4.1 Introduction:

The concept of intellectual property right is becoming important at the global level. During the last few decades all over the world after the establishment of WTO & GATT protection of intellectual property has become one of the central issues. Issues of generation, valuation, protection and exploitation of intellectual property (IP) are going to become critically important all around the world. India faces several challenges as regards IPR and their role in innovation. Weak physical infrastructure, inadequate intellectual infrastructure, poor public awareness are a few hurdles. The local communities or individuals do not have the knowledge or the means to safeguard their property in a system which has its origin in very different cultural values and attitudes. India has a rich heritage of traditional knowledge in the field of Ayurveda, Agriculture, Chemistry, Astrology and a number of other things where intellectuals right have not been protected in the modern sense of the term.

This chapter is devoted to presentation of the relevance of the protection of traditional Indian knowledge from intellectual property rights. The chapter is based upon case laws as is available from various judgements regarding intellectual property rights and traditional knowledge at various judiciary levels i.e. The District Court, High Court and Supreme Court. The chapter also analyses international judgements with reference to the subject matter under study.
This chapter explains the concept of traditional knowledge, in general with special reference to Indian context. It analyses the various sources of traditional Indian knowledge like Ayurved, Yoga, Sculpture, Metallurgy, Tantra, Astrology and other sciences including agriculture. The chapter further states incidences of sanction of patents for products which are in fact covered by traditional knowledge.

4.2 TRIPs - Its Nature and Scope:

The General Agreement on Tariffs and Trade [GATT] was nucleated in 1944 to foster a reduction in tariffs and quotas to arrive at ground rules for an effective trade liberalizing agreement. The GATT came into effect in 1948 and was mainly negotiated in 1947. In the 1970s, this graduated to include in its scope and coverage matters like technical standards and regulations, subsidies, anti dumping and government procurement. The Uruguay round between 1986 and 1994 resulted in the formation of the World Trade Organization (WTO). It elaborated many prior GATT obligations and extended its umbrella to service industries [banking, securities, telecommunications and insurance] and substantive rules of intellectual property law within the scope of Trade Related Intellectual Property Rights (TRIPs). These agreements and working procedures are expected to build business confidence and become key fact guiding decisions related to trade and investments.¹

The PRE-TRIPs ERA saw the world divided into groups of nations, following a wide range of standards in Intellectual Property Rights. For example, there were nations

- allowing patenting in all fields of technologies (products and processes)

• having restrictive patent laws providing for process patents in all fields of technologies but not for product patents in selected fields such as foods, agrochemicals, drugs and pharmaceuticals, chemical entities, etc.
• with diversity in “the term” of patents/copyright/trademarks/design registrations, conditions for compulsory licensing, “whether importation would be considered as working of patents” etc.
• with varying criteria for infringement and enforcement of IPRs.

These variations were serving as impediments for facile international trade in goods and services, especially in the area of technology transfer and legal diffusion of knowledge.

TRIPs recognizes that IPR are private rights, underlying public policy objectives of national systems for the protection of intellectual property, including development and technological objectives. It also recognizes the special needs of the least-developed nations in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.

TRIPs identifies the following IPR instruments and seeks to harmonize them at a global level:
• Copyright and related rights (i.e. the rights of performers, producers of sound recordings and broadcasting organizations)
• Trademarks including service marks
• Geographical indications including appellations of origin
• Industrial designs
• Patents
• Protection of new plant varieties
• Protection of the layout-designs of integrated circuits
• Protection of undisclosed information including trade secrets and test data
• Control of anti-competitive practices in contractual licenses

The 7 parts of TRIPs, distributed over 73 Articles [Table 3.1], outline the set of core universal standards with timeframe for protection and enforcement of IPR in Member Countries of the WTO. It is also expected to counter the growing menace of counterfeiting of products and services in the Member Countries of WTO.

TRIPs Articles and Obligations

The TRIPs agreement provides considerable room for its Members to implement the provisions and achieve a proper balance of various domestic/national interests. This would require a proper reading and critical interpretation of every article of the agreement.

The Council for TRIPs has been set up to (Article 68):

• monitor the operation of this Agreement and in particular, Members’ compliance with their obligations\(^2\)

4.3 Law & Cases Related with Intellectual Property Rights:

In this section the researcher has analysed law and cases related with intellectual property rights of various types.

Cases Related with Technology Transfer and Capability Building

Technology transfer is one of the significant issues related with Intellectual Property Right and Traditional Knowledge. Following articles of TRIPS are related with this issue.

**Articles 3 and 4** deal with the issues of national treatment and most favoured nation treatment. They require all members to treat nationals of other countries no less favorably than their own nationals on all matters concerning IPR, subject to certain exceptions already provided in convention/treaties related to IPRs. Similarly, advantages and privileges granted by a Member to the nationals of any other country should be extended unconditionally to the nationals of all other members.

**Article 5** deals with *Multilateral Agreements on Acquisition or Maintenance of Protection* and states that the obligations under Articles 3 and 4 do not apply to procedures provided in Multilateral Agreements concluded under the auspices of the WIPO, relating to acquisition and maintenance of IPRs.

**Articles 7, 8 and 67 of TRIPS** attempt to address such issues by creating flexible options in favour of the developing countries (DCs) and the least developing countries (LDCs) with respect to technology transfer and capability building.

- **Article 7** of TRIPs states, “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”

- **Article 8.1** states, “Members may in formulating or amending their laws and regulations, adopt measures to protect public health and nutrition, and to promote the public interest in sectors of vital
importance to their socio-economic and technological development, provided such measures are consistent with the provisions of the agreement.”

- **Article 8.2** of TRIPs states, “Appropriate measures, provided they are consistent with the provisions of the Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”

- **Article 67 deals with Technical Cooperation** between developed countries and DCs/LDCs in the WTO. In order to facilitate the implementation of this Agreement, developed country members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of DC and LDC members. Such cooperation shall include assistance in preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

A few examples of appropriate application of these provisions serve as illustrative examples of possible options.

**Case Study of US legislation limiting patentability of medical and therapeutic and diagnostic methods:**

This is one of the case study related with pharmaceutical technology.

On October 1, 1996 President Clinton signed an Omnibus Appropriations Bill that contained legislation limiting patentability of medical and therapeutic and diagnostic methods. The bill enacted into
law (P.L. 104-208) amended 35 U.S.C. section 287, by adding the following exemption from infringement liability: “With respect to a medical practitioner’s performance of a medical activity that constitutes an infringement under this title provisions of sections 281, 283, 284 and 285 of this title [which provide remedies for infringement] shall not apply against the medical practitioner or against a related health care entity with respect to such a medical or surgical procedure on a body”. Generally the thrust of this law is to prevent physicians or hospitals from monopolizing life-saving techniques or charging royalties from others’ use of such techniques.

It may be noted that the new law does allow for patenting of inventions in the medical and therapeutic field but makes exemptions for infringement of the IPR. This is an example of how legislation can be introduced to support “public interests” in a country and stay within the bounds of the TRIPs agreement.

Case Study of Move by countries in Africa:

The following case study related with the model bill formed by an Association of African countries.

In a recent move, all countries belonging to the Organization of African Unity (OAU) have formulated a model bill which states that ownership of new compounds made from natural products found in Africa “should rest with indigenous local communities for all times and in perpetuity.” This draft bill has been drawn up to harmonize African legislation on “bio-prospecting” by multinationals.

However, in a subsequent discussion and debate [Nature 398, 99 (1999)], a decision by 15 representatives of French-speaking countries in the OAU have recommended the latest version of the International
Convention for the Protection of New Varieties of Plants, known as the UPOV convention. A final policy is yet to be formulated.

**Case of Chinese Legislation Banning Unauthorized Transfer of Biological Materials from China:**

Following is the case of Chinese Legislation. This example is being cited even though China is not yet a member of the WTO. However, such legislations are well within the purview of the WTO obligations.

