlier threatened by P2P networks later based their model on what is sometimes called Grateful Dead business model or “reputational capital” model: Give away free music to build a loyal following, establish a brand name, and charge handsomely for the total entertainment package.\textsuperscript{38} As Janis Ian, a musician puts it:

“\textbf{The music industry is up in arms over the fact that it is harmed by free downloads. Nonsense… When Napster was running full-tilt, we received about 100 hits a month… Of those 100 people, 15 bought CDs… No record company is \textit{merely} interested in 180 (15x12) extra sales a year. But in my book that translates into $2700, which is a lot of money to me. … Face it – most people can’t afford to spend $15.99 \textit{[buying a CD just] to experiment. The music industry should be rejoicing at this new [on-line] technological advance!”}\textsuperscript{39}

Such networks also offer wonderful opportunities for emerging artists. The established music industry narrowed the pipe of production and distribution, and only established artists gained from the whole system. It can also help established artists to be more responsive to the margins of the market such as ethnic communities, sub-cultures and political movements. From a consumer’s perspective, it made available a world of music and literature, including that which was technically under copyright, but was no longer commercially available, or those which copyright owners would want to have shared or for which they have no continuing copyright. The ease and inexpensiveness of P2P networks have inspired millions to enjoy music in a way they hadn’t before.

\textbf{Conclusion}

As early as 1994, the authors of the “\textit{A Magna Carta for the Knowledge Age}”\textsuperscript{40} conceived of two possible models of development: the first, known as the “cyberspace” model, corresponded to the wishes of the protagonists who started the Internet. It was about free circulation and access to information and free expression. The second, called the “\textit{Information Superhighways}” model, envisaged the development of tools to control access to information. Thus, law and technology seeks to maintain a balance between two worlds: that of freedom and of property.

Without a balance between the ownership and exchange of ideas, we will lose a vital public space from which new innovations can emerge. Laws like CTEA shrink the scope of the public domain and ultimately reduce the resources available for free access. While we must appreciate the concerns of owners of copyrighted materials in the digital format, we should not over-protect them at the cost of public interest. Laws like DMCA should be reconsidered, and additional legislation aimed at expanding the realm of private property, thereby restricting access to information, should be discouraged.

Digital technologies can arguably be said to be still in their adolescent stage. The policies we frame today to regulate such technologies will determine how the future of innovation and access to information will be like. Erecting strong property barriers around ideas and information will hamper advancement of societies and will disrupt already stressed freedom of access to information. As Gernstein envisaged:

\textbf{“The biggest change is that the information you get over your laptop, Palm or pen probably won’t be free. And if it is free to peek at, you probably won’t be able to copy and paste it, print it or look at it second time, or store it on your hard drive in any way – unless you pay for the privilege.”}\textsuperscript{41}
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20 Ibid
21 See section 1201(a)(1)(B)-(E)
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24 17 U. S. C. §302(a)
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29 Article 5-Compilations of data or other material, in any form, which by reason of the selection or arrangement of their contents constitute intellectual creations, are protected as such. This protection does not extend to the data or the material itself and is without prejudice to any copyright subsisting in the data or material contained in the compilation.
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Intellectual Property Implications of Pharmaceutical Mergers & MNCs Joining Hands with Generic Companies

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Abstract
The Pharmaceutical industry is witnessing turbulent times. The drug discovery uncertainties, market pressures, product withdrawals and failures, patent expiries and generic competition, are all threatening the industry which has responded to these multiple pressures through a cascade of mergers and acquisitions. The dynamics of the industry has changed and so also the objective of the mergers in the pharmaceutical world. The recent spate of deals between the “Pharmaceutical Originator” and the “Generic” companies signify the blurring of the boundaries between the ever warring factions and signal an “amalgamation renaissance” in the pharmaceutical merger space. Intellectual Property is the key consideration driving these partnerships. The article throws light on the changing dynamics in the Pharmaceutical mergers, emerging business models in the Pharmaceutical industry and the Intellectual Property implications of the “Originator” joining hands with the “Generics”.

Introduction
The pharmaceutical industry is highly complex and the challenges faced by the it are numerous. It carries on its quest for addressing healthcare solutions especially for life threatening diseases through the most prudent way of research and development.

The development of a pharmaceutical drug is characteristically a high-cost venture and the uncertainties are enormous. The development of a new drug molecule from the bench to the market can require about 12 years and a typical investment in the order of US$ 1 billion. Adding to these discovery uncertainties are the market pressures, product withdrawals and failures, patent expiries and generic competition, to which the threatened industry has responded with a cascade of mergers and acquisitions.

Intellectual property (IP) is the cornerstone of any business enterprise and form the business assets of any “innovation-centric” pharma company. Intellectual property protection, especially traditional forms of IPR like patents and trademarks are crucial to these companies as they incentivize them in developing a new drug molecule by awarding monopolistic rights on the product. Patents often provide market monopoly and trademarks confer brand value to the new drug molecule, allowing the companies to achieve greater profit margins.

The relationship between IPR and business strategies of pharmaceutical companies is paradoxical. The business strategies of pharma companies, in particular, those which are “innovation-centric” are driven by their patent goldmines. Patent protection for drug molecules can assist the “innovation-centric” companies in keeping their competitors at bay and also help create necessary financial incentives for mergers and acquisitions. At the same time, patent depletion and patent litigations can be the primary drivers for the pharma companies in innovating new business solutions in the form of striking a money-spinning deal or a merger. In addition to the traditional forms of IPR, sui generis forms like data exclusivity, paediatric exclusivity which are extensions of a product patent protection for a original new drug molecule, also have greater impact on the business strategies of such companies.

I) Innovations and Intellectual Property Rights in the pharmaceutical space
Innovation models
There are two models of innovations in the pharmaceutical space, the first one being often referred to as the “Breakthrough invention”, which applies a pioneering approach in utilising new scientific knowledge that generates a new drug molecule. The second model of innovation is the “incremental innovation” brought about by incremental improvements of existing drug molecules, often through modifications and development of new applications.
The global “originator” or the “innovation-centric” pharmaceutical companies having multinational presence, colloquially known as “Big Pharma” are the ones who are usually engaged in ground-breaking research to generate a blockbuster therapeutic breakthrough. This “blockbuster” drug development model has been the quintessence of the Big Pharma till recently, and relies upon development projects to spawn blockbuster products and assist companies to retain their profit levels.

The global “originator” or the “innovation-centric” pharmaceutical companies not only obtain patent protection on active ingredient in the new drug molecule, but also obtain secondary patents relating to the same new active ingredient (incremental inventions), for example, new formulations, compositions, new dosage forms, routes of administration, salts, derivatives of active ingredient etc. The secondary patents which protect a myriad of minor developments prevent or delay the entry of generic products even after the patent protection for the original new drug molecule expires.

**Pharmaceutical test data and other forms of IP**

To introduce a original drug molecule the innovator pharmaceutical companies are required to make considerable investment in extensive testing and reporting on efficacy, safety and quality of the new medicine. Pharmaceutical test data generated by the originator companies is submitted to the health regulatory agencies to obtain marketing approval and these studies represent up to 60% of the research and development investments for the “originator” companies.

Article 9. of Trade Related Intellectual Property System (TRIPS) determines that the submission of undisclosed tests or other data to the health regulatory agencies must be protected against unfair commercial use. This kind of Intellectual Protection is known as market or data exclusivity. The data exclusivity term provided for an original drug molecule invented by the pharmaceutical inventions is 5 years in the United States and 10 years in the European Union (1).

The pharmaceutical companies also use trademark protection obtained for their drugs (e.g., a product name, brand name, or distinctive logo) to extend their market power beyond the patented drug’s expiry date. Patented drugs are usually marketed under their brand name rather than the generic name. The “originator” pharmaceutical companies can also obtain competitive advantage through Trade secrets and Copyrights.

According to IMS Health as restated in the 2004 AstraZeneca Annual Report, the United States, the European Union and Japan comprise the three major pharmaceutical markets (2). Half of the top ten “innovation-centric” companies are headquartered in Europe – GlaxoSmithKline, Sanofi-Aventis, Novartis, AstraZeneca and Roche – but a significant proportion of their research and development is undertaken in the United States (3).

**II) The field play of the “Generics” and “Innovation-centric” Pharmaceutical companies**

**Genesis of the Generic Pharmaceutical Industry**

Historically, international patent norms like Paris Convention of 1883 facilitated the growth of pharmaceutical industries in many countries which lacked the capacity to invent and produce drugs. While many industrially developed countries adopted product patents to promote further innovations, some of the developing countries realised the potential of the process patents in developing the domestic industry and adopted the same (4).

The flexibilities available in the Paris Convention also enabled these countries to provide access to medicines at affordable cost. The net result was the emergence of a strong and powerful generic industry in many parts of the world, including Asia. Some of these industries started penetrating the developed markets causing a...
potential threat to their dominance. These developments compelled the governments of the developed countries to initiate negotiation for new international norms to protect the new inventions in all new fields of technologies during the Uruguay Round of GATT negotiations started in 1986 (5). Trade Related Aspects of Intellectual Property Rights (TRIPS) was therefore brought in with the purpose of universalizing the standards of Intellectual Property Rights and bringing the rules of the game for the developing countries on par with the developed countries.

The warring factions: Generics versus Innovators

The advent of modern generic pharmaceutical companies can be contributed greatly to the 1984 US Drug Price Competition and Patent Restoration (Hatch-Waxman) Act. Generic competition for a patented drug arises when the term of the patent expires. However, the Act allows generic companies to develop their manufacturing capability and to conduct clinical trials prior to patent expiration, and use freely the patent holder’s clinical data, by showing that the generic drug is bioequivalent to the patented drug. The originator company on the other hand is also compensated for the loss of time in getting a drug regulatory approval by receiving automatic patent term extensions up to five years (6).

Yet another way the Hatch-Waxman Act has been exploited to extend patent rights is through patent litigation. When generics create a copy of a patented drug, the generic manufacturer files with the United States Federal Drug Authority (US FDA) an Abbreviated New Drug Application (ANDA), which formally seeks the FDA’s approval to sell a generic version of a brand name drug once it expires. The Hatch-Waxman Act requires that the generic manufacturer notify the original brand name manufacturer of its plans to distribute a generic. The originator company sues the generic company for infringement of its patented drug and t

The highly developed generic markets include United States, United Kingdom, Germany, the Netherlands, Canada and the expanding generic markets include France, Spain, Italy,

Russia, Latin America, Australia etc. (7). China and India are the leading Asian emerging market producers of the active pharmaceutical ingredients and their pharmaceutical industries most frequently originated as emerging competitors for a significant share of the global originator and generics markets. Indonesia, Malaysia, the Philppines and Thailand, house significant generic production capacity. Bangladesh has emerged as a pharmaceutical production centre taking advantage of its status as a least developed country (which allows its producers unique flexibility to bypass potential patent protection and market exclusivity restrictions otherwise applicable under the TRIPS agreement) (9).

Generics and innovators: Is there anything common?

The generic pharma companies and the originator MNCs are constantly competing with each other. The MNCs relies on patent litigation to keep the generics out of competition. They utilise the Hatch-Waxman provision that disallows a generic manufacturer from entering the market while there is ongoing litigation in order to settle IP disputes. Another route adopted by the “Big pharma” to resist generic competition is to establish their own generic companies (called “Authorised Generics”) and sell only versions of their own medicines that lose patent protection.

The generic companies on the other hand in the developing countries either join hands with other generic companies or
innovate and patent their incremental inventions in areas such as chemical synthesis, new methods of use, and new drug delivery systems and as they grow, even engage in basic research or new drug molecule discovery. The common unifying factor is therefore the desire to maintain robust competition.

III) Pharmaceutical Mergers: The need and objective

“It’s clear that you cannot stay in the top league if you only grow internally. You cannot catch up just by internal growth. If you want to stay in the top league, you must combine.” - Daniel Vasella, Chief Executive Officer, Novartis, July 2002.

Mergers and acquisitions have always been viewed as a core implement by the pharmaceutical companies for expansion and growth. The pharmaceutical industry since the 1980s has been characterized by a flurry of mergers and acquisitions. The innovator pharmaceutical companies had struck lucrative mega merger deals in the period between 1990 and 2000, and in this period, the volume and value of pharmaceutical mergers increased significantly as depicted in Figure 1.

Figure 1: Top ten Pharmaceutical deals 1994-2001

<table>
<thead>
<tr>
<th>Date</th>
<th>Acquirer</th>
<th>Target</th>
<th>Value (Bn)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jun-00</td>
<td>Pfizer</td>
<td>Warner-Lambert</td>
<td>87</td>
</tr>
<tr>
<td>Dec-00</td>
<td>Glaxo Wellcome</td>
<td>SmithKline Beecham</td>
<td>76</td>
</tr>
<tr>
<td>Dec-98</td>
<td>Zenea</td>
<td>Astra</td>
<td>37</td>
</tr>
<tr>
<td>Nov-95</td>
<td>Monsamb</td>
<td>Pharmacia &amp; Upjohn</td>
<td>28</td>
</tr>
<tr>
<td>Jan-95</td>
<td>Glaxo</td>
<td>Upjohn</td>
<td>15</td>
</tr>
<tr>
<td>Dec-98</td>
<td>Serox</td>
<td>Wellcome</td>
<td>14</td>
</tr>
<tr>
<td>Mar-01</td>
<td>Johnson &amp; Johnson</td>
<td>Synthelabo</td>
<td>11</td>
</tr>
<tr>
<td>Aug-94</td>
<td>American Home Products</td>
<td>American Cyanamid, ALZA</td>
<td>10</td>
</tr>
<tr>
<td>May-01</td>
<td>Bristol-Myers Squibb</td>
<td>DuPont Pharmaceuticals</td>
<td>8</td>
</tr>
</tbody>
</table>

Source: Cap Gemini Ernst and Young Analysis, Company Annual Reports.

The primary drivers of the pharmaceutical mergers illustrate four distinct strategies: creating market muscle, consolidating for cost reduction, broadening geographic coverage and pipeline stuffing. The late 1980s and 1990s was marked with first significant merger activity and the genesis of mega mergers. These transactions were intended by the global originator companies to reap the benefits of increased market muscle.

Glaxo in 1995 was facing shortfall in R&D pipeline, when Zantac, the world’s best-ever selling drug was coming to an end of its lifespan. Following its timely acquisition of Wellcome, the company renewed its pipeline overnight to create a substantial and innovative asset, which included drugs like Seroxat. Glaxo also achieved some of the most aggressive cost savings in the history of pharmaceutical mergers and acquisitions with its unconditional takeover of Wellcome – savings that ultimately delivered as shareholder value with a 400% increase in market capitalisation in the four years following the merger. Astra and Zeneca achieved geographic expansion and increased critical mass and above all, shored up two increasingly vulnerable portfolios with their merger in 2000. Pfizer, the pharma giant
has been down this mega-merger route, buying out Warner-Lambert in 2000 and Pharmacia in 2000° (10).

A flurry of recent pharmaceutical company mergers and acquisitions got plenty of attention with Pfizer’s acquisition of Wyeth for $68 billion (January 2009) to retain its number one position, United States drug multinational Merck’s purchase of Schering-Plough for $41 billion (March 2009) and Genentech’s deal with Roche all made headlines for their potential to help the resulting entities reduce costs and add new, promising drugs to company pipelines (11).

IV) “Innovate to Colloborate” – The Emerging Trend in Pharmaceutical Mergers

Colloborate to Innovate

Traditionally, the pharmaceutical multinationals placed a great deal of emphasis on mega mergers13. While the “Big pharma” was becoming mightier, these mergers were getting viewed as the ultimate collaborative models for intensifying research and development and gaining a financially lucrative pipeline. The blockbuster drugs were going strong.

A decade later, the consolidation has not however, led to an upsurge of new drugs. Analysts estimate that pharma R&D productivity today is two-fifths of what it was 10 years ago. Pfizer alone has spent more than $60 billion on research and development over the past eight years but has not produced a drug from its own labs with annual sales surpassing $1 billion. (11).

Merck and AstraZeneca combined two of their leading pipeline products to develop an innovative cancer therapy, GlaxoSmithKline (GSK) and Concert Pharmaceuticals pooled pipeline assets in part to distribute risk, and Pfizer and GSK combined their HIV pipelines and marketed products into a joint venture to increase their chances of success. Yet mergers have typically contributed to declines in R&D productivity. Rather than streamline and focus R&D, managements tend to retain most of the drug pipelines, physical assets, and the R&D talent of the combined companies, which makes decision-making and resource allocation even more difficult (12).

Pipeline Drought

Multinational pharmaceutical “originator” companies are under pressure as their new drug pipelines are drying up. This ‘innovation depletion’ has enormous strategic implications for the industry as a whole. Despite substantial increase in R&D budgets, in the last several years, the number of new compounds introduced in the market fell sharply in the late 1990s. Also, there is a growing realization that the companies can no longer rely on blockbusters alone. Almost 90% of the new molecules introduced earn less than 180 million dollars (USD) in annual sales and out of that close to 5% molecules are never profitable. Around 5% of the introduced molecules earn 180 to 460 million USD. Only a dismal 1-2% of the molecules are capable of earning more than 1 billion USD and attain the blockbuster status (13).

The Stanford Bernstein Report concludes that the industry’s best hope for survival lies in innovation, its traditional strength. But, it is important to note that R&D is not as productive as it used to be. The global industry saw 24 new drugs approved by the US FDA in 1998 with $27 billion R&D investment. In 2006, only 13 new drugs were approved, but investments in R&D rose to $64 billion (14).

According to estimates by PriceWaterCoopers, in 2007, only eight of the 27 new therapies that were launched globally were the first of their kind (breakthrough therapeutics), the rest being “me-too” treatments (incremental
innovations). Moreover, industry estimates say that there are just 18 to 20 new chemical entities existing worldwide with an exorbitant $80 to 90 billion being spent on their development (15).

**Patent Expiries**

The multinational drug majors are facing challenges from patent expiries, and their blockbuster profit engines are running dry. Generic drug manufacturers represent a significant threat to research-based pharmaceutical companies. For example, Schering-Plough’s Claritin patent expired in 2002; as the result of generic drug competition, sales of Claritin by Schering-Plough declined from $2.2 billion in 2001 to $1.8 billion in 2002 and to $0.7 billion in 2003.

Between 2007 and 2012, the top 50 pharmaceutical companies are facing patent expiries on $115 billion worth of drugs. Companies with patents set to run out on major drugs between 2007 and 2012 include Ratiopharm, Sandoz, Merck KgaA, Actavis, Apotex, Barr, GSK and Watson. Wyeth, so eagerly snapped up by Pfizer, faces a tricky situation of its own. Its two biggest selling drugs, Effexor for depression and Protonix for heartburn, will lose patent protection in 2010 and 2011 (16).

The year 2008 saw some major blockbuster patent expirations including Johnson & Johnson’s anti-psychotic Risperdal, Merck’s osteoporosis drug Fosamax, GlaxoSmithKline’s epilepsy treatment Lamictal, Pfizer’s cancer drug Camptosar and allergy drug Zyrtec, Abbott’s epilepsy drug Depakote and Wyeth’s heartburn drug Protonix. However, the year 2009 saw only a few major patent expirations, including Johnson & Johnson’s epilepsy drug Topamax and GlaxoSmithKline’s antiviral treatment Valtrex (17).

The latest report from PricewaterhouseCoopers, *Pharma 2020: Virtual R&D, Which path will you take?*, points out that: “Pharma’s traditional strategy of placing big bets on a few molecules, promoting them heavily and turning them into blockbusters worked well for shareholders for many years. The report quotes estimates that generic erosion will knock off between 2% and 40% of the revenues of the top 10 companies between now and 2015.

*“Innovate to Collaborate” models – the new trend*

“As adapt or perish, now as ever, is the inexorable imperative of nature.” — H. G. Wells. The growth dynamics in the world pharmaceutical market is witnessing a tumultuous change and the predictions are pointing towards the continuance of such turbulence in the foreseeable future. According to US research firm IMS Health “Growth in the key markets is steadily declining; the US market may even shrink this year (2009)”. The “innovation dearth” and the “patent expiries” are inducing the “innovation-centric” Big Pharma to adopt a radical rethink of their collaborative initiatives for attaining a sustainable development. “Pfizer-Wyeth” and “Merck-Schering” mega mergers only serve as a time-bound panacea for the ailing pharma behemoths to cope up with their receding product pipelines and are definitely not the permanent cure.

The ‘generic pharma’ on the other hand has evolved substantially and transformed itself from a reverse engineering led industry to a more sophisticated and research-driven industry with a global presence. In the wake of the depleting new product pipelines and the increasing amount of difficulty in development of new drugs, it is the emerging markets that provide the ground for hope to the “Big Pharma”. Annual pharmaceutical sales in emerging markets are expected to exceed $400 billion by 2020, equivalent to current sales in the US, plus five major European markets, according to IMS Health.
According to Tim Anderson, senior analyst at New York-based investment research firm Sanford C. Bernstein, the emerging markets particularly Brazil, Russia, India, China, Mexico, Turkey and South Korea - called the EM-7 offer a great hope for the “Big Pharmas”. The total size of the EM-7 markets is relatively small, just $91bn in 2008, versus global pharma sales of $79bn. Whereas global sales growth has steadily declined from 7.9% in 2004 to 4.8% in 2008, growth in the EM-7 has been 14.2% (2008) and higher, even reaching 27.2% in 2005, Anderson notes, as depicted below (19) (Figure 2-Data source: IMS Health and Bernstein Analysis).

![Figure 2](image_url)

The change in the dynamics of the industry has also brought about a paradigm shift in the characteristics of the merger frenzies in the pharmaceutical space. The “collaborate to innovate” business model is no more the profit engine for the “Big Pharma”. The new trend “innovate to collaborate” is catching up in the industry and the “big pharma” is scrambling to find smarter business solutions in the form of a novel “Hybrid Model” comprising “collaborate to innovate” and “innovate to collaborate” techniques for sustainable development.

V) Banishing Barriers — The coming together of Big Pharma and Generics

“It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change”- These are the words of eminent scientist Charles Darwin to explain the theory of evolution.

In other words, “change” is the key driver that the business enterprises must adopt in order to compete in the ever changing global environment. “Big Pharma” has taken a new step towards the emerging markets and Eastern destination in particular, whereas the “Generics” are reengineering their business strategies to emerge stronger and better. New business models are continuously evolving and the “Big Pharma” and the “Generics” who always had incompatible business strategies are finding it valuable to build their future together. The implementation of stronger IP regime in the developing countries is also one of the key trigger for driving these deals.

In June 2008, Japanese Pharmaceutical company Daiichi Sankyo bought a majority stake in Indian generics manufacturer Ranbaxy Laboratories16 (for $ 4.9 billion). In July 2008, UK-based GSK spent $410m to acquire a 16% stake in South Africa-based Aspen. GSK’s many moves into generics have all centered on emerging markets. One month later, GSK announced a license and supply agreement with India’s Strides Acrolab and Onco Therapies for
marketing injectables in emerging markets outside India and Africa. In June 2009, GSK announced a marketing deal with India’s Dr. Reddy’s Laboratories in emerging markets around the world. More recently, GSK acquired the branded generics business of US-based Bristol Myers Squibb in Lebanon, Jordan, Syria, Libya and Yemen for $23.2m (18).

Pfizer announced an expanded relationship with Indian firm Aurobindo (March 2009), as well as a deal with Indian injectable generics specialist Claris Life sciences (May 2009). In October 2008, French major Sanofi-Aventis acquired Czech Republic-based Zentiva for $2.6bn. In April 2009, Sanofi bought Medley, of Brazil, for $664m and Mexico-based Kendrick for $30m. For Sanofi, Zentiva not only boosted the company to leading place among global generics players, it also provided a platform for growth in the emerging markets of Central and Eastern Europe, Turkey and Russia. The Kendrick acquisition firmly established Sanofi in the growing Mexico market. The purchase of Brazil’s Medley instantly made Sanofi the biggest generics player in Latin America (18).

