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MESSAGE FROM THE PATRON

It is a matter of proud privilege and immense pleasure for me to introduce this Special Issue comprising of selected papers presented at the International Conference on Intellectual Property Rights organized by National Law University and Judicial Academy, Assam on 18th and 19th August 2018 to the knowledge loving readers. This law journal is the expression of the quality research in the field of IPR relevant to the need of society in the present globalized world. In the present day of developed technology and consequent Knowledge explosion it becomes imperative to acquire as much knowledge as one can and disseminate it along with one`s own experimentation among the members of the society . The world is moving very fast, the problems are cropping up very swiftly demanding handling of situations with proper solutions. The IPR is necessary for innovation and advancement in technology. National Law University Assam like any other National Law University in the country attaches great importance to new age technology and development in IPR. IPR is one of the main engine of industrial growth and economic development. NLUA Law and Policy Review is the harbinger of promotion of quality research. It has evinced wide appreciation and high commendation in the legal circle and has made its presence felt in the most reputed libraries throughout the country.

The present special issue on IPR is in continuation of the earlier issues of this bi-annual faculty run peer reviewed journal expressing multi-disciplinary as well as inter disciplinary approaches justifying the testimony that law is the lawyer's extroversion. It covers most timely and socially relevant articles with a number of positive suggestions. It contains the contribution of articles from academia as well as the students on diverse areas of IPR in general and contemporary issues.

The journal is the outcome of constant vigil, untiring efforts, imaginative vision and great zeal and mission of the Editorial Board for which they all deserve congratulations.

Prof. (Dr.) J.S. Patil

Vice-Chancellor

National Law University, Assam

Editorial

The NLUA Law & Policy Review is a referred journal listed by University Grants Commission (Sr. No. 37023) .This Special Issue of the NLUA Law & Policy Review (NLUAPR) Journal, 2018 is on Contemporary Intellectual Property Law dealing with the following broad themes:

- Intellectual Property and Technology;
- Harmonisation of IP and Anti-Trust Law;
- Innovation Ecosystem and Intellectual Property Law;
- IP Litigation and Growing Trend in India; and
- Plant Genetic Resources and Intellectual Property Rights with special emphasis on North East India.

This Special Issue comprises of selected papers presented at the International Conference on Intellectual Property Rights organised by National Law University and Judicial Academy, Assam on 18th and 19th August 2018. The brief abstracts of the articles are: **Abhishrut Singh**, in his article titled, "*Development Of Intellectual Property Law In India*" surmise the legal liabilities associated with intellectual property require in-depth consideration and comprehension as this domain still demands intense work. The laws on intellectual property are implemented in our country in the form of Intellectual Property Rights (IPRs), and these include patents, copyrights, trademarks, licences, designs, etc. The paper will lay its emphasis on how GST has affected intellectual property rights, the latter's association with agriculture, and the relative challenges and effects**. Anee Das** and **Prakreetish Sharma**, in their article titled, "*Traditional Knowledge In Context Of Indian Patent Act, 1970*" explained how the whole concept of protection Traditional Knowledge gained importance from an area of law which had been left mostly untouched. It would also aim to find out the best possible remedies available so as to prevent Bio-Piracy. **Aradhana Nair** and **Pavitra R**, through their article, "*Is Anything Under The Sun That Is Made By Man - 'Patentable? A*

Critical Review On Designer Babies" described how innovations have increased and importance for the human health care field has also grown. Recently University of California and the Broad Institute began battling over the patents related to CRISPR CAS9 - genome editing. Gene editing has its pros and cons. **Aviral Vats** and **Devang Gaur** in their article, *"Patentability Of Stem Cells: A Critical Analysis Of Indian Perspective*" delved on the uses of stem cells are a rather recent development in the field of medicine and have seen to catch a lot of issues in regards to the methods from which they are deduced from as an ethical predicament stands upon the procedure from which they are procured by and their usage.

Devapreeti Sharma, in her article, *"Observations On Intellectual Property Viz-À-Viz Biodiversity*" critically analysed how science and technology are expanding at unprecedented rates has led to the creation of new forms of Intellectual Property Rights (IPRs) which however, are at the cost of the Earth's resources. This threat forms the common ground between IPRs and biodiversity and raises several legal, ethical and commercial questions. **Digvijay Singh**, in his article, "*Understanding Intellectual Property (Ip) Strategy For Artificial Intelligence"* succinctly surmised how increasing demand of AI technology worldwide compels state to provide appropriate strategy of legal protection to the investors in the field. The intellectual property (IP) issues associated with the issue of protection of AI is difficult to understand. In the recent past, various approaches have been adopted under different IP laws including patents law, copyright law and trade secret in various jurisdictions to deal with this contentious issue. **Ipsita Kaushik**, in her article, *"Protecting Traditional Knowledge in India as Intellectual Property: A Way Forward*" raised issue of the dire to draw attention of various International fora, Policy makers and researchers towards traditional knowledge. The debate on the importance of protection of traditional knowledge has increased following various incidence of patent granted in the United States and European Union Patent Offices on the centuries old Traditional knowledge of indigenous people of India.

Karthik Shiva, in his article, "*The Upsurge Of Shadow Libraries – Bridging Knowledge Divide Or Subverting Copyright Regime?*" explains how access to top-notch research content and material proves to be costly to the scholars and this has led to the emergence of shadow libraries also known as 'pirate libraries. He opined that stricter anti-circumvention measures hindering fair use has slowly transformed into a free and open access movement which threatens to topple the very fundamentals of present copyright regime. **Kanay Pisal** and **Neha Rani** in their article, "*Trips Plus And Biodrugs: Modern Imperialism Versus Burgeoning Public Health*" explained the role of Patent Rights in Bio Drugs while differentiating it from other drugs. Further, it analyses and subsumes the National and International laws, Treaties and Conventions that affect and influence India's stand and policies for Patents and Bio Drugs. **Sai Prasnth**, in his article, "*Decoding the Genetics of IPR*" dealt with the pertinent issues of a creator right to own his 'creation' made through his intelligence and acquired knowledge, similar to the right he is endowed with, on his 'creations' out of his physical labour. **Sumedha Bhat**, in her article, "GOONDAS Act vis-à-vis Freedom of Speech and Expression: A critical analysis of the recent amendment (BILL) in the GOONDAS Act in the light of IP laws"questions the constitutional validity of the Goondas Act. Besides, the general unconstitutionality of prior restraint, the Act is at variance with the Supreme Court's understanding of the public order under an exception to the Article 19(2) and interpretation of privacy under Article 21 of the Constitution of India. Broadening the scope of such legislation to an area where it lacks constitutional authority, and instituting provisions with the crucial aftermath on fundamental rights, will make it prone to misuse and will have severe consequences on the civil rights of people. **Swati Verma**, in her article, "*Restrictive IPR conditions and Technology Transfer from FDI : Policy concerns in Indian context*" describes how foreign technology collaboration This pattern of technology procurement may largely restrict the extent of technology transfer to the licensee, and the vulnerability to abuses in technology collaboration contracts may exist in both within firm

and open market purchases. **Vishnu Shankar P.,** in his article, "*WTO Principles On Free Trade And Concept Of International Exhaustion With Special Reference To The National Treatment Principle*" challenge the principle of exhaustion of IP rights through the overall philosophy of free trade propounded by WTO, also analysed free trade principles of GATT and to find out whether international exhaustion could be the only international mandate which could further free movement of intellectual property goods.

Best wishes,

Editorial Board

DEVELOPMENT OF INTELLECTUAL PROPERTY LAW IN INDIA

Abhishrut Singh[1]

INTRODUCTION

In an era where innovation and technology is fast shaping the face of the world, the repertoire of intellectual property is exponentially increasing. This undoubtedly calls for the protection of intellectual property and their subsequent sharing and transfer. Touching the surface of the term, Intellectual Property Rights (IPRs) can be defined as the legal rights on over innovative and creative ideas. Even when the use of IPRs in the industrial scenario is being accepted to a large extent, their application in the agriculture field is comparatively new, and thus is being subject to wide debate and speculation.

From the '60s, the agriculture sector in our country has witnessed a lot of changes and inventions. The emergence of high-yielding seeds, hybrid varieties, genetically engineered crop plants has led to agriculture embracing biotechnology. IPRs have thus become indispensable in order to protect the rights of innovators and for food security. The paper takes up the effects and challenges of IPRs on our country's agro-sector. The significant IPRs related to this field are Plant Breeding Rights (PBRs), patents, trademarks, geographical indications etc. Even when patents are one of the most widely-accepted IPRs, their string-tight regulations, and some of the drawbacks associated with them has led to the use of other intellectual property rights.

Another domain that the paper touches down upon is the effect of introduction of the Goods and Services Tax (GST) on IPRs. The passing of GST sparked the debate over whether to consider intangible properties as 'goods' or 'services'. The ambiguity related with the classification of intangible properties, their rights and how it is affecting our intellectual property legislation is what the paper attempts to discuss.

Lastly, a bird-eye view will also be offered on the recent innovative developments on IPRs in our country.

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INTELLECTUAL PROPERTY RIGHTS (IPRs) AND AGRICULTURE: EFFECTS AND CHALLENGES

Agriculture has been hailed as the backbone of a country coupled with science and innovation. The Green Revolution in the '60s was one of the significant steps which brought up how these facets are intrinsically linked and it changed the way how plant breeding is viewed in the agriculture sector. Intellectual Property Rights (IPRs) are crucial with respect to staple crops as they are closely interlinked with food security and basic food needs.

