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INDIAN LEGAL IMPETUS

PATENTING DNA - THE ETHICAL, LEGAL AND SCIENTIFIC CHALLENGES
FOREWORD

With a number of achievements this year we yet again take immense pleasure in sharing with all our readers that Singh & Associates has been voted by clients and colleagues as the Arbitration Law Firm of the Year 2012 for the outstanding work it has done in this key practice area.

We bring to you the November 2012 edition of our newsletter, “Indian Legal Impetus”. With each edition we attempt and strive to bring forth the recent developments and some alluring legal happenings for our readers.

In this issue we begin by discussing the captivating topic of DNA patenting in our cover article, where we discuss the recent landmark efforts in the field of Genetics such as ‘The Human Genome Project’, which imparts a profound knowledge on Deoxyribo Nucleic Acid (DNA), also called as blueprint for life. This article debates whether the DNA patent system attains its goals of stimulating innovation for the public welfare and rewarding people for useful new inventions.

In the Intellectual Property Rights Patent’s section we present an article regarding plants breeder’s rights, this article brings out the importance of plant breeder’s rights and the use of new varieties which would act as a key factor in improving rural income and overall economic development. Moreover development of breeding plants can remove the threat of survival of certain plants which are endangered but of great use to mankind. Moving on to another article that throws light on the need of IP protection in fashion industry and presents a comprehensive overview of strategizing Intellectual Property rights in the fashion industry under the existing IP laws, like trademark, designs and patents. Further in IPR another article discusses the traditional cultural expression and highlights the needs for protecting indigenous knowledge through IPR. Lastly in the IPR we cover a recent judgment of the Hon’ble Delhi High Court in the case of Star India Pvt. Ltd v/s Piyush Agarwal & Ors.

In the corporate section we discuss, post merger obligation, applicability of non-compete clause and its status in India under the contract act and the topic of Corporate Social Responsibility (CSR), where we have tried to explain the concept and highlighted on the advantages of adopting the same.

Our next articles concentrates on the pharmaceutical market in the global scenario with new drug innovations and discusses the guidelines that Central Drugs Standard Control Organization (CDSCO) has come up with, the paper discusses the guidelines and throws light on the steps taken by CDSCO in regards to safety of the subjects of clinical trial.

Further our next article talks about the Muslim personal laws (Shariat) related to Custody matters and its applicability. Towards the end we have made an attempt to cover the issue of Honour Killing in the Indian Scenario.

Last but not the least, we present the latest developments in the field of law in the form of Newsbytes towards the end of this edition.

We hope that you find this issue informative and captivating. We invite all suggestions and comments for our newsletter by our readers, which would help us in making “Indian Legal Impetus”, a valuable reference point for all. You may send your comments, queries, opinion and suggestion at newsletter@singhassociates.in
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INTRODUCTION

The commercialization of research in life sciences over the past few decades is strongly influenced by the remarkable development and application of new genetic engineering technologies. The study of genomics greatly expanded when the scientists started to unravel the mechanism between genes and protein in health as well as in diseased condition. In 1990, the Human Genome Project was established in order to identify the genes in human DNA as well as to determine the order of the 3 billion base pairs in human DNA. In 2001, the human genome draft was developed which reported about 30,000-40,000 human genes, majority of which were implicated in diseases and disorders.

"Intellectual property has existed in some countries for centuries and biotechnology patents have been granted in several jurisdictions for years, but it is only in the past decade that heated controversy has risen around the patenting of biological entities."1

The topic of patenting of DNA has galvanized over the past decade because the application of the patent system in the field of biotechnology is mainly aimed to strike a reasonable balance between the rights of inventors and the public interest. Ethical, legal and scientific concerns intermingle that opens the mind to create a thought provoking discussion.

‘Patenting DNA’ or ‘Patents that assert rights over DNA’ raise a number of ethical issues due to various factors such as the special status of the DNA, legal criteria for patenting as well as the possible deleterious consequences for healthcare and research related to healthcare. It is therefore important to assess further the application of patent system in relation to DNA sequences.

In general view, it has been envisaged that the law has tended to be generous enough in relation to DNA sequences. In case of many granted DNA patents, the claims were broad in scope and it obtained all protection on all the uses of DNA, including the protein which the DNA produces. Many of these patents were granted only when the criteria for patenting such as inventiveness and utility were inadequately applied.

With regard to patent claims, four distinguished applications of DNA sequences are identified VIZ., diagnostic testing, research tools, gene therapy and therapeautic proteins.

DIAGNOSTIC TESTING

Diagnostic Testing’ is mainly based on the identification of DNA sequences that are significantly implicated in a disease. BRCA1 is a gene that has been found implicated in some forms of breast cancer2. BRCA1 has been used to develop a diagnostic test. BRCA1 test is protected by product patents as well as by use patents, which contains claims to the use of DNA sequence for diagnosis. There has been a considerable opposition to the grant of these patents, mainly because it creates not only exclusive market for Myriad Genetics, the owner of patents, but also prevents others from competing with them through the development of better diagnostic methods, using the same ‘BRCA1 gene’. Mutations of individual genes as those manifested in cystic fibrosis, haematochromatosis have been the subject of patents relating to diagnostic tests. The development of such diseases or disorders is affected by many numbers of genes (polygenic) as well as several environmental factors. Therefore, the identification of such genes is very important in the prediction of diseases, nevertheless, the process of such prediction is very complicated. The authenticity of such prediction is inevitably weaker as the effect of each gene may be smaller.

Although doubts exist that such genes enable reliable predictions to be made of diseases, some investment is being made into developing a new generation of diagnostic tests which aim to alert patients and their doctors to a predisposition to major diseases3. The grant of patents for such genes will be the motivating factor in promoting the investment in research in life sciences.

The knowledge of the DNA sequence in the gene and the disease-associated mutations is applied by using it as a basis for detecting and characterizing the gene in the patients. Hence the identification of the gene and a disease can be considered more than a discovery. It was argued that at the time genes such as BRCA1 were patented, the identification required lot of efforts and
human intervention\textsuperscript{3}. Despite the effort involved, the isolation of the gene BRCA1 was essentially considered a discovery, the application of which was useful. On the other hand, DNA sequences that have been characterized by \textit{in silico} analysis shall not be allowed due to the lack of inventiveness.

The term ‘inventing around’ means developing a similar product which performs the same function but put together in a different way from the existing inventions. Therefore if a patent also claims the products expressed by the gene in question, it becomes an arduous task for other scientists to ‘invent around’ such genes or the proteins expressed by it. Working with such patents requires an individual to seek a license from the holder of the patent. Broad patents not only thwart the development of improved diagnostic tests but also restrict other forms of research. Research into the genetic basis of diseases is much more expensive than the research and development for diseases associated with a single gene as the method is time-consuming and characterized by high degree of uncertainty\textsuperscript{4}. It is evident from the aforesaid, that without the promise of patent system investment in biotechnology and biomedicine through private funding, could be on the decline and patients would be denied potentially valuable diagnostic tests.

**PROPOSALS AND FUTURE DIRECTIONS**

- The criteria for patenting DNA sequences in particular the criterion for inventiveness should be more stringently applied.
- If a use patent could be defined, so that the owner of the patent is entitled to rights only to the use of the DNA sequence, for his specific diagnostic tests for the disease involving the use of the sequence, this could not only provide sufficient incentive for the disease involving the use of the gene, but also result in the development and marketing of a number of different tests for the same gene.
- For those patents in which the monopoly to the diagnostic use of a DNA sequence is not in the public interest those seeking to use the diagnostic tool or develop an alternative should seek a compulsory license from the relevant authorities.

**RESEARCH TOOLS**

DNA sequences that are used in research are termed as a research tools. Such sequences have no immediate therapeutic or diagnostic use. Two main types of research tools are Expresses Sequence Tags (ESTs) and Single Nucleotide Polymorphisms (SNPs). ESTs represent the coding parts of genes that led to the extensive application of this method as a method of locating genes. SNPs are also important research tools which are used in research to help locate genes associated with disease or identify genetic variation which may predispose to diseases.

The owners of patents commercialize them either by licensing them for particular sequences as in case of CCR5\textsuperscript{5} or by applying the knowledge aimed at discovering new drugs or other research. For example; in 2000, Incyte Pharmaceuticals has made claims in relation to over 4,500 human DNA sequences in more than 570 patent applications. In cases of patents that assert rights over DNA sequences whose claims amounts to routine discoveries with weakly demonstrated and speculative uses, the patents will seldom deserve the status of patentable invention\textsuperscript{6}.

**PROPOSALS AND FUTURE DIRECTIONS**

- It is recommended that when rights are asserted in terms intended to cover all sequences that contain the ESTs that are the subject of original patent, no patent should be granted.
- In general granting of patents which assert rights over DNA sequences as Research Tools should be discouraged.
- In case of public institutions which already have been awarded patents that assert rights over DNA sequences as research tools be strongly encouraged not to licence them exclusively to one or a limited number of licensees, even when not by doing so they may suffer some loss of revenue in short term. The need to seek multiple licenses for many sequences may hinder research and development, hence companies work together to extend the concept of the “research exemption” throughout the industry for DNA sequences which appear in patents and which have a use in research.