VI) India Impact

“Big pharma” employs acquisitions as key strategy for sustained growth and also adopt “networked” operating model as a strategy to boost efficiencies and gain access to technologies and emerging markets. The “networked” operating model employs third parties to improve efficiencies through in-licensing, out-licensing, collaborations and outsourcing services. Globally, pharmaceutical companies are shifting their outsourcing activities to Asian markets, with India emerging as one of the most attractive destinations, according to August 2009 report by Organization of Pharmaceutical Producers of India (OPPI) and Ernst & Young (E&Y) (19).

Figure 3

In addition, the report states that a trade association representing multinational pharma in India, said that India’s proximity to other emerging markets could augur well for the growth of the Indian industry. The report rated India highest in terms of cost-efficiency attractiveness among six destinations including China, Eastern Europe, Puerto Rico,
Singapore and Ireland. The product patent regime has also resulted in the need for new investments in R&D. According to the report, “In drug discovery and development services, India is emerging as a hot spot, growing at around 65%. India offers significant cost arbitrage in end-to-end R&D with potential savings of 61% as compared to the United States.”

VII) Intellectual Property Implications of “Big Pharma” joining hands with Generics

Intellectual Property is the key driver

Intellectual property is the key consideration in driving these deals. The characteristics of the deals between the “Generics” and “Big Pharma” would largely determine the impact that the deals would have on the IP protection. If the partnership between the “Big Pharma” and the “Generics” is based on the “innovation model” or “collaborative R&D” which stipulates the setting up of an exclusive R&D unit, then the “Big Pharma” would ensure in getting maximum IP protection for their products, apart from benefiting on cost advantage. If the arrangement is the Services Model, wherein the deals between the “Big Pharma” and the “Generics” would focus on the niche areas like clinical trial monitoring, regulatory affairs and data management, the Generics get milestone payments for a part of the development work and the IP rights would be retained with the “Big Pharma”. If the partnerships struck by the “Generics” with the “Big Pharma” are in-licensing strategies, then the Generics can acquire IP rights for a particular therapeutic, the drug can be manufactured locally and profits can be shared between them. This strategy also minimizes the regulatory procedures in that country if the products are already approved in other countries. If “Big Pharma” gets into marketing alliances with “Generics” for a fewer markets, then the “Generics” may acquire IP rights for a particular therapeutic in certain markets and share the generated profits with the “Big Pharma”. As the “Generics” are not yet ready for a start-to-finish model in new drug discovery, they can develop new molecules up to a certain extent and outlicense to the “Big Pharma”. This model would enable the “Generics” to capitalise on their core research i.e., retaining the IP rights which is crucial for competitive advantage and outsourcing the rest of the development to the “Big Pharma”.

Patent Battles

The proposed takeover of Ranbaxy by Daichi Sankyo was immediately followed by the announcement of settlement arrived between Ranbaxy and the pharma behemoth Pfizer in respect of the patent challenge over Pfizer’s highly litigated blockbuster drug, Lipitor. The amalgamation of generic and Big Pharma may result in lesser patent challenges and more negotiation settlements, which may aid “Big Pharma” in extending their market power by making payments to delay or refrain the generics from introducing the competing drug on the market. Such patent settlements would therefore affect patient’s access to cheaper medicines.

Patented Drugs

The partnerships between “Generics” and “Big Pharma” could lead to the introduction of patented drugs, especially for lifestyle diseases in the emerging markets. However, the “Big Pharma” has to adopt a differential pricing strategy in the developing countries dominated by generic medicines which are affordable. Even though the patented drugs may be introduced in India, the “Big Pharma’s” do not have the pricing power as they are strictly regulated by the Government.

Research and Development

The deals between Big Pharma” and the “Generics” can lead to a great deal of research and development getting accomplished in lower costs, especially in countries like India and China. The “Big Pharma” can utilize the cost advantage and the technical capabilities in India and China to develop newer drugs, at a lower cost and also gain access to their markets.
Access to medicines and Pricing
The partnerships between Big Pharma” and the “Generics” can lead to access to newer medicines produced through such partnerships at an affordable price. However, “Big pharma’s” entry into emerging markets would compel them to adopt a fair pricing policy in the developing countries where the patients do not have public health insurance schemes and pay out of their pockets. However, if such deals favour lesser patent litigations and introduction of patented drugs in the emerging markets and developing countries, then the pricing policy needs to be stringently regulated by the Governments to ensure access to cheaper medicines.

Conclusion
The “blockbuster model” of the pharmaceutical originator companies has been crumbling in the recent years as the discovery uncertainties in new drug discovery is high. A decade ago, the “buy-big” strategy was the order of the day. However, the dynamics of the industry has changed and so is the objective of the mergers in the pharmaceutical world. In the wake of the depleting new product pipelines and the increasing amount of difficulty in development of new drugs, it is the emerging markets that provide the ground for hope to the “Big Pharma” for sustainable development.

The generic companies do not have a might of their own to mobilize funds for new drug discovery and related investments for introducing a new drug molecule in the market. The best alternative available to them for sustainable growth is to be taken over by “Big Pharma” or enter into partnerships and collaborations with the “Big Pharma”.

After years of heated court battles and out-of-court settlements between the “Big Pharma” and the “Generics”, the ever warring factions are finding it valuable to build their future together. The recent spate of deals between the “Big Pharma” and the “Generics” signify the blurring of the boundaries between the ever warring factions and signal an “amalgamation renaissance” in the pharmaceutical merger space.

Intellectual Property is a key consideration in driving the partnerships between the “Big Pharma” and the “Generics”. The partnerships can harness a great deal of research and development getting accomplished in lower costs and can lead to access to newer medicines produced through such partnerships at an affordable price. On the contrary, these partnerships can impact patent challenges between the “Big Pharma” and the “Generics” and result in more patent settlements. Such patent settlements can impact the patients access to cheaper generic medicines. “Big pharma’s” entry into emerging markets would compel them to adopt a reasonable pricing policy in the developing countries where the patients do not have public health insurance schemes and pay out of their pockets.

Going forward, similar partnerships are a certainty. This “amalgamation renaissance” will remain for a long time and in these turbulent times, the pharmaceutical industry has no other choice. While there is no telling whether these partnerships would help the pharmaceutical industry to harness its strength, mitigate the risks, ward off the threats and cash in on the opportunities, IP would continue to drive them. This “amalgamation renaissance” will also significantly impact the IP policies of pharmaceutical companies and help them find a middle ground between the ever warring factions.
9. Trade secrets are confidential information and can include a list of customers or suppliers, a manufacturing or purification procedure, a formulation, a business plan for new product development, corporate merger – acquisition plans, or an invention.

10. Copyrighted materials such as advertising or promotional materials, various types of drug dossiers etc also can be protected by the “Big Pharma” and can last up to 100 years.

11. According to IMS Health data (2004), the major pharmaceutical markets together represent 88% of world sales; and the U.S. market alone accounts for about 47% of world sales. Not surprisingly, all “Big Pharma” companies to a significant extent concentrate their resources on these markets, especially in the United States.

12. Developed countries have pharmaceutical industries who are mainly responsible for invention and introduction of new and improved drugs in the global market.

13. A prime example of how this works is simvastatin (Zocor), a popular drug created and manufactured by U.S. based pharmaceutical Merck & Co., which lost its US patent protection on June 23, 2006. India-based Ranbaxy Laboratories (at the 80 mg strength) and Israel-based Teva Pharmaceutical Industries (at all other strengths) received 180-day exclusivity periods for simvastatin; due to Zocor's popularity, both companies began marketing their products immediately after the patent expired. However, Dr. Reddy's Laboratories also markets an authorized generic version of simvastatin under license from Zocor's manufacturer, Merck & Co.; some packages of Dr. Reddy's simvastatin even show Merck as the actual manufacturer and have Merck's logo on the bottom (8).

14. GlaxoWellcome stood out for the aggressiveness with which it realized merger synergies in 1995. The consolidation of the two companies was very publicly achieved within 100 days – it achieved cost savings of 10.8%, almost 4% above the industry range, and 16.8% reduction in combined expenses. One of the most obvious reasons to merge or acquire was a shortfall in the Research and Development pipeline.

15. Astra merged with Zeneca and AstraZeneca was formed. GlaxoWellcome tied up with SmithKlineBeecham and GlaxoSmithKlineBeecham was born. Novartis was created through the merger of Ciba-Geigy and Sandoz. Aventis was established with the merger of Rhone-Poulene and Hoechst AG.

16. India's largest pharmaceutical company, Ranbaxy Laboratories and one of the most prolific generic manufacturers had been increasingly aggressive in challenging Big Pharma's patents. In June 2008, Daiichi Sankyo acquired Ranbaxy, the generic industry's top 10 players, with operations in 49 countries and distribution to 125.

17. India met its WTO TRIPS obligations by mandating product patent production in the year 2005. The product patent protection is available to pharmaceutical inventions also. The Indian Pharmaceutical industry is gearing up to address the challenges and exploit opportunities thrown by the product patent regime by adopting different business strategies.

18. The Indian pharmaceutical company, Glenmark has in-licensed Crofelemer, Napo's proprietary anti-diarrheal compound in over 140 countries, including India. Indian company, Wockhardt has an in-licensing deal with Syro Pharma S.p.A for dermatology products (5). For example, the GSK-Aspen deal provides IP rights to Aspen for four drugs Eltroxin, Imuran, Lanoxin and Zyloric for marketing the drugs worldwide in all major markets except United States and Japan (20).

19. Differential pricing is a strategy adopted by MNCs for marketing drugs in developing countries. In April 2008, Merck & Co. when it launched Januvia (sitagliptin), an anti-diabetic drug, in India at one-fifth its American price. Since then, Merck has also launched new vaccines in India with differential pricing.
IP BYTES

-Interesting IP News From Around The World
Nerd Alert! Google Patent to Make Internet Perfect

June 17th, 2010
Google just got its patent approved for a technology that looks at user searches to identify holes and under-covered topics in the content sphere. With the information gained through this technology, content creators would be able to create stories and information plugs to fill the gaps in the World Wide Web. Nothing comes up when you search for “Lebron James’ or mom’s phone number”? Someone at a content farm, some day, will be right on it. It’s just a patent, for now, and no announcement has been made that this is actually going to be activated, but if they want to, the dudes at Google could make life miserable for content companies like AOL, Associated Content, and Demand Media who are trying to cash in on this game.

Source: www.complex.com

Dow wins patent suit over Nova Chemicals

16 June, 2010
Dow Chemical Co. has won almost $62 million in damages from Nova Chemicals Corp. in a jury trial in a case involving polyethylene technology. The jury -- in U.S. District Court in Wilmington -- on June 15 awarded $57.4 million in lost profit and $4.3 million in royalties to Midland, Mich.-based Dow, for a total of $61.7 million.

Dow had filed the suit against Alberta-based Nova in 2005, alleging that Nova was violating patents for a grade of linear low density PE used in grocery bags.

Dow officials contended that Nova had been importing material violating the patents into the U.S. market since 2003. In a June 16 statement, Dow officials said the verdict was “a critical step in establishing that Dow’s patents are valid and enforceable, and that Nova has been infringing on Dow’s rights.”

Both Dow and Nova rank among North America’s largest makers of Polyethylene.

Source: www.plasticnews.com

U.S. Patent for Method and System for Saving and Retrieving Spatial Related Information Issued to Tele Communication Systems, Inc.

16 June, 2010
TeleCommunication Systems, Inc. (TCS), a world leader in highly reliable and secure mobile communication technology, today announced the issuance by the U.S. Patent and Trademark Office of patent number 7,737,868 entitled “Method and System for Saving and Retrieving Spatial Related Information.” This patent provides users the ability to track multiple mobile communication devices, and the users associated with them, through a combination of location and time data that is automatically retrieved from the mobile device. Wireless carriers and mobile communications providers stand to benefit from this technology by offering business users and consumers the ability to track and analyze location and time data associated with both themselves and related assets.

With the expansion of smart GPS phones, graphical touch or non-touch devices, and location-based services (LBS), the challenge of “visualizing” location data is increasing. This patented TCS invention provides a simple and user-friendly
manner for visualizing extensive location-based data associated with time, such as number of stops, check-ins, duration of travel between stops or check-ins, and the associated travel time. Time and position information is displayed graphically on customizable maps, calendars, Gantt charts, and other visual aids. TCS now holds 115 patents worldwide with over 300 applications pending.

Source: www.marketwatch.com

5.4 Trillion Bounty for False Patent Marking Bounty Hunter

15 June 2010

Bounty hunters make their living by capturing fugitives from justice for a monetary reward (bounty). A more recent, modern day version of the bounty hunter is one who pursues patentees for false patent marking under 35 U.S.C. § 292. Recently, in the Federal Circuit case of Forest Group, Inc. v. Bon Tool Co., false patent marking bounty hunting was made lucrative by saying that each falsely marked item is an “offense” under 35 U.S.C. § 292, and thus subject to a penalty of “up to $500”. The bounty hunter would get half of the awarded penalty and the federal government the other half. As a result, a rash of such cases (more than 200) has been filed by such modern day bounty hunters as qui tam actions against various patentees alleged to be falsely marking their products.

San Diego patent lawyer Matthew Pequignot asserted a right to trillions of dollars in damages after realizing that patent markings on the lid of his daily cup of coffee had actually expired several years before. He however lost in a ruling by the U.S. Court of Appeals on the grounds that he failed to prove the defendant company intended to deceive the public with its false mark, a requirement under the recovery statute.

Pequignot had sued Solo Cup under a qui tam provision in the patent law that allows citizen whistle-blowers to sue companies that deceive the public with false patent numbers and to split the damages recovered with the federal government.

Hopefully the Solo Cup decision “will re-inject a sense of reason into the process.” However that conclusion alone does not decide the question of liability under the statute.

Source: www.ipwatchdog.com

ITC to Probe Apple over Mobile Patent

14 June, 2010

The US International Trade Commission (ITC) has announced that it has begun to investigate IT giant Apple as a part of a copyright infringement lawsuit against the company, filed by mobile phone maker HTC. The ITC has the power to prevent products being traded that violate US copyright and patent laws.

HTC filed the case against Apple in May, urging the court to block imports of Apple's gadgets into the USA, citing five alleged copyright infringements, three relating to telephone directories and two relating to power management.

ITC is already looking into a complaint filed by Apple that accuses HTC of infringing patents relating to the iPhone's user interface, as well as a further 10 patents relating to hardware and software technologies.

Source: www.itproportal.com
US Court stops launch of Dr Reddy's drug

13 June, 2010
Dr Reddy's Laboratories (DRL) received a major setback in the US yesterday, as a court there granted a motion seeking a preliminary injunction to block the launch of its generic version of Sanofi-Aventis' anti-allergic drug, Allegra D24 (fexofenadine hydrochloride/pseudoephedrine hydrochloride 180 mg/240 mg extended release tablet), which has a market size of about $180 million in the US. Analysts were expecting Allegra D2ch 4 to generate over $150 million in 3 years.

DRL said it intended to appeal against the verdict, saying it “strongly disagrees with the court's decision”. The company was planning to launch it 'at-risk' in the first quarter of 2011, since a patent litigation over the drug between DRL and Sanofi-Aventis is also pending in the US court.

If a generic drug is launched 'at-risk', the generic company will have to pay damages to the innovator if it loses the patent litigation. DRL is believed to be the only company to have received approval for this drug in March by the US FDA, following expiry of the 30-month automatic stay associated with patent litigation in the US.

According to the US rules for selling generic drugs, an innovator has to sue a patent challenger within 45 days of receiving the notification of a patent challenge, to prevent the drug regulator from approving the drug for the next 30 months, before the patent expiry or till a court gives its judgment.

Source: www.business-standard.com

BP Files Patent to Produce Oil from Seawater

11 June 2010
British petroleum giant BP filed patents late yesterday for its process of creating oil from seawater. CEO Tony Hayward stated that they are on track to collect some 25,000 to 50,000 barrels of oil daily from an announced flow of only 5,000 barrels per day at its former oil platform where eleven workers died in the Gulf of Mexico.

Industry analysts now speculate that the so-called oil "spill" has actually been the first full field-test of the new BP process that could revolutionize deep-water drilling. An official at ExxonMobil, speaking on condition of anonymity because of the sensitivity of the subject and embarrassment that his company had not thought to use this technique for the Exxon Valdez, said admiringly. "Hell, this changes everything. Instead of punching a hole and trying to collect the oil from that reservoir in a long straw, just punch the hole, let the oil flow into the seawater, and bang -- you just recovered ten times as much oil.”

Source: www.democraticunderground.com

RIM, Motorola resolve patent case

11 June 2010
RIM and Motorola have avoided extending a costly and lengthy court battle by settling a patent infringement case.

The Waterloo, Ont., BlackBerry maker has agreed to make an upfront payment as well as continuing royalties to Motorola as part of a licensing agreement between the two companies. Though neither firm disclosed details of the financial
settlement the agreement indicates both companies consider the technology at stake vital to the design and manufacturing of their devices.

The deal entails “a long-term, intellectual property cross-licensing arrangement involving the parties receiving cross-licenses of various patent rights,” The licences relate to a number of technologies vital to the design of smart phones, including 3G cellular technology, Wi-Fi networks and wireless e-mail.

Earlier this year, Motorola had brought a case against RIM before the International Trade Commission in the U.S alleging that RIM infringed on technology patents related to wireless networks.

Source: www.theglobeandmail.com

Apple patent bid combines solar with touch screen

7 June, 2010
Apple employees filed a patent for a technology to embed solar cells under the touch screens of handheld devices. Apple engineers clearly see the potential for solar power in multi-touch devices, such as the iPhone and iPad.

According to the patent description creating a single “stack” that combines the sensors for a multi-touch screen the solar cell frees up more surface area. The patent, which was filed in September 2008, also calls for the use of “light channels” to direct light to a solar cell underneath a touch screen, potentially using a parabolic reflector.

One of the notable aspects of the patent application is that it can be applied to a range of gadgets and could lead to the use of a double-sided solar panel that absorbed light from both the top and a glass-covered backing.

Source: www.cnet.com

Apple aim particle gun at DRM violators

3 June 2010
A new patent has appeared at the US Patent & Trademark Office for a system of digital rights management (DRM) that would identify the authenticity of a device based on the unique physical emission properties of a “particle gun.” The invention relates to DRM and more specifically to authentication or hashing functions. Authentication is a software security mechanism that establishes or confirms an entity as authentic, or true.

From Apple’s background and summary of the invention it appears that: “The the method of authentication includes generating a first challenge value on a sender, transmitting the first challenge value from the sender to a receiver, receiving the first challenge value on the receiver, generating a second challenge value at the receiver and computing a receiver response based on the first challenge value, the second challenge value and a secret. The computation of the receiver response can be based on physical emission properties of a particle gun. The method further includes transmitting the receiver response to the sender and verifying authenticity of an entity at the sender by comparing an expected value of the receiver response with a calculated value based on the first challenge value, the second challenge value, a secret and being based on the physical emission properties of the particle gun”

The inventors are Betouin Pierre, Ciet Mathieu and J. Farrugia.

Source: www.mactech.com
Cricket Beats GSM Cellular in TM Suit

3 June, 2010
Low-cost carrier Cricket Communications has won a trademark infringement lawsuit against GSM Cellular, whose marketing implied that it was affiliated with Cricket. Cricket was awarded summary judgment, a permanent injunction and about $77,000 in attorneys’ fees, ending a lawsuit filed by Cricket against GSM Cellular in 2008.

The lawsuit alleged that GSM Cellular flagrantly misled customers into thinking it was associated with Cricket by naming its business Kricket and prominently displaying the Cricket trademark and logo on signs, banners, posters, retail displays and store vehicles.

GSM Cellular also was accused of illicitly selling and distributing Cricket products, activating unauthorized phones on Cricket’s network and fraudulently accepting payments intended to compensate Cricket for providing wireless services.

Source: www.wirelessweek.com

Patent Fast Track Proposed

3 June 2010
Inventors frustrated with waiting for a decision on their applications from the U.S. Patent and Trademark Office may soon be able to pay for expedited review under a proposal to be announced Thursday. The proposal, which following a public comment period could go into effect next year, would be a major change for the Patent and Trademark Office, which has mostly reviewed applications on a first-come, first-served basis.

U.S. Patent and Trademark Office chief David Kappos is proposing a new three-track system for patent applications that would allow applicants to pay an undisclosed amount on top of the standard $1,090 filing fee to jump to the front of the line for expedited reviews.

"Not every application needs to go at the same speed. Some need to go fast and some need to go more slowly," Mr. Kappos said in an interview. The system will allow applicants to essentially select which innovations are the most important for patent examiners to tackle first, Mr. Kappos said.

Source: www.businessonmain.msn.com

Cold Cut Conflict

24 May, 2010
Subway Sandwich Company is these days attempting to obtain a trademark for the term “footlong,” which describe the 12-inch sandwiches the company has been aggressively marketing and riling their competitors in the process.

Trademarking the term would restrict the way the word can be used by other restaurants, and Subway, which was founded in Connecticut and whose franchise servicer is Milford-based Franchise World Headquarters LLC, believes it has exclusive rights to the word as it applies to its deli sandwiches.

Meanwhile, Subway's attempts to crack down on restaurants using the term footlong to describe its food products created
a buzz when the company sent a cease and desist letter to a mom-and-pop hot dog joint in Florida that has sold footlong hot dogs since 1960. However, those opposing say that “Footlong has been used to describe sandwiches of a variety of types for more than 50 years”.

In some cases, the power of advertising can give a descriptive word a second meaning, which is what Subway has successfully argued before the USPTO.

Source: www.ctlawtribune.com

Google sued over privacy invasion

10 May 2010
Google is facing another lawsuit! It is being alleged that they knowingly siphoned data from open WiFi networks over the past three years in at least several countries as a part of their program to build the Google Street View program, which falls under the umbrella of Google maps and ultimately Google Earth. Google already has several active cases of privacy breaches pending in multiple federal courts, so this is hardly new territory for the internet giant. While Google is maintaining their innocence, their defense may be on shaky footing.

The suit filed alleges that in collecting data to build up Google Street View, Google employs technology under what is known as the “776 patent” that is snooping on open WiFi networks. The information collected by the alleged use of the technology under the 776 patent could be anything from web pages being loaded, emails, video being viewed or downloaded, etc. Obviously all of this information could be potentially useful to marketers or Google itself, but it also raises the issue of privacy violation.

Source: www.helium.com
Inherent Anticipation vs. Accidental Results Doctrine and the Effect of the Former on Chemical Patents Under SmithKline Standards

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Abstract

Broadly stated, patent-eligible subject matter is patentable if the claimed subject matter possesses *Utility*, and is both, *Novel* under 35 U.S.C.A. § 102 and *Nonobvious* under 35 U.S.C.A. § 103. Though, the determinations of anticipation and novelty are being made in light of the prior art, it is perhaps the single most important and misunderstood aspect of substantive U.S. patent law till today. U.S. patent law defines Express and Inherent anticipation doctrines, as applicable for novelty determination, and Accidental Results Doctrine as opposed to that. However, recent decisions of *Schering* and *SmithKline* cases by U.S. courts have broadened the inherency doctrine in such a way that the entire fate of chemical, pharmaceutical and biotechnological patents has become uncertain and it seems to adversely affect the pace of research and development.

In light of various case laws related to accidental and inherent anticipation, we have reviewed herein the impact of SmithKline’s standards on chemical and biotechnology patents. Forecasting the prosecution and litigation settings we have suggested some tailored approaches of claim drafting to avoid inherency issues. We have also discussed the continuously widening horizons of S.3 (d) of the Indian Patents Act and the impact of SmithKline standards on its applications in future. With due honor to the Court’s decisions, we have also tried to seek attention of law makers to review these standards in light of the congressional purposes of these doctrines and to take such decisions more deliberately, especially when it is related to the human health and life.