The assignment of intellectual property rights to living things has been recent. Plant breeder rights (PBRs) were developed during the second half of the 20th century[2], which have been basically derived from the patent model of developed countries. PBRs are *sui generis* IPRs, meaning one of their kind; IPRs that do not fit into the classical division of industrial property and design are termed so. PBRs were developed to acknowledge and reward conventional plant breeding efforts. However, the *sui generis* PBRs provide lesser protection in comparison to patents, and in functionality, and they can only prevent commercial exploitation from the third parties[3]. PBRs are granted on the bases of distinctness, uniqueness, uniformity and stability of the plant breed in question. As they have lesser restrictions, they promote breeding in the private sector. Thus, even when it has been argued[4] that IPRs are for signalling competitiveness, because of those like PBRs, private sectors are benefitting more, as they have more incentives for involvement in agro-biotechnology[5].

PBRs or patents impose restrictions on farmers on their ability to sell and reuse breeder's seeds, thereby attracting private breeders.

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2 The Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development, London (2007).

3 Jayashree Watal, *IPRs Relevant to Agriculture, Intellectual Property Rights in Indian Agriculture* (July, 1998), http://icrier.org/pdf/jayashreeW.pdf.

4 ALLEN K.R., BRINGING NEW TECHNOLOGY TO MARKET (1ST ED. 2003).

5 Neil D Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*, Journal of Agricultural Law, 81:1-16.(2001).

In developed countries the annual purchase of seeds for many crops is the rule. On the other hand, the farmers in developing countries mostly replant, exchange and sell seeds from previous year crops, and annual purchase is rare. This puts farmers and breeders in developing countries on contrasting facets.

PBRs in India were introduced after initiatives taken by private seed companies in the late '80's after the adoption of the New Seed Policy in 1988. Since their introduction, a positive impact has been reported on private research and development[6]. In the Indian law, IPRs on plants and crops are governed by the Protection of Plant Varieties and Farmers' Rights Act of 2001. This act covers the rights of plant breeders and farmers and the protection of plant varieties. This Act also encourages the innovations and development in new crop varieties. The period for which various plant varieties are protected differs for different plants. The period is eighteen years for plant and vines, for extant varieties, it is fifteen years, and for other plant varieties, it is fifteen years.

Patents are one of the most important IPRs when it comes to the agro-biotechnological industry. Even when patents need to be disclosed to the public, they prevent third parties from making, using or selling the patented product or process. Patents as such cannot be acquired for any intellectual property as it needs to be novel, innovative and newly invented. Plants, animals and microorganisms are allowed to be patented for biotechnological applications, even when not all countries are as welcoming as others regarding their patenting.[7]

Apart from patents, trademarks, which have been widely used in industries, are also being used in agriculture, for instance to market seeds. Trademarks are used to distinguish the goods and services of one enterprise from another, thus preventing consumers from being deceived. Even when they need to be regulated from time to time, their use is not restricted to time.

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6 Pray, Carl and Tim Kelley, *Impact of Liberalization and Deregulation on Technology Supply by the Indian Seed Industry*, Draft of a World Bank Financed Project, World Bank, Washington DC (1997).

7 *Id* 2.

In order to protect geographical indications, the Geographical Indications of Goods (Registration and Protection) Act, (the GIG Act) was enacted in 1999. Geographical indications are the commercial marks used most commonly in agriculture. These also include appellations of origin. Geographical indications are the trademarks attributable to a geographical location of a product originating from that particular geographical location including the product's quality, reputation or other characteristics. These usually related to agriculture directly or to products, such as wine and spirits, derived from agriculture. They prevent third parties from wrongfully showcasing the product as their own. Famous instances include 'Champagne' for sparkling wine, 'Roquefort' for cheese from areas of these names in France, 'Scotch' for whisky from Scotland ,'Darjeeling' for tea from this district in India, etc. Geographical indications also protect plant varieties developed with traditional knowledge and associated with a particular region, and are not time-limited. Apart from these trademarks, trade secrets can also be used in agriculture to protect hybrid plant varieties. They do not need to be disclosed but unlike patents, they become ineffective the moment they are discovered by third parties.

Innovations in agriculture technology and the emergence of new plant varieties, high yielding varieties and hybrids, the IPR scenario is expected to take a leap and develop more in the coming years. Protection is needed for investment in technology development to flourish.

Despite the fact that IPRs are going to influence agriculture in positive manner, the fact remains that there are many issues related with it. For instance, there are ethical concerns over the relation of IP with agriculture as agriculture forms the 60% of the economy of our country, and human well-being is primarily dependent upon food, obtained from agriculture. There are also questions marks on the breeding of hybrid and high yielding plant varieties. It should also be ensured that with the development of IP in agriculture, the focus is on poor farmers, and not only on private sector and plant breeders. Another challenge is that IPRs hamper the diffusion of technology, and this may affect small and poor farmers, leading to uncertainties, risks

and lack of information. IPRs with relation to agricultural sector have been debated in our country amidst a lot of political controversies, and along with farmers' rights, they have continued to face the political heat. Their implementation at par with international standards have also witnessed a lot of public debacle with relation to fair and equitable sharing of benefits on commercialization of biological/genetic resources and traditional knowledge and practices originating from India.

EFFECT OF GST ON IPRs

GST was introduced in the constitutional framework by the One Hundred and First Amendment Act, 2016. Even when the government hailed the passing of the Goods and Services Tax (GST) Bill as the biggest taxation reform since Independence, this move by the Parliament witnessed a variety of reactions across the country. Though GST replaced the multistage cascading taxation on goods and services in our country by levying one tax for the whole nation, there is one aspect of intellectual property which the bill largely kept out of its focus.

Intellectual property, or intangible property forms a very important pillar of a developing economy like India, without which our country will be just a cheap market with the sales of goods, the so-called tangible property. The reserve of intangible property of our country is not substantially rich, and we are more or less dependent on foreign powers for most of our intellectual services. These IPRs are protected by a statute by the Central Government, and their transfer, transaction, and enjoyment is subject to taxation under the Services Tax.

Before the GST Bill was introduced, the Union government used to classify transactions related to IPRs as services under Service Tax, Chapter V, Finance Act, 1994, and the State government had the right to tax IPRs if their transactions involved the sale/deemed[8] sale of goods (under State Sales Tax/State Value Added Tax or Central Sales Tax). Intellectual property was taxed by licensing it to a developer or a manufacturer, as to how the intangible can be converted into the tangible, and levying a value added tax (VAT) on the tangible thereafter,

8 Constitution of India art.366 (29A) (d).

thus indirectly taxing the intellectual property. But the move by the Government, in which every property is to be taxed to a certain amount, will result in deterring the intellectual property market from flourishing. It will even lead to shutting down of indigenous intellectual property companies and endanger the future for the market of intangible property, which is an essential parameter for a developing economy. Under the GST model, the supply of information technology software which was for long classified as a service, is now taxed as a 'supply of service', thus sparking the dispute as to whether it is a 'good' or a 'service'. Such intangibles are the ones being worst affected by the dilemma between the classification of goods and services, and clarity is exigent to their transactions. Thus, the Bill requires exemptingcertain IP entities like technology transfer, licensing of technology, purchase of tools or computers, software etc. from GST.

At this juncture, we need to take into account another aspect which emerges from the goods versus services debate for taxing the intangible property. Prior to the introduction of GST, they were subject to the service tax or VAT depending on whether their transaction classified as good or service. In this domain, the IPRs have been bearing the brunt as the Union Government has been levying service tax while the state government, its value added tax (VAT). By the introduction of GST, this paradoxical taxation was supposed to be resolved. However, the Union and the State governments still have failed to reach a common ground on the issue of taxation of intangibles.

Under the GST model, intangibles per se, have been classified as goods, though their transactions such as licensing can still be taxed as a service, thus introducing a catch-22 and bringing us back to square one. The provision of Central GST and State GST has still left consumers at the same juncture as before. As a result of this, both the Union and the State governments are more or less still undecided while levying taxes on IPRs, thus providing no solution to the problem which threatens the domestic IP industry. For instance, if revenue from an IPR like licensing is 100 lakh in a state, and the state excises 4% VAT on it, it will amount to 4 lakh. However, as no product is being developed, no service tax will be levied. Under GST Bill, this tax on the

IPR (licensing in this case) is fixed, no matter whether a service has been offered or not.

Reviewing the provision for IPR in Central GST, its Section 9 provides that the CGST shall be levied on the transaction value[9] or the price actually paid or payable for the said supply of goods and/or services and at such rate to be notified on the recommendations of the GST Council. Subsequently, the rates have been notified as follows[10]:

Under Sl. No. 17, Heading 9973-

- Temporary or permanent transfer or permitting the use or enjoyment of Intellectual Property (IP) right in respect of goods other than Information Technology software at the rate of 12% (6% CGST and 6% SGST).
- Temporary or permanent transfer or permitting the use or enjoyment of Intellectual Property (IP) right in respect of Information Technology software at the rate of 18% (9% CGST and 9% SGST).
- Transfer of the right to use any goods for any purpose (whether or not for a specified period) for cash, deferred payment or other valuable consideration at the same rate of central tax as on supply of like goods involving transfer of title in goods.
- Any transfer of right in goods or of undivided share in goods without the transfer of title thereof at the same rate of central tax as on supply of like goods involving transfer of title in goods.