In September 1998, China adopted a broad set of regulations on the collection and use of its ‘human genetic resources’ as a restrictive measure to control exploitation by foreign biotechnology and pharmaceutical companies [20]. Official clearance and authorization will be required for any research project that seeks to “sample, collect, merchandise or export” human genetic resources from China. These are defined as “any materials of and from human beings that contain human genome, genes or gene products, or parts thereof.” China has simultaneously launched major initiatives in human genomics with budgets over 250 million Yan (i.e. US $ 30 million) for the next three years.

**Protection of Existing Subject Matter**

Article 70 is related with protection of existing subject matter. This is a very elaborate article which needs to be understood in its entirety as it deals with a very important aspect of a subject matter that is already in the public domain. *Members are under no obligation to restore protection to subject matter which on the date of application of the TRIPs agreement for the Member in question has fallen into the public domain.*

Some relevant sections of TRIPs are as follows:
• **Article 70.7** allows for amendment of claims enhanced protection in the case of IPR applications pending on the date of application of the TRIPs agreement.

• **Articles 70.8 and 70.9**, however, require the member States to make a provision for the filing of product patents in case of pharmaceuticals and agro-chemicals and also have provisions for the granting of Exclusive Marketing Rights (EMR) as of 1.01.1995.

**The Case Study of Amended Patent Act (1999)-India:**

In this connection the case of India’s amended patent act can be sited.

The Patents Amendment Bill (1999) in India had taken this feature into consideration while incorporating the conditions of “pipeline protection” and “exclusive marketing rights” (EMR) for pharmaceutical and agro-chemical products. Under this clause, items for the purposes of Section 24A in the Amended Patent Act, **EMR would not be given for any article or substance based on the system of Indian Medicine as defined in clause (e) of subsection (I) of section 2 of the Indian Medicine Central Council Act, 1970 and where such article or substance is already in the public domain.**

**Protection of Computer Programs:**

Modern world is the world of computer revolution. Protection of computer programs is becoming necessary day by day. With software playing a crucial role in business processes, its protection will become a major issue in the coming years, especially with the growth of e-commerce applications.
Some of the related regulations of Article 10 of TRIPs are as follows:

Computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (Article 10.1 of TRIPS).

However, the TRIPs agreement allows for reverse engineering of computer programs by fair means. This prohibits unauthorised copying of computer programs, but allows the practice of re-implementing functional components of protected programs in “clones”. These open provisions can be exploited to establish fair competition in the market.

- **Article 10.2** states that compilation of data or other material whether in machine readable form or any other form which by reason of selection or arrangement of their contents, constitute intellectual creations, shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself.

  This does not come in the way of any WTO member country protecting computer programs through other IPR instruments such as patents. USA is an example of a country where all the provisions of the copyright are available in addition to the possibility of patenting software for a variety of purposes.

- **Article 11** dealing with *Rental Rights* expects Members, in respect of at least computer programs and cinematographic works, to provide the authors and their successors in title the right to authorise or to prohibit the commercial rental to the public the originals or copies of their copyright works. A member shall be expected from this obligation in respect of cinematographic works unless such rental has led to widespread copying of such works.
which is materially impairing the exclusive right or reproduction conferred in that Member on authors and their successors in title. In respect of computer programs, this obligation does not apply to rentals where the program itself is not the essential object of the rental.

**Case Study of State Street Bank & Trust Co. vs Signature Financial Group**

This is a case related with cyber signature.

The controversial issue whether software per se is patentable needs to be resolved. Software is protected by copyright in most parts of the world. However, the 1998 judgement by the US Court on *State Street Bank & Trust Co. vs Signature Financial Group* decision held computer software for conducting methods for doing business to be a patentable subject matter. In 1993, Signature received a patent for its data processing system for hub-and-spoke structured funds. The system simplifies the calculating of net asset value (NAV) of funds participating in a hub-and-spoke system. Under the hub-and-spoke mutual fund structure, the hub receives and manages the assets that come in through different spokes or distribution channels. In a July 1998 decision, the US appeals court decided that using a mathematical formula with the aid of a computer is patentable when it produces “a useful, concrete and tangible result” such as a fund NAV. This decision by the US court adds a new dimension to protection of inventions related to software.

However, a harmonized approach on the issue by all countries will be essential to ensure fair trade among nations.
Domain Name:

Several steps have been initiated by nations for incorporating special clauses in their cyber laws that are being formulated by them. There have been several judgments from courts in various parts of the world in the last two years that discourage and penalize cybersquatting. This area is of critical importance in the field of e-commerce and needs rapid progress through international cooperation. In a few recent judgments on “domain name hi-jacking” or cybersquatting in the UK, the judges made the following observations: “Any person who deliberately registers a domain name on account of its similarity to the name, brand name or trade mark of an unconnected commercial organisation, must expect to find himself on the receiving end of an injunction to restrain the threat of passing off.”

Case of YahooIndia.com:

This is a case related with domain name.

Similarly in a trademark infringement case in 1999 brought up by Yahoo Inc, the Delhi High Court ruled that trademark laws are just as valid on the Internet as in the physical world. Yahoo Inc. filed a suit against Akash Arora and Netlink Internet Services, accusing the two of passing off their services on the Internet through their adoption of the domain name “YahooIndia.com”.

The court rejected the defendants’ arguments, noting that –

- Trademark law is applicable with equal force on the Internet as it is in the physical world
- using the same names will result in confusion and deception where the parties are in the same or similar business line
- a very alert vigil is a must and a strict view should be taken where there is copying over the Internet because of its easy accessibility
putting a disclaimer that the defendants have nothing to do with Yahoo! did not reduce the chances of deception and confusion. Such cases are on a continual increase.

**Protection of Undisclosed Information**

The protection of trade secrets and undisclosed information is an area that is attracting a lot of attention. *Article 39 of TRIPs* includes minimum standards for the protection of undisclosed information and data submitted to governments or governmental agencies as required in the case of pharmaceutical and agricultural chemical products, which utilize new chemical entities. Undisclosed information in the form of trade secrets is also protected under this article.

A survey conducted by the American Society for Industrial Security (A SIS) on intellectual property loss by Fortune 1000 companies and the 300 fastest growing companies in the US reveals that $44 billion were lost due to known and suspected intellectual property losses during a 17-month period in 1996-1997. The seriousness of this issue would be magnified if one is to consider that the $44 billion sum was calculated on the basis of the responses of only 12% of the survey participants. To guard themselves against trade secret theft, companies are encouraged to implement information protective measures, such as clearly identifying trade-secret assets, practicing “due care” when it comes to persons who are authorized to have access to trade secrets, and making use of codes. Though employment contracts broadly cover clauses on confidentiality of information, most business houses and institutions do not take adequate care of information security procedures within their organizations. The emerging trend is that companies are requiring their employees to sign invention assignment agreements in addition to confidentiality clauses as part of their employment contracts.
Case Study of Motorola vs Integrated Circuit Systems (ICS)

Motorola in July 1999, filed a lawsuit against ICS and several managers who left Motorola while working in its Timing Solutions Operation, to set up a new ICS operation. Motorola’s complaint was that ICS did this to gain access to Motorola’s business and technical trade secrets and that the managers who left, had breached fiduciary duties and misappropriated trade secrets. Though ICS and the former Motorola managers denied the allegations, a settlement was reached on March 27, 2000, where Motorola agreed to:

- dismiss the lawsuit in exchange for the defendants’ agreement to make an undisclosed monetary payment,
- refrain from using or disclosing Motorola’s confidential information, and to refrain from using certain design technologies for limited time periods,
- restrict further hiring and solicitation of Motorola employees and
- grant Motorola certain rights to use certain ICS intellectual property.

Case Study of Walmart vs Amazon.com:

Walmart had filed a suit in a US Court against Amazon.com, claiming that Amazon was attracting executives and employees of Walmart, together with their consultants, to access the trade secrets of Walmart. The case was settled in 1999. Under the terms of the settlement, Amazon agreed to reassign some of its employees where their knowledge of Walmart’s operations would not be used. Limits were also placed on the projects to which the former Walmart workers were involved in Amazon’s operations.
Case Study of ColorSpan vs Sentinel Imaging:

ColorSpan vs. Sentinel Imaging dealt with a case on infringement of Trade Secrets, in which ColorSpan was awarded $2.2 million in damages in a 1997 judgement. ColorSpan alleged that Sentinel had stolen part of its market of consumables for its wide-format InkJet printers by hiring two former ColorSpan employees who imparted trade secrets and customer information.