1. Introduction

Broadly stated, patent-eligible subject matter is patentable if the claimed subject matter possesses *Utility*, and is both, *Novel* under 35 U.S.C.A. § 102 and *Nonobvious* under 35 U.S.C.A. § 103. But “novelty” is an ambiguous term, embracing several overlapping and interrelated concepts, which have both subjective and objective aspects. Though, the determinations of anticipation and novelty are being made in light of the prior art, it has been one of the most misunderstood aspects of substantive U.S. patent law.

Two types of anticipation doctrines exist in U.S.: “Doctrine of Express Anticipation” which refers to the express disclosure of one element of the claim in a prior-art reference, and “Doctrine of Inherent Anticipation” where merely prior occurrence of a process or composition can anticipate a claim because of the elements those simply inhere in the process or composition, even if these elements were not recognized at the time of the prior occurrence. Traditionally, two provisions have circumscribed the reach of the inherency doctrine: inevitability of the results and the recognition requirement. However, there have been such instances in which a prior process or composition inherently met all of the limitations of a claim, but a court decided that the doctrine of inherent anticipation did not apply and rationalized the prior art as “accidental”. This third type is known as “Doctrine of Accidental Anticipation.”

Recently, the inherent anticipation has received substantial attention by pharmaceutical patent practitioners across the globe. The decisions of U.S. Courts over *Schering* and *SmithKline* have broadened the doctrine in such a way that the entire fate of new drug discovery and development in pharmaceutical and chemical sector has become uncertain. Under the new “SmithKline Standards”, inherent anticipation can invalidate a patent even though the claimed substance was not formed in detectable quantities or even if the claimed substance never existed; as long as it could have been made by the methods disclosed before the application was filed.

This article reviews the fate of chemical, pharmaceutical or biotechnological patents under new SmithKline standards. Through analysis of various case laws, we have tried to explicate our rationale why a review is warranted...
on the SmithKline’s decision. With due honor to the Courts’ decisions, we have tried to seek attention of law makers, to forecast the consequences of such laws. However, currently it seems that the U.S. courts are comfortable with the expanded standards of inherency, and therefore, forecasting its impact on prosecutorial and litigation settings we have suggested some claim drafting strategies to avoid inherency issues in future.

2. **Review of Case Laws**

For demarcation between the doctrine of inherent anticipation and accidental results, we have reviewed herein various case laws. We have further applied different tests on these cases to reconcile the two doctrines and to determine whether a product or process actually anticipates inherently.

2.1 **Tests to Establish Inherent or Accidental Anticipation**

According to the traditional test for inherent anticipation, a claim is anticipated and therefore invalid only when a single prior art reference discloses (expressly or inherently) each and every limitation of the claim. However, *Continental Can v. Monsanto*, decided that “to serve as anticipation when the reference is silent about the asserted inherent characteristic, such gap in reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.”

While the *Continental* decision intended finality and closure, the opinion proved to be as hollow as the plastic bottles in question. Over the next several years, two diverging lines of cases emerged, with Judges Rader and Newman asserting opposing views. While *Atlas Powder Co. v. IRECO* held that inherency is not necessarily conterminous with the knowledge of those of ordinary skill in the art, *Elan Pharmaceutical v. Mayo Foundation* stated that anticipation in the patent sense means that the subject matter was previously known. However, the recent decisions of *Schering Corp. v. Geneva Pharmaceuticals, Inc.* and *SmithKline Beecham Corp. v. Apotex Corp.* have restarted the argument for the appropriate tests to be used to determine whether the subject matter falls under inherent or accidental anticipation.

Professor Dan Burk and Mark Lemley’s ‘Public Benefit Test’ states that if the public already benefits from the invention, even if they don’t know why, the invention is inherent in the prior art. If the public doesn’t benefit from the invention, there is no inherency. However, this test does not make it sufficiently clear, what ‘public benefit’ means. We therefore, reviewed other tests to refine the Burk & Lemley’s public benefit test and found a new standard of enablement for the prior art. Here, if the process or product is useful, then the second prong is whether the product or process occurred under unusual conditions. If the answer is yes, the prior process or product does not anticipate. This test to a significant extent helps to resolve the confusion about inherent and accidental anticipation.

2.2 **Review of Case Laws and the Tests Applied by Courts**

Although the review is mainly focused on the chemical patents, considering the relevancy and historical significance few non-chemical patent case laws are also being reviewed here. For convenience, the case laws have been divided into Accidental and Inherent Anticipation.
1. **Accidental Anticipation**

   a. **Tilghman v. Proctor**

   *Tilghman* is the seminal case for accidental anticipation. The invention was a process for producing free fatty acids by subjecting triglycerides to high heat and pressure in the presence of water, resulting in a glycerin backbone and undamaged free fatty acids. The defendants sought to invalidate the patent by submitting evidence of a prior process for lubricating a piston with fat in a steam engine where free fatty acids were accidentally produced because fat, containing triglycerides, was subjected to high heat and pressure in the presence of water. The defendants argued that free fatty acids would necessarily be produced and the patent in question must be anticipated.

   Though, the Court assumed that the free fatty acids were accidentally produced in the prior art, it has been argued a lot that the process by which free fatty acids were actually generated was never fully understood.

   b. **In re Marshall**

   In *Marshall*, the claims at issue were directed to a process for achieving weight loss by periodically administering an anesthetic, Oxethazaine, prior to eating so as to contact nerve endings that release pancreatic hormones necessary for digestion. The prior art was the Physician's Desk Reference (PDR), which prescribed Oxethazaine to treat colitis, ulcers and other gastro-intestinal problems by dosing periodically prior to eating and at bedtime. However, the court found no anticipation, reasoning that "nothing in the PDR remotely suggests taking Oxethazaine to lose weight. If anyone ever lost weight by following the PDR teachings, it was an unrecognized accident. An accidental or unwitting duplication of an invention cannot constitute anticipation."

   However, it should be noted here that *Marshall* was cited only once by the Federal circuit in connection with an accidental anticipation analysis and the court's reliance upon *Marshall* is still unclear.

   c. **MEHL/ Biophile International Corp. v. Milgraum**

   The claims at issue in *MEHL/Biophile* were directed to a process for hair removal by aligning a laser light applicator substantially vertically over a hair follicle opening and applying through said aperture to the hair follicle a pulse of laser energy of a wavelength which is readily absorbed by the melanin of the papilla and having a radiant exposure dose of sufficient energy and duration to damage its papilla so that hair regrowth is prevented and scarring of the surrounding skin is avoided.

   To prove anticipation, the defendants introduced a laser instruction manual teaching tattoo removal. However, the court found no anticipation stating that "to anticipate, the reference would have to teach, either expressly or inherently, aligning the laser 'substantially vertically' over hair follicles. Noting that it is possible or even probable, that a laser would be substantially vertically aligned over a hair follicle in the process of removing a tattoo. However, if something happens only occasionally it is not grounds for anticipation because occasional results are not inherent."

   d. **Eibel Process Co. v. Minnesota and Ontario Paper Co.**

   The claims at issue in *Eibel Process* were directed to a machine for making paper where the wood-pulp slurry was fed at one end and moved along the mesh. Liquid drained through the mesh, and then the ultimate paper precursor was delivered from the mesh rollers. A problem with this process was that the paper precursor material contained ripples when it came off the mesh. The patentees discovered that elevating the apparatus, such that the wire mesh was on an incline, equalized the pulp gravity flow with the roller speed and minimized ripples in the slurry.
The prior art disclosed the same type of paper making machine having a somewhat elevated mesh, but to improve drainage, not to minimize ripples. The defendants pointed out that to achieve equal pulp flow and roller speeds, the elevation would have to vary depending on the thickness of the pulp and in some instances (e.g., thin pulp), achieving the desired results required utilizing a slight elevation, such as that in the prior art.

The Court held the claims were not anticipated because “in administering the patent law the court first looks into the art, to find what the real merit of the alleged discovery or invention is and whether it has advanced the art substantially. We think that Eibel made a very useful discovery, which has substantially advanced the art. Any pitch of the wire, used before Eibel, had not brought about such a result, and if it had done so under unusual conditions, accidental results, not intended and not appreciated, do not constitute anticipation.

(e). In re Seaborg

The claims at issue in Seaborg were directed to discovery of Element 95, now known as Americium. The prior art was the Fermi process for producing Uranium in a reactor, which inherently produces Americium as well.

The Federal Circuit held that there was no anticipation stating that “the reactor could not have produced any more than “a billionth of a gram [of Americium],” which “would have been distributed throughout forty tons of intensively radioactive Uranium reactor fuel…. this amount of an unknown unconcentrated isotope, if present, would have been undetectable…. If the earlier disclosure offers no more than a starting point for further experiments, if its teaching will sometimes succeed and sometimes fail, if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation.”

(f). In re Felton

The invention in Felton was a dropper/stirrer combination for testing blood samples. It was a cylindrical item with an opening at one end and a flattened structure at the other end. The circumference of the opening could vary to accommodate more or less viscous drops. The prior art taught a medicine dispenser for insertion into a body cavity with a basic cylindrical structure containing a medicament, with one end sealed with wax and the other end flattened and scored to break off so that medication could be dispensed.

The argument for invalidating the claim was that before the prior art medicine dispenser was sealed with wax and prior to scoring, it had an open end and a flattened end and therefore, this intermediate would be the same as some embodiments of the dropper/stirrer. The court found no anticipation, stating that “in view of the purpose for which the [prior art] was intended, it is apparent that it requires no critical dimension which would lead to a structure inherently having those characteristics. Therefore, it would be mere happenstance if any structure made according to [the prior art] met the limitations of the claims. An accidental or unwitting duplication of an invention cannot constitute anticipation.”

2. Inherent Anticipation

a. Verdegaal Brothers, Inc. v. Union Oil company of California

In Verdegaal Brothers, the invention was a process for making a concentrated liquid fertilizer by reacting sulfuric acid and urea, to form an end product where the new feature was “to provide a non-reactive, nutritive heat sink, capable of dissipating the heat of urea and sulfuric acid, in an amount at least 5% of the end product.” The prior art clearly disclosed all the elements of the claims in issue and added all the components of the claims to a previously reacted fertilizer in amounts that were inherently at least 5% of the end product. However, the prior art did not refer
to, or recognize, the totally reacted fertilizer as a “heat sink” (element (a)). The prior art used the totally reacted fertilizer for convenience so it would not have to remove the old fertilizer, not to dissipate heat as the patentee suggested. The court found that the claims were anticipated, stating “even assuming [the prior art] did not recognize that the heel of his process functioned as a heat sink, that property was inherently possessed by the heel in his disclosed process, and, thus, his process anticipates the claimed invention.

b. **MEHL/Biophile International Corp. v. Milgrau**

The claims at issue in MEHL/Biophile were directed to a process for hair removal using a laser. The defendants further presented a reference, disclosing laser-induced damage to melanosomes in Guinea pig skin. The Court stated that “the record shows that holding the collimated laser in contact with the skin would align it perpendicular to the skin surface and therefore substantially vertically over follicle openings. Hair follicles are inherently exposed to perpendicular application of the laser because Guinea pigs have so much hair. The result was a necessary consequence of what was deliberately intended (melanosomes destruction).

c. **In re Cruciferous Sprout Litigation**

The claims at issue in Cruciferous Sprout were directed to a method for preparing food rich in glucosinolates by germinating the seeds of specific crucifers that when harvested before the two-leaf stage contain high levels of glucosinolates. However, it did not recognize the presence of glucosinolates. The Federal Circuit found the claims inherently anticipated, stating that “while plaintiff may have recognized something quite interesting about those sprouts, it simply has not invented anything new. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate.”

d. **Continental Can Co. U.S.A. v. Monsanto Co.**

The claims at issue in Continental Can were directed to a container with several specific features. The limitation at issue is a bottom concavity of the container with an array of hollow ribs around the concavity. The prior art taught the same limitation, except the ribs were not disclosed to be hollow. However, one of the inventors of the prior art testified that because the ribs were made by the process of injection blow molding, they inherently would be hollow.

The Federal Circuit vacated the summary judgment of anticipation and remanded so the district court could ascertain whether the ribs were hollow. There was no decision on anticipation because of the factual dispute about whether the prior art process necessarily produced “hollow” ribs. However, the Court stated that “to serve as anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.”

e. **Atlas Powder Co. v. IRECO, Inc.**

The claims at issue in Atlas Powder are directed to a blasting composition with various components wherein the limitation at issue is a composition with sufficient aeration (i.e., interstitial air) entrapped to enhance sensitivity to a substantial degree. The prior art disclosed a blasting composition but did not recognize the presence of interstitial air, instead, advising to eliminate it. However, there actually was sufficient interstitial air to
meet the claim limitation of the allegedly infringed patent. The court found that it was irrelevant that the prior art did not recognize that air may act as the sole sensitizer of the explosive composition. In an extensive discussion on the rules of inherency, the court noted that “Inherency is not necessarily conterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.”

(f). Elan Pharmaceuticals Inc. v. Mayo Foundation for Medical Education and Research

The Elan cases involved amyloid precursor proteins (APP), which are now known to be broken down in the body into three fragments and one of those fragments, â-AP has been found in the plaques present in brain of Alzheimer’s patients. The APP gene can have a mutation known as the Swedish mutation, which affects the cleavability of the APP so that ATF-â-APP is formed.

Elan’s patent was directed to a transgenic rodent with the Swedish mutation where ATF-â-APP is detectable in brain homogenates. The prior art cited against the claims suggested introducing a Swedish mutated human gene into a mouse. However, the inventors of the prior-art neither reduced the production of transgenic mouse to practice nor did they recognize the formation of ATF-â-APP. Still, the district court found formation was inherent in the suggestion of transgenic mice with the Swedish mutation. However, the Federal Circuit reversed and explained that “When anticipation is based on inherency of limitations not expressly disclosed in the assertedly anticipating reference, it must be shown that the undisclosed information was known to be present in the subject matter of the reference. Facts asserted to be inherent in the prior art must be shown by evidence from the prior art.”

The Federal Circuit concluded that, because a person of ordinary skill in the art would not have known that the ATF-â-APP fragment existed, the mere suggestion of a transgenic mouse, even if enabled and even if it produced the metabolite in detectable amounts, would not anticipate. However, on December 18, 2002, the Federal Circuit, acting en banc, vacated the prior opinion without stating a reason. On October 2, 2003; the original panel issued another opinion. This time, the court simplified the case to one in which enablement has not been shown. This reduces the matter to a clear issue that a prophetic disclosure of an entire invention should be sufficient to establish inherency. This was confirmed by the next case discussed herein.

(g). Schering Corp. v. Geneva Pharmaceuticals, Inc.

Schering Corp. v. Geneva Pharmaceuticals, Inc. is a significant CAFC decision, which could be best characterized as marking the beginning of the re-evolution of the doctrine of inherent anticipation. Schering is noteworthy for several reasons. It is the first case where the doctrine of inherent anticipation was directly applied to the entire invention and not just a characteristic, component, function, or property of a previously disclosed invention. Second, in its novelty analysis, Schering removes the requirement that a person of ordinary skill in the art recognize anything about the invention, including its existence. Third, the invention need not actually have occurred; it can be prophetic. Lastly, the invention can be the unknown result of a prior process.

Essentially the dispute centered around two of the Schering’s patents. The earlier patent is directed to the anti-histamine loratadine (Claritin™), and the later patent is directed to a metabolite of loratadine, DCL (Clarinex™). The earlier patent did not expressly disclose DCL and did not refer to any metabolite of loratadine.
argued that DCL would inevitably be formed upon administering loratadine and hence, Schering’s loratadine patent is inherently anticipated.

The Schering court stated that DCL is not formed accidentally or under unusual conditions when loratadine is ingested but it necessarily and inevitably forms from loratadine under normal conditions. DCL is a necessary consequence of administering loratadine to patients. However, saying that DCL is “not formed accidentally” begs the question of then how an accident would be characterized.

(h). SmithKline Beecham Corp. v. Apotex Corp.

The SmithKline case revolves around Paxil® (Paroxetine hydrochloride (PHC) hemihydrate), a novel crystal form that was discovered during drug development. Apotex filed an ANDA in 1998, proposing to make PHC anhydrate according to the expired patent and stated that its product would not infringe the hemihydrate patent. SmithKline sued Apotex that the product would infringe because formation of some of the hemihydrate is unavoidable in a facility that is seeded with crystals of the hemihydrate, and the evidence showed that Apotex’s plant has been seeded.

The court stated that the claim to the hemihydrate covers any amount of hemihydrate, even if the amount is not detectable, and that Apotex would infringe the hemihydrate patent if its product contained even a single undetectable crystal of the hemihydrate. However, for analysis of its validity also claim was given the same scope; just as an undetectable amount would infringe the patent, it could also invalidate the patent by anticipation if it existed before the application. The court found that the compound itself was not novel when SmithKline filed its patent application for the hemihydrate. Even though the hemihydrate was not previously known or recognized, the court reasoned that the methods of the expired patent enabled one of ordinary skill to produce it, because there was no clear evidence that making the hemihydrate required a process different from the process for making the anhydrate.

3 Discussion

3.1 Impact of SmithKline Standards on the Fate of Chemical, Pharmaceutical and Biotechnological Patents

Unlike their mechanical and electrical counterparts, the chemical and biological disciplines readily lend themselves to the questions of inherent anticipation. To what extent broadening of inherency doctrine will affect the patentability has yet to be determined and as a policy matter it is still not clear whether a broad inherent anticipation rule is good or not. However, this rule creates tremendous uncertainty among patent holders and would-be patent applicants, of not knowing whether their patents might be invalidated by a reference, perhaps not even closely related to their own research.

Precisely when a missing characteristic can be deemed “inherent” or “accidental” has been the subject of considerable litigation. However, the Federal Circuit has opted to resolve this tension by essentially pushing the accidental prior use doctrine out of the law in Schering Corp. and SmithKline cases.

3.2 New Perspectives of Section 3(d) and Impact on Indian Pharma

The landscape of much of India’s generic pharmaceutical industry has changed in recent years in implementation of TRIPS requirements, where to safeguard the genuine concerns and aspirations of a developing nation, India allowed product-patenting for drugs, chemicals and food (agro products), vide the amendment of Indian Patents Act in 2005. It brought about an upsurge in patent filings and, in many cases, consequent litigations also. The impact was also expected on Indian generic pharmaceutical industry; however, S. 3(d) came to their rescue,
especially for those who believed in ‘patent busting’.

The real legislative intent behind Section 3(d) was to prevent ‘ever-greening’, which was a noble and genuine national interest. But some unscrupulous pharmaceutical companies turned a noble provision into some sort of weapon and started adopting a rather aggressive approach, by challenging the validity of some patents by directly infringing them. Currently, U.S. being the largest market for pharmaceuticals across the globe, any change in its patent laws will have deep impact on global pharmaceutical sector. Under the impact of new SmithKline Standards, the delicate equilibrium between the monopolistic interests of a patentee and the collective or public interest, will be significantly disturbed due to expansive, and generally misapplied, interpretation of S. 3(d).

Though, the broadened scope ostensibly seeks to protect the domestic generic industry in the short term, but the proponents of this sectional over reach fail to realize that the same provision works at cross-purposes. The resultant of this influence is going to harm both, intrinsically and extrinsically the same industry in the long term. Intrinsically, with its implicit intention of disallowing incremental improvements (e.g. selection inventions, product-by-process inventions, ‘new use’ inventions, etc.), which has traditionally been the forte of Indian pharmaceutical companies, and extrinsically because domestic generic industry would never get motivated enough to aggressively engage or re-focus itself on the process of core or innovative new drug inventions.

3.3 A Review is warranted on SmithKline Standards Because the Decision Threatens to Undermine Development of New Life Saving Therapies

A review is warranted on SmithKline’s decision to determine whether this dramatic expansion in the inherent anticipation doctrine is an appropriate application of patent laws. Review is particularly warranted because the decision in this case directly conflicts with a line of cases from the same courts, dating back to 1881. In its recent expansion of the inherent anticipation doctrine, the Federal Circuit has made no mention of the “accidental prior use” or any of the court’s previous relevant case law. Review is also warranted because the decision in this case threatens to severely undermine incentives for pharmaceutical companies to invest in new, life saving therapies.

Though it has been argued a lot that the doctrine of inherent anticipation, as applied in Schering and SmithKline, places a much needed check and balance on the unwarranted extensions and evergreening, regularly invalidating patents under an expansive application of anticipation by inherency seems to be an analytical shortcut. Though, the public may experience a short term benefit from the invalidation of the patents under SmithKline Standards by the entry of generic competitors to drive down prices for drugs, contrary to this public use policy these short term benefits are likely to be outweighed significantly by the long term costs in terms of decreased product development brought about by cutbacks in R&D expenditures. The most effective method of increasing the flow of useful scientific information is to reward those who uncover the significance of previously unappreciated prior uses. Thus without the incentives provided by the patent system, unappreciated prior uses are likely to remain unappreciated.

In light of the significant health care costs imposed on society by the Federal Circuit’s abandonment of the accidental prior use doctrine, review of the newly established “SmithKline Standards” is strongly warranted.

4. Future Strategies

The review and analysis in the previous sections of this article demonstrates that court do not seem to apply consistent standards when faced with accidental or inherent anticipation. However, the Schering and then SmithKline decisions, clearly suggests that a broad inherent anticipation doctrine is generally accepted by the Federal Circuit. Practitioners in the pharmaceutical industry have closely been following these decisions and
believe that these will affect the practices of patent prosecution, litigation and even the business standards.

4.1 Impact of SmithKline Standards on Patent Prosecution & Litigation
One of the early lessons that every patent practitioner is taught is to obtain as broad a patent as possible in view of the prior art. However, when the only difference between a patent and the prior art is a single claim limitation, the practitioner must now be sure that this single limitation is not only missing from the prior art, but must now also conjecture whether this can be found inherently in future studies. As the law currently implies that the recognition of the anticipated element need not be recognized or appreciated until the moment of litigation, the effect is that even a perfectly complete search of the prior art, and a “perfect” patent prosecution, the patent will still not survive a challenge in the court. While dealing with patents, practitioners should also appreciate the heightened sensitivity towards prosecution history estoppels as demanded by *Festo v. Shoketsu Kinzoku Kogyo Kabushiki Co.*

4.2 Claim Drafting Strategies in light of SmithKline Standards
The claims of a patent are central to virtually every aspect of patent law. The ruling in *Schering* shows that the law will not generally allow a pioneer-drug manufacturer to obtain a de facto extension of a patent on a drug by claiming in a later patent a chemical composition necessarily formed when a patient simply ingests the drug in its usual course of treatment. Likewise, after *SmithKline* the innovator companies seeking to extend product monopolies using polymorph patterns, should now be careful, for patent infringement theories based on ‘disappearing polymorphs’ and inevitable conversion’ which can be translated into invalidity of those same patents based on inherent anticipation. However, the long term impact of such cases may not be as dire if the companies obtain patent protection for an inherently anticipated compound through proper claiming.

Therefore, it should serve as a reminder that patent applicants should be particularly careful when drafting claims to a chemical species that could have existed before the application was filed, such as a new polymorph of a known compound, an isolated natural product, a drug metabolite, or even an impurity. This case also reinforces the importance of using claims of multiple types (uses, compositions, formulations, product-by-process) and varying scope, including claims to a pure or synthetic form of the invention or to different methods of using the invention. A compound claim might be anticipated under this standard, while a claim to its use or methods of making it might still provide effective protection.

5. Conclusion
*Schering* and *SmithKline* have refined the doctrine of inherent anticipation in a way that, if a thing existed in the prior art, whether or not it was recognized by person of ordinary skill in the art, the thing should not be patentable. Now the only remaining test for accidental anticipation would be whether the prior composition or process was occasional or unusual. Therefore, those who draft and prosecute patent applications, and those who litigate patents, especially for the chemical, pharmaceutical or biotechnological patents, need to be mindful in future of its rule to avoid being-sided by an inherent disclosure.