Here, the term "Information Technology software" includes any representation of instructions, data, sound or image, including source code and object code, recorded in a machine readable form, and capable of being manipulated or providing interactivity to a user, by means of a computer or an automatic data processing machine or any

9 The Central Goods and Service Act, 2017, The Gazette of India,Section 15.

10 Ministry of Finance, Department of Revenue, GST Notification No. 11/2017- Central Tax (Rate) (Notified on 28th June, 2017).

other device or equipment.

The GST Bill considers the permanent transfer/sale of a particular intellectual property right as a supply of service and consequently levies a 12% tax (6% CGST and 6% SGST) on it (but such an IPR should not be in respect of a software).Additionally, the temporary transfer (such as a license or an agreement) of any IPR excluding those relating to IT software is deemed to be taxable at the same rate.Thesale or licensing of intellectual property pertaining to software would be charged 18% tax (9% CGST and 9% SGST).

Before GST, as permanent transfer was not considered to be a service it was excluded from service tax. Additionally, the exclusivity test as laid down by the BSNL judgment[11] was the base for the determination of whether a transfer would amount to a good/sale or a service and taxed accordingly. GST has ruled out the provisions for the transfer to be considered exclusive or temporary as it is to be subjected to the same concurrent tax, no matter of whatever nature it is. The One Hundred and First Amendment Act, 2016failed to amend Article 366(29A)(d) which specifies that the transfer of the right to use any goods is to be deemed as a sale of those goods[12]. However, in a notification[13], the Centre has in a way has classified the right to use any good as a service.

The possible implications of the GST Bill should be carefully evaluated now that both the houses of the Parliament have successfully passed the Bill and it is on its full roll. If the IP-generating entities are not exempted from the Goods and Services Tax, and if the 'goods versus services' debate stands unresolved, IP services will loom in darkness, resulting in their eventual shutting down. Our country can draw lessons from other countries which have GST: countries like Malaysia

11 *Bharat Sanchar Nigam Ltd. v. Union of India,*3 S.C.C. 1, (Supreme Court of India: 2006).

12 Pratik Das, *India: GST Implication On Intellectual Property*, Mondaq (July 31, 2017), http://www.mondaq.com/india/x/615592/Licensing+Syndication/GST+Implication+On+Intellectual+Property#_ednref9.

13 *Id* 9.

have totally exempted IP-generating entities from GST, while some countries have kept GST at intangibles as low as 5-6%, only then this scheme of "one Nation, one Tax" would be benefitting and successful.

RECENT DEVELOPMENTS IN THE FIELD OF IPRs

In order to strengthen IPRs and to make IP legislation in India more rigorous, many steps have been taken, some of the significant ones are which being discussed below[14].

An important aspect to be mentioned under trademark law is that of 'registered brand names'. The supply of certain goods, such as *chena* or *paneer*, natural honey, wheat, rice and other cereals, pulses, flour of cereals and pulses etc. packed in unit container and bearing a registered brand name are to be levied tax at 2.5% CGST rate[15]. Doubts were raised on the definition of a 'registered brand name' and on what it entails. The Finance Ministry on July 5, 2017 issued a press release[16] clarifying the same. The statement noted that "registered brand name" has been defined in the notifications[17] and the same would mean brand name or trade name which is registered under the Trade Marks Act, 1999. In this regard, registered trade mark means a trade mark which is actually on the register and remaining in force[18].

Thus, if a brand name or trade name is on the Register of Trade Marks and is in force under the Trade Marks Act, 1999, it would be exempted from GST rate of 5% (2.5% CGST and 2.5% SGST). This may lead to situations where there are new suppliers in the market who are

14 Diljit Titus & Raj S. Mittal, *Recent Developments in Intellectual Property Laws in India*, Economic Times (Jun 23, 2015 11:52 am IST), https://economictimes.indiatimes.com/small-biz/legal/recent-developments-in-intellectual-property-laws-in-india-part-1/articleshow/47780038.cms.

15 Ministry of Finance, Department of Revenue, GST Notification No. 1/2017- Central Tax (Rate) (Notified on 28th June, 2017).

16 Press Release, Press Information Bureau, Government of India, Ministry of Finance, July 05, 2017, http://pib.nic.in/newsite/PrintRelease.aspx?relid=167146.

17 Ministry of Finance, Department of Revenue, GST Notification No. 2/2017- Central Tax (Rate) (Notified on 28th June, 2017) and *Id* 16.

18 The Trademarks Act, 1999, The Gazette of India, Section 2(w).

supplying goods in unit containers but have not acquired a registered trademark yet would be exempted from GST. This has largely backfired as small traders do not want to register for trademarks as it is preventing them from paying GST. However, this goes against the objective of the National IPR Policy 2016, which encourages commercialization of intellectual property at the very basal level. This would also lead to small traders not being able to protect their intellectual property as all they are focussed on is not paying GST.

Another significant development was regarding the Indian Patents Law, which has been modified to make it more compliant with TRIPS. The list of inventions to be patented has been broadened, the process of infringement suit on patents has been revised, and a uniform period of twenty years for patent protection has been introduced. The Indian Patents Office, in 2014, released the guidelines for insurance of pharmaceutical patents.Along with the Patents Law, the Protection of Plant Varieties and Farmers Rights Act were enacted in 2001 for the protection of Indian plant varieties. The Act takes into consideration the contribution of farmers in improving plant varieties and making plant genetic varieties available. The Act provides fifteen years of protection to plants and eighteen years for trees and vines.

A very crucial recent development is with respect to a law in Karnataka which has been amended to include the term "Digital Offenders". The Karnataka Government in 2014 amended the Karnataka Prevention of Dangerous Activities of Bootleggers, Drug Offenders, Gamblers, Goondas, Immoral Traffic Offenders and Slum Grabbers and Video or Audio Pirates Act, 1985 and expanded its purview to include digital offenders. The Act defines digital offenders as those who purposefully violate any copyright law for commercial benefit in a way which disrupts public order.

On another important aspect, the Indian IPR scenario is also working towards safeguarding personality rights and their protection and enforcement through the Court system. Actors and celebrities have stood up to protect their personality rights and ensure that undue credit is not taken of their reputation without their consent. Even

when there are no specific legislation regarding the same, Courts have been deft at giving the requisite protection to individual rights and sooner or later laws are expected for the same.

In order to protect domain name**,** a policy framework to proliferate Bharat domain name written in Devanagari script on the internet was instituted bythe International Domain Names (IDNs) Registry, in August 2013. The same was launched by the National Internet Exchange of India ("NIXI") in August 2014.

CONCLUSION

The IPR scenario in India is not as strengthened as per the international standards (as provided by TRIPS). There have been continuous debates over the application of IPRs to the agriculture sector, IT sector, software development, etc. The passing of the Goods and Services Tax (GST) Bill fuelled the debate over the fixed tax on intangible property. It is important to review whether intangibles are to be considered 'goods' or 'services' in order to levy tax upon them. If the required changes are not made, the IP sector of our country will loom into darkness.

The introduction of IPRs to agriculture sector has been hailed positively, but there are significant issues which need to be dealt with. The fact that innovations in agriculture technology are going to increase with effective IPR measures goes without doubt. This will allow plant breeders to produce more high yielding varieties and hybrid plants. However, the major issue of concern is for the small farmers, who depend on agriculture for their livelihood. These poor farmers do not have the means or the awareness to take in use a new technology, and the introduction of IPRs will prevent the flow of information about the technology, thus in turn leading to uncertainties and risks.

In order to counter the above mentioned challenges, our IPR policy needs significant reforms. First of all,if effective IPR laws are not made, India's significant repository of medicine and other scientific innovations will be lost. Second, the IPR policy should be changed in order to not jeopardise domestic innovators, and should have a balanced focus on both foreign and domestic innovators.

TRADITIONAL KNOWLEDGE IN CONTEXT OF PATENT LAW

Anee Das[1]
and
Prakreetish Sarma[2]

INTRODUCTION

Traditional Knowledge is considered to be backbone of cultural heritage. It is recognized by most of the indigenous people[3] and local communities and it can be various sorts of knowledge's that are held by such communities under their local laws, customs and traditions. It can also be referred as Indigenous Knowledge.[4] Such knowledge is developed over time has been bequeath orally through generation to generations within the communities[5] and hesnce it lives for years and years. It is commonly the knowledge of the practices existed in society which is handed on to the future generations by theirancestors i.e. regarding the material, its use, its method of preparing and so on. Such knowledge is always rooted with the local culture of the indigenous communities and distinguishes one community from that of other as different indigenous communities has its own and different Traditional Knowledge. Acquiring of such knowledge might help in achieving sustainable development which is one of the essential

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3 Indigenous peoples are those people regarded as indigenous on account of their descent from the population which inhabitated the country belongs, at the time of conquest or colonization or the establishment of present state boundaries and who, irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions.

4 It is the knowledge systems which is developed by a community as opposed to the scientific knowledge i.e generally referred to as 'modern' knowledge.

5 Ishita Chatterjee, Intellectual Property Rights and Traditional Knowledge, Manupatra (July. 23, 2018, 10:53 PM) http://www.manupatra.com/ roundup/363/Articles/IPR%20and%20Traditional%20Knowledge.pdf.

requirements. Along with this, it is also necessary to preserve social and physical environment in which Traditional Knowledge(hereinafter referred to as TK) plays a vital role.