The Assignment Agreement linked to IPR in addition to Confidentiality Agreements ensures a commitment from the employees to protect the company’s intellectual property which includes all creative aspects of employees’ work, innovations, company sensitive information—such as client lists, financial information, price lists, copyrights, trade secrets, trademarks. This is becoming crucial in times of mergers, acquisitions, aggressive “head-hunting” in ensuring proper protection, enforcement and transmission of intellectual property rights.\(^3\)

4.4 Rights of an IPR Owner

Intellectual Property Rights grant “Rights of Exclusion” to the holder. TRIPs attempts to harmonise patent laws in its Member Countries and also set up guidelines for minimum standards for enforcement of these rights.

A patent confers on the holder the rights to exclude others from making, using or selling the protected invention in the territory in which it is granted. This right is enforceable for a period during which the patent remains valid or till the period during which the holder maintains the patent rights through payment of renewal fees (maximum up to the full term of the patent, which is 20 years from the date of filing the patent.

application). Patent rights are territorial. Therefore a patent granted in country A is valid and enforceable only in country A. If it has not been granted in another country, say B, then the patentee who has a patent in country A cannot enforce his rights in country B. He must also maintain the granted patent in all the countries if he desires to have his rights enforced in those countries. Hence, the patentee must evaluate all the countries of relevance to his business and file the patents and have them granted in all those countries. It is also to be appreciated that national courts follow IPR laws as applicable in their own countries. They may, however, refer to and derive precedents from earlier judicial decisions from other countries. It is not binding on the courts to be led by preceding judgements as every case is to be evaluated and judged on the facts and merit.

Case Study of Licensing Agreements

Licensing agreements may be classified into the following categories:

- **Technology Licences:** Covering patents, patentable inventions, trade secrets, know-how, confidential information, copyrights in technical material (software, databases, instruction manuals), and *semiconductors mask works*.

- **Publishing and Entertainment Licences:** Cover copyrights in creative properties such as books, plays, movies, videotapes, television productions, music, and multimedia.

- **Trademark and Merchandising Licences:** Cover trademarks, trade names, trade dress (the way products or services are packaged or presented), and rights of publicity.

An excellent example of variable interpretation of a licence agreement is the dispute between *The British Technology Group Ltd*
(BTG) and Boehringer Mannheim Corporation & DePuy Orthopedics Inc. involving a set of pending patents and applications covering an invention concerning artificial hip joints.

The issue here was to what extent an agreement signed on February 28, 1989 between BTG and DePuy protects or indemnifies DePuy on the use of a disputed patent of BTG. The other issue in question was the royalty structure and obligations on DePuy if BTG settled its disputed patent with the other party concerned.

BTG was the owner of a patent termed “Church Patent” which claimed an invention for the socket in the hip joint. Church had also filed the same patent in the USA in 1983, claiming the priority from April 7, 1992. In November 1993 a patent referred to as the “Noiles” patent was filed in relation to the same invention by some other party. However, the Noiles patent covered the socket and the ball of the hip joint. This was assigned to a company called Joint Medical Products Corporation (JMP), which later disposed off its business to Johnson and Johnson Professional Inc.

Between 1985 and 1990 DePuy had an agreement with JMP under which DePuy’s sales force in the USA marketed JMP products in addition to DePuy’s products. DePuy was notified of the Noiles patent when it was granted in 1987. DePuy told JMP that they had made the same invention earlier and in 1988 JMP applied to the USPTO for a “reissue” of the Noiles Patent (i.e. opposition/interference proceedings).

In 1987 DePuy first became aware of the Church patent in the UK and decided to take a licence from BTG for sales outside of the USA. The Church patent in the USA was pending. However, they evaluated the chances of the Church patent being granted in the USA and felt that the Church patent may be cited as a prior art to the Noiles patent which in turn could make the Noiles patent invalid.
Accordingly DePuy signed a licence agreement with BTG in February 1989.

The judgment went into detailed analytical interpretation of the above licence agreement including the “tense sensitivity” of the word “license”. It also drew scenarios of what the interpretations could be in terms of commitments of BTG and DePuy:

- if either of the patents in the USA were declared invalid
- if either of them were valid
- if both were declared valid.

The judgment is fairly intricate.

**Criteria for Patent Infringement**

Infringement of a patent takes place when “the sole right to make use, exercise or vend the patented invention is denied to the patent holder by someone who puts the patented invention to practice without the legal consent/license of patent holder.”

**Case Study of SmithKline Beecham (SB) & SmithKline Beecham Seiyaku KK (SBS) vs Fujimoto Pharmaceutical Co.:**

[Tokyo District Court, 1998]

- SmithKline Beecham had filed a process patent in Japan on Cimetidine in September 1973- It was granted after eight years and was valid till September 5, 1993-
- In December 1986, Fujimoto imported the infringing product from Yugoslavia (now Slovenia) and sold 68,000 tablets in Japan. Fujimoto also manufactured a generic version of Cimetidine Cylock.
• SB claimed that Fujimoto had infringed their patent from December 1986 to September 1993.
  • Fujimoto argued that their process was not covered by the SmithKline patent.
  • The Judge found Fujimoto liable for patent infringement.
  • The court awarded SB and SBS Yen 500 million ($4.2 million) in royalties and Yen 2.5 billion ($21 million) in lost profit based on a 15% profit rate.

This is the largest award ever in a Japanese patent infringement case. [Source: Tessenson J and S Yamamoto, Managing Intellectual Property, n 85, p 32-35, December 1998]


The Facts

Fonar was awarded US Patent No. 48719660966 patent) dealing with the use of magnetic resonance imaging technique (MRI) in order to obtain multiple image slices of a patient’s body at different angles in a single scan referred to as multi-angle oblique (MAO) imaging. This resulted in shortening of imaging times and hence allowed for more patients per day.

US Patent No. 37898320832 patent) was also awarded in favour of Fonar for using NMR imaging technique to detect cancer by measuring electron spin relaxation times T1 and T2 in the sample tissue and then comparing them with the standard values in normal and cancerous tissue of the same type.
Fonar sued GE for infringement of these two patents asserting infringement of claims 1,2,4,5 and 12 of ‘966 patent and claims 1 and 2 of 1832 patent.

Fonar had also sued Hitachi for infringement but Hitachi reached an out of court settlement with Fonar.

The jury at the Eastern District Court of New York returned a verdict finding that the asserted claims were not invalid and were infringed by GE [902 F. Supp. 330CE.D.N.Y. 1995]). As compensation for the infringement the Jury awarded Fonar.

- $27825000 as lost profits on 75 machines of the 600 MRI machines GE sold
- $34125000 as reasonable royalty on sales of remaining 525 machines
- $13625000 as damages for GE’s inducement to infringe the patent. (This was withdrawn by the Fed. Cir. in a subsequent appeal by GE.)
- $35,000,000 as reasonable royalty damages for GE’s infringement of the ‘832 patent.

GE appealed against this judgement. The court then ruled that GE did not induce infringement of the ‘966 patent as it had no notice of the patent. Fonar failed to mark the scanners that are subject to inducement claim and that there is no liability for inducement to infringe where the original purchaser had a right to repair and service the scanners. Therefore, the damages of $13,625,000 was withdrawn. Also the court concluded that ‘832 patent was not infringed. The damage due to this was also withdrawn. The court then awarded Fonar prejudgment interest and entered a final award against GE in the amount of $ 68,421,726.
Proceedings at the Federal Court of Appeals

Fonar cross-appealed. The Federal Court of Appeals re-looked into the matter and concluded

- The ‘966 patent satisfied the best mode requirement as it disclosed adequate and appropriate information of the invention for anyone trained in the art to practice the invention.
- There was direct infringement of the ‘966 patent.
- Though Fonars’ patent had expired for a short period due to failure to pay a maintenance fee the lapse period did not apply to GE which had infringed the patent since 1992 and did not first begin infringing during the lapse period.
- The machines that GE serviced were not marked so that damages were not recoverable before Fonar gave notice to GE. Therefore GE did not induce infringement of the ‘966 patent.
- There was evidence that GE machines performed an equivalent step (b) and step (c) of claim 1 of the ‘832 patent and hence the patent ‘832 is indeed infringed by GE. The court reinstated the $35000000 as reasonable royalty damages for GE’s infringement of the ‘832 patent.
- GE was finally ordered to pay $ 128.7 million ($110.5 million as damages plus interests).

