INTELLECTUAL PROPERTY RIGHTS REGIME IN INDIA- AN OVERVIEW

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Contents

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1. Brief background on international Intellectual Property Law

1.1. Trade Related Aspects of Intellectual Property Rights (TRIPS)

- The TRIPS Agreement which came into effect on 1st January, 1995 is till date the most comprehensive multilateral agreement on Intellectual Property.
- The areas of Intellectual Property that the agreement covers are Copyrights and related rights (which includes rights of performers, producers of sound recordings and broadcasting organizations); Trademarks; Industrial Designs; Patents, including the protection of new Varieties of Plants; Geographical Indications and undisclosed information including Trade Secrets.
- The TRIPs Agreement is a minimum standards agreement, which enables members to provide a more extensive protection of Intellectual Property if they wish to do so.
- Members are free to determine the appropriate methods of implementing the provisions of the Agreement within the ambit of their own legal system and practices.

1.2. Doha Declaration

- The Round was officially launched at the WTO's Fourth Ministerial Conference in Doha, Qatar, in November 2001. The Doha Ministerial Declaration provided the mandate for the negotiations, including on agriculture, services and an intellectual property topic, which began earlier.
- The Doha Round's aim was to achieve major reform of the international trading system through the introduction of lower trade barriers and revised trade rules.
- The work program covers about 20 areas of trade. The Round is also known semi-officially as the Doha Development Agenda as a fundamental objective is to improve the trading prospects of developing countries.

2. India and Multilateral Treaties

- **Berne Convention for the Protection of Literary and Artistic Works**
  The Convention was adopted on September 9, 1886 at Berne and entered into force on December 4, 1887. This Convention relates to Copyrights and rests on three basic principles namely, national treatment, automatic protection and independence of protection. The Convention also contains a series of provisions determining the minimum protection to be granted and came into force in India on April 1, 1928.
- **Convention Establishing the World Intellectual Property Organization (WIPO)**
  The Convention was adopted on July 14, 1967 at Stockholm and entered into force on April 26, 1970. The Organization under this Convention was organized with two main objectives - to promote the protection of Intellectual Property worldwide and to ensure

administrative cooperation among the Intellectual Property Unions established by the treaties that WIPO administers. India became a member on May 1, 1975.

- **Agreement establishing the World Trade Organization (WTO)**
  The Agreement was adopted on April 15, 1994 at Marrakesh and entered into force on January 1, 1995. The World Trade Organization was established to provide the common institutional framework for the conduct of trade relations among its Members in matters related to the agreements and associated legal instruments. India became a member to this agreement on January 1, 1995.
- **World Trade Organization (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)**
  The Agreement was adopted on April 15, 1994 at Marrakesh and entered into force on January 1, 1995. The agreement popularly known as TRIPS covers various types of intellectual property and provides guidelines for minimum standards for protection, procedures and remedies for enforcement of Intellectual Property Rights and for issues relating to dispute settlement. India became a member on January 1, 1995.
- **Paris Convention for the Protection of Industrial Property**
  The convention was adopted on March 20, 1883 at Paris and entered into force on July 7, 1884. The Convention provides basic guidelines for the protection of industrial property relating to patents, industrial designs, trademarks, trade names, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition) and has substantive provisions for national treatment, right of priority and common rules. This treaty came into force in India from December 7, 1998.
- **Patent Cooperation Treaty (PCT)**
  The Treaty was adopted on June 19, 1970 at Washington D.C. and entered into force on January 24, 1978. The Treaty facilitates patent protection for an invention simultaneously in its member countries. The same came into force in India from December 7, 1998.
- **Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure**
  The Treaty was adopted on April 28, 1977 at Budapest and entered into force on August 19, 1980. The Treaty provides guidelines for the deposition of micro-organisms with any "international depositary authority" for the purpose of patent procedures. This treaty came into force in India from December 17, 2001.