According to World Intellectual Property Organization (WIPO), Traditional Knowledge comprises: "*tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and, all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields*".[6]

Exploitation of such knowledge for industrial or commercial benefits might possess the risk of harmful embezzlement of the same from its legal holders. Traditional Knowledge can be protected by preventing unauthorized utilization by the third parties beyond the arena of tradition and such protection focuses on the knowledge used by the indigenous community[7] on basis of technical, ecological, scientific, and medical or culture.[8] The community having the Traditional Knowledge is regarded as the owner of such knowledge as it has been derived and used by them for generations and they obtain the benefits for such Knowledge. And no individual has the exclusive right over such knowledge until and unless they invent new things to the existing knowledge.

Section 2 (ix) of the protection of Traditional knowledge bill, 2016, alludes Traditional knowledge as that form of knowledge which may or may not be codified, publically available or not that is ever-changing and transforming and is bequeathedfor at leastthree generations, whether consecutively or not i.e.in association with group or groups.

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6 Para 25 of WIPO/GRTKF/IC/3/9 –"Report of third session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore" (July 23, 2018, 11:00 PM) https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_3/wipo_grtkf_ic_3_9.pdf.

7 Any ethnic group with which having the earliest historical connection inhabiting within the geographic region.

8 Juhi Chowdhary, Intellectual Property and Traditional Knowledge, Legal service India (July. 23, 2018, 12:29 AM) http://www.legalserviceindia.com/article/l98-Intellectual-Property-and-Traditional-knowledge.html.

Such group or groups maintains practicesor develops know-how, skills, method of treatment, medicinal preparations, literature etc. but does not cover unauthorized commercial exploitation.[9]

As Patent is the rights of entirety granted to the inventor of an invention for a limited period of time andto obtain patent rights to an invention, such invention must qualifythe requirement of novelty, inventive-step and industrial application. In respect to traditional knowledge, it failed to fulfill the above criteria of patent protection as TK been bequeathed from generation to generation. Patent protects the inventions of an individual while TK is collectively held. Although traditional medicines play an integral part in healing ailments and wounds, yet they fail to meet novelty and non-obviousness as TK consisted of prior art.

Prior to Patent Amendment Act, 2002,Patent Act, 1970 did not talk about the protection of Traditional Knowledge. But after 2002 Act, patent Act 1970 considered traditional as non-patentable inventions and retained traditional knowledge out of the scope of patentable inventions.[10] TK mainly deals with traditional medicine knowledge and such knowledge remains as folklore within the families, tribes and cultures which are later bequeathed from generation to generations. The Most relevant provision that deals with TK is Section 3 (p) which was added by patent Amendment Act, 2005 that undertakesan invention which is in effect, is reciprocation of a component or components of Traditional knowledge as a means of medium.[11] This section refers that the invention on which patent is claimed should not be a mere replication of traditional knowledgeas well as it also denies patent protection on product or process relating to TK without any inventive step or technical improvement as compared to the existing traditional knowledge.This section will be effectual in preventing misappropriation of TK only within the territory of India and not in other countries.[12]

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9 Dr. Shashi Tharoor, Section 2(ix) of protection of Traditional knowledge bill, 2016, (July 24, 2018, 8:30 PM) http://164.100.47.4/BillsTexts/LSBillTexts/Asintroduced/3013.pdf.

10 Section 3(p) of the Indian patent Act, 1970.

11 *Id.*

12 Anu Bala, Traditional knowledge and Intellectual property Rights: An

In *Dhanpat Seth and others v. Neel Kamal plastic craters Ltd.*,[13]the court observed that "the plaintiff's incremental and cosmetic changes to a traditional device known as *Kilta* which had been used by the people in hills to carry agricultural produce from one place to other and therefore was a part of their traditional knowledge, and was not an invention" thus accordingly rejected the earlier granted patent.[14] It has partly acknowledged the significance of inventive step as applied to inventions derived from TK. When patent office examines any application for patent, as long as inventions derived from TK are not entitled to prior art; it securely flows through the grant process. But if during the process of application, when a TK is recognized properly, it limits the area of patents to the particular derived inventions.[15]

Under section 25 (1)of the Patent Act, 1970any person can object against the grant of patent to the Controller on any of the grounds expressed under this sectionthis is regarded as pre–grant patent opposition as the challenge is made before the patent is finally granted.Section 25 (1) (k) talks about objection against the grant of patent if knowledge or other know-how is known to be a Traditional knowledge of local or indigenous community in India or elsewhere which is absent during the claim of complete specification.[16]

The above provision is supported by other two provision i.e. section 25 (1) (d) and section 25 (1) (e) of the patent Act, 1970. Section 25(1) (d) of the Act states that "*the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim.*"[17] On the other hand, section 25 (1) (e) of the Act states that "*the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority*

Indian perspective, 355 (2011).

13 2008 (36) PTC 123 (HP) (DB) (India)

14 JP Mishra, An introduction to intellectual property Rights (2nd ed. 2009).

15 Shravan kalluri, Traditional Knowledge and patent strategy 17 (2012).

16 Section 25(1)(k), Indian patent Act, 1970.

17 Section 25(1)(d),*id.*

date of the applicant's claim."[18] Thus, a combined reading of the above sections highlights that in ourcountry,traditional knowledge's which includes traditionally well-known component or components cannot seek protection of Patent.

Sections 3(p) and 25(1) (k) should be read together as section 3(p) protects TK from being patented as invention is nothing but replication of traditionally known product, method or process and is the subject matter of patent application additionally Sec. 25(1) (k) allows any person to challenge or object the grant of patent over the alleged traditional knowledge as per the provisions of the Act.

However, objection can also be sought after grant of patent in Traditional knowledge under section 25 (2) of the Act, which is regarded as post-grant patent. Under this section, any "interested person" may oppose before the controllerthrough notice of opposition in prescribed manner on any of the recognized groundsat any time after the grant of patent but before the expiry of one year period from the date of publication of grant of a patent.Section 25 (k) of the Act states that *"the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere."*[19]

Based on the above grounds, patent granted on an invention can be revoked under section 64(1) (q) in respect to traditional knowledge. Section 64(1)(q) of the Act states that, "*the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or any indigenous community in India or elsewhere.*"[20]It means that if any patent is permitted for an invention replicating traditional knowledge,such patent may be cancelled at any point of time by the High Court on a petition by any interested person or that of by the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of

18 Section 25(1)(e),*id.*

19 Section 25 (2)(k),Indian Patent Act, 1970.

20 Section 64 (1)(q),*id.*

the patent.[21]Thus, it deprives an invention from patentability if there is any involvement of indigenous knowledge or indigenous community.

In *Ajay Industrial Corporation v. ShiroKanao of Ibaraki City*,[22] it has been held that "a 'person interested' within the meaning of section 64 must be a person who has a direct, present and tangible commercial interest or public interest, which is injured or affected by the continuance of the patent on the register."[23]

An integrated study of these sections repeats that patent protection cannot be granted on traditional knowledge intrinsicallywhich includes traditionallywell-known component or components.

DEFICIENCIES OF THE PATENT ACT, 1970 TO PROTECT TRADITIONAL KNOWLEDGE

There are various reasons that made difficult for the patent Act, 1970 to protect Traditional knowledge. They are as under:

i. As traditional knowledge is of collective nature, so it becomes difficult to identify the real inventor or a group of inventor of the knowledge.

ii. Lack of absolute monopoly rights over the traditional knowledge as such knowledge is bequeathed from generation to generations within the traditional communities. Since, the work has been created by the forefathers of the generations since decades so no one is entitled for monopolies.

iii. Lack of documented evidence is another deficiency. As traditional medicinal knowledge is held by the indigenous communities and been bequeathed generation to generation orally and it is known within the members of the community. Thus, it fails to fulfill the criteria of novelty and inventive step in order to obtain protection under patent law.

iv. Sometimes traditional communities belong to more than one

21 Section 64, *id.*

22 AIR 1983 Del 496 (India)

23 *Id.*

geographical region so it becomes difficult for TK to assign to a particular geographical region.

v. The Act does not provide for disclosure of source of origin of traditional knowledge or wrongly mentions it when used in an invention rather provide for only biological material used for the invention.[24]

NEED OF CONSERVATION OF TRADITIONAL KNOWLEDGE

i. The capability of the Traditional knowledge when turn into commercialization can earn wealth and can result in development of useful application and procedures for the benefit of human race.

ii. As TK is one of the worthy assets of indigenous community as such community is dependable upon TK for livelihood so it's needed to be protected against bio piracy.

iii. TK needs to be protected for sustainable human development.

iv. TK encourages in maintaining traditional practices and cultural heritages.

v. Protection of TK will be helpful in opposing the false claims of IPR.[25]

INVENTION VIS-À-VIS TRADITIONAL KNOWLEDGE

Within the definition of the Patent Act, 1970, every invention invented does not obtain patent protection and not all innovations or modifications made in an existing invention are "inventions".[26]However, the innovations that are not classified as "inventions" within the meaning of the Patent Act, 1970 are mentioned under section 3 of the Patents Act, 1970.[27] The Indian patent Act, 1970 provides protection to all categories of inventions with a strong limitation on the protections and deals with patentable subject matter. From perspectives of patent law, traditional knowledge allude to indigenous communities