However, with due honor to, and remaining consistent with the decisions of the Hon’ble U.S. Courts, we still raise our serious concern that in determining the proper scope of the inherent anticipation and accidental prior use doctrines, one must bear in mind the congressional purposes underlying these doctrines. The potential for unintended consequences in any change to the patent laws strongly suggests that such action should be approached with careful deliberation especially when it has substantial impact upon health and life of human being.
Conflict of Interests: None of the authors have any conflict of interest. This article is solely for the purpose of academic discussions.

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CITATIONS / ENDNOTES

5 SmithKline Beecham Corp. v. Apotex Corp. 403 F.3d 1331, 1343 (Fed. Cir. 2005).
9 See at 8.
10 See at 9.
14 Id. at 712.
16 Id. at 303.
17 Id. at 304 (citing In re Felton, 484 F.2d 495, 500 (C.C.P.A. 1973).
18 MEHL/Biophile Int’l Corp. v. Milgaurm, 192 F.3d 1363, 1364 (Fed. Cir. 1999).
19 Id.
20 Id. A second reference asserted by the defendants is discussed infra.
21 Id. at 1365.
22 Id.
24 Id.
25 Id.
26 Id. at 52.
27 Id.
28 Id. at 58.
29 Id. at 59.
30 Id. at 63.
31 Id. at 66.
32 In re Seaborg, 328 F.2d 996 (C.C.P.A. 1964).
33 Id. at 996-997.
34 Id. at 999.
35 Id. at 997.
37 In re Felton, 484 F.2d 495, 497 (C.C.P.A. 1973).
38 Id. at 497.
39 Id. at 498.
40 Id at 499-500 (citing Tilghman v. Proctor, 102 U.S. 707 (1880); Eibel Process Co. v. Minn. & Ont. Paper Co., 261 U.S. 45 (1933).
41 Verdegaal Bros. v. Union Oil Co. of Cal., 814 F.2d 628, 631
42 Id. at 632.
43 Id. The court relied on column 7 of the specification of the Stoller prior art patent, U.S. Patent No. 4,315,763, beginning at line 30. Id.
44 Id. at 633 (citing In re Oelrich, 666 F.2d 578, 581 (C.C.P.A. 1981); In re Swinehart, 439 F.2d 210, 212-13 (C.C.P.A. 1971).
59 MEHL/Biophile Int’l Corp. v. Milgraum, 192 F.3d 1362, 1364 (Fed. Cir. 1999); see also supra Part A.1.c.
60 Id. at 1366.
61 Id. at 1366-1367.
62 In re Cruciferous Sprout Litigation, 301 F.3d 1343, 1345 (Fed. Cir. 2002). The food was used to prevent cancer. Id.
63 Id.
64 Id. at 1346.
65 Id. at 1349-1350.
66 Id. at 1346.
67 See 10.
68 Id. at 1267.
69 Id. at 1268.
70 Id. at 1269.
71 Id.
72 Id. at 1268.
73 See 11.
74 Id. at 1345.
75 Id.
76 Id. at 1346.
77 Id. at 1348.
78 Id. at 1347.
79 See 10.
80 Id. at 1226.
81 Id. at 1225.
82 Id. at 1227, 1230.
83 Id. at 1228 (citing Cont’l Can Co. U.S.A. v. Monsanto Co., 948 F.2d 1264, 1269 (Fed. Cir. 1991)).
84 Elan I, 304 F.3d at 1229.
85 Id. at 1228, 1229.
87 See 8.
88 Id.
89 Id. at 1377.
90 Id. at 1380.
91 Id. at 1374-1376.
92 Schering, 339 F.3d at 1376.
93 Schering, 339 F.3d at 1378.
94 The district court had said that the claim would be indefinite and hence invalid if it covered an undetectable amount of hemihydrate; it construed the claim to require a detectable or a ‘commercially significant’ amount of hemihydrate. SmithKline Beecham Corp. v. Apotex Corp., 247 F. Supp. 2d 1011 (N.D. Ill. 2003). However, the Federal Circuit overturned that claim construction and held that the claim covered any amount, even a single undetectable crystal.
95 In the parliamentary debates, the Minister of Commerce and Industry stated that Section 3(d) was introduced to prevent the phenomenon of ‘ever-greening’. Another Parliamentarian, Sh. Suresh Kurup specifically cited the ongoing case of Glivec to highlight the ill effects of ever-greening. Lok Sabha Debates (22 March, 2005), http://164.100.24.230/Webdata/datalshom001/dailydeb/22032005.htm.
96 E. Hoffman-La Roche Ltd. & Anr v Cipla Ltd., CS(OS) 89/2008, Delhi High Court.
Understanding the Doctrines of Anticipation and its Impact on Life Science / Drugs Patents – An International Perspective

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**Abstract**

It is often unclear when a prior occurrence or disclosure of a claimed invention falls under the patent law doctrines of inherent or accidental anticipation. Courts have applied various tests in determining anticipation, and the cases are difficult to reconcile. Tests seemingly dispositive to establish an accident in one case may also appear dispositive to establish inherency. Tests can be used to reconcile the two doctrines and determine whether a product or process anticipates. The first prong is concerned with whether the prior process or composition was useful in the art. If the answer to the first prong is no, then the anticipation is accidental; if the answer is yes, the second prong is whether the process or composition occurred under unusual conditions or occasionally. If the answer to the second prong is no, then the anticipation is inherent; if the answer is yes, then the anticipation is accidental. In some contexts, genus-species anticipation can become a world of subjective interpretation that seems more appropriate when wrestling with obviousness. Yet to anticipate, a prior art reference must do more than merely disclose each of the claimed elements; it must also be enabling.

**Introduction**

It is well-known in patent law that a prior reference can defeat patentability by expressly disclosing all of the elements of a claimed invention. It is also well-known that a prior reference can defeat patentability under the statute without having to expressly disclose all of the elements in the claim. The elements may simply inhere in a disclosed composition or process. This latter type of reference is said to anticipate the claimed invention under the doctrine of “inherent anticipation.”

The prior occurrence of a process or composition can anticipate a claim under this doctrine because of elements that simply inhere in the process or composition even if these elements were not recognized at the time of the prior occurrence. Inherent elements include components or properties of a composition and steps, mechanisms of action, or results of a process. To establish a case of inherent anticipation, the process or composition or element thereof must have existed or occurred to a certainty (i.e., not possibility or probability).

There have been instances, however, in which a prior process or composition inherently met all of the limitations of a claim, but where a court decided that the doctrine of inherent anticipation did not apply (i.e., the claim was not anticipated). In these cases, the courts have rationalized the prior art as “accidental.” This has come to be known among patent practitioners as the doctrine of “accidental anticipation.” “Accidental anticipation” is somewhat of a misnomer because under this doctrine the prior art does not, in fact, anticipate.

As demonstrated by the recent Federal Circuit cases Schering Corp. v. Geneva Pharmaceuticals, Inc. and Elan Pharmaceuticals Inc. v. Mayo Foundation for Medical Education and Research, it is often unclear when an inherent prior occurrence or disclosure falls under the doctrines of inherent anticipation or accidental anticipation. Courts have not clearly defined what constitutes “accident.” Instead, courts seem to have relied on specific factual criteria. Additionally, courts have applied various tests in determining whether anticipation is inherent or accidental, and the cases are difficult to reconcile. Tests seemingly dispositive to establish an accident in one case may also appear dispositive to establish inherency.

In this study, it is proposed to decide which of the doctrines applies when all of the limitations of a claim inhere in a prior composition or process. Various cases are organized on the basis of the outcome: if the court found that the invention was not anticipated, the case was placed under the “Accidental Anticipation” rubric; if the court found that the invention was anticipated, the case was placed under the “Inherent Anticipation” rubric.
In some contexts, however, anticipation can become a world of subjective interpretation that seems more appropriate when wrestling with obviousness. In particular, so-called “genus-species anticipation” involve subjective interpretations of references. Yet to anticipate, a prior art reference must do more than merely disclose each of the claimed elements; it must also be enabling. In other words, the reference must disclose the subject matter in sufficient detail to enable a person having ordinary skill in the art (PHOSITA) to make it without undue experimentation. If the subject matter is enabled, then it is considered to be in possession of the public and the reference can serve as novelty-defeating prior art.

The study provides an overview of prior art, novelty, issues surrounding and arising from novelty requirement and examples of national/regional laws and practices concerning the prior art effect of earlier applications. The study also discusses anticipation and its impact on life science/drugs patents. It presents the doctrines of anticipation, disclosure obligations, focusing primarily on enablement, the most robust of the requirements and the tests applied by the courts on various life science/drugs patent cases. The enabling disclosures in patents do not serve a teaching function particularly well. Due to a number of factors, inventors are unlikely to review published patents and applications and, thus, are generally unaware of the patents of others. The patent disclosure itself does not directly foster further innovation. Enablement’s ability to inform the public domain, therefore, appears to be at best overstated by the courts.

The patent system confers on a patentee the exclusive right to prevent others from commercially using the patented invention in return for the public disclosure of the invention in order to enrich the existing body of technical knowledge in the world. It is a fundamental objective of the patent system that nothing be alienated from society which already belongs to it. Indeed, granting a patent on an invention already known would impose constraints on society in respect of the use of known information without offering any return or benefit. The line between what belongs to society and what can be withheld from it is, to a large extent, drawn by the notion of novelty. Accordingly, the novelty requirement is one of the most important internationally recognized principles provided under patent law.

1. Prior art
Prior art is all information that has been disclosed to the public in any form about an invention before a given date. Prior art includes things like any patents related to your invention, any published articles about your invention, and any public demonstrations.

Prior art (also known as state of the art, which also has other meanings, or background art), in most systems of patent law, constitutes all information that has been made available to the public in any form before a given date that might be relevant to a patent’s claims of originality. If an invention has been described in prior art, a patent on that invention is not valid.

In order to anticipate a claim, prior art is generally expected to provide a description sufficient to inform an average worker in the field (or the person skilled in the art) of some subject matter falling within the scope of the claim. Prior art must be available in some way to the public, and in many countries, the information needs to be recorded in a fixed form somehow. Prior art generally does not include unpublished work or mere conversations (though according to the European Patent Convention, oral disclosures also form prior art — see Article 54(2) EPC).

2. Novelty
Regardless in which country patent protection is sought, there are numerous criteria that must be met before a patent may be granted. Such criteria often involve the subject matter, novelty, obviousness, utility, and various other factors associated with an invention. One example of a subject matter restriction is found in European Patent Law, where patent protection cannot be awarded on business method inventions. Unlike subject matter restrictions, the novelty, obviousness, and utility
requirements are instead applied independent of the type of invention and relate to whether a invention is new, obvious in view of prior art, and has industrial usefulness, respectively. Still yet, other restrictions vary from country-to-country (i.e. foreign filing license requirements, etc.). The novelty requirement is the most prevalently used restriction in denying patent protection on an invention, and thus deserves the most attention when filing for a patent.

The divergences among national laws and practices in respect of the prior art effect of unpublished earlier applications seem to reflect different principles and objectives underlying the prevention of double patenting.

**Comparison of Novelty Requirements of Various Countries around the World**

The following chart illustrates the novelty requirements of various countries. The majority of the countries of the world are substantially consistent in their respective novelty requirements. For example, all countries with the exception of the United States define their novelty requirements to afford a near-absolute novelty, first-to-file system with few, if any, exceptions. However, differences do exist that result in significant ramifications on patent procurement practices.

**Chart – Comparison of Novelty Requirements of Various Countries around the World**

<table>
<thead>
<tr>
<th>Country</th>
<th>Public Use</th>
<th>Publicly Known</th>
<th>Published / Patented</th>
<th>Abandonment Restrictions</th>
<th>First-to-Invent / First-to-File</th>
<th>Grace Periods</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>Only in Country</td>
<td>Only in Country</td>
<td>Anywhere</td>
<td>Yes</td>
<td>First-to-Invent</td>
<td>Broad 1-Year Grace Period</td>
</tr>
<tr>
<td>Majority of European countries</td>
<td>Anywhere</td>
<td>Anywhere</td>
<td>Anywhere</td>
<td>No</td>
<td>First-to-File</td>
<td>Varies</td>
</tr>
<tr>
<td>Japan</td>
<td>Anywhere</td>
<td>Anywhere</td>
<td>Anywhere</td>
<td>No</td>
<td>First-to-File</td>
<td>Limited Conditional 6-Month Grace Period</td>
</tr>
<tr>
<td>China</td>
<td>Only in Country</td>
<td>Only in Country</td>
<td>Anywhere</td>
<td>No</td>
<td>First-to-File</td>
<td>Limited Conditional 6-Month Grace Period</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Anywhere</td>
<td>Anywhere</td>
<td>Anywhere</td>
<td>No</td>
<td>First-to-File</td>
<td>Limited Conditional 6-Month Grace Period</td>
</tr>
<tr>
<td>Singapore</td>
<td>Anywhere</td>
<td>Anywhere</td>
<td>Anywhere</td>
<td>No</td>
<td>First-to-File</td>
<td>None</td>
</tr>
<tr>
<td>Republic of Korea</td>
<td>Only in Country</td>
<td>Only in Country</td>
<td>Anywhere</td>
<td>No</td>
<td>First-to-File</td>
<td>Limited Conditional 6-Month Grace Period</td>
</tr>
<tr>
<td>Russia</td>
<td>Anywhere</td>
<td>Anywhere</td>
<td>Anywhere</td>
<td>No</td>
<td>First-to-File</td>
<td>Conditional 6-Month Grace Period</td>
</tr>
<tr>
<td>Australia</td>
<td>Anywhere</td>
<td>Anywhere</td>
<td>Anywhere</td>
<td>No</td>
<td>First-to-File</td>
<td>Conditional 6 / 12-Month Grace Period</td>
</tr>
</tbody>
</table>
3. Anticipation

The Federal Circuit Court explains “Anticipation” as a patent defense that must be based on a single prior art reference. For a claim to be anticipated, each claim element must be disclosed, either expressly or inherently, in a single prior art reference, and the claimed arrangement or combination of those elements must also be disclosed, either expressly or inherently, in that same prior art reference. Anticipation requires only one step to prove, if a single prior art reference is available. If a single document teaches all elements of a patent, in the same arrangement, the single prior art reference can invalidate the target patent. (Subject to a clear and convincing evidence standard for issued patents).

Fig. 1 (flowchart): Issue Analysis for Anticipation

Step 1 and 4: Determine Relevant Date

Step 2: Determine Characteristics of Person Skilled in the Art at publication date

Step 3: Determine Claim Construction

Step 5: Determine Characteristics of Person Skilled in the Art at filing date

Step 6: Determine Scope of Prior Art

Step 7: Determine Anticipation

Fig. 2 Claim not anticipated

Prior Art 1  Claim Coverage  Prior Art 2

Fig. 3 Claim anticipated

Prior Art 1  Prior Art 2
Anticipation and Life Science Patents
In recent years, there has been an explosive growth in life science research, especially in DNA recombinant engineering. The society has witnessed the completion of the human genome project, the success of animal cloning, pharmaceutical research, and other notable advances. These recent advances promise to bring us a higher standard of living by benefiting medicine, agriculture and industry. Therefore, inventions in the life science field must be adequately protected to ensure continued innovation. As a result, the growth of life science industry is directly proportional to the number of life science patent applications that have been filed and the relationship between patent law and life science invention is an issue of immediate interest.

The basis for deciding the fate of patent application involving biological material as well as other kinds of inventions is described in TRIPS Article 27(1). This is an attempt to bring some international uniformity to the access requirement for patent. However, it only sets the minimum patentability standards with which signatories must comply. National rules may vary beyond this minimum, and member states are free to set their own access requirements.

Among those three standards for access requirements, industrial application is a relatively self-explanation, and the majority of innovation in life science usually has some aspect of use or otherwise they would not be pursued. The more difficult concept in determining the patentability is the notion of novelty and nonobviousness, especially in a field that characterized by rapid growth, complexity, and comparative youth like life science, the subject matters are new and inventive today are frequently routine and obvious in only a few years’ time.

Anticipation and Drugs Patents
It is hard to dispute the significance of pharmaceuticals in modern society. Numerous drugs have been developed to treat ailments to a degree unimaginable several decades ago. Some of these ground breaking drugs are VIAGRA®, PROZAC®, and PAXIL®. Developing new drugs requires a huge investment by pharmaceutical companies; however, a successful drug can potentially bring its producer billions of dollars. Not surprisingly, these drugs often provide the backdrop for contentious litigation, as exemplified by the cases regarding both PROZAC® and PAXIL®. The process that a pharmaceutical company must satisfy to obtain approval from the Food and Drug Administration (FDA) to market a drug is long and cumbersome. These FDA requirements shorten the commercial life of patented drugs and, by decreasing the profits of pharmaceutical companies, endanger future research and development. By formulating a broad rule on inherent anticipation, the Federal Circuit appears to have substituted its own policy determination on pharmaceutical research and development in direct contravention of the policy choice that Congress has made.

4. Doctrines of Anticipation
Inherent Anticipation
Anticipation under § 102(a) occurs if the identical invention has been claimed on a single prior art reference. When more than one prior art reference is required to find unpatentability or if patentability revolves around a minor improvement of the prior art, the validity of the patent is evaluated for obviousness under § 103. In some cases, a prior art reference may anticipate if all the claimed limitations are not disclosed within the prior art but are deemed to be inherent within it. As Judge Rader said in *Atlas Powder Co. v. Ireco, Inc.*, “[u]nder the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.”

The doctrine of inherent anticipation applies in three basic circumstances: The first situation occurs when the prior art reference describes an inherent property. The second occurs when the prior art reference contains an inherent use.
third incident occurs when the prior art reference contains an inherent method of practicing the art. Since each of these circumstances requires different determinations of whether a patent has been anticipated, this article has developed separate factors for inherent properties, inherent uses and inherent methods.

**Inherent properties**
A patent can be anticipated if a prior art reference contains the same properties. The prior art reference need not expressly describe every property; instead, these properties may be inherently disclosed. The cases, *Schering Corp. v. Geneva Pharmaceutical, Inc.* and *In re Omeprazole Patent Litigation*, demonstrate how anticipation of inherent properties applies to the biotech industry.

In, *In re Cruciferous Sprout Litigation* an inherent property was claimed to be anticipated. Like the drugs in *Schering Corp. v. Geneva Pharmaceuticals* and *In re Omeprazole Patent Litigation*, the patent in, *In re Cruciferous Sprout Litigation* claimed a property of the sprouts that was inherent in the sprouts themselves. Because an inherent property was claimed to be anticipated, the factors for inherent properties should be applied. These factors include:

1. whether the inherent property was known when the prior art reference was published;
2. whether the inherent property is always produced; and
3. whether the prior art reference gives the public the benefit of the inherent property that the patent is attempting claim.

**Inherent Uses**
A patent can also be anticipated if the prior art reference contains an inherent use. Since artisans may not disclose every use for an invention, a use may be inherent in a prior art reference. The following cases, *MEHL/Biophile Int. Corp. v. Milgram* and *In re Woodruff*, establish how the anticipation of inherent uses relates to patent law.

In determining if a process or compound patent is warranted, the courts should analyze:
1. whether all the same steps are used in the prior art reference;
2. whether the use only occasionally results from the steps disclosed in the prior art reference.

**Inherent Methods**
Finally, a claim can be anticipated if it discloses a substantially similar method to the method claimed in the prior art reference. Even if the prior art reference does not explicitly state the same method, a method can still be inherent. The cases, *In re Baxter Travenol Labs, Glaxo, Inc. v. Novopharm Ltd.*, and *Glaxo Wellcome, Inc. v. Ben Venue Laboratory, Inc.*, demonstrate how the anticipation of inherent methods applies to the biotech industry.

In the cases mentioned above, the plaintiffs wanted to patent a process that was at least partially disclosed in a prior art reference.

In determining what constitutes an inherent method courts should analyze:
1. what the industry or corporate standard was at the time the prior art reference was published;
2. whether the process disclosed in the prior art reference always produces the result sought to be patented;
3. whether the amount of experimentation required to discover the subsequent inherent method was “undue.”
Accidental Anticipation

In the case of *Tilghman v. Proctor*, the Supreme Court found no anticipation. In explaining why the prior existence of the process would not constitute anticipation, the Court assumed, for the sake of argument, free fatty acids were accidentally produced and the claimed process was accidentally performed in the prior art.

The following potential accidental anticipation tests are derived from Tilghman:

1. The claimed process was unintended in the prior art
2. The result of the claimed process was assumed to be a necessary consequence of an intentional act
3. The claimed process was unrecognized in the prior art
4. The prior art had a different purpose
5. The claimed process was not useful in the prior art

In accordance to the case of *In Marshall*, the claims at issue were directed to a process for achieving weight loss by periodically administering an anesthetic prior to eating so as to contact nerve endings that release pancreatic hormones necessary for digestion. The prior art was the Physician’s Desk Reference, which prescribed oxethazaine to treat colitis, ulcers and other gastro-intestinal problems by dosing periodically prior to eating and at bedtime. The court found no anticipation, reasoning as follows: “Nothing in the PDR remotely suggests taking oxethazaine to lose weight. If anyone ever lost weight by following the PDR teachings, it was an unrecognized accident. An accidental or unwitting duplication of an invention cannot constitute anticipation.”

The following potential accidental anticipation tests are distilled from Marshall:

1. The claimed process was intended in the prior art
2. The result of the claimed process was unintended in the prior art
3. The claimed process was recognized in the prior art
4. The result of the claimed process was not recognized in the prior art
5. The prior art had a different purpose
6. The claimed process was useful in the prior art

In accordance to the case of *MEHL/Biophile International Corp. v. Milgrauem*, it was found that to prove anticipation; the defendants introduced a laser instruction manual teaching tattoo removal. Despite the defendants’ argument that the manual inherently disclosed the claimed process, the court found no anticipation.

The court stated that to anticipate, the reference would have to teach, either expressly or inherently, aligning the laser “substantially vertically” over hair follicles. The court continued, noting that it is possible or even probable, that a laser would be substantially vertically aligned over a hair follicle in the process of removing a tattoo. However, the court concluded if something happens only occasionally it is not grounds for anticipation because “occasional results are not inherent.”

The following potential accidental anticipation tests are derived from MEHL/Biophile:

1. The claimed process occurred occasionally in the prior art.
2. The claimed process was intended in the prior art.
3. The result of the claimed process was unintended in the prior art.
4. The claimed process was recognized in the prior art.
5. The result of the claimed process was not recognized in the prior art.
(6) The prior art had a different purpose.
(7) The claimed process was useful in the prior art.

The case of SmithKline Beecham Corp. v. Apotex Corp., discusses accidental and inherent anticipation only in dicta. It is important because it suggests that even an undetectable and unintentional amount of patented subject matter may result in infringement.

This aspect of the Federal Circuit’s analysis has far-ranging implications for the doctrine of accidental anticipation. It has long been recognized that “that which would literally infringe if later in time anticipates if earlier.”\(^4^0\) The discussion of anticipation in SmithKline is dictum. The Federal Circuit ultimately relied on the “public use” bar of §102(b) to hold claim 1 of the ’723 patent invalid.\(^4^1\) Moreover, it was not entirely clear from the record whether the hemihydrate form of PHC existed before the filing date of the ’723 patent.\(^4^2\) Therefore, the discussion of what would happen if the hemihydrate existed in the prior art is not the basis of the court’s holding and is dictum.

Nevertheless, based on the court’s rationale, infringement by accident is still infringement. Infringement and anticipation go hand in hand: if something infringes if later in time, then it anticipates if earlier in time. Therefore, had trace or undetectable amounts of the hemihydrate existed in the prior art, they should have anticipated. On the other hand, it would appear that trace or undetectable amounts of hemihydrate are useless. Thus, if the court’s dicta ultimately become law, this is the first instance where a useless prior composition would inherently anticipate. Hence, the first prong of our test would fail to distinguish accident and inherency. In that situation, the only remaining test would be the second prong, whether a prior art process occurred under unusual conditions or a prior art composition was obtained under unusual conditions.