- **Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks**

  Adopted on June 27, 1989 at Madrid and entered into force on December 1, 1995. The Madrid Agreement facilitates the registration of trademarks outside India; it came into force in India from July 8, 2013.
- **The Convention on Biological Diversity**

  The Convention on Biological Diversity (CBD), one of the key agreements adopted during the Earth Summit held in Rio de Janeiro in 1992, is the first comprehensive global agreement which addresses all aspects relating to biodiversity. India ratified the CBD on 18.02.1994. The Biological Diversity Act, 2002 under Ministry of Forests and Environment was enacted to meet the obligations of CBD and provides mechanism for equitable sharing of benefits arising out of the use of traditional biological resources and knowledge.
- **The Nagoya Protocol on Access and Benefit Sharing (ABS)**

  The Nagoya Protocol is a supplementary agreement to the Convention on Biological Diversity. The Protocol was adopted on 29 October 2010 in Nagoya, Japan, and entered into force on 12 October 2014. ABS's aim is the implementation of one of the three objectives of the CBD, the same being: the fair and equitable sharing of benefits arising out of the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity. India ratified ABS on 12.10.2014.
- **Marrakesh Treaty to Facilitate Access to Published Works by Visually Impaired Persons and Persons with Print Disabilities**

  The Marrakesh Treaty is a treaty on copyright adopted in Marrakesh, Morocco, on 28 June 2013. The treaty allows for copyright exceptions to facilitate the creation of accessible versions of books and other copyrighted works for visually impaired persons. The treaty sets a norm for countries ratifying the treaty to have a domestic copyright exception covering these activities, and allowing for the import and export of such materials. India was the first country to ratify the Marrakesh Treaty, which has come into force from September 30th 2016.

3. Patents

3.1. Patentability Criteria

- The TRIPS agreement and Doha declaration has provided policy space to the member countries to exclude certain subject matter from being granted patents. Thus, under Section 3 of the Patents Act, 1970, inventions based on traditional knowledge, patenting of animals, plants, plant variety and seeds etc. are not allowed.

- Section 3 (d) of the Patents Act, 1970
  - In order to prevent 'evergreening' (extension of the life of a patent over products that are about to expire on account of minor and incremental improvements in the invention) of patents, section 3 (d) of the Act provides that:
    - A mere discovery of a new form/ use/ property/ process etc. of a known substance which does not result in enhanced efficacy is not patentable.
    - Salts, esters, ethers, polymorphs, etc. of known substance are to be considered to be the same substance until these differ significantly in properties with regard to efficacy.
    - Mere use of a known process, machine or apparatus is not patentable unless such known process results in a new product or employs at least one new reactant.

3.1.1. Similar Provisions in Other Countries

In some countries, the features of patent legislation are similar to India's Section 3(d). Countries in the Asia-pacific regions are also planning to adapt similar provision of Section 3(d) to patent those drugs only which are breakthrough inventions.

Philippines: To toughen the criteria of patentability, Philippines have proposed to amend its law on identical lines.

Brazil: Brazil Patent Office drafted guidelines to restrict the patentability of new forms of compounds (polymorphs) or new property or new use of a known process unless this known process resulted in new product.

Argentina: The guidelines for patentability in Argentina for pharmaceutical and chemical inventions also exclude subject matter of polymorphs, hydrates and solvates as it is considered to be the intrinsic property of the substance so not an invention but a mere discovery. Further, in Argentina new form, new use, and new formulations are not patentable. The description of the product in accordance with the pre-existing formulation is not eligible for patent protection. The patent office of Argentina also provides definition for new form, new use, and new formulation in their Patents Act.

Japan: Japan's patent legislation mentions the subject matter as the new use of a drug can be patented if the usage is absolutely novel over the original and its use must be clearly differentiated.

Mexico: Mexico IP law in Article 19 (Mexican Industrial Property Law, 1991)

mentions that ''Juxtaposition of known inventions or mixtures of known products, or alteration of the use, form, dimensions or materials thereof, except where in reality they are so combined or merged that they cannot function separately or where their particular qualities or functions have been so modified as to produce an industrial result or use not obvious to a person skilled in the art''.

European Patent Office had also given guidelines regarding patentability of polymorphs. For polymorphs to be considered as inventive it must produce extraordinary technical effect compared to already known.