24 Section 25 (j) of the Patent Act, 1970.

25 MK Bhandari, Law relating to Intellectual property Rights (3rd ed. 2012).

26 Tanya Alpin& Jennifer Davis, Intellectual Property law- Text, cases and materials (2nd ed. 2009).

27 Sec. 3 of patent Act, 1970.

knowledge that is in existence since decades and as a tradition such knowledge is bequeathed from generation to generation within the communities. If the traditional knowledge is document then such will be characterized as prior art as it already been known to the public. So in such traditional knowledge patent cannot be granted. But at the same time use of such traditional knowledge does not restrain it from exploiting it commercially as it does not affects any rights of an individual or group.[28]

Under patent law, in order to meet the requirements for protection of patent an invention must consist of "novelty, inventive step and industrial application". Section 2(1) (j) of the PatentAct, 1970 states thatan invention needs to be a new product or process and must have innovative steps in it and such invention must be capable of industrial application in order to be qualified for patent protection.[29]

Novelty

Novelty is of core value. For purpose of patent, invention must be new and original that means there must be innovation or technology that has not been expected to be available by any prior publication in a document or vice-versa. The originality is based on the state of prior art. An invention is not original if there is any earlier publication and prior utilization of the same or of an identical invention. To be specific, Invention is something which is to be found that are not found by anyone previously. It is not necessary that inventions must be a complicated one; rather it can be a simple invention which can be claimed on basis of novelty as in *Raj Prakash v. Mangat Ram Choudhary*.[30] Section 2(l) of the Indian Patent Act, 1970 defines new invention as "*any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.*"[31]

28 *Supra* note 10.

29 Section 2(1)(j) of the Patent Act, 1970.

30 AIR 1978 Del I (India)

31 Section 2 (l) of the Patent Act, 1970.

As novelty i.e. originality refers to the prior non-acknowledgement of the invention to the general public, it indicates secrecy on the matter for claiming novelty.Previous publicationor previous use of the invention before registrationdenies novelty. Section 13 of the Patent Act, 1970 requires if any claim for grant of patent in complete specification is not new or has been familiar to public or used in the country before the formal request of priority date, then such request or claim will be rejected on basis of absence of novelty.[32]Based on the patent requirements in context of traditional knowledge, it is apparent that nearly about all categorization or types of traditional knowledge are available in public realm. More the common public is acquainted with the information; more the demand of novelty is defeated. With allusion to TK, indigenous communitiesare knowledgeable about the detailed information and such knowledge is in the uninterrupted use within the community. Thus, in absence of novelty products will be disqualified based on such knowledge for basis of patent protection that is treated as an invention.[33]

Inventive Step

Inventive step is the second essential condition for obtaining patent protection of an invention. Section 2 (ja) of the Patent Act, 1970 defines inventive step as "*a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.*"[34]In context of TK based invention, it must consist of inventive step and there must be sufficient establishments that TK based invention consist of inventive step which is enough for grant of patent. Though patent law protects derived inventions, it is necessary to plan a way to protect the development process of such latent inventions. Thus, the factor inventive step plays a vital role for

32 Section 13 of the Patent Act, 1970.

33 Shodhganga, "Protection of Traditional knowledge under the existing modes of Intellectual property Rights and surrounding issues", (July 29, 2018, 1:08 pm) http://shodhganga.inflibnet.ac.in/bitstream/10603/22605/11/11_chapter4.pdf.

34 Section 2(ja) of the Patent Act, 1970.

the individual or an institution who seeks to obtain patent invention derived from TK. As long as invention derived from TK involves an evident inventive step, it can be granted patent. But as the fact of Traditional knowledge is passed on from generations to generations, it gives a prima facie evidence that the present conservators are not the creators but the successors of the aforesaid knowledge. So, the present claimant has not contributed any of its skill, labor or creativity to institute a valid claim of patent; neither includes any technical advance to the existing knowledge. Thus, existingTK will be carried on as particulars that has been made available to public i.e. prior art and hence it invalidate inventive step as a condition to claim patent for traditional knowledge.[35]

In state of Kerala, since decades people have been using a plant named Arogyapaach for medicinal issue. In the tribal area of the Western Ghats in the state of Keralathroughout an ethno-botanical expedition, a group of scientist belonging to Tropical Botanical Gardens Research institute (TBGRI) observed that Kani tribes eating some seeds of wild plants to avoid fatigue and this gave them energy. Then the group of scientist held an investigation on Arogyapaach and thus developed a standard drug on the knowledge of kani tribe based on Arogyapaach named as *Jeevani*, an anti-stress, anti-fague, immune-enhancer drug. The secrecy of the knowledge was disclosed by three members of the kani tribes. However, the customary rights to practice and transfer medicinal traditional knowledge to the next generation is held by the tribal healers called plathis. However, an Indian pharmaceutical company namely Arya vidya pharmacy Ltd. was granted license to exploit the technology to manufacture the drug. Thus, among the various stakeholders a Trust fund was established for benefit sharing and thereafter obtain patent based on such discoveries which was granted by the patent office.[36]

Industrial application

It is the third essential condition for obtaining patent protection of an

35 *Supra* note 31.

36 *Supra* note 13.

invention.If an invention consist of novelty and inventive step, but lack usefulness behind it then such invention will not be granted patent. It does not mean that invention must be of commercial shape or vice-versa, it depends on the utility of the invention i.e. the invention must be useful in some kind of industry.[37]Section 2(1) (ac) of the Patent Act, 1970 defines capable of industrial application as "*in relation to an invention, means that the invention is capable of being made or used in an industry.*"[38]

From very inception of patent system, it is connected to the industrial and profitable growth of the country. So, only those inventions which are functional or practical as well as beneficial to the general public are granted patent protectionas per the basic principles of patent system. However, the use of traditional knowledge towards the societyis one of its positive facets that have been passed from generation to generations. Long existence of such information's has helped the society to use such traditional knowledge and to reveal the use of TK in any invention claiming for patent. Thus, it is the industrial application that is required to obtain patent.

BIOPIRACY BEING THE DUAL THEFT OVER THE INDIGENEOUS KNOWLEDGE

Bio piracy is an unlawful appropriation of patent legitimate rights over indigenous knowledge especially biomedical knowledge's i.e. knowledge relating to biology and medicine without reimbursing to the indigenous communities who evolve such knowledge. In simple words it means, wrongful grant of patent to an invention which neither possess novelty nor inventive step in regard to traditional knowledge which is already in existence i.e. in public domain.[39] It is the embezzlement of genetic resources or traditional knowledge by individual or institutions that tries to obtain exclusive monopoly rights over the assets and knowledge

37 BL Wadhera, Law relating to intellectual property (5thed. 2014).

38 Section 2(1) (ac) of the Patent Act, 1970.

39 Mangala Hirwade & Anil Hirwade, Traditional Knowledge protection: An Indian prospective, 32 (2012).

i.e. through patent system by exploitation of the community resources. The term 'Biopiracy' can also be used to indicate contravention of contractual accordance on the use of traditional knowledge that might cause damage to the provider. It can also be referred as dual theft because firstly, it allows stealing of inventiveness and innovations. Secondly, it gains economic value at the option of everyday livelihood of indigenous communities on the base of their common knowledge.[40]

In Neem patentCase[41]"patent was first filedin European Patent Office (EPO) by W.R. Grace and Department of Agriculture, USA for process of managing fungi on plant with the help of hydropholic neem oil. India opposed for committing bio piracy and raised objections toward the grant of patent and put forwarded therequired evidences that hydrophobic decoction of neem seeds were familiar and used for centuries in India, both in healing dermatological diseases in humans and in protecting agricultural plants form fungal infections. The EPO identified the lack of novelty, inventive step and possibly form a relevant prior art and revoked the patent. Since then, Indian traditional knowledge is known in general public."

In Turmeric patent Case[42] "Patent was granted by United State to "University of Mississippi Medical Centre" for use of turmeric in healing wounds. By granting patent it also granted the absolute rights to sell and distribute turmeric. India's Council of Scientific and Industrial Research (CSIR) challenged the university on the ground of novelty by supporting their claim by presenting documented evidence of TK. Thus, United State Patent and Trademark Office (USPTO) cancelled the patent on the ground of lack of novelty as turmeric is extensively used for centuries as medicines, food ingredientsetcin India."

In Basmati patent Case[43] "Patent was granted by United States Patent and Trademark office (USPTO) to a Texas based American

40 *Id.*

41 Patent no. 436257 B1, 1990 (US)

42 Patent 5401504, May1995 (US)

43 Case Number- 493, Patent number-US5663484A, Sep2, 1997 (US)

Company Rice Tec Inc for 'Basmati rice line and grains'.Patent was claimed over these novel Basmati lines and grainsby this company for inventing it. The application for patent was based on 20 very broad claims on having "invented" the said rice. Out of the 20 claims, the Indian Government had pursued to appeal only 3 claims made in the original patent application of Rice Tec Inc. stating that most of the varieties of Basmati own these qualities. The USPTO rejected the grant of patent."

Absence of proper documentation of related traditional knowledge has made it easier for offenders to commit Biopiracy.Thus, lack of legal protection over the biological resources and Traditional Knowledge has made it more vulnerable to bio piracy.

TRADITIONAL KNOWLEDGE DIGITAL LIBRARY

Traditional Knowledge Digital Library (TKDL) is an initiative by the government of India to protect India's traditional knowledge from misappropriation at international level and its access to TKDL been provided under the International Agreement at international patent office. The aim of this initiative is to prevent from bio-piracy and to promote innovation through traditional Knowledge in order to create new intellectual property for promoting access to medicines. This digital library is open to International Patent Office in order to keep a check by the examiner whether any claimed invention is covered under traditional knowledge or if it consists any prior art and hence not fit for the grant.In short, TKDL is a privilege for protection of TK from bio-piracy.[44]

The essential features of TKDL are as under:

a. It takes into account around 35000 medicinal formulations of Ayurvedic traditional knowledge.