**Genus Species Anticipation**

Most patent practitioners consider anticipation to be a straightforward, objective issue. Does a reference disclose each and every element of the claim? Of course, the issue can become slightly more complex when the concept of inherency comes into play, but, even then, objective evidence will either confirm or deny the inherent disclosure of the reference. In some contexts, however, anticipation can become a world of subjective interpretation that seems more appropriate when wrestling with obviousness. In particular, so-called “genus-species anticipation” involve subjective interpretations of references.

Most practitioners likely would consider anticipation to be a rather black and white issue. This is especially true when compared to the subjective obviousness standard. To anticipate the invention, a prior art reference must place the inventive compound or composition in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011 (C.C.P.A. 1964). Thus, the prior art reference must disclose each and every feature of the claimed invention, either explicitly or inherently. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995).

However, with regard to chemical patent practice, anticipation analysis can be very subjective. These circumstances are known as genus-species situations. In genus-species situations, a prior art species will always anticipate a genus. In stark contrast, the disclosure of a genus may or may not anticipate a species within a genus. The modern standard for whether such a genus anticipates a claimed species was described more than 40 years ago in the CCPA decision of *In re Petering*, 301 F.2d 676 (C.C.P.A. 1962).
Under these particular circumstances, the anticipation analysis becomes incredibly subjective. First, there is the injection of patent law’s “reasonably prudent person” analog, “the person of ordinary skill in the art,” into the standard. Second, the question of whether this person is able to “at once envisage” the species is no less subjective.

The basic proposition that inherent anticipation does not require express disclosure of a genus discussing each and every species likely remains intact. Disclosure of structurally similar compounds may be sufficient to anticipate if:
(1) the disclosure implies a sufficiently limited genus containing the patented compound; and
(2) the disclosure does not exclude the patented compound from membership in a preferable class.

In a sense, the analysis is encouraging to any drug developer, whether proprietary or generic, that identifies and elucidates detailed information about an active ingredient, its molecular structure or function. Broad, earlier disclosures of a generic drug structure would anticipate later filed directed or detailed structure/method claims only if the earlier disclosure is fairly directed toward the later claimed invention. This prevents the doctrine of inherent anticipation from being used to discourage follow-on drug development.

Enablement Standard of Anticipation
Anticipation is a strict standard because the invention as precisely claimed must have existed identically in the prior art to be anticipated. Anticipation can occur if the invention has been physically created prior to the patent applicant’s creation or if it has been described in a qualifying printed form. In other words, if the prior art is possesses the claimed invention through a physical embodiment or a written disclosure, then it anticipates that invention. Again, possession is central to anticipation law, and particularly enablement is essential to making this determination.

A bedrock principle of patent law is that a patent should not issue if it would remove technology that is already available in the public domain. The corollary is that inventions must be new; bestowed upon the public for the first time by the inventor. As the nineteenth-century legal historian George Ticknor Curtis wrote in his famous treatise on patent law, when the invention has already been described in the prior art

[T]he public has acquired nothing from the [disclosure] of the patentee which they did not possess before, and that the patentee has invented nothing, which he, as one of the public, could not have derived from the means of knowledge which the public before possessed. Hence it is, that the production of a prior description, which was in the possession of the public, negatives the title of the patentee as the first inventor.

To allow otherwise would not only add nothing to the sum of human knowledge, but “would in fact injure the public by removing existing knowledge from public use.” Thus, novelty serves to safeguard the public’s right to enjoy what it already possesses.

Unlike § 112 of the United States Patent Act, which specifies the requirements for applicant-generated disclosures sufficient to obtain a patent, § 102 of the United States Patent Act is a patent-defeating provision that says nothing at all about enablement. Rather, the courts have read the enablement requirement into anticipation under § 102. For example, the Court of Customs and Patent Appeals (C.C.P.A.) recognized in In re LeGrice that the “described in a printed publication” clause of § 102(b) is interpreted as a result of the judicially imposed limitation that this clause requires that the description of the invention in the printed publication must be an “enabling description.” The Federal Circuit adopted the LeGrice reasoning in Paperless Accounting, Inc. v. Bay Area Rapid Transit System, agreeing that the basis for applying
the enablement requirement to anticipatory prior art is “found in the description requirement of § 102(b)” There are indeed valid policy reasons for this requirement, but nonetheless it is a judicial addition to the statutory language. Hence, our proposed adjustment of the enablement requirement for situations alleging inevitable anticipation is likewise proper so long as based on legitimate policy rationales.

In importing the enablement requirement into § 102, the Federal Circuit has mechanically extended the “without undue experimentation” qualifier of patent-obtaining enablement under 35 U.S.C. § 112, ¶ 1, without considering whether that qualifier should apply to prior art relied on as proof of anticipation by inherency. For example, in response to questions raised in a petition for reconsideration of an earlier (and subsequently vacated) panel opinion in the same case, the Federal Circuit in *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education & Research* “clarified that invalidity based on anticipation requires that the assertedly anticipating disclosure enabled the subject matter of the reference and thus of the patented invention without undue experimentation.”

5. The Test for Anticipation

- Did the public already have access to the “invention” when the patent application was filed.
- An invention may become available to the public in an almost infinite number of ways; such as prior sale, ability to view, or a verbal description.
- The Act provides an exception for disclosures that directly or indirectly stem from the applicant. In these cases, the patentee is given a one year grace period after the disclosure to file an application;
- Although novelty requires that the invention must not have been previously disclosed anywhere in the world, the test for a finding of anticipation is very difficult to satisfy.
- Unlike the test for obviousness, it is inappropriate to “mosaic” documents.

Reeves Brothers test

The tests for anticipation were summarized by Mr. Justice Gibson in the *Reeves Brothers* case. This summary has become known as “the Reeves Brothers” test and has been followed in virtually every case since then. An alleged prior publication or prior patent, to invalidate a patent, must meet the vigorous tests of anticipation. It must:

(a) give an exact prior description;
(b) give directions which will inevitably result in something within the claims (“the infringement test”);
(c) give clear and unmistakable directions;
(d) give information which for the purpose of practical utility is equal to that given by the subject patent;
(e) convey information so that a person grappling with the same problem must be able to say “that gives me what I wish”;
(f) give information to a person of ordinary knowledge so that he must at once perceive the invention [without experimentation];
(g) in the absence of explicit directions, teach an “inevitable result” which “can only be proved by experiments”;
(h) satisfy all these tests in a single document without making a mosaic.

When determining anticipation, you cannot “mosaic” prior art documents. It is not enough that the prior document makes suggestions, which taken with suggestions from other and independent documents, may be shown to foreshadow the invention or important steps in it. Anticipation is not established by what may be qualified the imaginary assemblage of separate elements gathered from glosses selected here and there in several and distinct anterior specifications. If one must compile and combine previous unconnected publications in an attempt to show anticipation, then it follows that no one has previously done so, and therefore there has been no anticipation.
CONCLUSION

The different patent systems have opted for different approaches in respect of the prior art effect of earlier applications. These approaches are not randomly chosen alternatives, but reflect different patent cultures and societal objectives, including the relevant environments in which innovation is promoted and exploited.

The courts do not seem to apply consistent standards when faced with accidental or inherent anticipation. Since Tilghman, most courts recognize that even when a claimed composition or process was present in the prior art, under certain circumstances, anticipation may have been accidental. The difficulty lies in determining exactly what such circumstances are as different courts stress different reasons for finding or not finding anticipation.

Having analyzed various accidental and inherent anticipation cases, a decision tree is proposed consisting of the following two questions:

1. Was the allegedly anticipating prior art product or process useful; and
2. Was the product obtained under unusual conditions or did the process occur under unusual conditions?

If the answer to the first question is no, then the anticipation is accidental; if the answer is yes, then the second question must be answered. If the answer to whether the composition was formed or process occurred under unusual condition is yes, then the anticipation is accidental; otherwise, it is inherent.

Based on a review of major cases relating to the doctrine of anticipation by inherency and the Accidental Results Doctrine, it appears that the Doctrine of Accidental Results has rarely been applied in recent cases. It will be interesting to see if the Doctrine of Accidental Results would be applied if a court were presented with a fact pattern similar to that in Tilghman or in Eibel, (i.e., a case in which the results are truly accidental, unintended and unappreciated).

If the rationale of the recent Federal Circuit decision in SmithKline v. Apotex becomes the law, it would appear to abolish the first prong of our test, i.e., whether the prior composition or process was useful. Since that panel of the Federal Circuit virtually eliminated the concept of accidental infringement, it would appear that accidental anticipation is also virtually abolished. Remembering the axiom of patent law that “that which infringes if later in time anticipates if earlier,” even if an allegedly anticipating composition was a useless by-product, it may still anticipate. It remains to be seen if the Federal Circuit extends the SmithKline analysis to accidental anticipation cases or if it limits it to the unusual SmithKline fact pattern.

In some contexts, however, anticipation can become a world of subjective interpretation that seems more appropriate when wrestling with obviousness. In particular, so-called “genus-species anticipation” and the anticipation of ranges involve subjective interpretations of references. Yet to anticipate, a prior art reference must do more than merely disclose each of the claimed elements; it must also be enabling. In other words, the reference must disclose the subject matter in sufficient detail to enable a person having ordinary skill in the art (PHOSITA) to make it without undue experimentation. If the subject matter is enabled, then it is considered to be in possession of the public and the reference can serve as novelty-defeating prior art.

The factors put forth in this note give legal practitioners and the pharmaceutical/life science industry a clearer standard for anticipation. Applying the factors to relevant cases will help to better determine whether a patent has been anticipated. Additionally, the factors will allow businesses to more readily determine whether a patent is invalid, and in turn, help businesses decide whether to acquire a license or risk litigation.
BIBLIOGRAPHY


11. Janice M. Mueller and Donald S. Chisum, Enabling patent law’s Inherent anticipation doctrine.


19. Robert A. Matthews, Jr. and Louis M. Troilo, Schering corp. V. Geneva Pharmaceuticals, Inc.: Just how far can Inherent anticipation extend?


CITATIONS / ENDNOTES

See Verdegaal Bros. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”).

Verdegaal Brothers, 814 F.2d at 631.

Scalttech, Inc. v. Retec/Tetra, LLC., 178 F.3d 1378, 1384 (Fed. Cir. 1999).

339 F.3d 1373 (Fed. Cir. 2003).

346 F.3d 1051 (Fed. Cir. 2003).

Elan Pharmns., Inc. v. Mayo Found., 346 F.3d 1051, 1054 (Fed. Cir. 2003) (“To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate.”).

The PHOSITA is a hypothetical construct of patent law akin to the reasonably prudent person in torts. See Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed. Cir. 1987).

* Impax Labs., Inc. v. Aventis Pharma., Inc., 545 F.3d 1312, 1314 (Fed. Cir. 2008).


Id. (“Estimates about the cost of developing a new drug vary widely, from a low of $800 million to nearly $2 billion per drug.”). Masia also states that of “5,000 to 10,000 new chemical inventions that look promising . . . [only around] 250 compounds . . . enter into preclinical laboratory and animal testing. Of those . . . fewer than 10, on average, will show enough potential to qualify for Phase I human testing.”

Id. Since almost all initial investments cost at least one billion dollars, see supra note 2, for a product to cover its up front cost it must yield revenue more than that amount.

17 Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955 (Fed. Cir. 2001).

18 SmithKline Beecham Corp. v. Apotex Corp., 247 F. Supp. 2d 1011 (N.D. Ill. 2003), aff’d on other grounds, 365 F.3d 1306 (Fed. Cir. 2004), vacated en banc, 403 F.3d 1328 (Fed. Cir. 2005); and abrogated by 403 F.3d 1331 (Fed. Cir. 2005).

19 Id. at 1017-18.

20 Con‘T Can Co., Inc. v. Monsanto Co., 948 F.2d 1264, 1267 (Fed. Cir. 1991) (citing Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 780 (Fed. Cir. 1985); Lindemann Maschinenfabrik GmbH v. Am. Hoist and Derrick Co., 730 F.2d 1452, 1458 (Fed. Cir. 1984)).

21 Id.

22 Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed. Cir. 1987).


25 Id.

26 Id.

27 Id.

28 Carlson, supra note 40, at 307.

29 Carlson at 314-15.

30 Carlson at 310.


32 Id. at 303.

33 Id. at 304 (citing In re Felton, 484 F.2d 495, 500 (C.C.P.A. 1973)).

34 Id.

35 Id. at 1365.

36 Id.

37 Id.

38 Id.

39 Id.


41 SmithKline, 365 F.3d at 1321.

42 Id. at 1315.

43 The traditional forms of prior art references are printed publications or issued patents, both in the U.S. and abroad. Other forms of prior art are patents that have been abandoned to the public, 35 U.S.C. § 102(c), patent applications which eventually issue or which the PTO publishes, 35 U.S.C. § 102(e), derivation of the invention from a previous inventor, 35 U.S.C. § 102(f), or evidence of prior invention by another party, 35 U.S.C. § 102(g).


45 Graham v. John Deere Co., 383 U.S. 1, 5-6 (1966)

46 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS 305 (1890).

47 GEORGE T. CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS (2d ed. 1854).

48 Id. at § 292

49 U.S. v. Dubilier Condenser Corp., 289 U.S. 178, 186 (1933)

50 Bonito Boats, 489 U.S. at 148. Therefore the logic behind the novelty requirement “is fairly straightforward (because if) information is already in the public domain when the ‘inventor’ seeks to grant a patent to him, the patentee has no right to grant a patent to get this information.” Robert P. Merges, Uncertainty and the Standard of Patentability, 7 HIGH TECH. L.J. 1, 12-13 (1992).

51 Id. at § 102(c).

52 See 35 U.S.C. § 112, ¶ 1 (2000) (mandating that patent specifications contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same.).

53 See 35 U.S.C. § 102 (2000) (listing events that destroy novelty of a claimed invention or that result in a loss of right to patent it due to delay in filing patent application).

54 In re LeGrice, 301 F.2d 929, 939 (C.C.P.A. 1962).

55 Paperless Accounting, 804 F.2d at 665.

56 Id. at 162.


58 Elan Pharms., Inc. v. Mayo Found., 304 F.3d 1221, 1229 (Fed. Cir. 2002)

59 Elan Pharms., Inc. v. Mayo Found., 346 F.3d 1051, 1052 (Fed. Cir. 2003)


Id.


British Ore Concentration Syndicate Ltd. v. Minerals Separation Ltd. (1909), 26 R.P.C. per Lord Moulton at p. 147.

Bristol-Myers, 246 F.3d at 1378.

Also worth noting is that the rationale in SmithKline seems to conflict with In re Seaborg. In Schering, the court stated that In re Seaborg was distinguished because the by-product was undetectable. Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1379 (Fed. Cir. 2003). In SmithKline, however, the conclusion appears to be that an undetectable contaminant can still anticipate. See SmithKline, 365 F.3d at 1315 (implying that had the defendant “present[ed] clear and convincing evidence of inherent anticipation” at trial, the defendant’s prior art product—which was found to contain only trace amounts of the compound covered by the plaintiff’s patent—may have anticipated the claim at issue). In view of the above considerations, it appears that if the SmithKline rationale becomes law, then the only remaining test for accidental anticipation would be whether the prior composition or process was occasional or unusual, as exemplified by Eibl Process, Felton, and MEHL (tattoo removal aspect).

Elan Pharm., Inc. v. Mayo Found., 346 F.3d 1051, 1054 (Fed. Cir. 2003) (“To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate.”).

The PHOSITA is a hypothetical construct of patent law akin to the reasonably prudent person in torts. See Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed. Cir. 1987)

Impax Labs., Inc. v. Aventis Pharm., Inc., 545 F.3d 1312, 1314 (Fed. Cir. 2008).

Akzo N.V. v. U.S. Int’l Trade Comm’n, 808 F.2d 1471, 1479 (Fed. Cir. 1986) (“A[n]ticipation requires that each and every element of the claimed invention be disclosed in a prior art reference. In addition, the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public.”).
Mitigating patent risks through protection analysis, assessments of infringement liabilities, freedom to operate and defences is the only way forward in intellectual asset protection and wealth management

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INTRODUCTION
As the world transitions to a knowledge-based economy, IP assets are increasingly recognized as key business assets. Late 1990's, heralded an era in which the majority of business value came from intangible assets. The Intellectual Property (IP) industry is a multibillion dollar industry today. Although historical data is limited, British Technology Group, a consulting firm engaged in technology transfer, believes, the industry represents a $3.0 trillion per year market, of which only $180 billion has been realized in the form of tangible commercial value. Estimates vary, but experts believe that between 70% and 90% of the market value of publicly traded companies is attributed to Intellectual Property (Figure 1).

With intangibles predominantly driving the enterprise value, it becomes imperative that these intangibles are fiercely guarded against all threats and are proficiently managed for sustained growth and wealth creation of the industry. Investment vehicles such as the Ocean Tomo 300 Patent Index demonstrate that companies with comprehensive IP portfolios outperform other companies in terms of Market Valuation (Figure 2).
These successful companies realize the role patents and trademarks play in maintaining their competitive edge and in enhancing their market position. They invariably have well managed intellectual property portfolios designed to protect their inventive advantage and to maximize revenues through licenses, royalties and robust business alliances. They believe that mitigating risks to these assets is the only way forward in wealth management.

WEALTH CREATION AVENUES AND PATENT RISKS
Wealth creation happens in two ways – Innovation and Arbitrage. The gamut of IP management is around nurturing Wealth creation through Innovation.

Philips which has been in business for over 100 years is credited with some significant patents like the medical X-ray tube (1918), neon tube (1922), audio cassette tape (1963), VCR (1971), Audio CD (1983), GSM speech (de-) coder (1985), DVD (1996), CD-R, CD-RW (1997), Blue-ray disc (2002) and scores of other patents and inventions.

PRE 1985, Philip's business model was based on investments on R&D, the resultant R&D outputs were converted to products that were manufactured, marketed and sold resulting in return on investments. Globalisation changes led the company to focus on marketing, outsourcing the manufacturing to a third party. The advent of TRIPS agreement harmonizing the patent laws worldwide, created a pro-patent climate and Phillips adapted IPR as a strategic weapon in competition

Philips's patent filings which were around 877 in the year 1993 increased to around 3144 in the year 2002. Philips's current IPR portfolio boasts of about 95,000 patents based on 19,000 inventions with approximately 3000 new filings per year. Philips also owns more than 2,000 domain names in addition to the 22,000 trademarks and 6000 designs. Philips's successful transition from the manufacturing era to the knowledge based era was a result of its recognition of importance of IP and its protection.

It is the “knowledge economy” that defines the present business climate, and patents, the invaluable part of this knowledge economy generate the major chunk of revenue for the businesses. A patent is an exclusive right granted to a person who has invented a new and useful article or an improvement of an existing article or a new process of making an article. This right is territorial in nature and granted for a limited period. It is a form of industrial property and can be sold, wholly or partly, licensed, and transferred, generating the revenue.

Patents stimulate economic development in four main ways:

FACILITATE TECHNOLOGY TRANSFER AND INVESTMENT
The quid pro quo for issuance of a patent is full disclosure of the invention. Patent databases, are a rich source of useful technical information on existing patents. Relevant information extraction can lead to business opportunity exploitation as happened in the case of Azithromycin, one of the world's best-selling Antibiotics that helped turn around the fortunes of its manufacturer Pliva in Croatia. Patented in 1980, the drug was licensed to Pfizer, after Pfizer's scientists happened to stumble upon Pliva's patent in 1981, while searching through patent documents at USPTO.

ENCOURAGE R&D
The R&D carried out by industries or enterprise or other research bodies can result in inventions that can then be used to generate revenue for them through licensing. The researching body, enriched by licensing revenues, in turn can fund further R&D, creating a cycle of dynamic innovative activity. Companies like Dr Reddy's Research Foundation would not
have expanded had it not been for the patents in the field of high quality, low cost pharmaceuticals.

CATALYSTS OF NEW TECHNOLOGIES AND BUSINESSES

Patents are a powerful tool for stimulating the creation of new technologies and industries. Biotechnology, for example, could not have developed as it has done without the patent system. Toyota, the automobile major today owes its success to a powerloom patent that it licensed for £100,000 and used the capital, so obtained to set up the automobile company and fund the necessary R&D.

VENTURES, AND OTHER REVENUE-GENERATING TRANSACTIONS.

Today, licensing – the sharing and distribution of IP assets is increasingly the raison d'être of patents. United States patent export licensing revenue, has grown at an average rate of eight percent per year since 1982 (in real dollars), more than twice the rate of US real Gross Domestic Product over the same period. Total worldwide revenues from patent licensing increased from US$10 billion in 1990 to US$110 billion in 2000 and are expected to reach $500 billion by 2015.

RISKS

According To The Harvard Business Review (Rivette & Klein), U.S. companies waste roughly $1 trillion annually in unrecognized patent assets. If a company has to maintain its edge and strengthen its financial position realized through patents, it shall have to aggressively defend its portfolio and continuously work towards prudent management of its assets. This management begins with identifying the risks that patents are loaded with and taking requisite measures to a priori’ ring-fence the patents against the same. Following are the risks to patents –

Infringement, 1.1. Liabilities, litigation, Technology Transfer/Licensing Clauses and Patent Trolls. At times, evergreening, reverse engineering and patent misuse are also quoted as threats to patents.

OPEN SOURCE SOFTWARE – A PERSPECTIVE

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both copyright and patent law.

Copyright - literal and/or artistic elements such as code and/or user interface.
Patent - functional elements of the software.
freedom to access, modify and distribute source code without copyright restrictions.
PROTECTION
When patents are ridden with risks, it becomes imperative to conduct protection analysis to assess the reasonable way out and to work towards fortification of the same. Innovation may occur without IP protection, but its pace and depth may be adversely affected without it. Following are a few protection mechanisms available to counter the threats to patents.

INTERNATIONAL PROTECTION
The (TRIPS) AGREEMENT under the WTO sets the minimum standards for IP protection of member countries. An application filed under PCT has the effect of a national patent application in those PCT contracting states which the patentee ‘designates’ in his application. The date of priority in the international patent application can be the date of filing of the patent. Also called submarine patents as they surface at a much later date, during national phase.

INVENTOR’S LOG BOOK
The real protection of begins with the conception of idea itself. The purpose of the inventor’s notebook is to keep detailed records of the idea, written description of the invention and the drawings; and as the invention develops recording the progress.

STRATEGIC AND OPERATIONAL MEASURES
Strategic and operational measures include Conducting an internal IP audit to identify the type of patent, Prioritizing the IP on Cost vs. Benefit and Offensive vs. Defensive Value and then Implementing the Internal/External measures. Internal (inside a business) include Registering the patents in time, maintaining the validity through maintenance or renewal fees, confirming the ownership and steps to secure the confidential informations External (dealing with 3rd parties)

Business Transaction
Business transactions are a great way of protecting ones assets. IP is used as often to transact as to prohibit others from using them. Transactions ensure royalty to one and knowhow to the other, encouraging improvements and crosslicensing and thereby creating a productive cycle.

Due Diligence
Verification of the representations and warranties by seller and the assumptions and understandings of buyer to ensure that such assets are free of any encumberences Lawsuits / Threatened Claims is fundamental to any business transaction.

Patent Monitoring
Surveillance or monitoring or policing of patents is a vital protection measure to watch over potential infringers and generate business transacting possibilities.

Plan For Contingencies
Contingency fund or a wide range of indemnification provisions in agreements can help tide through difficult waters.