**GENE THERAPY**

Certain diseases are caused by mutations or mistakes in the human genome. A particular disease can be caused by number of different mutations in the same gene. Gene therapy treatments involve the use of DNA sequences. Hence if the gene is patented, treatment of gene therapy will depend on the availability of a license from the owner of the patent. It is recommended that once a gene associated with a disease is identified, the use of the relevant DNA sequences in gene replacement
therapy to alleviate the effects of mutation in that gene is obvious; hence, the protection by product patents should not be allowed.

**THERAPEUTIC PROTEINS**

Patents that assert rights over the therapeutic proteins assert rights over the DNA sequences as well as the protein characterization process itself. This is because; the DNA is pivotal to the production of the protein and is considered as an intermediate in the manufacturing process. Therefore, it is recommended that while rights asserted over DNA sequences which are used to make new medicines based on therapeutic proteins are generally acceptable. It should be narrowly defined. By this, it is meant that the rights to the DNA sequence should extend only to the protein described.

**CONCLUDING REMARKS**

Various research institutions and international bodies are involved in fostering healthy debates about the true impact of Patent system on health issues. It is also equally important to maintain a moderate view on the impact of genetics on health outcomes. The work of sequencing the human genome was a landmark achievement, but it is only a tiny step along a process that will take several years to reach its full potential. Nevertheless, the milestones achieved should be properly rewarded with incentives, in order to handle the barriers and mould the directions of research.

Clarifying the patents that assert rights over the DNA sequences suggest a set of strategies for encouraging right kinds of research and a more equitable distribution of benefits between the researchers and the society.

**REFERENCES**

5. US Patent 6,025,154
6. For Example, a patent claim to ‘An isolated DNA sequence comprising (or including or having) the sequence of SEQ Id No:1’ is much broader than as claim to ‘An isolated DNA sequence consisting of the SEQ ID NO:1’ as by long established practice the former wording permits additional sequences to be present whereas the latter wording does not.
In this modern technological era, when everybody is favoring new technologies, innovations and new developments in every field, generation of new varieties of plants with improved yields, which are of higher quality or better resistance to pests are now in demand in agricultural sector of the country. The progress in agricultural productivity in various parts of the country is largely based on improved plant varieties. More so, plant breeding has benefits that extend beyond increasing food production. The breeding and use of new varieties is a key factor in improving rural income and overall economic development. Furthermore, the development of breeding programs for certain endangered species can remove the threat to their survival in nature, as in the case of medicinal plants. This article emphasize on the understanding the Plants Breeders Rights (PBR), Small & Medium Enterprises (SMEs) and Breeder issues and challenges along with their protection and overall impact of the technology in the country’s economy.

Before going further, it is important to know about Plant variety protection and who can file PBR?

Plant variety protection is a form of intellectual property right granted to the breeder of a new plant variety. Plant variety protection is also known as Plant Breeder Rights. It is an independent sui generis (new) form of protection, tailored to protect new plant varieties and has certain features in common with other intellectual property rights. If any person who creates or discovers and develops a plant variety, may apply for PBR and once the PBR has been granted to the breeder, it means in practice the title holder is the owner of the variety and anyone else who wants to commercialize that protected variety requires the authorization of the holder of the PBR (i.e. the breeder of the variety). The PBR once granted is valid for 25 years. This authorization is normally in the form of a license agreement between the title holder and those who sell the variety. In order to protect a variety, it must be novel, distinct, uniform and stable. And must have a suitable denomination.

HOW UPOV HELPS BREEDER OR MICRO SMALL & MEDIUM ENTERPRISES (MSME)?

UPOV is an essential gateway for any breeder or MSME's to protect any variety of plants in the country. UPOV helps in the following ways to the breeder or to the MSME’s in protecting plant variety.

- Lowering "barriers to entry" into the breeding sector
  UPOV is the most active union process for any breeder to enter into the breeder sector. This minimizes the risk of infringing one’s product. With the help of UPOV, any breeder can register himself and enjoy the benefit of plant variety system.

- A simple and harmonized application system
  It can be easily understood that UPOV makes the PBR system more efficient and forceful. Prior to the UPOV it was very difficult for a breeder to apply for a plant variety registration, but now UPOV’s new policies have made the PBR easy and affordable.

- Harmonized system of variety examination

HOW AN SME GAINS BENEFIT FROM PBR

- Return on Investment
  PBR benefits SMEs in many ways such as it enables breeding companies to achieve good returns on their investment in various breeding programs. The PBR system which is good enough, provides a legal structure that allows associated breeders to improve their investments and thereby allows them to continue their breeding activity. It was very important for SMEs who can take advantage of their empirical knowledge and create and protect

2 http://www.upov.int/upovlex/en/upov_convention.html
their new plant varieties. Companies or individual breeders can use the protected varieties of other breeders freely and incorporate them into their breeding programs. They can also exploit the resulting new varieties freely which is one of the unique key of PBR under the UPOV Convention as discussed above. This feature reduces barriers for entering into the business and stimulating the development of the local breeding industry.

- **Licensing**

Licensing is one of the most important aspects of the PBR process. All the SME breeding companies should develop a unique licensing strategy to strengthen their presence in the local market and expand their activity abroad by entering into a partnership with foreign companies and various local breeders. Various universities and research institutions can take part in the PBR process and play a key role in the process. PBR also plays an important role in the establishment of the technology transfer to compete in the market. They may have the knowledge and expertise for research but perhaps neither the infrastructure nor the experience required for successful marketing. In this situation, seed producers and consumers, for example in the milling industry and/or farmers/growers associations, can assist in the financing of a breeding program and then be in charge of the multiplication and marketing of the resulting varieties. Ownership could be shared in different ways according to the funding by the different parties of the breeding activity. PBR sets up the legal framework, enhancing the relationship between researchers, PBR holders, licensees and users, hence creates a favorable environment for the development and transfer of technology in agricultural sector.

- **Facilitating access to foreign markets**

The main principle of UPOV convention is to provide the same and equal treatment to all the members of all the Nations of the Union

- **Development of SMEs in the plant/seed propagation sector**

Earlier it was seen that due to the huge demand of the variety in some part of the region, there is a risk of variety depletion or lack of variety in the market. In order to create the equilibrium, SMEs are now working in the remote areas of the country where getting license from breeder and provide the variety or seed in the market for the proper supply of the material is difficult.

### CONCLUSION

The Plant Breeder Right is an enormous tool which helps SMEs and breeders in registering new plant varieties. This form of IPR is now gaining importance in every part of the country. Government has taken new reforms in establishing PBR in the country. Various Agricultural institutions viz. National Dairy and Research Institute (NDRI), IARI (Indian Agricultural Institute), ICAR (Indian Council of Agricultural Research) etc, are now a part of PBR where they help innovators or breeders in understanding PBR, provide knowledge to the breeders; provide financial help and helps in registering new and improved plant varieties. Today many NGOs are working for promoting PBR benefits in remote areas of the country. Now it can be seen that the agricultural sector of the country is growing and new and improved varieties of plants are developed. With the increase in agricultural demand, new varieties of crops are also developed which cater to the countries requirements.
The trend of Intellectual Property (IP) protection of apparel is still in its nascent stage in India. Of late the fashion industry in India has seen a tremendous growth. The fashion industry is segmented into categories, which include custom clothing, designer clothing and luxury goods etc. The industry is not just limited to clothing but also extends to luxury items for better standard of living. The main reasons for its rapid growth are awareness of consumers, shift in the focus of consumers towards branded and designer clothes, knowledge of latest trends through media, exposure to western culture, and easy availability of designer ready-to-wear garments. Moreover, being up to date with latest fashion trends has now become a culture. Being more fashionable & using luxurious goods has now become a status symbol.

Fashion Industry has long being known for its ubiquitous nature of copying. Even the fashion oriented apparel producers flourish by imitating the designs of the leaders in the industry and take it to the masses at cheaper and affordable rates. This superfluous growth of the industry has given rise to increased concern regarding the IP protection of one's intellectual innovation and original creativity. The industry people have been found complaining about their innovations being imitated. There are number of IP rights applicable in the process of designing a garment from yarn to an apparel stage. However there are very few designers who are aware of these government enforced incentives of limited exclusiveness born during designing of their apparel.

In fashion industry, where there is a blurring difference between creativity & imitation, the strategic protection of one’s innovation may prove to be a valuable asset and may grant the holder of the right a competitive advantage in the fashion industry.