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44 Sunil Abraham &VidushiMarda, The Digital Protection of Traditional Knowledge: Questions Raised by the Traditional Knowledge Digital Library in India, (july. 30 2018, 12:58 AM) https://cis-india.org/a2k/blogs/giswatch-december-9-2016-sunil-abraham-and-vidushi-marda-digital-protection-of-traditional-knowledge-questions-raised-by-traditional-knowledge-digital-library-in-india.

b. The medicinal formulation particulars include descriptions, procedure of preparation and claim, botanical name of the plant and disease, which can be healed.

c. Translation of Sanskrit text of formulation to many foreign languages.

d. It will help in preventing biopiracy as it will be available to all the patent office's all over the world to search and examine any prevalent use and prior art.

e. This will remove the problem of grant of wrong patents as its knowledge will be available to the patent examiner.[45]

Hence, TKDL as a mechanism ensures patent office not to grant patent for application initiated on wealth of India's TK which has been in existence for millennium.

***SUI GENERIS* LEGISLATION**

As the present system strives to transfer traditional knowledge from public to private ownership, it's been difficult for the present IPR system to protect traditional knowledge.It is intended to be hold by individuals or corporations, whereas traditional knowledge is collectively held by a community i.e. having collective ownership.IPR system protection is for limited period of time which does not offers permanent protection whereas traditional knowledge is everlasting continuing through generations to generations. As the system bears a confinedinference of invention that must meet the conditions of novelty, inventive step and must be capable of industrial application whereas traditional knowledge is gradual, informal and happens every time.[46] So, *sui generis* or alternative law is of utmost necessary for protection of traditional knowledge at the domestic level as it will benefit the indigenous communities, protections will also be valid at the national legal framework.As the term *Sui generis* means of own kind and consist of set of nationally recognized laws which as an alternative system provide protection outside the IPR regime that addresses a specific

45 *Supra* note 23.

46 *Id.*

issues. Such legislation has the probability of covering all the facets of Traditional knowledge. Enactment of such legislation will held higher objective valuation of TK than the prospect of benefit sharing as it recognizes the economic, cultural and development character[47] and such system wouldrecognize the importance of protecting traditional knowledge against third parties claiming intellectual property rights over TK.[48]

Sui generis laws include the element of benefit sharing, provisions of prior informed consent, revelation of sources of biological resources origin, co-ownership of patents wherever applicable, includes disclosure of an traditional knowledge if applied in an invention.[49] Under such law, an invention need not be novel, non-obviousness and need not be of industrial application so traditional knowledge can be protected under such law and enactment of such law will also improve the livelihood as well as better protect the interest of traditional knowledge holders. Enacting such legislation will prevent traditional knowledge from bio-piracy as well as it will help in conserving the environment which will result in benefit of national economics. As a result, enactment of *sui generis* legislation will be helpful for protection, preservation and promotion of Traditional Knowledge. Thus, it will provide legal protection to Traditional Knowledge as well as it will develop the protection for the knowledge of local communities.

CONCLUSION

Traditional knowledge has been always a considerable element of indigenous community at large. It does not necessarily mean only knowledge but to an extent its formation and uses are part and parcel of a cultural tradition of a community. TK is generally not protected under Intellectual Property rights as the present system

47 Avtar Singh, Intellectual property Law (1st ed. 2013).

48 Shamama Afreen & Biju Paul Abraham, Biopiracy and protection of Traditional Knowledge: Intellectual property Rights and beyond, (july 30, 2018, 9:51 PM) https://www.iimcal.ac.in/sites/all/files/pdfs/wps-629_1.pdf.

49 Dr. Balavanth S Kalaskar, Traditional knowledge and Sui Generis law, 3 (2012).

authorizes individuals to protect their inventions but it does not authorize communities to protect their knowledge in all areas collectively and in those areas where Intellectual Property rights can be registeredcollectively, communities are not increasing their rights. Such emerging gaps between TK and IPR brighten up for more need of protection that will value the knowledge of indigenous communities. The collective right of a traditional community must be recognized as well be protected. In order to protect TK against biopiracysufficient steps must be taken up by all the governments of state. The local and indigenous people should be motivated to register their valuable TK officially at official register in order to avertembezzlement of their knowledge by third parties.

Though, existing IP laws is not competent to protect traditional Knowledge, so such laws must be complemented with *sui generis* law for TK that will confer ownership rights over the traditional knowledge holders who will exercise absolute right to legally decide about the use of such knowledge.Thus, there is very much need of binding laws for protection of TKand conserving the environment which will result in benefit of national economics.

IS ANYTHING UNDER THE SUN THAT IS MADE BY MAN - 'PATENTABLE? A CRITICAL REVIEW ON DESIGNER BABIES

Dr. Aradhana Nair[1]

and Pavitra R[2]

INTRODUCTION

The title of this paper begins with the famous judgement of 1980 by the US Supreme Court[3], which established a platform for the inventors to think, create and obtain patents for genetically modified bacteria[4]. The subject of patenting of 'Life Forms' has been drawing a great deal of attention all over the world. This decision led to opening of several developments in gene patenting and biotechnological[5] inventions. In the present situation genome[6] editing is gaining momentum. Gene is the important element responsible for lot of aspects that take care of human body. It is found that certain diseases and disorders are genetic in nature. The personality of a person also depends upon the genes. There is gene augmentation or gene therapy which is not similar to gene editing. In the first process a new gene is introduced to rectify the defective gene. In the second process there is alteration or modification of the DNA.

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3 Diamond v. Chakrabarty, 447 U.S.303 (1980). In this case,Ananda Mohan Chakrabarty had developed a genetically modified bacteria that was debated in the above case. In the ruling of the above case the statement was made to incorporate genetically modified bacteria patentable.

4 The term genetically modified bacteria are an artificial bacterium created to break the crude oil.

5 Biotechnology is a popular term form the generic technology of the 21st century. Although it has been utilized for centuries in traditional production processes, modern biotechnology is only about 50 years old, and in the last decades it has witnessed tremendous developments.

6 Genome is the entire sequence of DNA of an organism. The genome includes genes.

Innovations have moved to such an extent that there is a possibility of replacing the natural human beings with extra smart and attractive humans created through modification of the genes where the end product is called genetically engineered babies or designer babies. Hence a baby could be created with genes free from autism, Parkinson's and other diseases. One can design a baby with new hair colour, eyes colour, height and structure, active in sports or studies etc. Gene editing[7] is a method used to modify the DNA in a cell. It is not restricted alone to humans but could also be used in animals or any other organism. Gene editing technology today with CRISPR/ CAS 9[8] is growing fast. This process is adopted by taking consent of the parents and with the guidelines of the scientist. The consent of the person not born does not arise when it is being designed. But later there may be issues when the designed human may raise a concern as he or she is not made naturally but designed to be superhuman which they do not want too. There are many ways in which genetically engineering babies are created, may be by germline engineering or preimplantation genetic diagnosis[9]. Today we have CRISPR/CAS9.

However, the designing of babies is not a novel concept, it began in the year 1989. In the year 2000 Adam Nash was born in US to cure the ailment of his elder sister[10]. In UK in the year 2003, the designer baby was created for similar purpose[11]. Worlds first designer baby

7 Gene editing is genetic engineering where the DNA is altered or modified. Genome editing is the process where theDNA is modified, either by altering, removing or adding nucleotides to the genome.(Jul. 27, 2018, 8.32 P.M)www.allelebiotech.com/genome-editing/

8 Clustered Regularly Interspaced Short Palindromic Repeats. CAS9 means CRISPR associated protein which cuts the DNA at the target site. It is widely used as it is of low cost, simple

9 Germline engineering is genetic alteration within the germinal cells, or the reproductive cells such as oocyte and spermatogonium. Preimplantation genetic diagnosis is genetic profiling of the embryos prior to implantation or in oocyte before fertilisation. This process is also used to identify genetic diseases.

10 Molly Nash was born with genetic disorder where her body could not produce healthy bone marrow. Hence a genetically engineered baby was created so that blood from his umbilical cord could be used.

11 Genetically engineered baby was created and named as James Whitaker

created with DNA of three parents was born in Mexico 2016. China also developed designer babies with an intent to cure diseases. India is still in the process of development. The entire purpose with which the innovation had been brought into existence was for curing diseases or rectifying a disorder. Till the medical purpose of designing babies is considered, it is ethical and well accepted. But once the shift changes to fanciful approaches it becomes difficult to justify the process. With the designing of babies, it appears that nature has transferred the application (app) to design babies into human hands. It is worth appreciating that science has developed to incorporate such innovations. When such innovations are promoted there is a need to analyse all possible issues in continuing with such practices.