STATUTORY PROVISIONS
The Indian Patent Act 1970, has been devised to protect the moral and statutory rights of individuals with regard to patent matters. For eg sec 104 to 110 deal with infringement issues and grounds under sec 64, for revocation, can be pleaded as defence in a suit. Compulsory licensing can be rightfully demanded and permission for importation sought. US laws also have similar provisions regarding patent issues.
SAFE HARBOURING

CRIMINAL AND ADMINISTRATIVE SYSTEM
In addition to moving court to enforce protection of one’s intellectual asset, an individual can seek help of other systems such as U.S. Department of Justice via Criminal Division (CCIPS), U.S. Attorney’s Office (CHIPS), the FBI, U.S. Immigration & Customs Enforcement (ICE), The National Intellectual Property Rights Coordination Center (IPR Center) or the Administrative System via U.S. Customs and Border Protection by Detention, Seizure and Forfeiture of Merchandise, U.S. Patent and Trademark Office by Patent reexamination, “Special 301” Process and (STOP!) Initiative are specifically launched to deal with IP issues.

ALTERNATIVE DISPUTE RESOLUTION
ADR in the form of Arbitration where a Neutral 3rd Party Makes Binding Ruling and Mediation where the Neutral 3rd Party Facilitates Resolution can help settle patent issue and save on cost and time.

IP INSURANCE
Patent protection and enforcement measures are not enough. They have to be supplemented by adequate and appropriate insurance cover which is of the following types: Defence and indemnity:

- Enforcement
  - IP asset protection
  - IP exploitation Agreement

These policies are however, issued only by a handful of insurance companies in international markets and in India, the concept is still in infancy.

PATENT POOLS
A patent pool is one mechanism by which two or more companies practicing related technologies put their patents in a pool to establish a clearinghouse for patent rights.

DEFENSIVE PUBLISHING OR TECHNICAL DISCLOSURES
Defensive publishing implies disclosing an invention to the public in a well-recognized technical journal or publication in order to ensure that nobody else is able to patent it. Defensive publication is, however, generally never done for a major breakthrough in technology or a core technological invention.

REVERSE ENGINEERING
Though not considered a traditional method of protection, Reverse Engineering (RE) is the process of discovering the technological principles of a device, object or system through analysis of its structure, function and operation to come up with a new product without utilizing any physical part of the original. RE is opted today for legacy software systems to replace incorrect, incomplete, or otherwise unavailable documentation and in pharma sector for generic products.
EVERGREENING
Evergreening is adopting legal and business strategies to obtain multiple patents on a product, over a period of many years, effectively extending the term of exclusivity that the patent holder has, and in turn, protect his invention for a longer term than originally granted. However, evergreening is a subject of perpetual debate in the IPR circle.

ASSESSMENT OF INFRINGEMENT LIABILITIES
The scope of liability for patent infringement may extend to all participants in the commercial economy, viz., Vendors, OE’s, resellers and customers and it’s assessment hence crucial for wealth management. In March 2010, Microsoft was found guilty of willful infringement of two VirnetX patents, originally developed by SAIC for CIA; and ordered to pay $105.6 million as damages to the company. Venturing into else's domain without ample assessment of liabilities cost it dear.

Losses related to patents, however, do not necessarily result only from damages granted by courts. In Bajaj v TVS litigation, TVS incurred losses on investments in product development and marketing of “Flame” due to a temporary injunction issued by a lower court. **Patents are expensive ventures and** the cases state the fact that assessment of infringement liabilities must be done at a very preliminary stage. For example, Generics must be aware of the patent liabilities before entering any regulated market. Launching generic drugs without proper assessment of patent expiry of existing drugs in such market could lead to heavy losses.

Determination of infringement is a mixed question of law and fact, and is of the following types-

2. **LITERAL INFRINGEMENT** - if an accused device falls directly within the scope of properly interpreted claims. It can be

2.6. Direct Infringement, Inducement to Infringement, Contributory Infringement, Process Patent infringement OR,

**INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS** where a claim is not literally infringed, but if the accused product and the patented product is substantial equivalents of each other, infringement is found.

Determination of infringement by a court is a two-step process:

(1) Scope of the claims (claim construction) is ascertained by giving ordinary and accustomed meaning to the words, construing claims in view of the disclosure in the specification and the prosecution history, and using extrinsic evidence for technical terms found ambiguous, and then

(2) Courts decide whether the claimed invention has been infringed (i.e., whether the claims as properly interpreted cover the accused product) through various 2.7. **TESTS**, viz.,

**THE GRAVER TANK TRIPARTITE TEST** - infringement may be ascertained if the accused product and the claimed invention perform substantially the same function, in substantially the same way, to obtain substantially the same results. Lack of one of these (must often the “way”) removes the accused product from infringement. Or,

**THE INSUBSTANTIAL DIFFERENCES TESTS** where the infringement may be found even if the differences between the claimed and accused products are insubstantial. Factors such as known interchangeability of the accused and claimed elements, evidence of intentional copying; and an attempt to design around the patent may be relevant to the differences being insubstantial.

Doctrine of equivalence must be applied on an element by element basis.
FREEDOM TO OPERATE

Patent litigation is an expensive, uncertain and risky affair. Companies, therefore, prior to launching a new/reformulated product or a new/redesigned process, entering into business transactions and often even prior to initiating a new line of research for a new product seek to minimize the risk of infringement by securing their "freedom to operate" (FTO), i.e. ensuring that the commercial production, marketing and use of their new product, process or service does not infringe the intellectual property rights of others. An FTO Analysis using tools like Infringement analysis, Technology landscaping and Competitor monitoring begins with an extensive search of patent literature for issued or pending patents; involves; looking for broad patents, patent family and validity searches and carefully analysing patent claims disregarding the older ones(>20 years).

An FTO analysis IS AN IMPORTANT WEALTH MANAGEMENT INSTRUMENT as it
a) Informs of the risks to making, using and/or selling a product
b) Helps develop a strategy to avoid third party patents and minimize risk of litigation (possible re-examination)
c) Helps detect a possible infringement
d) Serves as a tool for negotiating with the patentee.

Significant effect of this analysis is that it creates an opportunity to exploit the limitations of the patents such as patents being territorial (exploring markets where no licence is needed to commercialize the product) or having limited duration (monitoring the expiry of the term after which the patent is in public domain) or limits of scope (aspects of an invention not covered by the claims are not patented) and strategising the investment and efforts towards Purchasing the patent, Cross-licensing, Inventing around or creating Patent pools for obtaining the FTO and building up on assets.

DEFENCES

In its purest form, patent litigation would be resolved simply by comparing the claims of the patent with the accused product or process. In practice, however, the scope of a patent’s right to exclude depends not on the claims alone, but on practically everything having to do with the claims, at any time before a final judgment. Defendants charged with infringement can look to events taking place, before an application was filed, for invalidating prior art or statutory bars, during prosecution of an application, or a subsequent reexamination for prosecution history estoppels or inequitable conduct, and after issuance of a patent to find laches or equitable estoppel. Consequently, a range of defenses are available for combating an infringement suit. Sec 107 of The Indian Patent Act 1970, states that in any suit for infringement of a patent, every ground on which it may be revoked under sec 64 shall be available as a ground for defence. A counter claim for revocation may be a good defense measure though there is no express provision for the same. Sec 64(1) and sec104 impliedly concede this right. Let us have a look at the types of defences-

NON INFRINGEMENT

In the first, the defendant denies any infringement and tries to prove that their product or process does not infringe upon the existing valid patent for one or more reasons. Through infringement analysis techniques the judge or jury decide the infringement.

PATENT INVALIDATION

The other most common tack in patent infringement lawsuits is an attempt to invalidate the patent on one or more grounds of Obviousness, best mode, anticipation, and double patenting.
PROSECUTION HISTORY ESTOPPEL
Entitles a competitor to rely on the patentee's course of action in obtaining a patent to determine what products or processes are not equivalent to the claimed invention. Subject matter given up to secure a patent cannot be reclaimed in litigation. Amendment and argument are two ways of initiating estoppel.

LACHES
The neglect or delay in bringing suit which causes prejudice to the adverse party bars a patent holder's claim for damages accrued prior to suit.

EQUITABLE ESTOPPEL
Defendant may plead and prove that patentee's conduct made him infer no enforceability of the patent, relied on that conduct and shall be materially prejudiced if the patentee is allowed to proceed with his claim.

INEQUITABLE CONDUCT
Inequitable conduct, sometimes referred to as “fraud or unclean hands” is another defense. The respondents raising this defense must show that the complainants intended to mislead the patent office when they applied for a patent.

LICENSING
With this defense, the respondents merely must show that they received an implied license, prior settlement, or authorization from the patent owners includes Lack of candor, assignor estoppel, and nonjoinder/misjoinder.

PATENT MISUSE
The defense often appears under other names (“antitrust,” “monopoly,” and “unfair competition”) that reflect the true nature of the defense: The respondents must demonstrate the anticompetitive effect of the patent on the market.

EXPERIMENTAL USE
Importing / selling / use of patented product or process done for experimental purpose or for imparting education or submission of information under existing law can be pleaded as defense in a suit.

Other defences for a suit may include defence of Domestic industry, advisory letters, qualitative advantages, defense need for multiple sources of supply, patent exhaustion, market expansion, acquiescence, permissible repair, reissue patent etc.

ASSET AND WEALTH MANAGEMENT
Review of protection mechanisms regarding their benefits in mitigating patent risks, building up enterprise value and subsequent wealth management must consider validation and substantiation with relevant facts. These evidences come in the form of study of monetary value attached with the various threat mitigating techniques, the amount of revenues generated through business transactions, money lost or won through litigation cases and wealth built up by sales of reversed engineered or generic products. Next, a whole range of patent related activities such as patent asset actions, patent trading indices, patent investment funds, patent insurances and patent-based loans serve as, indices of value patents command in business environment today, and how these activities contribute to the process of wealth creation.
The world leader in terms of number of patents is 'International Business Machine (IBM)'. IBM owns nearly 26000 US patents and 45000 patents. It garnered 4,914 U.S. patents in 2009, setting an all-time high and maintaining its lead against competitors such as Samsung with 3,611 patents and Microsoft with 2,906. This tally is more than the number of patents granted last year to Microsoft, Hewlett-Packard, Oracle, Apple, Accenture, and Google combined.

The race for patents is not merely a matter of bragging rights. Patents produce considerable income: IBM's Fees from licensing and custom-developing intellectual property for other companies through Sept. 30 were on track to top $1.1 billion in 2009. Pfizer relies on a single set of patents covering cholesterol drug Lipitor for a fourth of its total sales, an estimated $11 billion last year. Qualcomm collected almost all its revenue—$10.4 billion in 2009—from selling licenses for and making the chips containing its patented 3G mobile-phone technology, known as CDMA. In all, Microsoft's portfolio was assessed at 3.3 times that of IBM's.

The number of litigations pertaining to patents has been rising as represented in Chart 1. Indicating increased awareness to protect and monetize patents.

However, the growth in compensation amount awarded by the courts has grown disproportionately as compared to the growth in the no of cases. Chart 2 captures the growth in compensation amounts since 1993 to April 2010.
Based on data from 2005 to 2009, if we estimate a trendline, the expected compensation for the year 2010 would be closest to USD 3.5 billion, as shown in Chart 3 below.

Yet another interesting fact is that the ticket size for the compensation is going up as well, particularly from 2005 onwards. Chart 4 captures the changing contours of the damages awarded. While from 1982 to 1989 > 100mn USD compensation cases constituted 1% of the total damages awarded, in 2005 the >100mn USD compensation cases comprised 30% of the total damages awarded, and constituted 86% of the damages in 2009.

The above trends clearly bring out the fact that litigation in Patents is becoming an increasingly effective tool towards protection of wealth created through Innovation.

A brief look at the TOP LITIGATION CASES OF THE YEAR 2009
a) Microsoft Word Slapped with Injunction in the matter of i4i v. Microsoft. Microsoft to pay $300 million, and a permanent injunction, to cease selling the ubiquitous word processing program Word.
b) RealNetworks DVD Software Gets Enjoined – RealNetworks settled with six movie studios regarding RealDVD, a RealNetworks Inc. software program barred in October 2008, who brought the lawsuit, agreeing to pay $4.5 million to the studios for litigation costs.

c) Microsoft Wins Reversal of 2 Massive Patent Damage Awards - Microsoft won reversal of two damage awards; $388 million against Uniloc and $511 million against Alcatel-Lucent.

d) Versata Wins $139 Million Patent Award - Versata Software won a lawsuit with damages worth $138.64 million against German software vendor SAP AG.

e) Merck Gets Singular Win Over Teva –US Patent No. 5,565,473, was found valid and enforceable, and Teva’s “ANDA” filing found infringing the patent.

f) Largest Patent Damages Award Ever –Centocor Ortho Biotech Inc. received a federal jury verdict of $1.67 billion against Abbott Laboratories.

As already seen licensing is the raison d’être of many businesses today.

Intellectual Ventures, a $5 billion small start-up with a business model of licensing has built up a portfolio of about 30,000 purchased patents and applications, and over 2000 internally-developed inventions. The acquired patents have produced about $1 billion and own patents about $80 million in licensing revenue in 2009, alone.

Acacia Research’s fourth quarter 2008 revenue from 20 new licensing agreements covering 15 different technologies was $18.3 million compared to $12 million in the year ago period. It's second half 2008 revenues at $32.1 million had set a new record of sorts. Acacia, in 2009, began generating revenues from 48 licensing programs, up 71% compared to 20 licensing programs at the end of the previous year.

During first few months of 2010, Software giant Microsoft entered into licensing agreements with various companies like LG, Samsung, Tom-Tom and Amazon for undisclosed royalties.

IP portfolios can be managed beneficially with various business transactions including licensing, and intellectual assets well guarded to ensure economic growth of organisations.

Revenue generated by Non Practising Units over the years accentuate the fact that wealth creation is predominated by patent management. Between 1995 and 2008, awards to NPEs ranged from $2.2 million to $10.6 million with a median at about $4.4 million. (chart 5).

Source PricewaterhouseCoopers
When narrowed down to the last seven years, difference in awards was more than triple in favour of NPEs—the median was at $12 million for NPEs, compared to $3.4 million for practicing entities. A survey of nine technology companies reported that more than 80 percent of 1217 licensing requests and 166 lawsuits pending for patent infringement of 2008 against 185 licensing requests and 97 pending lawsuits of 2004, were from NPEs. Between 2005 and 2008, out of 10 damages awards exceeding $100 Million, 4 were awarded to NPEs.

With so much of money at stake, companies need to be deliberate in their approach towards intellectual asset protection and its management for ensuring commercial success.

As a fitting example of reverse engineering, Imitrex, has turned out to be a good revenue earner. Dr Reddy’s Laboratories, which entered into an out of court settlement with GSK on the patent challenge litigation of the anti migraine drug Imitrex, has already netted over Rs 200 crore in the first quarter of 2009-10 as an authorised generic.

**CONCLUSION**

An enterprise’s wealth today is its intangible assets and prudent wealth management the key function of its success. Focus on innovations and offensive defence of its intangibles is what gives an enterprise its competitive edge. Patents form important components of intangibles and contribute significantly to the generation and management of revenues. Identifying and mitigating risks to patents is hence crucial for sustainable development and growth of the enterprise. Whatever manner is chosen to limit the chances of facing potentially risky and expensive wealth erosion threats, all companies would do well to look into the matter early on in the research and commercialization process. Systematically evaluating one’s freedom to operate, addressing the patent infringement issues with a proactive approach like assessing liabilities before venturing into an unknown, or even familiar territory, helps improve the robustness of the ecosystem and facilitates wealth management.

The various facts and figures available to study the monetary impact of patents on an enterprise’s value demonstrate that all threats to patent, whether litigation or troll are expensive affairs and need effective strategies to be countered. Defences in an infringement suit, alternate dispute resolutions and various business transactions such as licensing are some strategies that help protect the intellectual asset as well as manage the wealth so created.

Concepts of evergreening, reverse engineering, patent trolls and ‘misuse of patent’ are issue of perpetual debate in the IPR circle, on being a threat or a protection. Whatever the debate, it needs to be understood that one enterprise’s loss is another’s gain and hence the economic value implicit with these aspects, cannot be discounted.

In conclusion, to drive enterprise value and market capitalisation, a thorough analysis of patent environment whether regarding protection mechanisms or FTO or infringement liabilities or defences available is critically important. It helps a company to not only mitigate risks but also create, realise, protect and manage the intellectual assets and wealth.

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SYNOPSIS OF THESIS ON:
Doctrine of Best Modes and Enablement of the Invention in Complete Specifications Challenges the Validity of Patents. Comment in the Context of Recent Judgment

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Abstract
The patent system provides the inventor with a period of exclusivity during which the inventor has the right to prevent others from making, using, or selling the invention. In return, the public receives a free right to practice the invention after the patent expires.

In order to make sure that patents are self-speaking and enable the public to practice the invention, the patent statute establishes certain disclosure requirements. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. This is the enablement requirement, which ensures that the invention is communicated to the interested public in a meaningful way. Furthermore, the inventor must disclose the best mode of practicing the invention that is known to him. This is the best mode requirement which helps against inventors that are tempted to withhold key elements that are essential to the most advantageous practice of the invention while seeking full benefit of the patent system.

A patent can be invalidated for failure to comply with either of these standards and hence both these requirements must receive careful attention during the preparation of a patent application.

An analysis and comparison of the statutes in the United States of America and Indian legal systems has been explored through case laws and discussions to determine the impact of the best mode and enablement requirements in challenging the validity of patents.

The Enablement Requirement
The enablement requirement refers to the requirement of 35 U.S.C. 112 and Section 10(4) of the Indian Patent Act, that the specification describe how to make and how to use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent.

The purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention.

Test of Enablement
Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of Mineral Separation v. Hyde, which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. Accordingly, even though the statute does not use the term “undue experimentation,” it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. A patent need not teach, and preferably omits, what is well known in the art. Any part of the specification can support an enabling disclosure, even a...
Undue Experimentation

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue.” These factors include, but are not limited to:

(i) The breadth of the claims;
(ii) The nature of the invention;
(iii) The state of the prior art;
(iv) The level of one of ordinary skill;
(v) The level of predictability in the art;
(vi) The amount of direction provided by the inventor;
(vii) The existence of working examples; and
(viii) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The determination that “undue experimentation” would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

How to Make the Claimed Invention

As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement is satisfied. Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid.

How to Use the Claimed Invention

If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, the enablement requirement is satisfied.

Quantity of Experimentation

The quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether “undue experimentation” is required to make and use the invention. An extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance. The test is not merely quantitative, since a
A considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Time and expense are merely factors in this consideration and are not the controlling factors.  

The Best Mode requirement  

The best mode requirement, obligates patent applicants to disclose subjectively what the inventor believes is the best method of practicing the invention, if there is one. The idea behind the best mode requirement is to prevent the patentee from retaining as a trade secret the best manner of practicing the embodiment while disclosing only inferior approaches to the public in order to retain a competitive advantage.  

The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention.  

The best mode requirement is a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure as required by the statute. The requirement does not permit inventors to disclose only what they know to be their second-best embodiment, while retaining the best for themselves.  

The failure to disclose a better method will not invalidate a patent if the inventor, at the time of filing the application, did not know of the better method or did not appreciate that it was the best method. All applicants are required to disclose for the claimed subject matter the best mode contemplated by the inventor even though applicant may not have been the discoverer of that mode. 

Failure to disclose the best mode need not rise to the level of active concealment or grossly inequitable conduct in order to support a rejection or invalidate a patent. Where an inventor knows of a specific material that will make possible the successful reproduction of the effects claimed by the patent, but does not disclose it, speaking instead in terms of broad categories, the best mode requirement has not been satisfied.  

If the failure to set forth the best mode in a patent disclosure is the result of inequitable conduct, not only is that patent in danger of being held unenforceable, but other patents dealing with the same technology that are sought to be enforced in the same cause of action are subject to being held unenforceable. 

Factors to be considered  

I. Determine what the invention is 

The invention is defined in the claims. The specification need not set forth details not relating to the essence of the invention. Unclaimed matter that is unrelated to the operation of the claimed invention does not trigger the best mode requirement. Patenteer’s failure to disclose an unclaimed preferred mode for accomplishing a routine detail does not violate the best mode requirement because one skilled in the art is aware of alternative means for accomplishing the routine detail that would still produce the best mode of the claimed invention.  

II. Specific example is not required 

There is no statutory requirement for the disclosure of a specific example - a patent specification is not intended nor required to be a production specification.
The absence of a specific working example is not necessarily evidence that the best mode has not been disclosed, nor is the presence of one evidence that it has. Best mode may be represented by a preferred range of conditions or group of reactants.28

III. Designation as best mode is not required

There is no requirement in the statute that applicants point out which of their embodiments they consider to be their best; that the disclosure includes the best mode contemplated by applicants is enough to satisfy the statute.29

Requirements for Rejection for Lack of Best Mode

The examiner should assume that the best mode is disclosed in an application, unless evidence is presented that is inconsistent with that assumption. It is extremely rare that a best mode rejection properly would be made in ex parte prosecution. The information that is necessary to form the basis for a rejection based on the failure to set forth the best mode is rarely accessible to the examiner, but is generally uncovered during discovery procedures in interference, litigation, or other inter partes proceedings.

Examiner must determine whether the inventor knew that one mode was better than another, and if so, whether the disclosure is adequate to enable one of ordinary skill in the art to practice the best mode.

According to the approach used by the court in Chemcast Corp. v. Arco Industries, a proper best mode analysis has two components:

(I) Determine whether, at the time the application was filed, the inventor knew of a mode of practicing the claimed invention that the inventor considered to be better than any other. The first component is a subjective inquiry because it focuses on the inventor’s state of mind at the time the application was filed. Unless the examiner has evidence that the inventors had information in their possession:

(i) at the time the application was filed
(ii) that a mode was considered to be better than any others by the inventors, there is no reason to address the second component and there is no proper basis for a best mode rejection. If the facts satisfy the first component, then, and only then, is the following second component analyzed:

(II) Compare what was known in (I) with what was disclosed - is the disclosure adequate to enable one skilled in the art to practice the best mode?

Assessing the adequacy of the disclosure in this regard is largely an objective inquiry that depends on the level of skill in the art. Is the information contained in the specification disclosure sufficient to enable a person skilled in the relevant art to make and use the best mode?

A best mode rejection is proper only when the first inquiry can be answered in the affirmative, and the second inquiry answered in the negative with reasons to support the conclusion that the specification is non-enabling with respect to the best mode.
Conclusion

Different countries have different statutes with respect to disclosure. Countries such as United States of America, India and Australia require that the inventor disclose the best mode of carrying out his invention, while Europe has no such requirement. Principles governing the disclosure requirements are not uniform for all Patent Offices. Different specifications are required to be written for different jurisdictions. This disparity leads to inconsistencies while filing patent applications in different countries, which makes the patent vulnerable to being invalidated.

The interpretations of the disclosure requirements are not uniform. An inventor may be granted a patent through the Patent Office, only to have the patent invalidated years later in court. A review of patent invalidity cases in the late 1980s and early 1990s found that there was a difference in the manner in which judges treated best mode cases. Specifically, judges with patent experience rejected best mode arguments 74.1% of the time, while judges without patent experience rejected best mode arguments only 61.5% of the time. Thus, it can be argued that best mode decisions are highly subjective and open to the individual philosophy of the judge in question.

Due to the subjective nature of the best mode requirement, potential infringers often utilize the best mode requirement as a way of circumventing technical issues and focusing on the state of mind of the inventor. They adopt the “try the person, not the patent” technique in order to invalidate the patent.

The requirements for disclosure of the invention are, for the most part, not laid down in specific detail. This allows flexibility in providing a disclosure adapted to the needs of the technical field and the nature of the invention. The applicant has to work out in each case what is appropriate and how much needs to be disclosed.