The conventional argument for IP protection entails basically three schools of thoughts. First, it is often very difficult and a costly affair to fabricate a unique design or textile. Second, once a unique invention is in the market without any legal protection, others would find it easier and inexpensive to imitate. Third, if the law does not endow the inventor with government enforced incentives of limited exclusiveness, the imitator will copy the original creation and will outrun the creator without having to pay any royalty.

PROTECTION THROUGH DESIGNS ACT

The Indian Designs Act, 2000, protects the features of shape, configuration, pattern or ornament or composition of lines or color or combination thereof applied to any article whether in two dimensional (for example, pattern on a textile) or three dimensional (for example, shape of an apparel) or in both forms, by any industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye.1

This is the most relevant form of protection available to the Fashion Industry. Designers keep on experimenting with the color, pattern and fabric combinations. This form of IP protection is sought by creators who are planning to mass produce or make manifold copies of their creation. Protection through this act also facilitates the creator in preventing others from infringing his their product.

PROTECTION THROUGH PATENTS ACT

The innovative fabrics can be protected through Indian Patents (Amendment) Act, 2005. The textile companies can patent their product if it is novel, involves an inventive step and is capable of industrial application. Many companies have already patented their innovative fabrics, such as Nomex, Lycra and Goretex, which have become a valuable asset for the organization.

For instance, a corporation ‘Aquatic Design’2 patented a layered fabric that has the qualities of being waterproof, breathable and elastic that makes it highly desirable in action sportswear. Similarly, Grindi Srl., an Italian company, obtained a patent for its innovative fabric, Suberis, made of cork, smooth as velvet, light as silk, stain-resistant, waterproof and fireproof.

1 http://ipindia.nic.in/ipr/design/design_act.PDF
PROTECTION THROUGH TRADEMARKS ACT

According to Section 2 (zb) of the Indian Trade Marks Act, 1999, trade mark means ‘a mark capable of being represented graphically and which is capable of distinguishing the goods or services of one person from those of others and may include shape of goods, their packaging and combination of colours.’ A mark can include a device, brand, heading, label, ticket, name, signature, word, letter, numeral, shape of goods, packaging or combination of colors or any such combinations.3

This form of IP protection helps the owner in protecting not only his brand name or the logo that may become a valuable asset to the organization, but also in protecting other distinctive features of their products. For instance, the US Navy recently got a registered trademark on a camouflage pattern used on its uniforms. Bettina Liano has registered the distinctive pocket stitching on the garments as a trade mark, while Burberry holds the trademark rights in both the brand name ‘Burberry’ and their distinct Burberry check pattern. In Fashion Industry the consumers are often willing to pay premium prices for a product of their choice bearing the trademark of their preference.

LACK OF IP PROTECTION IN FASHION INDUSTRY

Although the designs can be legally protected via Designs Act & Trademarks Act, the fashion industry can very well survive without IP protection because of two interrelated factors referred to as “induced obsolescence” and “anchoring.”

The induced obsolescence occurs when an apparel or a design becomes out-of-fashion or unfashionable before they actually wear out. Anchoring is the technique through which the designers keep the consumers glued to the latest trends. They anchor the consumers by constantly conveying them what to wear through their fashion shows. Thorough this mechanism the fashion industry indicates that the style has changed and it’s time to makeover the wardrobe.

The lack of IP protection in fast-paced fashion industry and the presence of two interrelated factors actually promote the operation of the fashion industry. In fashion industry, there is blurring of the line between ‘imitation’ and ‘inspiration.’ Imitations of the original creation contribute to the creativity and innovation that drives the industry. It is believed that if IP protection is extended to fashion industry as well, it might hamper the creativity of the designers.

CONCLUSION

This article presents a comprehensive overview of strategizing Intellectual Property rights in fashion Industry under various sub domains of IP; like designs, trademarks and patents. Although a plethora of IP protection is available to the creators during the process of development of a fabric from fiber to attire phase, in reality the designers seem to be least concerned of the availability of IP rights. The designers producing the facsimiles of the original creations indirectly promote the operation of the Fashion Industry.

Fashion Industry is considered to be a very impulsive sector where more a product is copied the more fashionable it becomes; and in a way this serves to drive the industry. It can be rightly said that the cure may be worse than the disease in this sector.

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3  http://en.wikipedia.org/wiki/Indian_trademark_law
INTRODUCTION

The term traditional cultural expression refers to the work of indigenous people and the traditional communities, but the term has not been precisely defined. The term Traditional Cultural Expressions (TCEs) in the international community is also referred to as “folklore” and some nations prefer using the term “folklore” in their national copyright laws. The term “folklore” means the traditional beliefs, myths, tales, and practices of a group of people, transmitted orally. The term “folklore” was coined by William Thomas in the year 1846. Mr. Thomas meant to include manners, customs, observations, superstitions, ballads, proverbs and so on, in the term ‘folklore’, which he summarized as the lore of the people.

Traditional Cultural Expressions (TCEs) are in two forms, tangible and intangible. These include:

- Verbal expressions or symbols (stories, epics, legends, tales, riddles, etc.)
- Musical expressions (songs, instrumental music)
- Expressions by action (dance form, play, ritual, etc.)
- Tangible expressions (drawings, designs, paintings, body art, carvings, sculptures, pottery, terracotta, warli painting, mosaic, woodworking, rockwork, metal work, jewellery, basket, needlework, glassware, textiles, carpets, etc.)
- Intangible expressions reflecting traditional thought forms
- Architectural forms

TCEs reflect a community’s cultural and social background and consist of characteristic elements of a community’s heritage. They are often made by authors who are unknown or unidentified, or by communities or individuals recognized as having the right, responsibility or permission to create them in accordance with the customary law and practices of that community. TCEs are often evolving, developing, and being recreated within source communities.

TCEs are vital to the cultural and social identities of indigenous and local communities, they embody knowledge and skills, and they transmit core values and benefits. Their protection is linked to the promotion of creativity, enhanced cultural diversity and the preservation of cultural heritage.

Many international communities refer TCEs as “Traditional Knowledge” or “Indigenous knowledge”. These terms refer to the long-standing traditions and practices of certain regional, native, local communities. Traditional knowledge also includes the perception, knowledge and teachings passed on from generations to generations. Some forms of traditional knowledge are expressed through stories, legends, folklore, rituals, songs and even laws.

CHARACTERISTICS OF TCEs

Following are the characteristics of Traditional Cultural Expressions/Folklore:

1. they are handed down from one generation to another, either orally or by imitation;
2. they reflect a community’s cultural and social identity;
3. they consist of characteristic elements of a community’s heritage;
4. they are made by ‘authors unknown and/or by individuals communally recognized as having the right, responsibility or permission to do so;
5. they are often not created for commercial purposes, but as vehicles for religious and cultural expressions; and
6. they are constantly developing and being recreated within the community.

MAJOR INTERNATIONAL EVENTS FOR THE PROTECTION OF TCEs

- In 1967, the Berne Convention was amended to introduce optional copyright protection for folklore at the national level, in Article 15(4). According to the framers of this amendment, reflected in Article 15.4 of the Convention, it aims at providing international protection for expressions of folklore/TCEs.
- In 1976, the Tunis Model Law on Copyright for Developing Countries was adopted. It included sui generis protection for expressions of folklore.

1 http://www.arl.org
2 WIPO handbook
3 View or opinion expressed by author Molly Torsen at Santa Clara Law School’s Conference
4 WIPO handbook
In 1982, an expert group convened by WIPO and the United Nations Educational, Scientific and Cultural Organization (UNESCO) developed a sui generis model for the IP-type protection of TCEs. The WIPO-UNESCO Model Provisions, 1982. They establish two main categories of acts against which TCEs are protected, namely ‘illicit exploitation’ and ‘other prejudicial actions’.

In December 1996, WIPO Member States adopted the WIPO Performances and Phonograms Treaty (WPPT), which provides protection also for a performer of an expression of folklore.

In April 1997, the ‘UNESCO-WIPO World Forum on the Protection of Folklore’ was convened in Phuket (Thailand).

In 1999, WIPO organized regional consultations on the protection of expressions of folklore for African countries (March 1999), for countries of Asia and the Pacific region (April 1999), for Arab countries (May 1999), and for Latin American and the Caribbean (June 1999). Each of the consultations adopted resolutions or recommendations, which included the recommendations that WIPO and UNESCO increase and intensify their work in the field of folklore protection. The recommendations unanimously specified that future work in these areas should include the development of an effective international regime for the protection of expressions of folklore.

In late 2000, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was established. The Committee has made substantial progress in addressing both policy and practical linkages between the IP system and the concerns of practitioners and custodians of traditional cultures. The studies have formed the basis for ongoing international policy debate and assisted in the development of practical tools. Drawing on this diverse experience, the Committee is moving towards an international understanding of the shared objectives and principles that should guide the protection of TCEs.

In 2007, the United Nations adopted the U.N. Declaration on the Rights of Indigenous Peoples (2007) which highlighted the need to final legal approaches that fall outside the framework of the Berne Convention.