When the origin of gene editing is looked into, it is in the year 1973 the first organism that was genetically engineered for antibiotic resistance was created[12]. Then in 1982 the synthetic insulin was developed as a part of the genetic engineering. So, it was for betterment of human health and development of therapeutic practices and reduction of diseases being the motive of genetic engineering. Research flourishes further with Monsanto, genetically modified crops and in 2003, "selfish gene"[13] being researched upon. In 2012, University of California-Berkeley and the Broad Institute of Harvard University independently discovered the CRISPR/ CAS9- a bacterial immune system can be adapted to serve as a gene-editing tool.[14] The use of CRISPR/ CAS9, led to the conflict between claimants of patent. The University of California, Berkeley and the Broad Institute began battling over the

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to help his ailing brother. The UK government had opposed the procedure, because it was felt that is unlawful and unethical but they went ahead with it. The process was adopted in US. Background of designer babies, (Jul. 27, 2018, 8.55 P.M), https://mcsdesignbaby.weebly.com/backround-info.html

12 The bacterium E. coli created by Herb Boyer and Stanley Cohen giving a new dimension to the world of genetics.

13 It is a theory where cells and organisms exist simply as packages to protect and transmit genes.

14 Rowan Jacobsen, *A Brief History of Gene Editing*, Pacific Standard (Jul. 27, 2018, 9.20 P.M), https://psmag.com/magazine/a-brief-history-of-gene-editing

patents related to CRISPR/ CAS9. In 2016, the USPTO had granted patents first to Broad Institute even though University of California were the first one to apply for patents. The Broad Institute got their patent application processed fast by paying extra fees. An interference proceeding was initiated by University of California to check if the claims were the same in patent application. University of California had not specifically mentioned in their patent application about the exact use of CRISPR/CAS9 on eukaryotic cells. The patent dispute got settled in favour of Broad Institute in the year 2017. The judgement of the USPTO was that in the year 2012 the patent application only claimed the process of gene-editing with CRISPR on prokaryotes such as bacteria. Whereas the Broad Institute had a limited scope of a using CRISPR/CAS9 technology on eukaryotes such as plants and animals. Hence anyone who wants to adapt CRISPR/CAS9 technology would have to obtain license from both the parties as one of them holds patent with a wider ambit and the other with plants and animals.[15]

JURISPRUDENTIAL PERSPECTIVE OF GENE PATENTING

Babies are designed and produced by genome editing. The technology to edit the gene demands for intellectual property protection. There is a need to analyse jurisprudential base of designing babies with intellectual property lens.

If Lockean theory is applied designing of babies is a part of one's labour and hence his property. Creativity is the component that needs to be protected and is the base of arguments where intellectual property protection is warranted. Creativity in the world outside is well accepted. When the jurisprudential aspect of intellectual property is looked upon, there are many justifications provided for the need of protection. The theories of justification are extended to all kinds of property that is tangible and intangible. The same features that apply to tangible property is extended to intangible property like sale, lease, gift and all other types of transfer. Hence taking Lockean theory of

15 Heidi Ledford, *Broad Institute wins battle over CRISPR patents*, Nature International Weekly Journal of Science (Jul. 28, 2018, 3.20 A.M), https://www.nature.com/news/broad-institute-wins-bitter-battle-over-crispr-patents-1.21502

property the innovative process of genome editing fits into intellectual property protection.

The Hegelian justification of property is where property is an integral part of one's personality. The core aspects of one's life like liberty, identity and privacy is extended to property. When a person owns a tangible property, he fights for the security, ownership, freedom and enjoyment of the property. It is a right in rem and therefore is the valuable asset which becomes a part of his personality. Now when intangible property is considered the same features that forms the core value like privacy, liberty and identity is extended and it is justified that intangible property needs protection as it is part of the creator's personality. This personality theory of justification can be extended for genome editing. The creator's efforts are appreciated when the skills of editing the DNA is concerned and it authorises for intellectual property protection.

But when the other side of the personality is being edited without the consent of the person, it becomes an issue and hence needs proper regulation.

When utilitarian theory is taken for the protection of designer babies, the element of public good is considered. Public good of this particular property is only with respect to curing of ailments or correction of some genetic issues and not with the fancy designing features being adopted. If Hohfeld's analysis of right and duty is considered the protection to intellectual property is justified as it becomes the duty of the state to protect the rights of the creator. Since every right cannot be protected due to reasons like national security, environmental protection and other moral issues, state has incorporated limitations to protection through legislation. The limitations are put through S.3 of the Patents Act 1970.

There are three theories that could be developed by taking into consideration the purpose of designer babies.

a) The first theory is ineliminable theory, where the either the medical conditions of the parents prohibit or leads to medical

problems in conceiving a child naturally or due to the genetic disorder of the sibling, a genetically engineered baby is created. So, the ineliminable theory focuses on the need created by nature for producing a baby by use of technology which is justified.

b) The second theory is that of contentment and recreation. Where due to sound financial background of the parents they have the leisure to make choices about modifying the DNA of the baby. The choices may vary from disease free baby to creating a baby according to one's creative and imaginary ideas. It is with the second theory that regulation becomes important.

c) The third theory is of forced acceptance. The present generation may knowingly or unknowingly shape the characteristics of the future generation which may not be acceptable to the future generation. This may lead them to live in compulsion with the traits developed artificially. This theory of gene editing needs regulation.

AN ANALYSIS OF THE DESIGNER BABIES THROUGH S.3 OF THE PATENTS ACT 1970

There are various grounds provided for inventions not patentable. When genome editing is concerned there is a need to analyse various provisions provided under the Act. Hence when the analysis is done, S.3 (a)[16] refers to inventions against the well-established natural laws. Genes are natural hence genome editing where the human or animal genes are tampered through various technological innovations cannot claim protection. S.3(b)[17] specifies that the creativity through inventions are not encouraged for protection where through its use or commercial exploitation affects public order or the core moral values or inventions affecting human, animal, plant or environment.

16 S.3 (a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;

17 S.3 (b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment

Gene editing cannot be encouraged as it clearly falls within S.3(b). Further S.3(c)[18] differentiates between discovery and inventions. All that is discovered cannot be protected. Genes are naturally present. Hence it cannot be per se protected. When this argument is raised it is accepted that it is not the gene that is calling for protection but the editing of the gene which is not natural and is created so needs protection. S.3 (i)[19] explains that any process which is used to cure the diseases and defects or efficiency in humans or animals cannot be protected. Gene editing when carried out for curing the diseases or defects in human or animals cannot be monopolised. But when it is used for designing one's own baby the concept shifts from curing and treatment to one's desires and fancies. So, the question arises if it falls under the provisions of non-patentable inventions. S.3(j)[20] stresses on plants or animals in whole or any part of them cannot be patented as it naturally occurs. Therefore, genes cannot be protected per se but the technology used for gene editing can qualify patents.

THE ADVANTAGES AND DISADVANTAGES OF GENE EDITING

If the advantages are analysed, it is mainly argued that:

a. This would lead to disease free society. As majority of the genetic diseases would be in control or completely eroded. Hence people would have a better life and longer one too.

b. The society would be blessed with variety of performers. The skills of the future generation would be in the hands of the present generation. So, the society will witness skilled musicians, dancers, artists, authors, intellectuals with high efficiency etc.

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18 S.3(c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;

19 S.3 (i) any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

20 3 (j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

c. Will lead to further growth of science and technology.

When the disadvantages are analysed:

a. Only the economically sound families can afford or think about gene editing. Since it is patentable and not so common a technology it would certainly be highly priced. So, in short, the rich class of society can afford for healthy and longer life. The disparity on the grounds of class system becomes stronger.

b. The naturally talented born humans will face a lot of challenges with competition from genetically engineered humans.

c. The consent of the genetically engineered human is not possible to be obtained before modifying the genes. The human personally may not be contended with the modification. Like for example; When a blue-eyed female is designed and brought up there are chances where she may develop the taste for natural black eyes. When she understands the truth that she was designed that way, she may not accept it but she would have no other option.

d. At present we are in testing grounds and we predict that genetically engineered babies would live better. Only time can prove if our predictions are correct. In future the modification may lead to new unknown problems.

e. This process will help rich class of society to genetically engineer the sex of the embryo. Indirectly contributing to the prohibited norms of the society.[21] If Gene editing is encouraged and not regulated then it may lead to sex selection by parents.

CONSTITUTIONAL VALIDITY FOR GENETICALLY ENGINEERED BABIES

Editing of the gene may lead to challenges of constitutional validity of the process in future, where the designed babies will have better

21 In India, sex selection is prohibited through Pre-Conception and Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 and Medical Termination of Pregnancy Act, 1971.

physical features as compared to the natural born babies. Therefore, there arises a distinction between the natural born babies and the designed babies. The other part of the challenge would be the problem where economically sound families can think about the designed babies and the economically unsound families may not be able to cope with it. Disparity arises in economical and physical aspects of the designer babies. If a proper regulation is not drafted then inequality will be the end result, between both the babies as well as the parents. This will further lead to strengthening of certain sociological problems like racism, class-based violence's etc.

These challenges can be possibly addressed with a regulation that clearly balances the issues of disparity. The regulation should specify that there would not be any difference between genetically engineered babies and normal babies. It is only the origin of the embryo been modified, otherwise the baby is normal. This regulation will act as a disclaimer for future issues raised about disparities and need for extra benefits by either side of the group.

International Perspective of Regulatory bodies

There is a need to relook into ethical aspects of genetically engineered babies because innovations shift from need based patterns to dreadful pattern. There is a confusion about the destruction to be created by the invention in future. A comparative analysis will help to decide and strengthen the regulatory mechanisms needed.