Conclusion of this case

Fonar is a strongly innovation led and IPR sensitised company. It has a sound corporate IPR policy. It drafts its patents with extreme care, especially as it is involved in complex convergence technologies. Despite this focused thrust on its IPR, it failed to pay maintenance fees on time leading to the lapse of patent rights on the ‘966 patent for a short period.
It also failed to mark the instruments with “patents pending” which helped GE to escape the charge of “inducing infringement” while servicing the Fonar instruments. However, its litigation strategy and approach shows a good coordination between its technical and legal teams.

It may be noted that Fonar’s annual revenue was only $17 million. However, it won an award of 128.7 million for the infringement of its 2 patents. The exact amount obtained from the out of court settlement with Hitachi is not known but was substantial.

It also illustrates the value of protecting corporate intellectual assets. This case brings on board the importance of a cohesive approach to management of IPR in a corporate.

**Case Study of Genentech Inc. vs Novo Nordisk, A/5, Novo Nordisk of North America, Inc. and Novo Nordisk Pharmaceutical, Inc.:**

[No. 96-144, 1997 US Fed. Cir. 13 March 1997]

This case deals with a sophisticated technique in Biotechnology and illustrates the problems with any emerging technology vis-a-vis varied interpretations by the courts. In this case the same patent claims were interpreted differently by the District Court and the Court of Appeals to decide on the adequacy of the disclosures in the patent specification for any skilled person in the act to reproduce the invention.

It also drives home the point that drafting of patent specifications has to be done with extreme care and with the use of appropriate technical terms, build up a proper protection.

**The Facts**

Genentech was assigned the US Patent 4,601,980 (‘980 patent) which described a recombinant DNA method for producing a ‘191-’192
amino acid human growth hormone (hGH) expression product that is identical or essentially identical and functionally equivalent to the natural hormone. The product is useful in treating hypopituitary dwarfism in children.

Novopharma does not produce human growth hormone by direct expression. Rather, it produces it by what is called a “cleavable fusion expression” process using a bacterial host, which expresses a fusion protein consisting the hGH molecule and the additional amino acids. In a final step, the additional amino acids are cleaved leaving a hGh product of 191 amino acid.

The Issue

A patent infringement action was first brought in the United States District Court on November 30, 1994. On May 12, 1995, Genentech moved for a preliminary injunction under U.S. Patent 4,601,980 to prevent Novo from importing, marketing, using, selling, offering for sale or distributing in the United States, its Norditropin (reg.brand) recombinant hGH product.


On appeal the Court of Appeals of the Fed. Cir. vacated the injunction. [Novo Nordisk of North Am., Inc. vs. Genentech Inc., 77 F.3d 1364, 37 USPQ2d 1773 (Fed. Cir. 1996)]

The court based its judgment on interpretation of the specification and prosecution history, and concluded that because the claim used the phrase “human growth hormone unaccompanied by . . . other extraneous protein,” it was limited to processes for directly expressing either hGH or
met-hGH [Id. at 1371, 37 USPQ2d at 1779.] As the parties agreed that Novo did not use direct expression to produce these proteins, the court of appeals concluded that Novo did not infringe the patent.

Genentech then asserted its newly issued US Patent 5,424,199 (the ‘199 patent). The ‘199 patent has the same specification as the ‘980 patent and contains a single claim disclosing a method for producing hGH by expressing DNA coding of hGH-conjugate protein. The method consisted of expressing the conjugate protein consisting of hGH and an additional amino acid sequence that was cleavable by enzymatic action and then cleaving extracellularly the conjugate protein to produce hGH.

On June 27, 1996, the District Court again issued a preliminary injunction, this time based upon the ‘199 patent, enjoining Novo from importing, marketing, using, selling, offering for sale, or distributing in the United States its Norditropin (reg.-brand) recombinant hGH product [Genentech vs. Novo Nordisk A/S, 935 F. Supp. 260 (S.D.N.Y. 1996)]. The District Court based its decision upon, inter alia, a finding that Genentech would likely overcome Novo’s defense that the 199 patent was invalid for lack of an enabling disclosure.

Novo appealed to the Federal Circuit, challenging the grant of the preliminary injunction.

The Proceedings
Genentech had to establish its right to a preliminary injunction in light of four factors –

- a reasonable likelihood of success on the merits
- irreparable harm if the injunction were not granted
- the balance of hardships
- the impact of the injunction on public interest.
Novo’s argument was that the patent specification would not have enabled a person of ordinary skill in the art to practice the claimed invention without undue experimentation. Novo also claimed that the specification fails to contain a written description of the claimed invention. Regarding enablement, Novo argued that the patent is invalid because it does not contain sufficient detail concerning the practice of the claimed method. Novo stated that the mere generic statement of the possibility of cleavable fusion expression, along with the DNA sequence encoding hGH, a single enzyme (trypsin) for cleaving undisclosed conjugate proteins, and a statement of that enzyme’s cleavage sites as being potential amino acid extensions conjugated to hGH is not an enabling disclosure commensurate in scope with the claim.

Genentech argued that those skilled in the art of recombinant protein expression and purification at the time of filing, July 5, 1979, would have been able to use cleavable fusion expression to produce hGH without undue experimentation by using the teachings of the specification, along with methods and tools well known in the art.

The court observed that –

- column 7, lines 29-59, does not describe in any detail whatsoever how to make hGH using cleavable fusion expression. For example, no reaction conditions for the steps needed to produce hGH are provided, and no description of any specific cleavable conjugate protein appears.

- The relevant portion of the specification merely describes three (or perhaps four) applications for which cleavable fusion expression is generally well-suited and then names an enzyme that might be used as a cleavage agent (trypsin), along with sites at which it cleaves (“arg-arg or lys-lys, etc.”).
Thus, the specification does not describe a specific material to be cleaved or any reaction conditions under which cleavable fusion expression would work. This specification provides only a starting point, a direction for further research. The specification indicates that it purports to solve a problem.

The specification for the ‘199 patent, which is the same as the specification for the ‘980 patent, does not provide a specific enabling disclosure concerning what the new claim recites, viz. obtaining hGH by cleaving an hGH-containing conjugate protein. The patent now purports to claim the unresolved problem that which the ‘980 patent overcame. No one had been able to produce any human protein via cleavable fusion expression as of the application date. The court further stated-

“If, as Genentech argues, one skilled in the art, armed only with what the patent specification discloses (a DNA sequence encoding a human protein, in this case, hGH, and a single example of an enzyme and its cleavage site), could have used cleavable fusion expression to make a human protein without undue experimentation, it is remarkable that this method was not used to make any human protein for nearly a year. DNAs encoding desirable human proteins were known at the time of filing (e.g., insulin, described in the British patent), and a great many researchers were attempting to produce human proteins using recombinant DNA technology. This failure of skilled scientists, who were supplied with the teachings that Genentech asserts were sufficient and who were clearly motivated to produce human proteins, indicates that producing hGH via cleavable fusion expression was not then within the skill of the art.

Moreover, it stands to reason that if the disclosure of a useful conjugate protein and the method for its cleavage were so clearly within the skill of the art, it would have been expressly disclosed in the specification, and in the usual detail.
In addition, as indicated above, the specification of this patent was clearly drafted to claim the invention of obtaining hGH unaccompanied by extraneous protein, the cleavage of which was identified by the specification as a problem in this field. Genentech’s inventors knew how to enable that which they had invented. These facts underline the inadequacy of the specification in enabling that which it provided only a means to avoid.

The record indicates that the disclosure of trypsin and its cleavage site does not enable the production of any conjugate protein from which hGH can practically be cleaved and thus produced in useful form without further undue experimentation. Genentech has not shown that the 199 patent provides that teaching.”