LEGAL PROTECTION TO TCES AND IKS

The legal protection for TCEs should be considered in a comprehensive manner, and not as an end in itself. Before framing any policy in this regard it is very important to understand the needs and expectations of the TCEs/folklore custodians/guardians.

Indigenous and local communities have called for various forms of protection; these include:

- protection of traditional literary and artistic productions against unauthorized reproduction, adaptation, distribution, performance and other such acts, as well as prevention of insulting, derogatory and/or culturally and spiritually offensive uses;
- protection of handicrafts, particularly their ‘style’;
- IP protection to prevent unwanted use by others: communities may wish to gain IP protection in order to actively exercise IP rights to prevent the use and commercialization of their cultural heritage and TCEs by others, including culturally offensive or demeaning use.
- IP protection to support economic development: some communities wish to gain and exercise IP in their tradition based creations and innovations to enable them to exploit their creations and innovations commercially as a contribution to their economic development.

An integral part of developing an appropriate policy framework within which to view IP protection and TCEs is a clearer understanding of the role, contours and boundaries of the so-called ‘public domain.’ The term ‘public domain’ is used here to refer to elements of IP that are ineligible for private ownership and the contents of which any member of the public is legally entitled to use. The ‘public domain’ is often characterized by indigenous and other stakeholders as having been created by the IP system and does not therefore respect the protection of TCEs that customary and indigenous laws require.

The global experience in the area of TCE protection so far has shown that it is difficult to provide a single comprehensive solution which will suit all legal and cultural environment, traditional communities in all countries.

The options include existing IP Laws (including unfair competition), sui generis aspects of IP laws, as well non-IP laws like customary laws, contract laws, common law remedies, criminal law remedies, rights of publicity, to name a few.
TCEs can be protected under the Trade Marks Laws, for instance some indigenous name, traditional images, symbols can be registered as trademarks. In Australia, certification marks have been registered by the National Indigenous Arts Advocacy Association (NIAAA) and in New Zealand the Maori Arts Board, Te Waka Toi, is making use of trademark protection through the development of the Toi iho™ Maori Made Mark.5

TCEs often have a strong link with a specific locality. This means that geographical indications can also protect TCEs, in particular when they are in the form of tangible products such as handicrafts that have qualities derived from their geographical origin – for instance, the Olinalá craft products from that region in Mexico.

Many countries and several regional organizations have elected to protect TCEs through sui generis measures. Most have done so within their copyright laws, following largely the Model Provisions, 1982. Others have elected to establish stand-alone IP-like laws and systems, examples of which are: the Indigenous Peoples Rights Act of 1997 of the Philippines; The Special Intellectual Property Regime Governing the Collective Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and their Traditional Knowledge of Panama, 2000; the Special Intellectual Property Regime Governing the Collective Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and their Traditional Knowledge of Panama, 2000 and the related Executive Decree of 2001; the Pacific Regional Framework for the Protection of Traditional Knowledge and Expressions of Culture, 2002.

The Secretariat of WIPO continues to undertake, upon request, legal-technical cooperation activities for the establishment, strengthening and effective implementation of systems and measures for the legal protection of TCEs. As a component of this program, it is developing a comprehensive ‘Practical Guide’ for lawmakers, policy makers, communities and other stakeholders, and is also preparing more tailored guides for other interested parties, such as commercial users and handicraft organizations. In addition, the development of model contracts, codes of conduct and guidelines for use by folklore archives, museums and other institutions to assist in managing the IP aspects of their cultural heritage collections is being explored.

5 wipo handbook
outsiders, increasingly they are being used for commercial gain.

In India, the legislation that takes care of the rights relating to literary and artistic works, sound-recordings, films, and the rights of performers and broadcasting organizations, is the Copyright Act, 1957. The Indian Copyright Act does not contain any provisions for the protection of folklore or expressions of folklore. There is also no separate legislation along the lines of the Model Provisions, to serve the purpose of offering legal protection to expressions of folklore.

From the aforesaid it is clear that like many countries of the world India too has no provision to protect expressions of folklore in the intellectual property laws or in any other legislation. As such, exploitation of folklore expressions without taking the permission of the communities and compensating the communities concerned, is not illegal. The general outlook of those business interests who extensively borrow from the collection of the folklore of the communities or tribal settlements is that of exploitation of material available in public domain.

The reason for lack of adequate protection for TCEs/folklore in India is the lack of knowledge and awareness about the need for IP protection. It is very important to understand the need to protect the TCEs/folklore and the expectations and needs of the communities who are the owners/custodians of TCEs.

It is important to consider a few factors:

- The existence of an appropriate legal system within the country of origin or the country where protection is sought
- The existence of goodwill and reputation in a TCE
- The cost of protection
- The length of time it will take to set up the system of protection
- The support of stakeholders
- The ability to promote the system of protection
- Ensure that values of TCEs holders are given meaningful consideration.

The legislators can consider the policies framed by WIPO and frame guidelines for the use and exploitation of TCEs.

**CONCLUSION**

The fact that TCEs are the product of social relations suggests that they are subject to evolution and that these cultural endeavors do not exist in a vacuum from other considerations and aspirations in human development. Further research is needed to understand how the preservation and innovation of TCEs intersect with considerations such as gender equality, education (including inter-generational transmission of language and knowledge within the communities), sustainable livelihoods and cross-fertilization of ideas with other cultures.
TRACING THE BEGINNING OF CORPORATE SOCIAL RESPONSIBILITY

Corporate Social Responsibility [hereinafter referred to as “CSR”] came into common use in the late 1960s and early 1970s but if we were to turn the pages of history, we would know that the history of social and environmental concern about business is as old as trade and business itself. For example laws to protect forests, can be traced back almost 5,000 years. In Ancient Mesopotamia around 1700 BC, King Hammurabi introduced a code in which builders, innkeepers or farmers were put to death if their negligence caused the deaths of others, or major inconvenience to local citizens.

With industrialization, the impacts of business on society and the environment assumed an entirely new dimension. The “corporate paternalists” of the late nineteenth and early twentieth centuries used some of their wealth to support philanthropic ventures. By the 1920s discussions about the social responsibilities of business had evolved into what we can recognize as the beginnings of the “modern” CSR movement. It was in 1929, that the Dean of Harvard Business School, Mr. Wallace B. Donham commented in his speech delivered at North Western University:

“Business started long centuries before the dawn of history, but business as we now know it is new - new in its broadening scope, new in its social significance. Business has not learned how to handle these changes, nor does it recognize the magnitude of its responsibilities for the future of civilization.”

Almost seventy years later, these words ring just as true. Today also there are so much of talks going about the same but very little done in this regard.

DEFINING CORPORATE SOCIAL RESPONSIBILITY

Corporate social responsibility (CSR), also commonly as called corporate conscience, corporate citizenship, social performance, or sustainable responsible business/ responsible business). CSR differs from place to place, from industry to industry. It is difficult to define CSR precisely because it will always have a location-specific context. The world business Council for Sustainable Development defines CSR as, “Corporate Social Responsibility is the continuing commitment by business to behave ethically and contribute to economic development while improving the quality of life of the workforce and their families as well as of the local community and society at large.” It is basically a form of corporate self-regulation integrated into a business model.

FRIEDMAN VERSUS RUSSELL

Milton Friedman indicated that one and only one social responsibility of a business is to use its resources and engage in activities designed to increase its profits, as long as it stays with the rules of the game, which is to say, engages in open and free competition without deception of fraud.

On the other hand Kirk Russell insisted that every right is married to a duty, every freedom owns a corresponding responsibility. Hence, there cannot be genuine freedom unless genuine order also exists in the moral realm and in the social realm.

It’s not only in the times of Friedman and Russell that two completely contrasting opinions about CSR existed, even today there are a number of people, in fact most number of people following the Friedman’s way. Without even realizing that today, there is no way to avoid paying serious attention to corporate citizenship/CSR, as the cost of failing is very high. There could be countless win-win opportunities waiting to be discovered. It is to be understood that every activity in a firm’s/any sort of corporate set-up’s value chain overlaps in some way with social factors, from how to buy or procure to how to conduct the research, and its quite strange that yet very few companies have thought about it. The goal is not only to earn profit but leverage company’s unique capabilities in supporting social causes as well as improving its competitive context at the same time.

METHODOLOGY OF CORPORATE SOCIAL RESPONSIBILITY

CSR is the procedure of assessing an organization’s impact on society and evaluating their responsibilities. It begins with an assessment of the following aspects of each business:
Corporate social responsibility is maintainable as it involves activities that can be upheld by an organization without negatively affecting the business growth. CSR is not only about protecting the environment, taking ecological accountability into consideration or having a recycling policy, it is about considering the whole representation of the company, from internal processes to the clients, taking in every step that a business takes during day-to-day operations and for its wholesome growth.

Organizations have to recognize that CSR is just a way in which companies manage their business processes to produce an overall positive impact on the community at large. It is very important big and small both companies to understand that besides growing their businesses, it is also important to shape responsible and supportable relationships with the society.