Colombia: Decision 486[1], which establishes the common IP regime for Colombia, Bolivia, Ecuador and Peru, does not specifically exclude polymorphs from patentability, the Colombian PTO (SIC) has usually set very high standards regarding the compliance with the clarity and inventive step requirements, resulting in many patent applications directed to polymorphs being rejected.

3.2. Data Exclusivity

- It is clarified that Article 39.3 of the TRIPS relates to the 'data protection' when data pertinent for seeking approval of the authority is shared with the marketing regulator. The text of this Article does not specifically state that member countries would need to comply with the requirement of 'data exclusivity'. It only states that the regulator will need to protect it from unfair commercial use. Therefore, no additional obligations such as 'data exclusivity' which are not present in text can be interpreted. The obligation on the authorities is to keep the test data secret and not allow it to be accessed by third parties through unfair means. Data exclusivity includes both non-disclosure of data by the market regulator and non-reliance of the regulator on this data submitted for according marketing approvals to another applicant, which would be a TRIPS plus provision.
- A large proportion of the Indian Pharmaceutical industry is producing generic drugs. Extending data exclusivity at this stage would have a considerable impact on the Indian industry especially in the short run. More importantly data exclusivity provisions will impact access to medicines which is a major social/ human cost for a country which still has a large population living below the poverty line.

[1] http://www.wipo.int/wipolex/en/details.jsp?id=9451

3.3. Patent Linkage

- Patent Linkage is a TRIPS-Plus measure and is undesirable for the impact it will have by delaying introduction of generics. There is no express provision under the TRIPS Agreement providing an obligation on the member countries to provide for protection akin to Patent Linkage. In the case of Article 39.3 of TRIPS, the obligation is restricted to protection of the confidential information provided to the regulatory authority and does not extend to determining the conditions under which the regulatory authority may grant approval.
- A review of the Doha Declaration on the TRIPS Agreement and Public Health adopted on November 14, 2001 clarifies any further doubts in this regard. Paragraph 4 of Doha Declaration has expressly noted that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, the Agreement should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.
- Indian Patents Act does not contain any provision to link the patent rights to marketing approvals for a product. Moreover, the Drugs and Cosmetics Act does not require the Drug Controller General of India (DGCI) to see whether a patent exists on a drug on which an application for marketing approval has been received nor is he empowered to do so. The office of DGCI is not technically qualified to take a view on the existence and scope of a patent before granting market approvals. Any such attempt by the Drug Controller would be substantively ultra vires of the delegated powers to him.
- Patent rights are private rights and enforcement of these by interested parties is available through the civil courts. A private right cannot be enforced *suo-moto* by a public authority.

3.4. Compulsory License

- The provisions relating to Compulsory Licenses under the Patents Act are fully compliant with Articles 30 and 31 of the TRIPS agreement and Article 15 of the Paris Convention.
- There has been only 1 CL issued in India; this was for a drug **'Nexavar'**, a life-extending drug in the treatment of liver and kidney cancer**,** an order upheld till the Apex Court. Comparatively, there have been several cases of CL in the world, including developed nations; US has statutory provisions for Authorization which are akin to CL.
  - The patentee was not meeting the reasonable requirements of the public- as against a requirement of nearly 23,120 bottles monthly (to cater to 80% of the estimated

patients in India), the company imported NIL bottles in the year 2008 and only 200 bottles in 2009. Then, the price was INR 2,80,000 (USD 4,400), which came down to just INR 8,880 (USD 140).

- **Royalty** fixed by Controller of Patents at 6% of net sales (the maximum as per UNDP recommendations) was enhanced to 7% by IPAB.

3.4.1. Compulsory Licenses issued in other Jurisdictions

- **United States of America**

The United States quite often steps over private patents and uses them under the garb of 'government use' provisions, however the courts have had progressive equitable doctrines to deny injunctions to patentees with valid patents that are admittedly infringed. Such actions are akin to compulsory licenses.