The Court of Appeals held that –

- Claim 1 and hence the ‘199 patent are invalid as a matter of law for failure of the specification to enable the practice of the claimed method.
- Genentech had failed to show a likelihood of success on the merits since the ‘199 patent is invalid for failure of the specification to meet the enablement requirement.

Accordingly, Court of Appeals vacated the injunction and instructed the district court to dismiss Genentech’s claim for infringement of the ‘199 patent on the ground that the patent is invalid.4

Lessons Learnt

Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. While every aspect of a generic claim certainly need not

---

have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. That requirement has not been met in this specification with respect to the cleavable fusion expression of hGH

- In case of an invention whose application is of an unpredictable technology in the early stages of development, an enabling description in the specification must provide those skilled in the art with a specific and useful teaching.

4.5 Law & Cases Related with Traditional Knowledge:

In this section the researcher has analysed law and cases related with Traditional Knowledge.

Traditional knowledge is dynamic and is not frozen in time. In addition to the constant flux in traditional knowledge, there are complex economic and emotive issues in attempting its “invitro” documentation in Databases that preserve in a fair manner the cultural, spiritual and well being of the knowledge holders with equitable sharing of benefits from the utilisation of their knowledge.

The problems in the creation, standardisation and maintenance of such a portal for encapsulation of global traditional knowledge are fraught with difficulties involving multiple terms, expressions, forms, languages etc. Other allied issues are:

- Continuous process of verification, adaptation and creation, altering in form and content in response to changing environmental and social circumstances
- wide variability in community knowledge
- unstructured retention of knowledge
moral issues centering unconsented placement of community knowledge into public domain for easy access. This accepts that not all community knowledge is in public domain as they may be closely held within families, groups or individuals. It may disturb their tradition-based knowledge protection and transmission system

- imposing on community privacy and sentiments
- fear of unfair commercial exploitation
- indiscriminate exploitation of the natural habitat
- perception that publication of community knowledge would create societal imbalances, etc.
- inadequate legal protection of community traditional knowledge

However these are not insurmountable issues as advanced IT techniques should be exploited to find innovative solutions.

The present IPR system addresses the need of an industrial society and is generally debated as predatory to interests of traditional indigenous societies. It must be appreciated that a variety of opinions have been expressed in such debates. Newer forms of IPR and innovations are required to address issues linked to protection of traditional knowledge. The concept of community registers for community innovation and knowledge has been developed by several NGOs [6-7]. The content and structure of these “databases” and community registers are therefore most critical for them to be useful, effective and enforceable.

Some of the relevant databases are [8]:

- NAPRALERT which is a database drawn from over 100,000 technical papers, referencing more than 43,000 species of plants and animals and documents over 100,000 chemical compounds.
- Database of ethno-pharmacology of Indian medicinal plants is being constructed in a collaborative programme between The
Royal Danish School of Pharmacy and the Tropical Botanical Garden and Research Institute (TBGRI), Trivandrum.

- Council of Scientific and Industrial Research (CSIR, India) volumes on Wealth of India with details on India’s plant and mineral wealth
- CSIR’s CDROM on Medicinal and Aromatic Plants Abstracts.

These are clearly inadequate to serve the total needs of patent offices. The critical point of contact of traditional knowledge systems with modern IPR system is the definition of prior art as it provides a practical criterion to evaluate whether and invention is “new” or “novel”. Recent revocation cases establish beyond doubt the need for systematic and authentic documentation of traditional knowledge so that patent examiners in any country can refer to them in their regular literature search while establishing teachings from prior art and avoid erroneous issue of patents especially those based on or linked to traditional knowledge.

The issues and revocation of several patents (turmeric US Patent 5,401,5041, neem EPO Patent no. 436257, ayahuasca US Plant Patent 5,751 discussed as case studies in later sections) related to traditional knowledge demonstrate this feature. A recent study by an Indian expert group indicated that, out of 726 US patents, which were granted under A61L35/78 and other International Patent Classification (IPC) having a direct relationship with medicinal plants, 374 (49%) patents were found to be based on traditional knowledge. It is not obvious as to how many of these granted patents would survive if challenged or re-examined based on a rigorous prior art search of traditional knowledge. This is a point of much concern and must be addressed with urgency.

It has been suggested that SCIT Working Group of WIPO on Standards and documentation in collaboration with International Patent
Classification (IPC) Committee of Experts undertake a project on the development of a Traditional Knowledge Digital Library (TKDL). The TKDL portal would have a web based search interface providing full text search and retrieval of traditional knowledge. Issues and sensitivities will have to be addressed while creating and maintaining TKDL. Some lead work in this area including Traditional Knowledge Resource Classification (TKRC) has been initiated in India at the behest of the Department of Indian Systems of Medicine and Homeopathy. It is envisaged that several such activities would be initiated in various parts of the world to document their regional traditional knowledge, which ultimately is accessible through a common TKDL portal in the Internet. Under the SCIT implementation plan of WIPO, a feasibility report on traditional knowledge database has been planned. Another IT based network initiated by WIPO is to establish a global IPR information network centered on WIPO and serving all the Member States is the WIPONET. This link would serve to enhance information access concerning intellectual property rights, reduce costs, time and encourage information dissemination and sharing. Easier availability of information would aid examiners in Patent and Trademark offices across the world to assess the current state of traditional knowledge while conducting their examinations thereby inducing greater reliability in the patent granting process. It would also serve to gel the learnings from traditional practices on a worldwide basis and provide an impetus for further innovation.

**Case Study**

Revocation Challenge of US Plant Patent 5,751 (Da Vine Patent) at the USPTO by The Centre of International Environmental Law (CIEL) on Behalf of the Coordinating Body of Indigenous Organisations of the
The Patent as claimed

The US Plant Patent No. 5,751 filed by Miller on November 7, 1984 and granted on June 17, 1986 claimed to have invented a “new and unique” variety of Banisteriopsis caapi distinguished from typical forms of the plant by:

- Leaves of different sizes, shapes and texture
- Different size pedicelse
- Greater pubescence
- Different flower colour and size and
- Absence of samaras or nuts (i.e. the plant is sterile)

The patent states that the new variety is “particularly characterised” by the “rose colour of its flower petals, which fade with age to near white” and by its “medicinal properties”. Miller stated that he had obtained a cutting of the plant from a “domestic garden in the Amazon rain-forest of South America.” He added that he was investigating the plant for its medicinal value. In summarising the “invention” the patent claims that the new variety “is an attractive house plant which seasonally blooms” and that is being investigated for its “medicinal value”.

The patent claims that the new variety is distinctive from typical forms of B.caapi that were derived solely from a comparison between a plant grown by the patentee at Harold Lyon Arboretum, Oahu, Hawaii and the description of B.cappi contained in the Gates Monograph. The patent does not mention any comparisons having been made with mounted specimens from public collections of the major herbaria located in the United States that specialise in this Malpighiaceae family or in plants of the region where the sample of B. caapi was collected.
Background of the US Plant Patent Act

35 U.S.C. section 161 et seq., permits a patent to be awarded to a person who:

- Invents or discovers and
- Asexually reproduces
- A distinct and new variety of plant
- Other than one found in an uncultivated state.

The Act is designed to give patent protection to distinct and new cultivated sports, mutants, and hybrids, so that plant breeders have an incentive to preserve for posterity newly created plant varieties that might otherwise be lost. The Act does not award property rights to those who discover previously unknown varieties already existing in the wild (found in the uncultivated state); rather it is intended to recognize and protect inventions of plant breeders “who work in aid of nature”.