An initiative is also required from countries having developing economy to have CSR as a part of their business. This can be achieved by having specific departments and teams in their companies (having number of members depending upon the size of their organization/company) that develop specific policies, strategies and goals for their CSR programs and set separate budgets to support them.

**ISSUES AND CHALLENGES**

The prime purpose of including CSR in corporate business is to make the corporate business activities as well as the corporate culture both sustainable in three ways: economic, social and environmental. Paying equal amount of attention to all the three dimensions, but many companies think that corporate social responsibility is a much exterior part of their business, whereas most think it to be an irrelevant issue for their business as satisfying their customers/clients is more important for them. It is further felt that customer satisfaction is only about price and service, but concentrating on only these aspects of business makes them blind folded towards other important changes taking place worldwide that could blow the business out of the water. The change is named as social responsibility which is an opportunity in itself for the business.

Some of the drivers pushing business towards CSR include:

**Inefficiency of the Government**

In the past, governments have relied only on legislation and regulation to deliver social and environmental objectives in the business sector which has lead to certain failed initiatives.

**Demands for Greater Disclosure**

There is a growing demand for corporate disclosure from stakeholders, including customers, suppliers, employees, communities, investors, and activist organizations.

**Increased Customer Interest**

It has been seen and proved through a survey conducted in the year 2002 in 25 countries by *Environics International*

The same study found that almost 50 percent of consumers had considered punishing a company based on its social actions, and that nearly 30 percent had actually avoided a company for that reason. Further it was proved that the ethical conduct of companies have a growing influence on the purchasing decisions of customers.

**Increased pressure from the Investor**

Investors are changing the way they analyze companies’ performance, and are making decisions based on ethical concerns too.

**Change in employee behaviour**

Employees are increasingly looking beyond paychecks and benefits and seeking out employers whose operating practices match their own principles. In order to hire and retain skilled employees, companies are being forced to improve working conditions.

**ADVANTAGES OF MAKING CSR A PART**

The concept of corporate social responsibility is now firmly rooted around the globe as a business agenda. But in order to move from theory to concrete action,
many hurdles need to be overcome. The positives of a CSR initiative are that it can bestow an organization both in terms of finances as well as managerial talent and also attract right people to work on the initiatives. Thus looking at the initiatives by Corporate around the world one feels that we can expect more from them.

There is an urgent need to address the various CSR initiatives and also a need to build a mechanism through which such efforts are recognized and rewarded. It would not be wrong in saying that transparency and dialogue can help to make a business appear more trustworthy, and push up the standards of other organizations at the same time.

Some of the positive outcomes that can arise when businesses adopt a policy of social responsibility include:

Examples of benefits to a Company:
• Improved financial performance;
• Lower operating costs;
• Enhanced brand image and reputation;
• Increased sales and customer loyalty;
• Greater productivity and quality;
• More ability to attract and retain employees;
• Reduced regulatory oversight;
• Access to capital;
• Workforce diversity;
• Product safety and decreased liability.

Examples of benefits to the Community and the General Public
• Charitable contributions;
• Employee volunteer programs;
• Corporate involvement in community education, employment and homelessness programs;
• Product safety and quality.

Examples of benefits to the Environment
• Greater material recyclability;
• Better product durability and functionality;
• Greater use of renewable resources;
• Integration of environmental management tools into business plans, including life-cycle assessment and costing, environmental management standards, and eco-labeling.

It would certainly not be wrong to say that the leading global companies of 2020 will be those that would provide their customers and clients with goods and services and even reach out to them in a manner and with a approach that accommodates solutions to world’s major challenges, such as poverty, climate change, resource depletion, globalization and demographic shift.

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Companies enter into merger(s) to achieve economies of scale, increase their market share, gain technical know how, create their presence in new markets etc. If the entire process of Merger is not executed in a well planned manner the objective of entering into merger may get defeated. The process of Merger can be divided in two parts i.e. Pre Merger Obligations and Post Merger Obligations. Pre Merger Obligations are generally given more importance than post merger obligations, however, it needs to be understood that post merger obligations are equally important as the pre merger obligations and if they are not handled carefully then the merger may not achieve the desired results, resulting in loss of reputation of the merging entities and/or decline in shareholders net worth.

All the factors relating to post merger obligations such as estimated cost, expected timeframe, legal issues should be duly analyzed along with pre merger obligations by the merging entities before taking the final decision of merger. Post Merger Obligations can be divided into Administrative Acts and Statutory Compliances. The time frame and cost involved for the completion of Administrative Acts and Statutory Compliances depends upon size of the merging entities.

**STATUTORY COMPLIANCES**

The statutory compliances with respect to merger can fall under the following enactments/authorities broadly:

- Companies Act, 1956
- SEBI Laws and Regulations (If any of the Merging Entity is a Listed Company)
- Taxation Authorities such as
  - Income Tax Department
  - Central Excise Department
  - Sales Tax/VAT Department
  - Service Tax Department
- Foreign Exchange Management Act, 1999
  (If there is involvement of Foreign Funds or there is a foreign Collaboration of the Merging Entity)

Apart from above, there are other compliances which a Company is required to carry out:

- To follow up Pending Litigation Matters of the Transferor Company
- To Transfer Intellectual Property Rights such as Patents, Trademarks, Copyrights etc. of the Transferor Company in the name of Transferee Company
- To Modify the Contracts or Agreements executed between the Private Parties included Foreign entities and the merging entities, if required
- To make changes in the Letter Heads and Boards displaying the name of the company which are placed outside the Registered Office and Branches of the Transferee Company
- To get transferred the assets and liabilities of the Transferor Company in the name of Transferee Company
- If there are any Government Approvals or Licenses etc. in the name of merging entities then the respective Government authority or license issuing authority will have to be intimated about the merger.

**ADMINISTRATIVE CONDUCT:**

There are a number of Administrative conducts which are required to be carried out to complete the Process of Merger, out of which some of the conducts are as follows:

- To reorganize the organization structure with regards to employees, as the employees of the Transferee Company will become a part of the Transferor Company and they will have to be suitably designated.
- To frame revised policy for the employees of the Transferor Company
- To inform the Bankers and Financial Institutions of the Transferor as well as the Transferee Company
- To restructure the insurance policies of the employees and insurance policy of assets of the Transferor Company
- To make necessary changes to the website of the Transferor Company and give new E-mail Ids to the Employees of the Transferor company
- To get the Pending Contracts/Orders in hand of the Transferee Company Executed
- To Change the Accounting Policies of the Transferor Company
To inform the Clients, Customers, Debtors and Creditors of the Transferor Company
To Make changes in the Internal management policies of the Transferor Company

The number of Administrative conducts and the Statutory Compliances which needs to be complied with, changes according to the nature of work and organization structure of the merging entities. Statutory Compliances should be followed in strict sense and should be completed as soon as possible so that the merged entity may not face any legal hurdle. Statutory Compliances also become a bit easy as the scheme of merger is approved by the Shareholders of the Company and the Hon’ble High Court. Administrative conducts should also be completed as soon as possible and extra care should be given especially with regards to the employees, clients and customers of the Transferor Company.

Employees of the Transferor Company become a part of the Transferee Company post merger, which involves a change in their work environment all together. It needs to be ensured by the Management of the Transferee Company that the Employees of the Transferor Company get the respect which they used to get earlier. If the employees are not satisfied with the new management they may leave the Company and such an act will not work in favor of the merged entity, as the employees are vital assets of the Transferor Company. Similarly post merger, the Clients and Customers of the Transferor Company should not have any complaints with regards to the service or the quality of products of the transferor Company.

CONCLUSION

Post Merger Obligations have an important role to play in order to achieve the desired results after merger. A careful Due Diligence of the Pre and Post Merger Obligations will help the merging entities to take an informed decision before entering into a merger. Also the execution of Post merger Obligations should ensure that they are carried out in time and with adequate care so that the merged entity achieves the desired results.
A non-compete clause is well known under the Contractual Laws as the clause being made out into any agreement between two parties where one party is the employer and the other party is the employee. By virtue of this non-compete clause, the employee undertakes and gives his acceptance to the condition of the employer that during the course of the employment or even after the employee leaves the services/job of the employer, he will not be the competitor of the employer in the form and nature of the employment of the employer. The Non-compete clause finds place under the agreements and contracts throughout the globe.

When we see the Indian legal scenario about the non-compete clause, it is prohibited under the Law of Contracts.

Section 27 of the Indian Contract Act-1872 provides that “Every agreement by which anyone is restrained from exercising a lawful profession or trade or business of any kind, is to that extent void.”

Exception: One who sells goodwill of a business with a buyer to refrain from carrying on a similar business within specified local limits so long as the buyer, or any person deriving title to the goodwill from him, carries on a like business therein provided that such limits appear to the court reasonable, regard being had to the nature of business.