The nature of the technology and complexity of the invention can have a significant influence on how much an inventor must disclose in order to satisfy the disclosure requirements. There is no need to clutter a patent application with words and drawings that disclose details that would be well known to those skilled in the art. In general, the best practice is for the inventor to provide a full disclosure to the patent attorney and for the two of them to make decisions regarding what should be disclosed in the application in order to make sure that there has been compliance with the disclosure requirements. All decisions must be handled on a case-by-case basis. It is of utmost importance that the inventor acts in good faith. Honesty and good faith are the key elements required to avoid a challenge to validity of any resultant patent based upon failure to comply with the disclosure requirements.

One of the functions of the patent system is to encourage the publication of new technology. It is in the interest of the public to have the best information available. However, too stringent disclosure requirements can hinder rather than promote. Disclosure standards must be realistic.

It is rarely completely clear, in any art at any date, exactly what the skilled person knows, and what he does not. A patent applicant should disclose the invention in full and careful detail, so as to minimize the risk of subsequent invalidation.

Some courts have expressed regret or concern with stripping a patent from an inventor who failed to document best mode properly without malice or intent to deceive. Losing on best mode due to clerical error or oversight of seemingly unimportant matters seems counter-intuitive to the philosophy of protecting investment as a reward for ingenuity.

Even if only in force in one or two countries, the best mode requirement has an important influence: if an inventor has to disclose it in one country, he may as well disclose it in all. No country requires the best mode to be specifically identified: thus, it can (at least in theory) be buried in Example 63 of a 250-page specification, with nothing to distinguish it from ninety-five other methods of carrying out the invention. There are proposals to remove the
obligation from US law, on the theory that the requirement is subjective and difficult to judge, and that it increases the cost of litigation.

The abolition of the best mode and enablement is contrary to the philosophies of the patenting system. The inventor may enjoy a limited period of monopoly in exchange for complete disclosure of the claimed invention to the public. Without satisfying the best mode and enablement requirement, the public is deprived of the information needed to practice that invention once the patentee’s exclusivity expires. This causes an obstruction to the various companies’ entry into the market which would have resulted in access to lower-cost products for the public.

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Managing Knowledge in Institutional Frameworks ...Enabling ideas to commercial fruition

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Abstract
Institutions in their path to productivity and excellence have to engage in effective knowledge dynamics and enabling teamwork for positive knowledge proliferation to maximize on the global human and infrastructure resources. The last few decades has experienced a gradual time-coalescence of the generative, application and trading phases of knowledge in addition to the intersection of remarkably diverse fields creating an effervescence of convergent technologies that may not have traversed the human mind until recent times.

All activities pivoting on knowledge in the knowledge canopy derive value from their interdependence. It is well established that societal growth is catalysed by the organic human drive to excel and compete. The key ingredients that sustain competition are appropriate combinations of knowledge (i.e. cumulative human experience), creativity, vision (the ability to look beyond the horizon) and effective implementation (actions). The knowledge paradigm is on a fast changing trajectory exploring new pathways involving global collaborations, increasing drive to gain strategic ownership of knowledge domains for speedy value creation, wealth generation and wealth realization. This is demanding reengineered thinking and newer landscaping of the organisational turf. To meaningfully participate in such activities, institutions of today and tomorrow will have to develop among other professional expertise, 21st century techniques in knowledge engineering, information metering, institutional management of their intellectual property, transferring their knowledge base appropriately to derive optimum value from them.

The challenge is to design and operate institutional innovation processes that would preserve intellectual excellence and at the same time be amicably fit into a disciplined formal knowledge management system. This requires appropriate people to people contact and connection between people to knowledge to enhance capacity for effective action. This presentation briefly reviews approaches being taken globally by academic and commercial enterprises in the area of Knowledge Management to achieve desirable benefits.
The first stage of knowledge incubation is idea nucleation followed by growth as it proceeds along the path to its conversion to technology for viable utilization in society. It should be appreciated that the realizable value of knowledge does not necessarily depreciate with age, as in many instances its value dramatically appreciates with the discovery of associated phenomena leading to enrichment of the global knowledge domain and in several cases a judicious application of the existing knowledge opens up new vistas in technologies leading to a revival and restart of the knowledge life cycle in that field. As ideas mature and value add to the field of their application, investment risks for their exploitation by enterprises decrease and they begin to attract investments for industrial growth. Competitiveness then demands protection of the developed knowledge in the form of intellectual property that leads to the segregation of the global knowledge domain into proprietary and non-proprietary regions thereby making management of intellectual property an imperative.

True societal growth is nurtured when knowledge is shared by the knowledge workers without fear of piracy of their knowledge. Intellectual Property Rights (IPR) provides the legal framework for such a fearless sharing of knowledge. The global IPR platform is intended to give exclusivity to the intellectual creation to the original creator for a limited period with appropriate societal safeguards to controls any undesirable monopolistic practices by the original creator that may destroy healthy competition in the market place.

Therefore one of the major challenges in today's people centric institutional knowledge management is establish processes for the scanning and recording of knowledge, its utilization, mapping of the proprietary and non-proprietary knowledge domains, valuation of knowledge for fearless knowledge transactions with appropriate IPR protection and benefit sharing among the knowledge creators, appliers and its beneficiaries in society. This would need a seamless integration of diverse aspects of the innovation process, project planning, intuitional management of the intellectual assets, etc.

These demands have set new intuitional benchmarks for project management and productivity and a realization that collective and collaborative working with appropriate benefit sharing arrangements would unleash the potential of human excellence. Different working models of knowledge management have been practiced and the concept of Communities of Practice (COP) has been found to be fairly effective in various organizations to eliminate barriers to sharing, enhance collaborative working, avoid reinventing the wheel, reduce cycle time for innovations and their conversion to technologies, cost reduction through common realization of issues, sharing of best practices, improve speed top market, improved customer satisfaction, etc,

One of the best expressions of knowledge management in my opinion is the poem written by India's poet laureate Gurudev Rabindranath Tagore where he very succinctly touched on the philosophy of knowledge evolution, sharing, research and excellence as we recall "where words come from the depth of truth... into ever widening thought and action"
Where the mind is without fear and the head is held high
Where knowledge is free
Where the world has not been broken up into fragments
by narrow domestic wall;
Where words come out from the depth of truth
Where tireless striving stretches its arms towards perfection
Where the clear stream of reason has not lost its way
into the dreary desert sand of dead habit
Where the mind is let forward by Thee
into ever-widening thought and action
Into that heaven of freedom; my father
let my country awake.

- Rabindranath Tagore (1901)

What we therefore need is a revitalized “mind without fear and with a head that is held high” to continually excel in our zeal for knowledge ad(d)venture.
Intellectual Property (IP) Audit
- A Legal Perspective

Mr. Prerak Hora¹

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Introduction
An enterprise's value is determined based on its assets' quality and not quantity. Further, the value also largely depends as that perceived by its various stakeholders – shareholders, creditors, government, consumers, etc. These assets may be broadly divided into two categories: (i) **tangible** or **physical** assets - building, machinery, infrastructure, etc; and (ii) **intangible** assets – patents, ideas, trademarks, designs, know-how, etc. Conventionally, physical assets have been responsible for the bulk of the value of an enterprise, and were also considered to be largely responsible for determining the competitiveness of an enterprise in the marketplace. However, in today's information and knowledge-based economy, this traditional wisdom no longer holds true. A business's intrinsic value is now largely determined by its quality of intangibles. The information technology revolution and the growth of the service sector have furthermore contributed this turnaround.

Today we all are living in an information and knowledge society. With the increasing adoption of the Internet and various other web technologies, the flow and dissemination of information and knowledge is just getting augmented. While this seems to be an optimistic sign, it poses a number of challenges in managing the same, especially when such the information and knowledge is in the form of IP.

Intellectual Property ("IP") refers to creations of the human intellect and is in the form of inventions, literary and artistic works, logos, names, images, designs, etc used in commerce. Intellectual Property Rights ("IPR") refers to the rights related to IP. For e.g. an idea or an invention is regarded as IP whereas the right associated with such IP (i.e. a patent) is considered as IPR. IPR is the tool to protect such creations and take the form of patents, trademarks, copyrights, trade secrets, designs, etc.

Importance of IP protection and management
All enterprises use some form of IP to successfully conduct their businesses regardless of their size, nature or industry. IP is an important asset not only for business users of IP but also for creators of IP. Various sorts of IP and circumstances surrounding its creation often make it impossible for such businesses and creators to be fully assiduous of its IP. Even if creators and users understand the importance of IP protection, many still do not know how to do so in the most efficient and effective manner. Without an effective IP protection and management system, creators and companies are sure to dispel business opportunities.

One of the best ways that can be adopted to effectively address this issue is by conducting an 'IP audit'.

What is IP audit?
Typically, the term 'audit' refers to a business audit which includes formal examination and verification of a company's accounts with the objective of acquiring and understanding the overall picture of a company's financial position.

Just like a business audit, an IP audit involves the evaluation of a company's IP assets and potential liabilities. There is no clear cut definition of IP audit. However, from businesses' point of view, it can be interpreted to mean a systematic assessment of various processes and procedures adopted in creating or generating IP, including IP assets owned, used and/or acquired by a business and understanding the IP rights/liabilities associated thereto.

An IP audit provides an assessment of the intangible assets of a company. The audit examines and evaluates the strengths and weaknesses in the procedures used to protect each intangible asset and secure appropriate IP rights. Where necessary, the audit provides tools to develop additional processes, make improvements to existing processes, and take corrective measures to help ensure capture of future IP rights.
Briefly the objectives and significance to undertake an IP audit include:

- ascertaining and protecting unutilized or under-utilized IP and IP rights.
- ascertaining pending and registered IP.
- reviewing under-prosecution applications.
- reviewing past IP litigation history.
- ascertaining IP creation and ownership rights.
- ascertaining whether the IP rights pose any challenge or threat by others.
- developing a comprehensive IP protection program.
- undertaking valuation of a company's IP assets.
- effective management of a company's overall IP portfolio.

Absence to conduct an appropriate IP audit has certain disadvantages as well. These include:

- unable to unlock the potential value of IP.
- missed growth opportunities.
- jeopardizing company's viability.
- low market share and profitability, poor leadership, etc.
- unintentional third party infringements.

**When to conduct an IP Audit?**
An IP audit may be undertaken by a company in a number of instances. These include:

- acquisition of a brand, technology or product;
- sale of a business enterprise;
- for the purposes of IP asset valuation;
- to identify procedures followed by the company with respect to its IP and to frame systematic guidelines for its better protection and management;
- to detect defects;
- to detect whether any third party rights, including IP rights, are being violated;
- to keep updated with changes in the legal environment;
- as part of an ongoing IP management program;
- for enforcing or defending IP rights;

**Who should conduct the IP Audit?**
The designation of an audit team depends on the nature and scope of the audit. In case of an internal audit, a company's own personnel may have sufficient time, knowledge and understanding of the facts and issues involved to perform the audit. These personnel are often those who are involved in developing, recording and safeguarding the company's IP. In many situations, the scope of the audit may be such that internal personnel may not be sufficient to conduct the audit exercise. In the instances where the company personnel may not have the required time, skills or expertise to perform a full-scale audit, outside counsel and legal practitioners may be brought in to conduct the audit.

When such external people are used, they are sure to bring in considerable knowledge and experience in conducting and managing IP audits efficiently and effectively. Sometimes an audit may be a specific audit which may require a skilled expert to conduct the same, for example, a technology or a software audit. Such external counsels should not only have experience in conducting and managing IP rights uncovered through the audit, but they must also have experience in...
obtaining remedies for any defects found in the audit. The skills should include litigation skills, because the types of issues that an audit seeks to reveal and treat will likely be relevant if litigation materializes, for example, a suit for infringement.

Lastly, the audit team should be sensitive and must respect attorney-client communication and the same must not be revealed by the audit team to any other party except after obtaining prior permission from the client.

Scope of the Audit
The relevant considerations in setting the scope of an IP audit include:

- Size of the company.
- Duration and the extent and magnitude of company's business operations.
- The purpose of the audit.
- The strategic or other significance of IP in the company's corporate plan.

The appropriate scope of the audit is often situation specific. Further, depending on its purpose, an IP audit may be narrow or extensive in scope. However, it is always safer and better for the IP audit to be broader rather than narrower in scope.

What is the IP audit process?
The IP Audit process involves certain internal and external activities. These include:

(i) Audit Objective & Scope
First and foremost, identify the objective of the audit. Once the objective is identified, it will be easier to establish whether the audit has to be an internal one or an external one and whether the same has to further be a specific one or a comprehensive one.

The appropriate scope of the audit is often situation specific. For example, if a company is conducting an audit of its company-wide procedures for acquiring, perfecting and enforcing its IP rights, an IP audit of broad scope is appropriate. Audits more narrow in focus may be appropriate when, for example, a company is facing possible trademark litigation and an investigation limited to the trademark at hand may be all that is required. In M&A transactions, an audit of full scope may be appropriate if a buyer is contemplating an acquisition of a substantial ownership interest in a seller or its assets.

(ii) Internal Identification of IP
Before appointing the audit team, the company must first internally identify IP that it has created, owned and/or acquired. Further, the team must internally make a final review of the same and categorize it under its IP portfolio if it's able to do so. For example, a company may have various domain names, brands and logos. It can categorize these under its trademark portfolio.

(iii) Identification & Appointment of the Audit team
Once the audit objective and scope is finalized and the company has identified the IP which requires undergoing the audit exercise, the company must then identify and appoint certain people who will finally conduct the audit exercise. The audit team may be internal or external depending on various factors such as the audit objective & scope of the audit, skills required, etc.
(iv) **Information Gathering**

Once the audit team has been appointed, substantial information will need to be gathered and presented before the audit team can efficiently commence their detailed audit investigation. Such information may include the following:

- nature of intangible assets.
- relevant material pertaining to the intangible assets such as brochures, advertisements, marketing materials, etc.
- various contracts and agreements such as license agreements, vendor and customer contracts, R&D agreements, government contracts, etc.
- all global intellectual property filings and registrations including related details thereof such as litigation history, assignment, licensing, etc.

Someone at the company should be designated the task to coordinate the gathering of various documents and information relevant to the audit.

To obtain this information, the audit team may also send a questionnaire to the company’s employees that use or develop IP, asking them to list all patented, trademarked, copyrighted, and confidential material used or developed by the employee and conduct searches of available databases for information regarding the company’s products, services, and advertising, that involve the use of patents, trademarks, copyrights. These searches may reveal assignments, security interests, or other impairments of the company’s IP rights, and the company’s possible infringement of third party IP rights. A final IP audit report should be prepared that identifies each IP asset owned by the company and specifies the date of acquisition of each IP asset, its developer, any license, assignment, or transfer, and whether it has been registered with any federal or state agency.

A sample questionnaire capturing the above information is annexed at the end of this article.

(v) **Internal People Involved**

The audit team so appointed will need timely and updated information, documents, etc from the company personnel. Generally, the company identifies certain people which will cooperate with the audit team. These internal personnel would generally include the company’s legal team and employees who have been in the company for substantial time and/or have an in depth knowledge of its business.

(vi) **Interactions with Company Employees**

The IP audit process usually starts with interactions with the company’s employees and senior executives / management. The interaction and the responses to the questionnaires developed for this purpose play a significant role in guiding the IP audit team to obtain a clear understanding of (i) the scope and extent of the company’s business, (ii) the nature of the products and services offered, (iii) connection of the products and services with IP, (iv) internal procedures followed with respect to generation/creation, protection and management of IP, and (v) reasons and rationale behind certain decisions and actions of the company. Such interactions bring out important facts, which play a crucial role in identifying IP potential and risks within the company.

(vii) **Review of Internal Procedures**

For the purpose of identifying, documenting, evidencing, registering, protecting and defending IP, it is very important to develop elaborate and strong internal policies and procedures. Lack of these may result in irreparable damage to the companies at a later stage. Mismanagement of IP at the point when it is created, often leads to time-consuming
and unnecessary efforts to prove the ownership of IP and date of creation. Companies may also face infringement proceedings, if diligence is not exercised to avoid incorporation of third party IP. It is, therefore, very crucial to review such policies and procedures as a part of the IP Audit process. This process may eventually help in establishing an IP strategy for the company.

(viii) Review of Documents

Review of agreements

The audit team has to review various contracts and agreements to which the company is, or has been, party to. This will assist in establishing whether any IP has been created under any agreement, and if yes, who owns the rights to the same, how is the IP exploited, etc. Documents to be reviewed should include contracts/agreements with consultants, contractors, freelancers, employees, joint development agreements, research & development agreements, IP licensing and IP assignment agreements, transfer of technology agreements, distribution agreements, marketing or co-marketing agreements, franchise agreements and other business arrangements.

The aforesaid review and analysis of documents helps to ensure that the agreements contain clauses assigning the IP developed by the employees to the company and obligations relating to confidentiality and non-compete.

Reviewing litigation related documents is also immensely vital. This will help in ascertaining and examining IP disputes pending with courts in India or abroad or before any international authority such as the WIPO. IP litigation and claims often involve important aspects of the business and the outcome of such disputes can have a significant impact on the company’s viability.

Description of all claims and pending or threatened litigation, arbitration, administrative and regulatory proceedings by or affecting the Company, its current or former directors, officers or employees should also be examined. All correspondence relating to IP disputes, cease and desist notices, affidavits, letters alleging infringement, letters threatening lawsuits, plaints for IP infringement, criminal complaints for copyright infringement, details of opposition proceedings initiated with regards to registration of IP should also be examined carefully.

Review of documents recording registration of IP

These documents are examined to ascertain the correctness of the information recorded on various IP registers. For example, in case of a trademark (the correctness of the name of the owner, correctness of description of goods / services and classes), in case of copyright (correctness of the name of the author and the holder of various rights in the copyrighted work), etc.

This is most important in case of group companies. It is often found in group companies that no conscious decision is taken regarding the ownership of IP while registering it. This leads to conflicting or concurrent rights being recorded, creating legal complexities and also problems at the time of hiving off of one of the group companies or in cases of mergers and acquisitions.

Once the documents examination and ascertainment has been done, the audit team must ideally conduct a formal database search to validate their finding as well as to understand the actual factual position. IP database search can be conducted with various registries such as the Trade Marks Registry, the Designs Office, the Patents Office, etc.

(ix) Conducting Interviews

The audit team can also conduct interviews with various stakeholders of the IP development and management
team. Quite many times, when there are many persons to be interviewed, the audit team prefers to send a questionnaire to such persons for the purposes of obtaining the requested responses. Such persons may be present and/or former employees, contractors, etc.

(x) **Issue of IP Audit Report**
Just like a due diligence report is issued post due diligence exercise, in case of an IP audit, an IP Audit Report is issued once the audit is completed. The report states the objective of the audit, the audit plan and how it was executed and the results of the analysis. It describes and evaluates defects uncovered in the audit, proposes and describes specific remedial action that needs to be taken or that has been taken and responds to any other specific need for information the parties commissioning the audit may have. For example, there may be certain changes to be undertaken in the way IP is identified or protected internally.

If the audit was conducted in the context of an acquisition transaction, the report should provide the information necessary to decide whether the rights available are the rights required by the acquiring party, and should provide a basis for valuing the rights to be acquired. Necessary remedial action can be implemented either before the transaction is consummated or after the acquisition (with appropriate adjustments in the purchase price to reflect the risks or cost of the cure) by way of condition precedent or condition subsequent.

The audit report will definitely be highly confidential and is generally given only to the management or the concerned department head/s. Privileged attorney-client communications is generally embodied or summarized in the report and care must also be taken in its distribution to assure that the privilege is not inadvertently waived.

(xi) **Filings**
Prior to conducting the audit exercise or even post recommendation stage, if any recommendation pertains to some filing to be undertaken then the same must be immediately taken care of so as to avoid any disaster at a later date. For example:
- If prior to undertaking an audit, there is an existing litigation on trademark front then the necessary filings must be made by the company before it undertakes the audit exercise.
- The audit may uncover areas or IP which require it to file copyright and trademark registration applications and affidavits of continued use of trademarks.

(xii) **IP Chart**
If the company does not have an existing chart which can facilitate in capturing its IP portfolio, then it is advisable to draw up an IP chart which can capture various types of IP under one document. A sample chart is annexed to this paper.

(xiii) **Develop policies, guidelines and procedures**
If the company does not have any existing policies, guidelines and procedures with respect to identification, development and protection of IP, then it is advisable to develop the same for its overall better management.

(xiv) **Conduct Periodic IP Audits**
A company must revisit the Audit Report and ensure that the company and all its employees are adhering to the recommendations outlined in the Audit Report as well complying policies, guidelines and procedures so drafted above. Further conducting periodic IP audits will also help a company to keep its IP portfolio up-to-date.
Conclusion

An IP audit provides information on the nature and strength of the intangible assets by studying the IPR associated with those assets.

An IP audit can be a relatively simple exercise that can have a meaningful role in avoiding various circumstances - violation of others' rights, protecting one's IP/IPR, minimizing the risk of third party IP violation, clarifying IP ownership issues, etc. It also serves as a guiding tool for maintenance, management and safeguarding of IP rights.

As companies understand the value of their intangibles and rights associated thereto, the importance of IP is bound to grow. As a result, the role of IP audit and valuation has a long way to go. Professionals will surely hone their skills in order to conduct meaningful and an effective audit and valuation which will further help companies in safeguarding against appalling future surprises.
### SAMPLE CHECKLIST

<table>
<thead>
<tr>
<th>INTELLECTUAL PROPERTY (IP)</th>
<th>Patents</th>
<th>Trademarks</th>
<th>Copyrights</th>
<th>Designs</th>
<th>Confidential information</th>
</tr>
</thead>
<tbody>
<tr>
<td>IP created by</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td>IP creation date</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td>IP expiry date</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td>Is the IP registerable?</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
</tr>
<tr>
<td>If YES (Y), is it registered?</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
</tr>
<tr>
<td>Is the IP in use?</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
</tr>
<tr>
<td>Where is IP used?</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td>Can it be further exploited?</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
</tr>
<tr>
<td>eg, through royalty, licensing, etc.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the IP being commercially exploited?</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
</tr>
<tr>
<td>Do contracts exist?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) with employees</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
</tr>
<tr>
<td>b) with contractors</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
<td>Y/N</td>
</tr>
<tr>
<td>What is the current approx. value of IP?</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>
Review: Myriad Genetics Judgement: Gene Patenting and Patentability Criteria

Aliasgar Dholkawala

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1 Associate; Krishna & Saurastri Associates) With help from: Mita Sheikh (Senior Associates; Krishna & Saurastri Associates) and Janaksinh Jhala (Associate; Krishna & Saurastri Associates)
A district court in US recently gave a ruling against gene patenting invalidating Myriad Genetics claims in seven patents on BRCA 1 and BRCA 2 genes. These genes are associated with repair of damaged DNA and destructions of cells in which the damaged DNA cannot be repaired, thus preventing cells to duplicate without control and turn into cancer. Certain variations in BRCA 1 and BRCA 2 gene cause an increased risk of breast cancer. The patents held by Myriad have been a source of contention since Myriad’s lab is the only place in the US where diagnostic test relating to breast cancer can be performed. The challenged patents cover BRCA 1 and BRCA 2 gene sequence and diagnostic test for detecting hereditary and ovarian breast cancer. The claims in suit were directed to the isolated DNA containing all or portions of BRCA 1/2 gene sequences as well as method to identify the presence of mutations in these gene sequences correlating with a predisposition to breast and ovarian cancer.

In a summary judgment issued by Judge Robert W. Sweet of the United States District Court for the Southern District of New York it was held that DNA sequences in isolation were insufficiently distinct from naturally occurring genes in the body (which are the product of a naturally occurring process). They therefore constitute unpatentable subject matter under section 101 of the US patent law which forbids claims on laws of nature, abstract ideas and natural phenomena, which include products of nature.

Though genes may be isolated from human body or may be otherwise produced by means of a technical process, they were granted patent protection even where structure of genes were identical to that of the naturally occurring one. The reasoning behind according protection to gene patents was that identifying, classifying and purifying genes outside human body was a result of a technical process which human beings alone were capable of putting into practice. Hence, inventions relating to DNA sequences should be subjected to the same criteria of patentability as in all other areas of technology i.e. novelty, inventive step and industrial application. A mere DNA sequence without indication of a function or application does not contain any technical information and was therefore regarded as an unpatentable subject matter.