Grounds for re-examination of the patent

The Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA), an umbrella group representing over 400 indigenous tribes of the region, discovered in 1994 that Miller had obtained his patent. Indigenous peoples were unable to fathom how a plant known and cultivated by them throughout the rainforest since time immemorial for religious and medicinal purposes could have been “discovered” and patented by an outsider. Learning that Miller intended to install a pharmaceutical laboratory in Ecuador to process ayahuasca and other plants, they further feared that a bilateral intellectual property reciprocity agreement on the verge of approval between the United States and Ecuador would force indigenous peoples of the Amazon to recognize Miller’s proprietary rights over their sacred plant.
On behalf of COICA and the Amazon Coalition, CIEL filed a “Request for Re-examination” of U.S. Plant Patent 5,751 (the Request) on March 30, 1999. The grounds for the re-examination of the patent were:

The claimed differences distinguishing the “Da Vine” cultivar from typical forms of B. Caapi are either of no significance or do not exist, such that “Da Vine” is not distinct from B. Caapi generally, and thus cannot be a new variety for the purpose of the Plant Patent Act. The traditional Amazonian healers have long known about the psychotherapeutic value of this variety as they used it to treat a wide array of organic malfunctions whose origins may be emotionally or psychologically precipitated, that indigenous peoples often believe are related to witchcraft, [lack of distinctiveness, novelty, and usefulness of the cultivar].

“Da Vine” is indistinguishable from typical forms of B. Caapi that both occur naturally in Amazonia and are cultivated by indigenous peoples there, and thus fall under the statutory prohibition against patenting wild plants.

Issuance of the Da Vine Patent does not meet public policy and morality aspects of the Patent Act’s utility requirements because it purports to create private rights over the use of an entire species which forms a sacred element in the most important rituals of a large number of cultural and ethnic groups of South America. For centuries, shamans of indigenous tribes throughout the Amazon Basin have processed the bark of Banisteriopsis Caapi, along with other rainforest plants, to produce a ceremonial drink known as “ayahuasca” or “yage.” The shamans use ayahuasca in religious and healing ceremonies to diagnose and treat illnesses, meet with spirits, and divine the future. According to tradition, ayahuasca—which means, “vine of the soul” in the Quechua language—
is prepared and administered only under the guidance of a shaman. Indigenous peoples have characterized the ayahuasca vine as a religious and cultural symbol analogous to the Christian cross or Eucharist.

The opponents also raised the issue that uncited prior art available in major US herbaria before the patent application was filed in November 1984 reveal, however that the claimed distinction from typical forms of B. Cappi, is in fact non-existent.

The point in question is whether accession sheets in herbarium collections are printed publications within the meaning of 35 U.S.C. as they are

- Dried samples of parts of plant specimens
- Written entries that identify the collector and include his or her notes describing the plant, the date and place it was collected
- Notations of the date the sheet was mounted in the collection

The point therefore to be established is to what extent the information in herbaria is indexed, catalogued and made accessible to the public including inspection for patent purpose. Issues of “public accessibility” and “probability of dissemination” become important.

The opponents argued that the herbarium sheets were mounted and added to the University of Michigan Herbarium in January 1981 more than a year prior to the date of the Da Vine patent application. They therefore should constitute prior art under 35U.S.C. Section 102(b) and for the purpose of the request for re-examination.

**The USPTO Decision**


The rejection was made on the narrowest grounds possible, under the statutory bar of 35 U.S.C. 102(b). Section 102(b) that prohibits, inter
alia, the issuance of a patent when the invention was patented or described in a printed publication more than one year prior to the date of patent application.

The rejection noted that the accessioned specimen sheets from the Field Museum in Chicago (offered as Re-examination Request Exhibits 1 and 2) contain specimens of B. Caapi whose major defining feature is flower colour indistinguishable from that of Da Vine. These sheets were known and available in the United States more than one year prior to the filing of Miller’s patent application. Because Da Vine’s major defining characteristic was its flower color, the PTO concluded that it could see no patentable distinctions between Da Vine and the plants mounted in the specimen sheets. Accordingly, Da Vine failed the § 102(b) statutory bar.

Herbarium specimen sheets recognized as “printed publications” by permitting 102(b)’s statutory bar to be met by these specimen sheets, the PTO confirmed in its rejection that such sheets qualify as “printed publications” for the purpose of determining a plant’s patentability. This is the first time the PTO adopted this interpretation of prior art publications. However, the interpretation is a logical extension of earlier decisions that recognized as printed publications single copies of doctoral dissertations cataloged in university libraries, and single copies of grant proposals indexed and publicly available on file with the National Science Foundation.

In a separate proceeding at the PTO, the three groups have called for changes in PTO rules. They argue that the PTO should require that patent applicants identify all biological resources and traditional knowledge that they used in developing the claimed invention. Applicants should also disclose the geographical origin, and provide evidence that the source country and indigenous community consented to its use.
Implication of this judgment

This landmark judgment- actually lays the foundation stone for establishing “non-conventional” forms of documentation of traditional knowledge as prior art. In this case it was a herbarium that was taken as prior art as it was accessible to “any one in the public” who was interested to know about it. Similarly the argument of “witchcraft” being a traditional practice based on symptomatic was extended to the concept of “psychotherapy” in modern terminology.

This paves new ways for structured documentation of traditional knowledge especially in the project on “Traditional Knowledge Digital Libraries”.5

Case Study

The BASMATI RICE Issue

US Patent No. 5663484 dated 2nd September, 1997 was granted to Rice Tec, Inc Alvin Texas, USA. This patent application No. 272353 was filed on July 8, 1994.

The Patent has been challenged by the Agricultural and Processed Foods Exports Development Authority (APEDA) at the USPTO on behalf of Government of India. The use of the term “Basmati” by Rice Tec has also been challenged on the grounds of inappropriate Trademark usage and violation of “geographical indication”. Basmati rice has been grown for centuries in the Greater Punjab Region (India and Pakistan).

This case study brings together several issues related to IPR into one and illustrates the complexities and inter-connections between the various IPR tools. The linkages and cross implications of the different IPRs in the market place and international trade are also demonstrated.

The matter is still under consideration in various courts and IPR granting offices. Their decisions will pave the way for new directions in evolving legal frameworks for protection of inventions, traditional knowledge, geographical indicatons, trademarks, etc.6

The Patent Claims

The summary of the invention related to a rice plant when cultivated in North Central or South America is as follows:

- The invention relates to novel rice lines and to plants and grains of these lines and to a method for breeding these lines. The invention also relates to novel means for determining the cooking and starch properties of rice grains and its use in identifying desirable rice lines.

- Specifically one aspect of the invention relates to novel rice lines whose plants are semi-dwarf in stature, substantially photo-period insensitive and high yielding and produce rice grains having characteristics similar or superior to those of good quality basmati rice.

- Another aspect of the invention relates to novel rice grains produced from novel rice lines. The invention provides a method for breeding these novel lines.

- A third aspect of the invention relates to the finding that the “starch index” (SI) of a rice grain can predict the grain’s cooking and starch properties, to a method based thereon for identifying grains that can be cooked to the firmness of traditional basmati rice preparations and to the use of the method in selecting desirable segregants in rice breeding programs.

---

There are 20 claims in the patent. The key patent claims are given below.

Some of the key claims are:

1. A rice plant, which plant when cultivated in North Central or South America, or Caribbean Islands
   (a) Has a mature height of about 80 cm to about 140 cm;
   (b) Is substantially photoperiod insensitive and
   (c) Produces rice grains having
      • An average starch index of about 27 to about 35.
      • An average 2-acetyl-1-pyrroline content of about 150 ppb to about 2,000 ppb.
      • An average length of about 6.2mm to about 8.0 mm an average width of about 1.6mm to about 1.9mm and an average length to width ratio of about 3.5 to about 4.5
      • An average of about 41% to about 67% whole grains and
      • An average lengthwise increase of about 75% to about 150% when cooked.

2. The rice plant of claim 1, wherein said starch index of 1) consist of the sum of percent amylose of about 24 to about 29 and of alkali spreading value of about 2.9 to about 7.

3. The rice plant in claim 2, wherein said rice grains additionally have an average burst index of about 4 to about 1.

4. The rice plant of claim 2, wherein said rice grains consist of less than about 20% chalky, white belly or white centre grains.

Claim 15-17 are very general and broad in character. They are:

15. A rice grain which has
    • A starch index of about 27 to about 35
• A 2-acetyl-1-pyrroline content of about 150 ppb to about 2,000 ppb
• A length of about 6.2 mm to about 8.0 mm a width of about 1.6 mm to about 1.9 mm and a length to width ratio of about 3-5 to about 4.5
• A whole grain index of about 41 to about 63
• A lengthwise increase of about 75% to about 150% when cooked and
• A chalk index of less than about 20

16. The rice grain of claim 15 which has a 2-acetyl-1-pyrroline content of about 350 ppb to about 600 ppb.

17. The rice grain of claim 15 which has a burst index of about 4 to about 1

The issues under debate.