One such observation was made by Justice Rader in Paice LLC Vs. Toyota Motor Corp wherein he observed:

"*District courts have considerable discretion in crafting equitable remedies, and in a limited number of cases, as here, imposition of an ongoing royalty may be appropriate. Nonetheless, calling a compulsory license an "ongoing royalty" does not make it any less a compulsory license.*"

Various judgments have been pronounced by the Courts in the US in similar light. A list of instances which highlight the pro-public stance dating back to as early as the year 1934 are enumerated below:

- In May 2017, the US Court of Appeals in Nichia Corporation Vs. Everlight Americas Inc., held that the patentee was not entitled to an injunction or a restraining order and stated that monetary damages could adequately compensate Nichia for Everlight's infringement of its patent.
- In 2008, the FTC obtained an open compulsory license to patents held by Negotiated Data Solutions LLC (NData), for use in Ethernet technologies.
- In September 2006, a court granted Johnson and Johnson a compulsory license to use three of Dr. Jan Voda's patents on guiding-catheters medical devices for performing angioplasty.
- In August 2006, a court granted Toyota a compulsory license on three Paice patents for hybrid transmissions, for a royalty of $25 per automobile.
- In July 2006, a court granted Direct TV a compulsory license to use the Finisar patent on integrated receiver decoders (satellite set top boxes), for a royalty of $1.60 per device.

- In June 2006, a US court granted Microsoft a compulsory license to use two patents owned by z4 Technologies that relate to Digital Rights Management systems used by Microsoft for its Windows and MS Office software programs.
- In 2005, Ebay Inc Et Al Vs. Merckexchange LLC, the Supreme Court of the United States did not grant an injunction in light of public interest.
- In 2005, Johnson & Johnshon Vs. Ciba Vision refusing to enjoin the use of patented contact lens technology on the ground that "millions of innocent lens wearers will suffer real adverse consequences if sale of ACUVUE®OASYS is enjoined".
- In 2001, ExxonMobil and the National Petrochemical & Refiners Association asked the US Federal Trade Commission (FTC) to force Unocal, another oil company, to grant licenses to patents on reformulated gasoline. The patents were necessary to be in compliance with clean air regulations in California. In 2005, the FTC obtained a zero-royalty compulsory license on a portfolio of patents, as a condition of Chevron acquiring Unocal.
- In 1934, City of Milwaukee v. Activated Sludge Inc**.,** US court refused to enjoin the City of Milwaukee from infringing a patent relating to the treatment of sewage on the ground that this would cause grave harm to the public interest, as citizens would have no other option than to dump their garbage in Lake Michigan. While denying the injunction, the court appeared to suggest that damages would suffice, effectively paving the way for a de facto Compulsory License.

- **Germany**
  - Following an oral hearing held on 30 and 31 August 2016, the German Federal Patent Court ('Bundespatentgericht') has confirmed the injunction to grant Merck a compulsory licence for the distribution of its HIV medicament, "Isentress".
- **Canada**
  - On May 7, 2004, Torpham successfully appealed a rejection of a compulsory license application involving Merck patents for the manufacture and sale of Lisinopril. Torphan had sought a license to the use the patents for purposes of manufacturing and exporting to the United States.
- **Italy**
  - On 23 February 2005, the Autorità garante della concorrenza e del mercato (the AGCM) opened an investigation into abuses of a dominant position by refusals to license rights to active pharmaceutical products by two large pharmaceutical companies -- GlaxoSmithKline and Merck & Co Inc (Cases A363 and A364). On 21 June 2005, the AGCM ordered a compulsory license for Merck patents on antibiotics that use the active ingredients Imipenem Cilastatina.
- **Indonesia**

- On October 5, 2004, Indonesia issued a government use compulsory license to manufacture generic versions of two HIV-AIDS drugs, lamivudine and nevirapine, until the end of the patent term in 2011 and 2012 respectively.

- **Malaysia**
  - The Malaysian government on September 20, 2017 confirmed that it approved "the use of Rights of Government under Patent Act 1983 (Act 291) by exploiting the patented invention of Sofosbuvir tablet 400mg."
  - The last time Malaysia instigated the Rights of Government was in 2003 for anti-retroviral drugs (treatment for HIV infection). This sets Malaysia to be the first country to initiate such move in the world.