Indian law is therefore very clear and strict on this point, any such non-compete agreement shall not be binding on the parties and the same shall be null and void. By using the term void ab initio, for such type of agreements it has shown that it has kept such non-compete clause in the agreements beyond consideration. Indian courts have also consistently refused to enforce post-termination non-compete clauses in employment contracts as “restraint of trade” is impermissible under Section 27 of the Indian Contract Act-1872, and have held them as void and against the public policy because of their potential to deprive an individual of his or her fundamental right to earn a living.

However considering the developed social, legal, and corporate circumstances, and the required confidentiality and the integrity of the employment, the judiciary has inclined its view towards giving some regard to the non-compete agreements. In the case of ‘Niranjan Shankar Golikari Vs the Century Spinning and Manufacturing Company Ltd.’, the Hon’ble Supreme Court observed that “restraints or negative covenants in the appointment or contracts may be valid if they are reasonable.” Further in one case - V.F.S. global services Pvt. Ltd Vs Mr. Suprit Roy, 2008(2) Bom CR 446, the Bombay High court established the principle that a restraint on the use of trade secrets during or after the cessation of employment does not tantamount to a “restraint on trade” under Section 27 of the Act and therefore can be enforceable under certain circumstances. In the case of Mr. Diljeet Titus, Adv Vs Mr. Alfred A Adebare & Ors 2006(32)PTC 609 (Del), Delhi High court held that “The real test was the degree of employment control to determine whether it was a contract of service…”.

Like these there are several other judgements of various High courts which have laid down certain tests or guidelines to check the validity and legality of imposition of restrictions on such non-competing agreements. It shows that Indian courts may in certain circumstances enforce confidentiality agreements intended to protect an employer’s proprietary rights.

In foreign judiciary subject to certain limitations and reasonable boundness, the non-compete agreements are declared to be enforceable to the reasonable extent. For example: In ‘HRX Holdings Pty Ltd Vs Pearson(2012) FCA 161’, the Federal Court of Australia upheld a post employment restraint preventing a senior employee from competing with his former employer for two years. The court upheld the two years non-compete clause with consideration. The court held the restraint reasonable because

a) The employee was the “humanface” of the company and had intimate knowledge of the former employer’s client relationships, pricing arrangements and strategies, and

b) The employee had received compensation for the restraint in the form of the remuneration and shares for all but three months of the restraint period.

Keeping in view, the increase in cross border trade and an enhanced competitive climate in India, confidentiality, non-compete and non solicitation agreements are becoming increasingly popular, especially in the IT and technology sectors. A huge number of out sourcing and IT companies are including confidentiality, non-compete and non solicitation covenants in agreements with their employees, with terms ranging from a few months to several years after the employment relationship is terminated. The companies claim that such restrictions
are necessary to protect their proprietary rights and their confidential information. In the same way, foreign companies doing business in India often seek to include confidentiality, non-compete and non-solicitation covenants in their agreements with senior management and employees, as is customarily done in certain abroad countries.

Although section 27 of the Indian Contract Act states that all agreements in restraint of any profession, trade or business are void, the current trend as per various judicial pronouncements leads to the conclusion that reasonable restraint can be permitted to some extent and does not render the contract void ab initio. Reasonable of restraint depends upon various factors, and the restraint in order to prevent divulgence of trade secrets or business connections has to be reasonable in the interest of the parties to ensure adequate protection to the covenantee. On careful analysis of section 27 keeping in view the exception provided with it, it can be safely concluded that the section implies that, to be valid an agreement in restraint of trade must be reasonable between the parties and consistent with the interest of the public. So the question arises as to

1. What is public policy and
2. what is reasonable

It is to be widely discussed regarding the public policy. It is illusive, varying and uncertain. It is difficult to give precise definition of the term public policy. Concept of public policy is capable of expansion and modification. It is the province of the judiciary to expound the term “Public policy”. There are several guidelines given by the judiciary to determine as to what is public policy and what is not. Some of these can be expressed as – any agreement tending to injure the public interest or public welfare is against the public policy. Further it can include as to – whatever tends to injure the operation, restraint of liberty, commerce and natural or legal rights, whatever tends to the obstruction of injustice or violation of statutes and whatever is against good morals can be said to be against Public Policy. What agreements are actually against the public policy and what are not, is totally the discretion of the courts.

So far as the term “Reasonable” is concerned, simply in general understanding it means-“according to reason.” Whatever a reasonable man would do using common sense and knowledge, under the given circumstances, will account as reasonable. Therefore the test of reasonability depends on the facts and circumstances of each case. Whether an agreement containing non-compete clause is valid and suitable to restrain, or not, is also a total discretion of the courts and which is varying based on the facts of the case.

To validate such non-compete clauses certain reasonable restrictions may be imposed like:

i) Distance: Suitable restrictions on employee prohibiting them to practice same profession within a stipulated distance, the stipulation being reasonable.

ii) Time limit: If there is a reasonable time provided in the clause then it will fall under reasonable restrictions.

iii) Trade secrets: the employer can put reasonable restrictions on the letting out of trade secrets.

iv) Goodwill: Article 27 of the Indian contract Act provides an exception on the distribution of goodwill.

In addition to this the Judiciary uses the tool of ‘Injunction’ to prevent a third party from releasing confidential information, using trade secrets etc. & ‘compensation’.

Certain efforts have also been made by the Legislators to substantiate the confidentiality etc. such as – Section 72 of I.T. Act-2000, deals with breach of confidentiality & privacy and any breach will attract imprisonment up to two years, or fine of Rs. One Lac.

**CONCLUSION**

Although such Non-compete clauses are valid in foreign countries, but in regard to the Sphere of the Indian judiciary, it does not find such wider and effective scenario like that in foreign countries. Article 21 of the Constitution of India guarantees the right to livelihood and since it is a fundamental right it is held to be inviolable. This makes the enforcing of non-compete clauses in India even more difficult. At the same time it is also very pertinent to be considered that, the time and the circumstances-socio, legal, economical & corporate, have changed and developed in India and Abroad to a greater extent and in order to fill the lacunas of law and the developed circumstances, social engineering (Social engineering is a beautiful concept propounded by Roscoe Pound – social engineering is a means of trying to control human behaviours with the emphasis of laws. This principle is based upon the thought that laws are a deterrent to future crimes. As written by the Roscoe Pound in the ‘Jural Postulates’, he lays the foundations for assumptions in which a civilized society should be able to live…) is required to be done. The recent trends of the Indian Judiciary tending to validate the non-compete clauses to the reasonable and justful extent in the various agreements as discussed above is an attempt to that effect and are commendable.

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INTRODUCTION

The Indian Constitution preserves the pride of being the longest and most comprehensive Constitution to have bestowed with utmost importance and dignity to its citizens in terms of right to life and personal liberty irrespective of his/her economic strata in the society. But undoubtedly not many of us are aware that somewhere or the other this privilege is not been achieved in a holistic manner, talking in terms of the one who unfortunately happen to fall under the category of “poor” in our society and at the lure of some petty money, these vulnerable ones become subjects at the hands of some Pharmaceutical Companies, who use them for clinical trial of their drug innovation. In 2004 one of the most shocking landmark incident happened when 14 participants who were administered drug without their consent and knowledge of its adverse consequences, died during the course of the clinical trials at Bhopal Memorial Hospital and Research Centre, which was established exclusively for treating the victims of the 1984 gas leak.1 Yet another striking and recent news witnessed in a National Newspaper on 18th Aug, 2012 was the death of 211 people from January to June 2012 due to serious adverse effects of drugs administered to them during clinical trial conducted by the Drug Companies.2

CLINICAL TRIAL: A POSITIVE OR NEGATIVE PRACTICE?

In general prospective when analyzed, clinical trial is a positive requirement to strive towards the growing developments in the present Pharmaceutical market worldwide. Moreover now that Government has also finally given positive node to foreign pharmaceutical companies to invest in India, it is a good sign for India that global clinical research is gradually exploring India. But the biggest question is how far India can exploit this opportunities and at the same time to come up with measures to protect the rights and safety of the subjects of clinical trial, so as to make such trials both methodologically and ethnically valid is a big concern.

It is worth appreciating that very recently Government is seen to have shown positive responses towards the long controversial issue of rights and safety of research subjects after decades of debate, protest by various organizations and experiences of the vulnerable poor subjects. In this review, this article attempts to throw light on the Central Drugs Standard Control Organization's (CDSCO) role and steps taken towards protecting and ensuring rights and safety of the subjects of clinical trial.

PRESENT REGULATORY MEASURES IN INDIA REGARDING CLINICAL TRIALS


Out of all the above laws, The Drugs and Cosmetics Act –1940 plays a significant role in terms of clinical trials. In 2002 certain important amendments were made to the Drugs and Cosmetics Rules, 1945 with regard to conducting of clinical trials for import and manufacture of new drugs. As a result, it is mandatory to obtain prior approval from the Drugs Controller General of India (DCGI) before any institution conducts clinical trials for a new drug.3 Further Schedule Y of the Rule specifies that the Clinical Trial should be conducted in compliance with the protocol and Good Clinical Practice (GCP) Guidelines specified for the purpose as well as with all applicable statutory provisions.