India fears the patent will severely damage exports from its own farmers to the US. In 1998, they exported almost 600,000 tonnes of Basmati rice.

In June 2000 the APEDA on behalf of the Indian Government filed voluminous scientific evidence to the US Patents and Trademarks Office, insisting that most high quality Basmati varieties already possess these characteristics. The US Patent and Trademarks office accepted the petition to re-examine its legitimacy.

India has also objected to RiceTec calling the rice ‘Basmati’ insisting the name should be used only for rice grown in the Basmati region of India and Pakistan. The Indian government is claiming similar status for Basmati rice as that granted to Champagne, Cognac and Scotch whisky (Article 23 of TRIPs)
India’s legal challenge is being supported by Action Aid.

The International Center for Technology Assessment (ICTA; Washington, DC) and the Research Foundation for Science, Technology & Ecology (RFSTE; New Delhi) have filed a suit to restrict the use of the terms Basmati and Jasmine to rice varieties grown in India and Thailand respectively. Petitions filed with US government agencies (USDA and FTC) say that the mislabeling of American rice is deceptive, and threatens the livelihood of millions of Asian rice farmers.

The effort is to stop US rice millers, producers and trade associations from marketing low quality US aromatic rice under the terms ‘Basmati’ and ‘Jasmin’ in order to receive a premium price.

The Texas Company RiceTec Inc for example, sells US grown rice as “Texmati” which they define as American ‘Basmati’ and ‘Jasmati’ which they claim as American Jasmine.

Jasmine and Basmati rice types are grown in Asia. The petitions assert that current US regulations allow US companies to deceive consumers and threaten the livelihoods of millions of Indian and Pakistani farmers who grow Basmati rice and Thai farmers who grow jasmine rice.

Current US rice standards allow companies to use the terms “Basmati” and “Jasmin” as generic terms that can apply to rice grown anywhere.

One petition filed with the Department of Agriculture, demands that it amend its rice standards on “aromatic” rice to clarify that the term “Basmati” can only be used for rice grown in India and Pakistan, and the word “Jasmin” grown in Thailand.7

---

The other petition, filed with the Federal Trade Commission (FTC), demanded the agency initiate a trade regulation to prevent U.S. grown rice from being advertised or otherwise represented as “Basmati” or “Jasmin”.

The status of Legal Actions

- In September 2000 Rice Tec withdrew four of its claims related to uniqueness of its rice in the US Patent that dealt with specifications regarding the starch content and length of the grain in the claims 4, 15, 16 & 17. This is a major victory for APEDA’s challenge of the patent. The matter is still under the re-examination process with the USPTO.
- In January 1999 Rice Tec withdrew its application to use the trademark “Texamati” in the UK.
- In 1997 a Greek Court rejected a trademark application by Rice Tec for rice it described as American Basmati. This was also a challenge by APEDA.

Judgements on these issues are awaited with interest.

Learnings From Leading Case Studies

In the next sections a few recent case studies are discussed to highlight the concerns evoked in this chapter.

Case Study of Equitable sharing of benefits with Indigenous Tribes

The Tropical Botanic al Garden and Research Institute, Thiruvananthapuram, Kerala State, India (TBGRI) developed an innovative procedure for the equitable sharing of benefits with the tribal families who discovered the anti-fatigue properties of the plant Trichopus Zeylanicus.
• Members of the Kani tribe, living in the Western Ghats region of the state of Kerala drew the attention of the All India Coordinated Research Project on Ethnobiology (AICRPE) team to the energy and strength giving properties of the fruits of Trichopus Zeylanicus.

• Scientists from Regional Research Laboratory Jammu (India), and TBGRI verified the tribal claims by chemically analysing the fruits and developing an anti-fatigue drug named Jeevani.

• The invention has been patented by TBGRI and licensed for manufacture to an Ayurvedic pharmaceutical company.

• The agreement between TBGRI and the company contains the following benefit sharing provisions:
  • 50% of the licence fee, and
  • 2% royalty at ex-factory sales price to be paid to Kani tribal families

• Additionally, TBGRI arranged for the cultivation of the plant by 50 tribal families on the basis of a buy-back arrangement with the company and receive a steady annual income by domesticating the plant for commercial use.

Case Study of Sharing of benefits with community Xa21 Gene Work

Pamela Roland (University of California at Davis) cloned the “Xa21” gene in 1995. The genetic material was taken from plants native to West Africa. This gene is known to confer resistance to bacterial blight in rice.

• The University of California took the patent for this gene.
• The genetically engineered blight resistant rice plants help to reduce the quantity of chemical pesticides used in traditional rice cultivation.

• Significant amount of the breeding work linked to location of the Xa21 gene was conducted at the International Rice Research Institute in the Philippines.

• University of California at Davis subsequently established a “Genetic Resources Recognition Fund” to be used to finance graduate fellowships for students from the countries that originally provided the plants carrying the gene.

• It should be noted that in this case it was possible to identify the communities that contributed to locating the gene.⁸

Case Study of Costa Rica Conservation Programme

In 1991, an agreement was reached between Costa Rica’s Institution Nacional Biodiversidad (INBio), and Merck & Company in which INBio agreed to provide Merck pharmaceutical extracts of wild plants, insects, and microorganisms from Costa Rica’s conserved wildlands for Merck’s drug screening programme. In exchange Merck would give a renewal for two-year research and sampling budget of $1,135,000 and royalties on the resulting commercial products. A similar agreement has been signed between INBio and Bristol-Myers-Squibb in return for a smaller advance payment but with higher rates in future royalties.

Case Study of Shaman Pharmaceutical

Shaman Pharmaceuticals is integrating indigenous knowledge, modern science and reciprocity into Novel Drug Discovery Approach.

It is a company located in San Francisco (USA) which focuses on isolating bio-active compounds from tropical plants that have a history of medicinal use. Its field research teams consist of ethno-botanists, western trained medical doctors, local botanical collaborators, indigenous healers and herbalists. These teams assist in focused selection and collection of plant candidates for screening and development from various locations for further work in Shaman. Starting in 1990, using this approach, they brought two products within 24 months to the clinical trial stage. They filed patents on anti-diabetic agents based on their findings. Their community reciprocity strategy for sharing of benefits is driven by the expressed needs of the people from the communities they derive their collaborators. This includes short, medium and long-term reciprocity arrangements.

Short-term compensation included building an airstrip extension in the Ecuadorian Amazon, organizing public health workshops and forest conservation workshops, offering direct medical care to their partner communities and providing clean drinking water systems to communities in Ecuador and Indonesia.

- Medium term approaches have been to provide scholarships and fellowships to scientists working in the field of traditional medicine and also to enhance infrastructural features for research in science and technology for the community.
- As a part of their long-term strategy, the company has formed a Healing Forest Conservancy as a nonprofit organization dedicated to conserve cultural and biological diversity, and sustain the
development and management of natural and bio-cultural resources that are part of the heritage of native populations.

The results of these pilots have to be evaluated for their effectiveness in due course.

**Case Study of “Revocation of Turmeric Patent”**

The recent case of revocation of the Turmeric Patent [US Patent 5401504] in a proceeding initiated by the Council of Scientific and Industrial Research (India) at the USPTO illustrates the significance of proper documentation of traditional knowledge. Non-availability of an authentic database of traditional knowledge and practices can often lead to erroneous granting of patents in such areas by patent offices around the world.

The title of the patent granted by the US Patent Office was “Use of Turmeric in Wound Healing” assigned to the University of Mississippi Medical Centre, Jackson, Mississippi, USA.

**Chronology of events in revocation of the Turmeric patent:**

- US Patent 5401504 granted: 28.03.1995
- CSIR request for re-examination At USPTO: 28.10.1996
- 1st Office action rejecting all patent claims: 28.03.1997
- Response by patentee
- Second action report
- Patentee’s interview with examiner
- and proceedings concluded
The Claims

1. A method of promoting the healing of a wound in a patient, which comprises essentially administering a wound healing agent consisting of an effective amount of turmeric powder to the said patient.