3.5. Foreign Filing Permission

- According to section 39 of the Act, residents cannot apply for patents outside India without prior permission. As per the provisions, any person resident in India intends to file or make any filing application outside India is required to take following action:
  - File an application in India and wait for six weeks before filing such application outside India;
  - In case he is not interested to file application in India before filing outside India, then he is required to take prior permission by filing form 25 with the prescribed fees.
- Prior foreign filing permission is intended to prohibit publication of the information relating to such inventions which are relevant for defense or atomic energy purpose.
- On receiving the request for foreign filing on form 25, the Patent Office scrutinizes the invention disclose in the application/ document submitted with form 25 as to whether they are relevant for Defence or atomic energy purpose before granting permission and only relevant applications are forwarded to Ministry of Defence and Department of Atomic Energy for decision.
- However, in all other cases the Foreign Filing permission is expeditiously given by the Patent Office. Although the time period prescribed for such permissions is 21 days under Rule 71, however the same are being disposed by the Office within a period of one week, and definitely not more than two weeks. It may be noted that such permissions are processed on priority basis. In most of the cases, the time required now has been reduced to 3 to 5 working days.
- Delhi High Court in *Puneet Kaushik vs. Union of India (2013)* has held that the applicant should either file the application in India before filing outside India to take priority of Indian application or else take permission from the office.

4. Copyrights

- The approval of the National IPR Policy and the transfer of administration of the Copyright Act, 1957 to the DIPP has given a fillip to reforms in the area of copyrights; their registration, enforcement and overall strengthening of the system. With IPRs being dealt with under a single umbrella, there has been a convergence of approaches and creation of synergies.
- The creation of an institutional mechanism for implementation and coordination of the various areas of the IPR Policy, especially on enforcement, with the various agencies will go a long way in addressing the problem in the times to come.

4.1. Civil and Criminal Enforcement under the Copyright Act, 1957

- The Copyright Act provides for both civil and criminal remedies for infringement. Section 55 provides that "The owner of the copyright shall be entitled to all such remedies by way of injunction, damages, and accounts and otherwise as are or may be conferred by law for the infringement of a right."
- Chapter XIII (Sections 63-70) provides for a range of criminal penalties for infringing copyrights which are punishable with terms of imprisonment that may extend up to three years along with a fine which may extend to Rupees Two Lakhs.

4.1.1. Technological Protection Measures (TPMs) and Rights Management Information (RMIs)

- The Indian Copyright Act was amended in the year 2012 to bring it in conformity with the WIPO Internet Treaties viz WCT and WPPT. Criminal remedies have been provided to prevent circumvention of TPMs and altering of RMIs. Further, civil remedies are also available for RMIs.

4.2. John Doe Orders against Infringing Websites

- Online copyright piracy is assuming gigantic proportions across the globe, and no country is immune to this menace. A possible and substantially effective solution to this problem lies in the civil remedy of website blocking orders or John Joe orders.
- The judicial orders, “John Doe orders” in effect as they are issued against persons, whose identity is unknown, are targeted at specific websites, so-called “pirate” or “rogue websites”, as the overwhelming majority of the content hosted on such sites infringes copyright. Notices, even if ineffective, are still issued to the ISP and, if identifiable, to the owner of the domain and/or website in accordance with the statutory provisions. Plaintiffs are then able to obtain court injunctions ordering specific named websites to cease the infringement of their copyright.

- ISPs providing Internet bandwidth connectivity are directed to enforce the injunction by blocking the access of Indian subscribers to the websites subject of the order. The concerned Government Departments are directed by the court to require ISPs act as per court orders, in accordance with terms and conditions of the license agreement they have with the Department of Telecommunication for the provision of internet services.
- Recent past has seen rising trend in Indian Film Industry to obtain "John Doe" orders prior to release for blocking access to any website which might be deemed to host links to pirated content.

4.3. Anton Piller orders

- Other than the extensive police powers under the Copyright Act, plaintiffs have various civil powers to enforce their right. Copyright owners and associations can employ civil procedure to search the defendant's premises as seize the pirated copies.
- This is done via 'Anton Piller' orders obtained from civil courts which permit court-appointed officers, accompanied by representatives of the plaintiffs, to search premises and seize evidence without prior warning to the defendant.
- Similar to John Doe Orders, these orders can be obtained unilaterally (ex-parte).