RECENT POSITIVE APPROACHES BY CDSCO WITH REGARDS TO SAFETY OF THE SUBJECTS OF CLINICAL TRIAL

The coming up of the remedial shield as “Draft Guidelines for determining quantum of Financial

1 http://www.livemint.com/Politics/D0gBgwCn3huK72506p8K5H/The-dark-underbelly-of-Indias-clinical-trials-business.html
3 Refer to Rule 21(b) of the Drugs and Cosmetics Rules,
Compensation to be paid incase of clinical trial related injury or death is a significant step that CDSCO has taken with the aim of protecting the rights, safety and well being of the subjects participating in the trial. Ironically, the Drug and Cosmetics Rules is silent about any specific provision for payment of compensation to victims who suffer serious adverse injuries or death as a consequence of clinical trial, however the Good Clinical Practice (GCP) Guidelines for Clinical Trials of India under Para 2.4.75 provides such compensatory measures. With the objective of incorporating specific procedures to be followed for payment of compensation in case of trial related injury or death, steps are being taken to come up with certain standards through this draft rule to determine such compensation, once it is finalized and enforced.

In assessing or deriving an amount to be called as appropriate compensation in the case of trial related injury or death, the guidelines have primarily taken the following parameters into consideration:

i) Age of the deceased;
ii) Income of the deceased;
iii) Seriousness and severity of the disease the subject was suffering at the time of his/her participation into the trial;
iv) Percentage of permanent disability;

### LACUNAS/INSUFFICIENCY OF THE GUIDELINES IN DETERMINING COMPENSATION

- **Income Factor**: The guideline determines that higher is the financial earning capacity, higher would be the compensation payable to the subject of clinical trial who suffers any injury or death. It apparently reflects that comparatively one who is financially sound would get more compensation than the poorer one. Moreover those individuals who are incapable of earning due to any physical or mental disability, old age or any other reasons would be most affected if income factor is taken into consideration to determine the amount of compensation.

- **Seriousness and severity factor**: The guidelines insist on immediate nexus between the trial and the injury or death that subsequently may occur. However, the determination of compensation should not be restricted to direct short-term injury during the trial. In many cases, the injury to the research participants is not immediate but may show only after few months in a gradual process.

- **Disability factor**: It may vary from individual to individual depending upon his/her physical strength, resistance power, racial characteristics, genetic make-up, individual biochemistry etc. The draft should have demarked the difference between permanent and temporary disability.

Apart from the aforesaid guidelines, another pertinent step taken by CDSCO that reflects the seriousness and strictness towards ensuring safety measures to the subjects of clinical trial is the recent order published on 16th August 2012 under the heading “Ensuring rights/safety of clinical trials subjects in India” where strict instructions are given to the Ethics Committee involved in clinical trial to keep vigil on the clinical trials being conducted under their jurisdiction. Further under the same heading a notice has also been published emphasizing on written consent to be taken from the subjects of any clinical trial who is administered with any new drug after the Investigator provides all relevant information pertaining to the study to be undertaken on him (the subject) so that the subject is aware of the nature of possibilities of adverse effect of the study and that the consent given to such study should be free and in conscious mind.

### CONCLUSION

As India is approaching towards globalization in the recent developments in the Pharmaceutical sector occurring worldwide, based on its comparatively low cost and skill base, India portrays to be a prospective hub for many big foreign Pharmaceutical Companies for drug innovation. So as to exploit this opportunity for the betterment of the country, it is pertinent that introduction of any drug innovation in the market should be preceded by a successful clinical trial which should be both methodologically and ethically valid. Inspite of the appreciable steps taken so far, our law framers further need to put efforts to raise the standard for a more rigid and stricter vigilance mechanism on the Pharmaceutical Companies who conduct such clinical trial at the cost of the lives of some vulnerable and poor individuals who are not even aware that in our Country, there is existence of “right” to lead a safe and healthy life that the Supreme law of the land—the Constitution guarantees to each and everyone irrespective of their economical conditions, race or any other difference.

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4 Refer http://www.cdsco.nic.in/compention.pdf
5 Refer to http://cdsco.nic.in/html/GCP.htm
6 Refer http://www.cdsco.nic.in/EHICS%20ORDER.pdf
7 Refer http://www.cdsco.nic.in/EHICS%20NOTICE.pdf
STAR INDIA PVT. LTD. VS. PIYUSH AGARWAL & ORS.
[ALONGWITH CS (OS) 3232/2012 AND CS (OS) 2780/2012]

HIMANSHU SHARMA

FACTS

Star India Pvt. Ltd (plaintiff) broadcasts matches organized by the Board of Control for Cricket in India (BCCI), thereby the plaintiff has rights over every information pertaining to the matches organized by Board of Control for Cricket in India (BCCI) including the right to create and broadcast Short Message Services (SMS's), on the basis of the agreement, dated 10.08.2012 entered into between it (plaintiff) and the BCCI. Through this agreement plaintiff claims exclusive rights of providing value added services through SMS's for the 72 hrs.

The defendants are also providing information, including broadcast Short Message Services (SMSs) and value added services, pertaining to the cricket matches broadcasted by plaintiff, by creating a separate data base, wherein the information comes from the public domain. From that information bank the information is further transferred to various persons, including mobile service users. Hereby the plaintiff claims the infringement of its exclusive rights.

ISSUES INVOLVED

1. Whether the rights which are claimed by the plaintiff are or are not covered under the Copyright Act, 1957, or putting it differently, can they arise or exist independently of the Copyright Act, 1957.
2. Whether the information which is available in the public domain after the first broadcast of the audio recording or visual recording or both, does plaintiff posses the exclusive right over the same.

ARGUMENTS BY PLAINTIFF & DEFENDANT

1. The plaintiff states that in terms of its agreement dated 10.08.2012 with the BCCI, the plaintiff has exclusive media rights. Therefore for the period of 72 hours as provided in the agreement dated 10.08.2012 the media rights i.e. the right to all information emanating from the event, belong exclusively to the plaintiff.

In response to this defendant contended that plaintiff has no legal right as claimed, therefore the suits themselves be dismissed on the ground that once no legal right exists, the same cannot be enforced.

It is argued that the rights of the plaintiff exist independently of the Copyright Act, 1957 (hereinafter referred to as “the Act”) i.e the copyrights provided under the Act are not exhaustive of the rights which can be created in respect of an event/live event. Therefore the rights mentioned under the agreement dated 10.08.2012 emanating from the event, belong exclusively to the plaintiff.

In response to the plaintiff’s statements, it is argued on behalf of the defendants that once there is a specific statute, being the Copyright Act which occupies the field, and which Act specifies only specific rights to a “performer” and his assignees, then, except such rights as specifically provided under the said Act, no other exclusive right, be it called by whatever name, can be claimed or granted to the performer and the assignee of the performer i.e BCCI or its further assignee (s).

2. The plaintiff argued that the acts/performances of the performers in the cricket match event are recorded in a visual recording and/or the sound recording exists as specified in Section 38A. Therefore reproduction or communication of such work without a license or permission amounts to infringement of copyright as per Section 37 and 51.

The defendant contented that visual or audio or both performances is/are not utilized by the defendants, so there no violation of any right of the plaintiff. As information existing in public domain is news, which no-one can monopolize.

COURT’S OBSERVATIONS AND FINDINGS

1. On the observations made by court of the Copyright provisions and in order to decide the issue that whether the rights which are claimed by the plaintiff are or are not covered under the Act, the court discusses various provisions of the Copyright Act:
   - Section 38: performer’s Right (to testify that whether the cricket match is performance), “Section 2(q) “performance”, section 2(qq) “performer” Section 38A. Exclusive right of
performers, Section 13. Works in which copyright subsists, “Section 16. No copyright except as provided in this Act. The court reached on the conclusion that a conjoint reading of Sections 13 and 38 shows that a copyright subsists in seven classes of works i.e. literary work, dramatic work, musical work, artistic work, a cinematograph film including video film, a sound recording, and a performer’s performance. That the Cricket Match falls within the ambit of the term ‘Performance’, therefore the cricketers, commentators and empire are Performers as under Section 2 (qq) of the Act.

2. The court found the plaintiff’s argument hollow and shallow, as the agreement cannot result in creation of legal right. As the news in public domain is not and cannot ever be monopolized especially because content/information from a copyright work is not the subject matter of copyright as per Sections 13, 14 and 38A and thus no rights can be claimed in the same in view of the reading of the applicable provisions of the Act, and more particularly Sections 16 & 13(4).

3. The principle of fair dealing and public policy quite clearly goes against the concept of there being a monopoly for 72 hours in favor of the plaintiff with respect to news created from the event which is available in public domain.