Myriad genetics has decided to appeal against the District Court’s ruling, however if the decision is upheld, it will have far reaching effects for patents in biotechnology and medicine. It will shake the very foundation of the concept on which gene patents have been granted.

Across the Atlantic another case of gene patenting involving Monsanto Vs Cefetra provides a different insight with regard to gene patenting and the scope of protection accorded by such patents. Monsanto is the holder of European patent EP 0546090 relating to ‘Glyphosate tolerant 5-enolpyruvylshikimate-3-phosphate synthases’ and a particular variety of soya bean known as Roundup Ready or RR soya bean in short. Glyphosate is a non-selective herbicide. In a plant, it works by inhibiting the Class 1 enzyme 5-enol-pyruvylshikimate-3-phosphate synthase (also called ‘EPSPS’), which plays an important role in the growth of the plant. The effect of glyphosate is that the plant dies.

The European patent claims a gene sequences to class II EPSPS enzymes enzymes which are not sensitive to glyphosate, hence plants containing this enzyme survive the use of glyphosate. Monsanto has inserted the claimed gene sequence into the DNA of soya plant to produce a genetically modified plant which is resistant to the use of herbicide Roundup containing glyphosate. The European patent is valid, inter alia, in the Netherlands. Monsanto relied on this patent to prevent importation of soya meal from Argentina into European Union.

Soyabean is cultivated on a large scale in Argentina most of which belongs to the RR variety. Monsanto has no protection for its RR variety in Argentina. Soya meal made from this soya bean contains trace amount of the DNA sequence claimed in European patent EP 054 6090. Monsanto thus opposed the importation and marketing of the soya meal on the grounds...
that it infringed its EP patent since the soya meal contained its claimed DNA sequence.

Grant of biotechnology related inventions in EP is regulated by Directive 98/44/EC of the European Parliament. Gene patents are conferred patent protection under article 3 and article 5 of the EP directive which provides for patent protection to biological material as well as gene sequences isolated from its natural environment or produced by a technical process even where the biological material or gene sequence previously existed in nature or share a similar structure to the one already existing in its natural form. Article 9 further defines the scope of protection conferred by patents covering products containing genetic information. It extends to all materials in which the product is incorporated and in which genetic information is contained and performs its function.

The decision was held in favor of Cefetra as the court sided with argument put forward by Cefetra that DNA present in the soy meal can no longer perform its intended function in the product. It may be inevitable that DNA from the original seed may be present in the subsequent products; the DNA may not perform its intended function in the subsequent products.

The above two cases provide views as to how biotechnology patents are accorded protection in different jurisdictions around the world. The Myriad District Court ruling for now suggests that materials isolated from nature cannot be considered as a patentable subject matter and the same casts the doubt for the similar patent applications pending with USPTO. It would be interesting to note that a similar provision has already been present in the Indian Patents Act which debars patentability of living substances occurring in nature. The Draft Manual of Indian Patent Practice and procedure provides for patent protection to genetically modified gene / amino acid sequence which are novel, involves inventive step and has industrial application. However, from the very reading of this draft manual one can make out that the Indian Patent office also discourages patents on isolated gene sequences which are identical to the ones occurring in nature while providing patent protection to genetically modified ones. It however does not provide any further information on the criteria to judge similarity or dissimilarity between sequences. It is known that even a single base pair change in the sequence can have surprising effect in its functions at times whereas in other cases, it may have no effect at all. It is increasingly becoming important to lay down the criteria for scope and protection of biotechnology invention in the era of biopharmaceuticals and biosimilars fast replacing conventional drug molecules. Should a situation similar to the above two cases arise in India, it will be interesting what the courts would have to say in such a scenario.

CITATIONS / ENDNOTES

2 Association for Molecula Biology et. al., Vs United States Patent & Trademark Office et. at.,
4 Patent Baristas: Monsanto looses After EU Court decides that Soy Meal no Longer has Functional DNA
Building Brands Through Geographical Indications

Anuradha Maheshwari

1Director, Institute of Intellectual Property Studies. With inputs from Aditi Kamath and Swetal Patel
The saga of human evolution is replete with major and minor developmental milestones, social, political, economic and environmental; not the least being the marked genetic mutations reflected in man’s physique and features proclaiming his geographical lineage and habitat. The ethnicity of the people, including the art, craft, goods and trade coming from the region are unmistakably stamped with the distinctive style and attributes of their geographic origin, such that the goods, like the inhabitants acquire a reputation linked to the region. Infact, historical accounts, stories, fables and folklore abound in references to myriad products that have been uniquely distinctive and are the proud hallmarks of the region in which they are produced like the Mughal meena bazaar, Mathura dairy products or the Greek feta cheese (made traditionally in Greece from ewe’s milk and finds mention in Homer’s Odyssey). In each case, a geographic name became associated, far beyond the borders of that geographic location, with a product known for highly desirable and seemingly unique characteristics. Over a period of time these regional goods came to be associated with certain skills, know-how, processes that could not be replicated independent of the region and consequently came attached with a price tag that became a harbinger of the growth and well being of a nation.

The 14th and 15th century medieval Europe saw a surge in the development of regional trade linked to the promotion of local arts and crafts and process know-how through a system of rewards and monopolies. The monopolies were granted to a community of artisans and individuals as creators and as beacons of standards of the representative quality of artifacts coming from a region. Against this backdrop we find the genesis of the development of the modern day international intellectual property law system, in particular through the promotion of the beautiful and stunning “Venetian Glass” art form, then prevalent in Venice, Italy.

As property in intellectual creations gained recognition as a right of the creator, geographical indications seeped into the arena of intellectual property to be protected as a much needed boost to international trade. Though initially, at the time of the Paris Convention 1883, they were recognized as ‘appellations of origin’ and ‘indications of source’; today, they have an individual identity, and are one of the prime revenue builders for a nation. As mentioned in the TRIPS (Trade Related Aspects of Intellectual Property Rights) they are known as geographical indications, and are defined as ‘any indication, name or geographical name, figurative representation, expression conveying territorial origin or source of goods and refers to the protection of products originating from a certain geographical area. The TRIPS Agreement of 1995 is said to be the first multilateral treaty dealing with the term ‘geographical indications’.

The term includes any direct or indirect reference to the geographical source, characteristic or qualities of a product. In an effort to protect geographical names, three concepts were developed, from the most all-encompassing to the most specific: indication of source, geographical indication and appellation of origin. All appellations of origin are geographical indications and all GIs are indications of sources. An appellation of origin must indicate specific qualities, reputation or other characteristics essentially or exclusively attributable to the geography of production, like Nagpur oranges, Darjeeling Tea, Sheffield Cutlery etc. Whereas, basmati rice or a feta cheese unlike appellations of origin would be mere geographical indicators of products but without the attachment of geographic names.

While the politics of GIs are intriguing, at heart the debate about geographical indications is a struggle about commercial linguistics, myth maintenance, and who will extract the monopoly rents from those myths. This is what makes the geographical indications debate both so interesting and so parallel to conventional trademark law. Though like the trademark the distinctive function of a GI is to link the product and services to its origin and help identify the producer or artist who made the product, the overall advantages of a geographical indication far outweigh that of the former.

As opposed to the private monopoly right of a trademark, GIs create public community rights benefiting a larger group
collectively and sidesteps the threat of unfair monopolistic trade practice. Registered GI products typically function like ‘club goods’ and do not belong to the realm of any one producer to be exploited by him exclusively. On the contrary it’s a right to be collectively exploited by the community of craftsmen etc involved in the production of the goods, stimulating thereby a healthy competition inter se, and generating a set of non-rivalrous rights that do not diminish one producer's right over another. Typically, they articulate the obligations that must be complied with by all the users of a given indication and set out the rights to be protected against third parties. These rights enjoy a far broader scope of protection primarily because they cannot be assigned or exhausted like other intellectual property rights, in the sense that they cannot be further sold or licensed commercially. The most fascinating attribute of Geographical Indications is that they though they function like a trademark; the rights remain with the community in perpetuity (to be renewed periodically), while the knowledge underlying their status remains in the public domain. They perpetually benefit an entire community of producers, stimulate the economic growth of the region and the country and most importantly protect goods that are already famous. Infact, the Geographical Indication status pre-supposes the existence of a certain reputation already enjoyed by the products and services they seek to protect legally.

However, it must be borne in mind that their specificity and distinctiveness is essentially born out of the territory of the produce, from the unique geographical characteristics such as soil, climate and traditional skills like process know-how, craft etc. At issue is whether a product with essentially similar characteristics can be produced in a different physical/human environment or not. It is therefore important to recognize that GIs require more than the protection of geographical names because of the triple association always between the product, its place of origin and quality related factors. Also, consumer acknowledgement/acceptance plays an important role in determining the eligibility of a product as a geographical indication. To qualify for legal protection it is necessary that the name and reputation of the particular product has been established by pre-existing trade.

GIs and Consumer protection:
Once protected, a Geographical Indication has multiple advantages; it protects the interests of honest producers and traders, generally the economically backward traditional craftsmen by preventing unfair competition, cartelization, and commercial abuses specifically unauthorized use. Through the creation of internal competition and fair play protected geographical designations help to improve not only the quality and reputation of products in the domestic market but ensure a wider product access and greater prosperity through their exports into international domains.

More importantly Geographical Indications effectively serve as a guarantee and assurance of authentic quality products minimizing thereby consumer deception. In the battle for monopolistic conquests, the welfare of the consumers is usually overshadowed by the ambitions of the producers. The aspirations to supersede one another, leaves the consumer faced with the quandary of having to choose between varieties of products of barely acceptable quality. They not only have to overcome the issues of quality delivery, but also have to worry about the originality of the product. The promise of GI for the consumer infact stretches from the seal of origin guaranteeing the source to the quality indicators that point to goods with a definite history and traditional knowledge evoking a certain aura, mystique and exoticness associated with the locale.

A key factor in the growth of brands and their legal regulation is the separation between the consumer and producer. In the last century this distancing process accelerated rapidly for manufactured goods, but less for agricultural goods. Now however, with modern packaging, transport and global trade, the separation between consumer and producer has rapidly increased in agriculture too. In such circumstances, registered GIs are one method by which a small-scale producer, far away geographically from the consumer, can reach through to that consumer with a consistent quality message.
GI registered goods are a huge draw with consumers also because of the traceability factor (of the raw materials) and that it gives them the flexibility to develop preferences especially for the palate & appearances included with respect to food products, like say a basmati rice over surti kolam or a Dehradun Basmati over an Amrisari, a Kashmiri Zafran over Spanish or a Cabernet over a Chardonnay (wines). Goods assume value linked to the perceived exoticness of the locality of production, uniqueness of product and it being not commonly available like a commodity. In various studies conducted across Europe some interesting consumer behaviors came to light, chief among them being that consumers were willing to pay a premium price for GI products as follows:

- 40% of European consumers ready to pay a 10% premium price for GI products - EC Study 1999, tea, champagne.
- 75% of Italian consumers ready to pay a 20% premium price - Etude Nomisma Qualivita de ’03.
- In case of special and unique geographical attributes, as in the case of specialty salts gourmet cooks are willing to pay $80 a pound for such varieties versus 30 cents for common table salt, for eg the Indian black salt, Portuguese Algarve salt, Australian Murray River Pink Flake Salt, Il Buco Handcrafter Italian Wooden Sea Salt, French Fleur De Sel and Clay-tinged red Alaea Hawaiian Sea Salt - Businessweek, 2004.
- History & tradition associated with production process command a higher price and value like in the case of Parmesan cheese & Parma ham. Parmesan Cheese is one of the oldest Italian Cheeses developed about 2000 years ago in the castled city of Parma, Italy, the same place which is credited with the delicious Parma ham. It is the culinary tradition of that location that has enabled it to build its reputation.
- Mystique elements like process secrets with legends & folklore- intrigue the consumer more than regular products in the market place like a Parma Ham or a Feta cheese.

**GIs and Brand development:**

What is observed in the context of the above is that in the clamour for the protection of a geographical indication, one is in essence protecting is a community intellectual property and very often a domestic or international brand. For example Darjeeling Tea, Basmati Rice is a brand both in India and abroad, which explains why the Government and the local producers both want to protect them fiercely for fear of infringement or dilution of the brand. Brand names allow producers to achieve market recognition, differentiate their offerings and gain legal protection apart from enhancing revenue generation through premium pricing of their products.

However, the power of branding has eluded producers of commoditized products. A promising new development is the use of geographical origin as a basis for branding commodities. That explains why a Moet or Chandon are so sought after as Champagnes. A study of GIs reveals how diligently and consciously producers and governments have toiled to develop their products into brands and how building an image of quality leads to quick consumer acceptance adding special value for both the producers and the consumers. A case in point would be the promotion of Colombian coffee as one of the world’s best coffee brands.

**COLOMBIAN COFFEE**

Till 1959 public perception of the best coffee producer was Brazil. Colombia received almost no mention then though it produced 12% of the world’s coffee and was second to Brazil. The National Federation of Coffee Growers of Consumers undertook the branding exercise of their rich homegrown coffee through the use of a character maned Juan Valdez and his mule, and used the catch line –“Buy Colombian when buying Coffee”. They went on to promote it as the “richest Coffee in the world” and used other tag lines like “50 % tax bracket 100% Colombian Coffee”- “No Colombian, no thank you”. The campaign succeeded and was quite fruitful in securing them as one of the leading coffee producers; although in 1959. By 80’s awareness about Colombian Coffee reached 96%, where 62% believed Colombia grows the best coffee and were willing to pay a 15% premium on Colombian coffee. The marketing strategy of the FNC resulted in an increase from 9.1
Likewise Cuba fought hard and long to save its world famous brand of ‘Habanos’- the premium quality cigars more commonly referred to as Havanas. Their origin can be traced to 1492 when Columbus arrived on the shores of Cuba and their quality can be attributed to the geo-climatic conditions of Cuba and a clever blending of five different varieties of tobacco leaves to produce the variant in the market place. However, over a period of time Habanos became a generic term to designate high quality cigars from all cigar producers in the world threatening the Cuban Cigar industry and market. Eventually the Cuban authorities took drastic steps to control the damage to the geographical name and along with various lawsuits, signing several bilateral agreements with other cigar producing and marketing countries, developed a marketing strategy in the 80s to support and complement the protection efforts. The first step was to establish a communication strategy based on the Habano appellation of origin. And the second started in 1991 by unifying the various versions of the logo and design for Habano that existed in other languages and using just one: Habanos. From then on the Habanos logo has the same image all over the world and the Habano Cuban cigar trademark printed on the boxes of brand names is the guarantee that these cigars are backed by the Habano ‘Denomination of Origin’ Protection. This is a guarantee of quality and origin that is awarded to only the best cigars manufactured in Cuba under the strictest quality control measures, with the best leaves selected from the island’s tobacco regions.

Therefore, mere registration as a GI does not guarantee the returns for either the community of producers or the economy itself. In order to facilitate consumer awareness and investment returns, it is essential to build this pseudo-trademark into a brand and maintain it at that. Some regions have become synonymous with high quality products like Champagne in France, Cuban Habanos, Darjeeling Tea, Basmati rice, Swiss watches, knives & chocolates, Japanese electronics, German Auto etc.

Which is why post 2000, India as a WTO member and a TRIPS signatory, has woken up to the merits of GI protection for an agro based traditionally rich country like ours. Apart from enacting the Geographical Indications Act 2000 it is actively encouraging local producers of famous indigenous products to protect them though a process of registration at the Geographical Indications registry based in Chennai. Today we can boast of more than 200 applications and 120 registered GIs strengthening the implications of GI policies, both nationally and internationally, for India. While the most fundamental benefits of GI registration for producers is to cash in on the reputation theory, the actual profitability of the GI product crucially depends on the size of the market for these products. Without a sizable international market, a GI label and its expected price premium would fall short of the costs needed to be incurred to continue with the production, establishing thereby the need to focus on building strong GI brands. Among the existing Indian GIs, Darjeeling tea and Basmati rice are the front runners in terms of international market and exportability.

**Indian success at brand building:** Darjeeling Tea

The first attempt on the part of the Tea Board of India (which was constituted in 1954 under the Tea Act of 1953), towards protection of the ‘Darjeeling’ brand was undertaken way back in 1983, with the creation of the ‘Darjeeling’ logo. The Tea Board then obtained domestic protection for the Darjeeling logo as a ‘certification trade mark’ under the Indian Trade and Merchandise Marks Act 1958 (now the Trade Marks Act, 1999). In the same year, the logo was registered as a trademark in several other countries like the UK, the USA, Canada, Japan, Egypt, Germany, Austria, Spain, France, Portugal, Italy and Switzerland. Today it is a protected mark in 21 destinations with three more pending. In the absence of a separate law dedicated exclusively to GI’s in India during that time, the word ‘Darjeeling’ was also registered as a trademark. When the Geographical Indication Act in India was enacted in September 2003, the Tea Board applied for GI protection of
‘Darjeeling’ in October 2003 and in 2004 became the first application to be registered in India as a GI.

Further, in order to prevent the misuse of ‘Darjeeling’ and the logo, the Tea Board has since 1998 hired the services of Compumark, a World Wide Watch agency who monitors and reports all cases of unauthorized use and attempted registration of the name and logo. From 1998 to 2002 the Board spent an equivalent of USD 200,000 to protect against infringement. International disputes relating to Darjeeling tea have been settled through negotiations undertaken by the Tea Board of India with the foreign companies. For example Bulgari, Switzerland agreed to withdraw the legend ‘Darjeeling Tea fragrance for men’ pursuant to legal notice and negotiations by the Tea Board. Almost 15 cases in the last four years against infringement and misuse of the word Darjeeling Tea worldwide have been fought against countries like Russia, USA, Japan, France, Germany, Israel, Norway and Sri Lanka etc.

The quality, reputation and characteristics of Darjeeling tea are essentially attributable to its geographical origin. It possesses a flavour and quality which sets it apart from other teas, giving it the stature of a fine vintage wine. As a result it has won the patronage and recognition of discerning consumers worldwide for more than a century. Today as one of India’s premier GI brands production yields have also increased in its 86 tea gardens from 545kgs/hectare in 2003 to 650kgs/ha in '05 producing approximately 10 million kgs. of tea. Incidentally the activity has also played a major role in the empowerment of women of that region as nearly 50% of the laborers in the tea gardens are women. Consequently, Darjeeling tea that is worthy of its name cannot be grown or manufactured anywhere else in the world.

**Dilution**

However when a geographical name becomes a generic term for similar kinds of products or the same product being produced in a different geography, the brand of the GI is said to be diluted. The exotic appeal of the product is lost and the product reputation suffers, becoming tarnished or blurred, leading to the genericide of the brand. This is a common marketplace phenomenon and normally occurs when popular geographic designators are used by many, to the extent of registering them as trademarks. Pepsi Snacks attempted to usurp and register a geographical name ‘Bikaneri Bhujia’ (actually produced by hundreds of small producers) it as a trademark in order to capitalize on the known geographic association and market appeal of the food product and was forced to withdraw the application. In similar instances we find the Champagne brand being protected through watchful and fierce guarding against infringement worldwide, and the Scotch Whisky Association in the UK taking offenders passing off the ‘scotch’ name to court, as they have done with Khoday Distilleries (Peter Scot case) and Pravar Sahakara (Indian Whisky-Scottish drumbeater wearing kilt) in India.

Brand dilution also leads to commoditization of products jeopardizing the interests of local artisans and craftsmen who lose out in the marketplace as well of the consumers who cannot ascertain the origin of the commoditised products. For example the famous Persian carpets could be imitated by carpet weavers outside Persia. The same is true of Italian restaurants, German Beers etc.

**Basmati Rice:** This particular strain of rice is naturally grown in the northern part of India and south eastern parts of Pakistan and is a much in demand premium quality aromatic rice. However, there have been various imitations and modifications in many countries pertaining to the name Basmati, wherein rice was sold as Texmati, Calmati, Kasmati, etc. Due to this, the Government of India has fought over 100 trademark cases in over 30 countries over the term Basmati.

**Darjeeling Tea:** Thought he actual production capacity is 10 million kg, 40 million is sold. This happens due to most of the production from Sri Lanka and Kenya (Pure Darjeeling).
The Parma Ham Case is not only illustrative of the dangers of dilution of geographical brands but also serves as an outstanding example of maintaining a supply chain integrity, that helps protect a geographical indicators. Asda a UK supermarket owned by Wal-Mart was recently taken to court by the Consorzio del Prosciutto di Parma and Salumificio, the Italian Parma Ham Trade Consortium, claiming dilution of the Parma ham brand. They alleged that Asda sold the product sliced and prepackaged in the UK, whereas the reputation of the brand and the protected designation was not merely based on the place of production but also on how thin the slices were and the way it was packed. The genuine way to slice it, as claimed by the Consorzio was to make sure it was done in Parma at the plants in the designated area, approved by organization responsible for monitoring Parma ham production. On an appeal to the House of Lords Asda was restrained from the retail sale of Parma ham which had not been sliced, packaged, and labelled in accordance with the laid down specifications.

Conclusion:
As mentioned earlier, mere registration of a geographical indication does not ensure its visibility in the market place. Consumers also ought to be made aware of its prominent position by implementing the rights granted with registration, necessitating thus, intellectual property awareness as well as information on GI products. The encouragement of GI registration too should be accelerated, along with aggressive campaigns to promote them.

The article would be incomplete without due reference to the critical socio-economic developmental role that GI brands play in the progress and advancement of a community. It is now apparent that promotion of geographical products is bound to result in industrialization and standardization of production processes as is seen in the case of products like wine, ham, cheese etc as opposed to home made, backyard processes. So, without compromising on traditions, a greater degree of uniformity and mechanization of production processes have crept in. Geographical identities are increasingly recognized as a tool that farming communities could use effectively to add value to agricultural produce, improve brand recognition and protect their product against competitors.

Considering that GIs generally draw upon products such as agriculture, fisheries, handicrafts, and artisanal products, any trade advantage obtained from the GI status is basically pro-poor. This is in contrast with the other forms of intellectual property rights such as patents and trademarks where the gainers are mostly rich people (ICTSD 2004). Due to the community benefit endowed upon the producers of a geographical indication, there most obviously would ensue a competition for premier position within the community itself, stimulating further growth and development and a regular income flow in exchange for guarantees it offers. In India the development role of GIs is amply illustrated through the examples of Moradabad brass workers and the ‘bidri’ workers of Karnataka, of which we shall highlight the later.

Community Development: Bidriworks:
Bidri in India is an 800 year old art form from the Bahamani kingdom influenced by Persian artisans who had migrated to the kingdom from Persia. Its specialty lies in the detailed ornate patterns made of zinc and copper, with silver inlay work. The luster of the artifacts is due to the sand sourced from the fort of Bidar. The priceless labour involved, was however, unorganized for many years and left the skilled artisans at the mercy of the exploitative middlemen and highly impoverished.

NABARD in 2002 started the cluster development program by setting up a Bidri colony in the district of Bidar, Karnataka. This eventually led to the formulation of a self help artisans group. The Karnataka Handicrafts Development Corporation secured the GI tag in 2008 for the whole scale of activities there, improving consequently the lot of the artisans as also helping preserve the traditional knowledge and local know-how. And of course one needs to emphasize how the entire protection process also encouraged diversification of production and scaled up the demand for the products both in the domestic and international markets.
Geographical indicators therefore, are often looked upon as the ideal IP rights due to their characteristic of benefiting multiple entities and the various stakeholders involved in the promotion of a product, such as the producers/organizations, Government, local communities and regions in a collective and proactive way and the role they play in taking a nation forward both socially and economically.

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There is nothing that can be called completely “original”...
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Our creativity is only an expression of
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