5. Trademarks

- The Trademarks Act, 1999 provides for registration and better protection of trademarks for goods and services and for the prevention of the use of fraudulent marks.
- A Trade Mark is a sign, design or expression, a source identifier denoting a certain company/ persons/ product and distinguishing it from the products of others.
- The Trademarks Act, 1999 provides for both Civil and Criminal remedies in case of infringement.
- The Trademark Rules, 2002 have been amended after extensive stakeholder consultation to allow for accelerated examination of applications and simplification of procedures. The Trade Marks Rules, 2017 were notified on 6th March, 2017.
- These amendments have resulted in streamlining the process and will lead to improved functioning.

6. Designs

- Industrial Design recognizes the creation of new and original features of shape, configuration, surface pattern, ornamentations and compositions of lines or colours applied to articles which in the finished state appeal to and are judged solely by the eye.

- The registration and protection of industrial designs in India is administered by the Designs Act, 2000 and corresponding Designs Rules, 2001.

7. Semiconductor Integrated Circuits Layout Design

- Protection of original Layout-Designs of Semiconductor Integrated Circuits is governed by the provisions of the Semiconductor Integrated Circuits Layout Design Act 2000. The Act promotes protection of Intellectual Property of Semiconductor Integrated Circuits Layout Designs.
- Act provides exclusive rights to the creator of layout design for 10 years. Exclusive right enables the owner to commercially exploit the creation and in case of infringement, get reliefs permitted under the Act.
- Act also provides for establishment of Semiconductor Integrated Circuits Layout-Design Registry (SICLDR) which examines the layout-designs of the Integrated Circuits and issues the Registration Certificate to the original layout-designs of the Semiconductor Integrated Circuits.

8. Geographical Indications

- The Geographical Indications of Goods (Registration and Protection) Act, 1999 provides for registration and protection of Geographical Indications related to Goods. Goods refer to any agricultural, natural, manufactured goods, goods of handicraft or of industry and include food stuff.
- Definition of GIs under the Act is wider as compared to the definition in TRIPS which only covers Agricultural Products, Food Products and Wines & Spirits.
- The objectives of the Act are:
  - Confer legal protection of Intellectual Property inherent in Geographical Indications;
  - Economic prosperity to producers of Geographical Indications by exclusion of unauthorized persons from misusing Geographical Indications and protect consumers from deception.
- The GI Registry has received 552 GI Applications, of which 303 have been registered (291 GI are of Indian origin & 12 are of foreign origin) as on 31st December 2017.

9. Plant Varieties (Ministry of Agriculture)

- In order to provide for the establishment of an effective system for protection of plant varieties, the rights of farmers and plant breeders and to encourage the development of

new varieties of plants, the Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPV&FR) has been enacted.

- A unique aspect of the PPV&FR Act is that it confers three concurrent rights- to breeders, farmers and researchers.
- The Act recognizes the farmer as cultivator, conserver and breeder. The Act establishes nine rights for farmers, of which the most important are the right to seed and the right to compensation for crop failure.
- Protection of Plant Varieties and Farmer's Rights Authority is established as per the Act. The Authority has the mandate to promote the development of new varieties of plants and to protect the rights of the farmers and breeders.

10. Genetic Resources (Ministry of Environment, Forest and Climate Change)

- Pursuant to the Convention on Biological Diversity, India enacted the Biological Diversity Act in 2002 which covers conservation, use of biological resources and associated knowledge occurring in India for commercial or research purposes, or for the purposes of bio-survey and bio-utilization. It provides a framework for access to biological resources and sharing the benefits arising out of such access and use.
- The Act provides for establishment of the National Biodiversity Authority (NBA). Prior approval of the NBA is required if anybody seeks any kind of Intellectual Property Rights on research based on biological resources or knowledge obtained from India. The NBA may also impose benefit sharing conditions.
- The NBA is empowered to take measures to oppose the grant of any Intellectual Property Rights in any country outside India on any biological resource obtained from India or knowledge associated with such a biological resource.