2. The method according to claim 1, wherein said the turmeric is orally administered to the said patient.

3. The method according to claim 1, wherein the said turmeric is topically administered to the said patient.

4. The method according to claim 1, wherein the said turmeric is both orally and topically administered to the patient.

5. The method according to claim 2, where the said wound is a surgical wound.

6. The method according to claim 1, wherein the said wound is a body ulcer.

There was no comprehensive database, which one could search to directly identify the relevant prior art. Some 32 references were cited in the revocation proceedings by CSIR at the USPTO. A few typical ones are given below:

- Ayurvedic Healing (1989)
- The Wealth of India (1950)
- Indian Materia Medica (1976) [page 417]
- Economic and Medical Plant Research (1990)
- Home Remedies (1958)
- The Ayurvedic Pharmacopea of India (1986)
- Selected Medicinal Plants of India (1992)
Based on these references, the USPTO took a decision in favour of the opposition and revoked the granted patent. The basis was that the invention claimed in the patent lacked novelty with respect to prior art.9

Lessons learnt

The turmeric opposition has exposed several issues vis-a-vis traditional knowledge systems and Intellectual Property Rights, such as:

- The strength of the US Patent System which is transparent enough to enable fair proceedings.
- Significance of following the patent information especially linked to gazette notification of the patents filed, issues, etc. Familiarity with patent office practices or a rigorous follow-up is necessary to meet statutory deadlines for filing of oppositions, submission of documents to the statutory offices, etc.
- Problems of establishing relevant prior art due to non-existence of any comprehensive, reliable and authenticated database on information related to traditional and ethno-medicinal practices. In the present case, a nationwide hunt to identify relevant literature had to be made. In several cases one would have to conduct a global search. A global programme is necessary to construct a good database. While constructing a database, one will have to structure the information so that it is easily indexed for user-friendly

---

retrieval. Several indexing fields will have to address details, such as approximate date of creation of that knowledge, geographical area of its origin, the community involved in the activity, description of the process or product, their applications broad indications, etc.

- Appreciation of the techno-legal issues involved while tackling soft information.
- Training of S&T personnel to critically read and interpret patent claims to assist in any techno-legal proceedings.
- These proceedings will alert patent offices to look for appropriate prior art before granting patents in fields related to claimed inventions derived from traditional practices.

**Case Study of Revocation of Neem Patent**

European Patent No. 436257B1 was granted to W.R. Grace & Co and US Department of Agriculture in 1995 based on the patent application number 90250319.2 filed on 20.12.1990. The patent was filed for the method of controlling fungi on plants by the aid of a hydrophobic extracted enema oil.

Legal opposition to the patent was lodged by the Research Foundation for Science, Technology and Natural Resource Policy in India, International Federation of Organic Agriculture Movement, Magda Aelvoet, the Belgian Minister of Environment.

The key ground for opposition was that the invention lacked novelty and originality, as there was an Indian testimony on prior knowledge of insecticidal - and fungicidal properties of Neem. Moral issues were also raised as grounds for this opposition.

Biopesticide manufacturer Abhay Phadke of Ajay Bio-Tech (India) Limited provided critical scientific and technical evidence against this
patent. His affidavit with the EPO, claiming that in the early 1980s he had informed the officials at Rhone Poulence Agrochimie, Lyon, France, about the pesticidal properties of neem. The evidence was accepted as preliminary ground along with other evidence from literature.

On the September 30, 1997, the European Patent Office (EPO) delivered a favourable interim judgment. -

The Opposition Division of the EPO issued a provisional statement of nine pages in the instant case, whose summary ran as follows:

“3.7 In summary, it appears that the present patent cannot be maintained in view of the affidavit A2 (Articles 54 and 56 EPC). Moreover, the content of the affidavits A3 and A4 could possibly form a very relevant prior art with regard to the inventive step.”

The opposition division had asked the applicants for more detailed information concerning the extraction process that resulted in the production of a substantially azadirachtin free extract, in order to proceed to the next stage of this case.

The EPO also concluded that the opponents did not substantiate the grounds of opposition based on morality, lack of novelty and lack of clarity.

What then survived was the ground of “lack of inventiveness”.

Subsequently, in 1998, Phadke submitted another affidavit with details regarding experiments on and demonstration of properties of Neem-based products. Based on Phadke’s evidence, the Opposition Division in 1999 held that all features of the claims of the patent had been disclosed to the public prior to the patent application during field trials in the two Indian districts of Pune and Sangli in Maharashtra in the summer of 1985-86.

During the oral proceedings in May 2000, Phadke was called upon as the main witness. He presented details of the work done in 1985-86 on
Neem oil formulation in a laboratory and in the field, including names of the 16 farmers who had participated in the trials. The Opposition Division was convinced that there was adequate evidence in prior art, teaching the same invention and that there was no inventive step. The patent was therefore revoked.

It should be appreciated that the opposition division of EPO did not give much importance to the ethical and moral arguments of the case. This once again demonstrates the importance of authentic documentation of the knowledge base and the ability to provide convincing evidence of prior and knowledge in revocation proceedings.10

Case Study Revocation of Tissue Culture of Cotton Cells Patent

Indian Patent No. 168950 tided “A method of producing transformed Cotton Cells by tissue culture” was granted to Agracetus of USA based on the patent application number 919 Cal 87 (filed on 24.11.1987) by the Indian Patent Office.

The main claim of the patent states:

A method of producing transformed cotton cells by tissue culture of immature cotton plants for regeneration into mature cotton plants, the process comprising exposing hypocotyl tissue of the said immature cotton plant on a medium to a culture to transformation component non-oncogenic Agrobacterium tumefaciens and harboring a TI plasmid having a T-DNA region, including both foreign chimerix and a selection agent resistant gene. It may be noted that India follows a system of “pre-grant” opposition in contrast to the “post-grant” opposition in most countries. Accordingly, this patent application was examined by the Indian Patent Office.

---

10 World Trade Organization, Committee on Trade and Environment (1996), Report of the WTO Committee on Trade and Environment, (Press/TE014), Geneva, WTO.
Office as required by the Indian Patent Act, 1970. The Indian Patent Office found the application satisfying all the aspects of patentability and notified its acceptance in the Gazette of India, Part III, Section 2 as required by the rules. A period of 4 months is made available to the public to file in any opposition to the accepted application under Section 25 of the Indian Patent Act.

As no opposition was filed by anyone, the accepted application was then granted to Agracetus.

Under section 64 of the Indian Patent Act, on application, a patent can be revoked by the High Court. Several grounds can be considered for revocation.

In addition, Section 66 of the Indian Patent Act, 1970 has a provision titled “Revocation of patent in the public interest”. It states, “Where the Central Government is of the opinion that a patent or mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette and thereupon the patent shall be deemed to be revoked.” No appeal is preferable on the decision of the Government revoking a patent under section 66.

The fate of the Agracetus patent

There was mounting criticism from the farmer community in India that this patent was prejudicial to their interests as it would impact the farming of a major crop of national importance and have negative ramifications on the Indian economy.

The government then exercised section 66 to revoke the patent.
Conclusion

The demand on natural resources is continually on the rise. Productivity of traditional knowledge in agriculture, food procurement and development of new medicines is plateauing. Using traditional community knowledge to find useful leads and exploiting advances in biotechnology for discontinuous increase in productivity are imperatives for the future. Establishing inventiveness and non-obviousness in patenting of inventions in genetic engineering will continue to challenge legal frameworks. Ownership of knowledge and legal use in cooperative development of pharmaceutical activities, making rapid innovations with quick diffusion in the market place with fair sharing of benefits will be the key means to success. This will require a “mother’s” committed touch from governments, NGOs, corporates and communities to create cooperative frameworks for intellectual property rights, respect for community/ traditional knowledge systems and the need to nurture all forms of innovations for the benefit of mankind.

This chapter discusses various case studies related with intellectual property right and traditional knowledge.