VERDICT

1. The court laid that the hiatus of two minutes is required with respect to the defendants using the content/information in the first audio and/or visual broadcast of the plaintiff, except of course with respect to momentary events for which there need not be any time lag.

2. Thereby the obiter laid down by court is that the defendant should not use the original audio and/or visual recording except for fair dealing, but so far as the information which comes in public domain, there cannot be any bar upon the defendants to use the same.

3. The suits are therefore dismissed by the Court.

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Applicability of the Shariat Law to proceeding for custody of the children under the Guardians & Wards Act when the parties are governed by Muslim law, is the legal proposition that is dealt with by this article.

The Guardians and Wards Act, 1890, is the enactment that regulates and governs the law relating to appointment and declaration of guardians; duties, rights and liabilities of guardians and all laws relating to the Guardian and Ward. As per Section 4 of the Guardians and Wards Act, 1890 a minor is a person who, under the provisions of the Indian Majority Act is deemed not to have attained the age of majority. As it is well known that the age of majority for a person in India has been defined under Section 3 of the Indian Majority Act, 1875 stipulates “that every person domiciled in India shall be deemed to have attained his majority when he shall have completed his age of eighteen years and not before”. Thus on the face of it an inference is drawn that all persons are considered minors if he or she has not attained the age of 18 years.

While India being a secular and democratic country, gives privileges and protection for various religions that flourish under the protection of the Constitution. People of different religions are governed by their respective Personal laws in all questions pertaining to succession, inheritance, marriage, divorce, etc. It is a false presumption that prevails that the Guardians and Wards Act, 1890 applies equally to all persons irrespective of their religion, customs and practices. It is pertinent to note that, the framers of the Guardianship Act were well aware of the diverse religious demography that exists in India. Keeping this in mind section 6 of the G&W Act was enacted, which states that, “in case of a minor, nothing in this Act shall be construed to take away or derogate from any power to appoint a guardian of his person or property or both, which is valid by the law to which the minor is subject”.

The custody of a minor child in Islam is called Hizanit, which literally means the care of the infant. As per the Shariat law that applies to Muslims, the father is considered to be the natural guardian of his children irrespective of sex, but the mother is entitled to the custody of her son till the age of 7 years and of her daughter till she attains puberty. Thus under the Muslim law a male would attain majority/adulthood when he reaches the age of 7 years and a female would attain majority on attaining puberty.

The question that emerges is whether the Muslim personal law (Shariat) would also be applicable to a proceeding under the Guardianship Act. As stated earlier Section 6 gives scope for the application of the personal law to which the minor is subjected to. Further Section 17 of the G&W Act also stipulates that a guardian has to be appointed in consonance with the personal law by which the parties are governed.

The said legal proposition was amply dealt with by the Hon’ble High Court of Delhi in Akhtar Begum vs Jamshed Munir, which held that “the personal law of the parties has to be kept in view in deciding an application for custody by virtue of the mandate of Section 6 of the Act. If a Court does not keep that in view it would be acting illegally and with material irregularity”.

Further the Hon’ble High Court of Delhi while dealing with a habeas corpus petition in Mohammad Nihal Vs State, has taken the aid of Section 2 of the Muslim Personal Law (Shariat) Application Act, 1937 which states that, regarding matters pertaining to succession, inheritance, marriage, divorce, guardianship, etc, where the parties are Muslims, the Muslim Personal Law (Shariat) shall be applicable. The Hon’ble Court has held that, “if some doubt prevails pertaining to the applicability of Shariat laws in guardianship matters, it stands clarified by virtue of Section 6 of the G&W Act. When a court is called upon to determine the welfare of a minor so far as appointment of a guardian is concerned, this exercise will have to be determined in consonance with Shariat Law”. The Hon’ble Court further reiterated that in consonance with section 2 of the Majority act which states that its provisions do not impact on matters of marriage, dower, divorce and adoption, the Indian Majority act cannot be looked into while ascertaining the age of a minor and the personal law of the parties would be the driving factor.

CONCLUSION

Although the personal law of the parties is to be taken into consideration while deciding the custody of the child, the welfare of the Child is of paramount importance and cannot be over-ruled by the personal law and the welfare of the child must be the deciding factor. However, at the same time the personal law cannot be completely sidelined as the personal law would be an important facet of the welfare of the child and must also be taken into consideration.
INFORMATION

INDIAN PATENT OFFICE (IPO) PUBLISHES GUIDELINES FOR INDIAN PATENT APPLICATIONS RELATING TO PLANT (HERBAL) COMPOSITIONS

MRINALINI GUPTA

The Controller General of Patents has issued guidelines for processing of patent applications relating to Traditional Knowledge (TK) and biological materials on November 08, 2012.

The guidelines have been issued in lieu of the fact that a number of the Indian Patent Applications relating to herbal (plant) compositions/extracts/alkaloids and other biological resources from India are being granted in India even though their corresponding Foreign applications in the jurisdictions (US/EP/JPO etc.) having an access to the Traditional Knowledge Digital Library (TKDL) are rejecting the corresponding applications. Different Examiners & Controllers have been analyzing the patentability criteria of inventions differently due to the lack of any standard procedures.

EXTERNAL COMMERCIAL BORROWINGS [ECB] POLICY FOR 2G SPECTRUM ALLOCATION

SHIPRA MAKKAR

As per the existing policy on the subject, the eligible borrowers in the telecommunication sector are permitted to avail of ECB for the purpose of payment for spectrum allocation, under the automatic route. Successful bidders of 3G auction are also permitted to make the payment for spectrum allocation initially out of Rupee resources to be refinanced with a long-term ECB under the approval route subject to certain conditions.

On a review of the ECB policy and keeping in view the large outlay of funds required to be paid directly to the Government within a limited period of time, the Reserve bank of India vide A.P. [DIR Series] Circular No. 54 dated November 26, 2012 has made the following relaxations for the 2G spectrum auction:-

(i) Refinancing of Rupee resources

The successful bidders making the upfront payment for the award of 2G spectrum initially out of Rupee loans availed of from the domestic lenders would be eligible to refinance such Rupee loans with a long-term ECB, under the automatic route, subject to the following conditions:

a. the long term ECB shall be raised within a period of 18 months from the date of sanction of such Rupee loans for the stated purpose from the domestic lenders;

b. the designated AD Category I bank has evidenced the payment of upfront fees to Government of India in the form of a Receipt/Challan from Department of Telecommunication and

c. the designated AD - Category I bank shall monitor the end-use of funds.

(ii) Relaxation in ECB-liability ratio and percentage of shareholding

The successful bidders in the 2G auction will be allowed to avail of ECB under the ‘automatic route’ from their ultimate parent company without any maximum ECB liability-equity ratio subject to the condition that the lender holds minimum paid-up equity of 25 per cent in the borrower company, either directly or indirectly.

(iii) Bridge Finance facility

The successful bidders can avail of short term foreign currency loan in the nature of bridge finance under the ‘automatic route’ for the purpose of making upfront payment towards 2G spectrum allocation and replace the same with a long-term ECB under the automatic route subject to the following conditions:-

(a) the long term ECB is raised within a period of 18 months from the date of drawdown of bridge finance; and

(b) the long term ECB is in compliance with all the extant guidelines on ECB.

NEWSBYTE

SHIPRA MAKKAR

The Department of Industrial Policy & Promotion, vide Press Note 9 [2012 series] dated 3rd October, 2012 has revised a condition of minimum capitalization norm for the Foreign Direct investment in the NBFC Sector.

Earlier only 100% foreign owned NBFC’s with a minimum capitalization of US$ 50 million could set up step down subsidiaries for specific NBFC activities,
without any restriction on the number of operating subsidiaries and without bringing in additional capital.

However, with the revised guidelines, now the NBFC’s having foreign investment more than 75% and up to 100% with a minimum capitalization of US$ 50 million can also set up step down subsidiaries for specific NBFC activities, without any restriction on the number of operating subsidiaries and without bringing in additional capital.

LIAISON OFFICE/BRANCH OFFICE IN INDIA BY FOREIGN ENTITIES – REPORTING TO INCOME TAX AUTHORITIES

According to the present guidelines, the Liaison offices [LOs]/Branch offices [BOs] are required to furnish copy of the Annual Activity Certificate [AAC] to the Director General of Income Tax [International Taxation].

The Reserve Bank of India vide A.P. [DIR Series] Circular No. 6 dated November, 26, 2012, have made a requirement of the copies of the AACs submitted to the DGIT [International Taxation] to be accompanied by audited financial statements including receipt and payment account.

Further, at the time of the renewal of permission of the LOs by the AD banks, they may note to endorse a copy of each such renewal to the office of the DGIT [International Taxation].
INDIAN LEGAL IMPETUS

PATENTING DNA- THE ETHICAL, LEGAL AND SCIENTIFIC CHALLENGES