11. Traditional Knowledge and Traditional Knowledge Digital Libraries

11.1. Traditional Knowledge (TK)

- Traditional knowledge (TK) is integral to the identity of most local communities.
- TK is a key constituent of a community's social and physical environment and, as such, its preservation is of paramount importance.
- Objective - protect the ancient and traditional knowledge of the country from exploitation through bio-piracy and unethical patents.
- The rich endowment of TK and biodiversity plays a critical role in health care, culture, food security, identity, religion, environment, trade and development.

11.2. Traditional Knowledge Digital Library

- The Traditional Knowledge Digital Library (TKDL) was established in the year 2001.
- TKDL is a collaborative project between the Council of Scientific and Industrial Research (CSIR) and the Department of AYUSH. The same is a home-grown effort to ensure patent offices around the world do not grant patents for applications founded on India's wealth of age-old Traditional Knowledge.
- Digitalization of the traditional medicinal knowledge which is available in public domain in the form of existing literature is related to codified systems of Ayurveda, Unani, Siddha and Yoga.
- TKDL is a unique, proprietary database that integrates diverse knowledge systems and languages. It is based on 359 books of Indian Systems of Medicine, which are available at a cost of approx US$ 1000, in open domain and can be sourced by any individual/organization at national/international level[2].
- Access to around 3,30,044 Traditional Medicinal Formulations is available in patent compatible format in five international languages under TKDL Access Agreement to 10 Patent Offices, namely EPO, USPTO, JPO, CIPO, UKPTO, IP Australia, IPO, DPMA-German, Chile and Malaysia.
- The idea to establish a TKDL came into the picture amid India's efforts to revoke the patent granted by the United States Patent and Trademark Office (USPTO) on the wound healing properties of turmeric and the patent granted by the European Patent Office (EPO) on the antifungal properties of neem.
- By using the information technology tools and the Traditional Knowledge Resource Classification System (TKRC), the library has been successful in converting and structuring ancient texts into 34 million A4-sized pages along the lines of a patent application.
- TDKL is an effective mechanism for defensive protection, facilitating the prior art search and bridging the language barrier.
- The ancient texts have been translated into various languages viz. English, French, German, Japanese and Spanish.

11.2.1. Traditional Knowledge Resource Classification

- Traditional Knowledge Resource Classification (TKRC) is modeled on WIPO's International Patent Classification (IPC).

[2] http://www.tkdl.res.in/tkdl/langdefault/common/Abouttkdl.asp?GL=Eng

- It consists of some 27,000 subgroups for Ayurveda, Unani, Siddha and Yoga, and like the IPC, is indispensable for the retrieval of relevant information.

12. Statements/ Comments/ Views favoring India's stance on access to Health Care

12.1. The United Nations Secretary-General's High-Level Panel on Access to Medicines Report

- The United Nations Secretary-General Ban Ki-Moon constituted a **High-Level Panel on Access to Medicines** in November 2015, with the proposed objective "to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."
- The Report issued in September 2016 has been structured in 4 chapters including a) Health Technology Innovation and Access, b) Intellectual Property Laws and Access to Health Technologies, c) New Incentives for Research and Development of Health Technologies, d) Governance, Accountability and Transparency.
- In summary, the main recommendations of the report are as follows:
  - WTO members must make full use of the TRIPS flexibilities as confirmed by Doha Declaration to promote access to health technologies when necessary.
  - WTO members should make full use of the policy space available in Article 27 of TRIPS agreement by adopting and applying rigorous definitions of invention and patentability that are in the interests of public health of the country and its inhabitants. This includes amending laws to curtail the evergreening of patents and awarding patents only when genuine innovation has occurred.
  - Multilateral organizations such as UNCTAD and WTO should strengthen the capacity of patent examiners to apply rigorous public health-sensitive standards of patentability taking into account public health needs.
  - Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. The use of CL should be based on the provisions found in the Doha Declaration and the grounds for the issuance left to the discretion of the governments.
  - WTO members should revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license.

- Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities.
- Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfill the rights to health.

- **The report also elucidates the following aspects as being TRIPS Plus provisions; this reiterates India's steadfast stand regarding such provisions:**
  - Patents for new uses or methods of using a known product (evergreening)
  - Prohibition on pre-grant patent opposition
  - Test data exclusivity periods
  - Patent term extensions for 'unreasonable' regulatory or marketing delays
  - Patent linkage
  - Limits on compulsory licensing grounds
  - Limits on parallel imports
  - Enhanced obligations regarding border measures, civil and administrative procedures, remedial provisions and the criminalization of certain violations beyond what is required by the TRIPS Agreement

12.2. Joseph Stiglitz, Nobel Prize for Economics (2001)

(Source: Stronger IPR is about Big Pharma profits, not health. Economic Times, March 01, 2015)

- "If patent rights are too strong and maintained for too long, they prevent access to knowledge, the most important input in the innovation process. In the US, there is growing recognition that the balance has been too far tilted towards patent protection in general (not just in medicine)."
- "Greater IP protection for medicines would, we fear, limit access to life-saving drugs and seriously undermine the very capable indigenous generics industry that has been critical for people's well-being in not only India but other developing countries as well".

12.3. Bernie Sanders, Senior U.S. Senator

- "Access to health care is a human right, and that includes access to safe and affordable prescription drugs. It is time to enact prescription drug policies that work for everyone,

not just the CEOs of the pharmaceutical industry. Americans pay, by far, the highest prices for prescription drugs in the entire world.[3]"

- "Health care must be recognized as a right, not a privilege. Every man, woman and child in our country should be able to access the health care they need regardless of their income.[4]"
- "We pay, by far, the highest prices in the world for prescription drugs. One out of five Americans can't even afford the prescriptions their doctors are writing…..in my view healthcare is a right of all people, not a privilege, and I will fight for that"[5].

12.4. World Health Organization

(Source: Report of the Commission on Intellectual Property Rights, Innovation and Public Health, 2006 Page: 132-133)

- "Countries can adopt legislation and examination guidelines requiring a level of inventiveness that would prevent evergreening patents from being granted. The TRIPS agreement gives freedom to WTO Members to determine the hurdle required for the inventive step".
- "The intention here is to rule out from patentability variations on a known drug, by treating them all as the same substance, except where it can be demonstrated that a drug has superior efficacy. In that sense, the legislation is trying to make a distinction in law between evergreening (where there are no additional therapeutic benefits) and incremental innovations (where there are)".

12.5. Parliamentary Debate (Relevant Comments)

(Reference Date: 18th December, 2004, Bill to further amend the Patents Act, 1970)

- Comments of one of the members from the Opposition[6]:
  - "India has benefited from the low cost generic industry to dominate 30 per cent of the low-cost drugs in the world….
  - Secondly, it (the bill) is vague about the evergreening effect in which companies extend their patent rights by switching from capsules to tablets, for instance. This

[3] Source: IP Watchdog Blog. Available at: http://www.ipwatchdog.com/people/bernie-sanders/
[4] Source: https://berniesanders.com/medicareforall/
[5] Source: http://www.ontheissues.org/2016/Bernie_Sanders_Health_Care.htm
[6] Para 80, Novartis A.G v. Union of India (CIVIL APPEAL Nos. 2706-2716 OF 2013) Supreme Court of India. (2013)

extends monopolies. Parliament must make sure that it protects the rights of India to make these generic drugs. We should remove the provision that allows this evergreening. What should and what should not be patentable has also been left open to interpretation. Earlier, the new use for a substance could not be patented. Now this has been qualified to allow it by putting "mere new use" instead of "new use".

- Comments of the minister who had sponsored the Bill with regard to section 3(d)[7]
  - "There are so many provisions here. In regard to evergreening, I just want to read out section 3(d) which says that a mere discovery of a new property or a new use for a known substance or the mere use of known process in a new product – these are exceptions, these will not be granted any patent – and substances obtained by a mere ad-mixture resulting only in aggregation of properties of the components thereof or, processes of producing such substances will not be given patents."

[7] Para 84, Novartis A.G v. Union of India (CIVIL APPEAL Nos. 2706-2716 OF 2013) Supreme Court of India. (2013)