If US approach to the ethical issues of designer babies is looked into, they began with the invention without a second thought on the consequences. Some of the doctor's fear from modifying the genes as it is going against the nature but it is justified as curing of diseases also is a way of going against the nature. For others it is the normal surgical process.[22] There is no regulatory framework to govern the gene editing process. But as of now the process is monitored by the scientists and the Food and Drug Administration, Centres for Medicare

22 *Ethical Problem*,Designer Babies (Jul. 28, 2018, 3.20 A.M) https://sites.google.com/a/jeffcoschools.us/designer- babies/the-ethical-problem

and Medicaid services, and the Federal Trade Commission.[23] There are advisory bodies like Recombinant DNA Advisory Committee to review clinical trials and to monitor about the norms to be followed[24].

Animals (Scientific Procedures) Act 1986, governs the gene editing among animals in UK. In 2015 the mitochondrial donation was upheld for IVF babies.[25] When the ethical part of the designer babies in UK is considered they have created a board, Human Fertilisation and Embryology Authority (HFEA) where every kind of research on human embryo, is not entertained and it is essential to obtain a license from the authority. There are prohibitions laid down such as:

a. any kind of development beyond 14 days of human embryos outside the human body is prohibited.

b. In any way a genetically altered embryo cannot be implanted into the womb. Exceptthe mitochondrial donation as mentioned above.[26]

Hence in UK gene editing is monitored and allowed only for curing and treating certain disorders, like improving the genome for reduction of miscarriages, but not for any other purpose.

From the year 2000, China conducted lot of researches in gene editing and were successful by 2015. China has taken the lead in gene editing by being successful in various animals and organisms were genetically engineered. The laws in China are very clear and prohibits

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23 Christopher Coble, *Legality of Designer Babies,* Find Law, December 7, 2015 (Jul.30, 2018, 2.56. P.M) https://blogs.findlaw.com/law_and_life/2015/12/legality-of-designer-babies.html

24 R Alta Charo, *The Legal and Regulatory Context for Human Gene Editing, Issues in Science and technology*, Volume XXXII Issue 3, Spring 2016 (Jul.30, 2018,5.33. P.M) issues.org/32-3/the-legal-and-regulatory-context-for-human-gene-editing/s

25 It helps in preventing serious disorders from being transmitted from mother to the baby, where the healthy mitochondria are donated by a healthy woman and implanted into the cells of the baby.

26 *Genome Editing*, Post Note, House of Parliament, Parliamentary house of Science and Technology, (Jul.30, 2018, 3.36. P.M) researchbriefings.files.parliament.uk/documents/POST-PN-0541/POST-PN-0541.pdf

any kind of meddling with human egg plasma or genes.[27] But still the research was permitted because the researched egg was not to be used for further development. The restriction imposed by their regulators is the hindrance for their research but still the gene editing is being used without the permission of the national regulators. It is being reviewed by the medical board.[28] Just like in US the State Food and Drug Administration regulates the gene therapy. Human somatic cell genome editing will also be regulated by CFDA. Besides CFDA the Health and Family Planning Commission (HFPC), will play an active role in genome editing, as presently they are regulating the IVF clinics. There would be an active involvement of consultations from departments like, Ministry of Science and Technology, Chinese Academy of Sciences, Chinese Academy of Medical Sciences, and Chinese Academy of Engineering, to provide regulatory mechanism.[29]

Lot of development in research of gene editing has affected Korea too. Where in Korea impact of these developments were assessed through a programme called, "Technology Impact Assessment". Korean Biosafety and Bioethics Act does not directly regulate the process of gene editing. There is a provision under Art 47 on Gene Therapy. This provision provides for regulation on research of gene therapy among humans. Gene therapy incorporates in it the procedure of alteration in genes and the transfer of the genetic material. Though the Bio Act 2016 tries to ban gene therapy on human embryos, there is no clear guidelines as to complete regulation on genetically engineered babies.[30]

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27 The Guidelines on Human Assisted Reproductive Technologies, "using human egg plasma and nuclear transfer technology for the purpose of reproduction, and manipulation of the genes in human gametes, zygotes or embryos for the purpose of reproduction are prohibited"

28 Lauren F Friedman, *Tweaking the genes in human embryos is technically legal in many countries, and a new experiment could open up the floodgates*, Business Insider India, (Jul.30, 2018, 6.26 P.M) https://www.businessinsider.in/Tweaking-the-genes-in-human-embryos-is-technically-legal-in-many-countries-and-a-new-experiment-could-open-up-the-floodgates/articleshow/47032030.cms

29 *International Research Oversight and Regulations*, NCBI Resources, (Jul.30, 2018, 7.08 P.M) https://www.ncbi.nlm.nih.gov/books/NBK447261/

30 Na-Kyoung Kim, *Gene-Editing: Interpretation of Current Law and Legal*

One of the strictest nations with respect to gene editing is Australia. The Prohibition of Human Cloning Act, 2002 in Australia provides for 15 years imprisonment for any kind of gene alteration. The government encourages research in genetic engineering. There are certain strict conditions laid along with it like the embryo after alteration should not be placed in womb of the woman. The consent of the parents has to be obtained and the embryo must be destroyed within 14 days of development.[31] Since there is lot of development taking place through CRISPR technology there are chances of this law becoming more flexible. With respect to plants and animals there is a change.

Research on human embryo is accepted in Japan. The research on gene editing was successful but were refused from clinical trial considering the harmful effect on future generations. The debate on ethical issues of genome editing is matter of concern. Till date there is no proper regulatory mechanism. Developments in gene therapy exists but not in genome editing.

European Medicines Agency (EMA) takes care of the human and animal medicines in the European Union. The EMA constituted a committee named as Committee for Advanced Therapies to monitor and regulate medicines made from genes. Clinical trials with respect to genes is out of the jurisdiction of EMA. Hence EU Directive on Clinical Trials was made. This directive and the Food and Drug Administration requires every member state to adopt strict supervisory mechanism based on international regulations.[32]

In India human gene editing is regulated by the guidelines issued by Indian Council of Medical Research (ICMR), National Guidelines for Biomedical and Health involving human participants and The National guidelines for Stem Cell research. These are mere guidelines

Policy, Development and Reproduction, (Jul.30, 2018, 7.24 P.M) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5651701/

31 *Why Our Gene Editing Laws need to catch up*? Medical Republic, (Jul.30, 2018, 6.43 P.M) medicalrepublic.com.au/gene-editing-laws-need-catch/11200

32 *International Research Oversight and Regulations*,NCBI Resources, (Jul.30, 2018, 7.43 P.M) https://www.ncbi.nlm.nih.gov/books/NBK447261/

where as it is only through a proper statutory regulation efficiency can be achieved as compared to the guidelines. Germline gene editing is banned in India. A three-tier monitoring mechanism as suggested by Takshashila foundation should be established at laboratory, clinical trial and by public[33].

There is a need of a regulatory body at international level to provide guidelines to all nations signatory to the regulation. To draft a law according to such guidelines. Taking the gravity of the effect of the innovation in future,U.S. National Academy of Sciences, the U.S. National Academy of Medicine, the Chinese Academy of Sciences and Britain's Royal Society organisedan international summit on human gene editing in Washingtonheld in December 1 to 3, 2015.The second three day international summit on genetic engineering was organised by Academy of Sciences of Hong Kong, the Royal Society of London, the U.S. National Academy of Sciences, and the U.S. National Academy of Medicine in Nov 2018.

In both these summits express concerns towards gene enhancement was shown by different groups. The problems of social inequalities or other manipulations that would take place was discussed. The need for a regulatory mechanism was also highlighted.[34]

CONCLUSION:

The title of the paper uses the statement used in US case which appropriately applies here as the innovative concept of designer babies can be patented as it falls in all the criteria of protection. The problem arises with tinkering of gene the entire natural process of development of the baby is modified according to human desire. In future there are possibilities that the designed humans may ask for separate rights or special treatment as they fall in the minority group. An appropriate

33 Madhav Chandavarkar, Anirudh Kanisetti, Shambhavi Naik, Ajay Patri, *A Framework for Governing Gene Editing*,The Takshashila Institution Bengaluru, India(Jul.31, 2018, 7.43 P.M)takshashila.org.in/wp-content/uploads/2017/10/TDD-Governing-Gene-Editing-MC-AK-SN-AP-2017-061.pdf

34 *Human Genome Editing*, Japan Times, Sept 26 2016, (Jul.30, 2018, 11.28 P.M) https://www.japantimes.co.jp/opinion/2016/09/26/editorials/human-genome-editing/#.W19JrvZuJy0

regulation is needed to regulate the functioning of designing the babies or gene editing. Hence anything under the sun made by man can be patented but when it affects the natural process a kind of regulatory control is needed.

However, there is still a long way to travel towards genetically engineered babies as small genetic mutations can help to design the baby but for characteristic changes like height, weight etc, it will be a hefty task. As for change in height of a human, there would be a need of somewhere around 93000 genes variation which is a difficult task. Genetic enhancement is still being researched.[35] Nothing remains impossible in future. So as a precautionary measure it would be good that we equip ourselves with proper regulatory framework. A complete ban on the process would not be an ideal solution. Only time will reveal if the technology of CRISPR is a bane or a boon. Let there be a ray of hope through regulations so that it doesn't amount to mass destruction. By providing patents to such innovations there is a need to ask if the state is ethically on the right path.

SUGGESTIONS

1) The gene editing should be strictly monitored by the governing mechanism of the state.

2) At international level there is a need for a convention based on the issues of gene editing. At least WIPO should develop a mechanism to regulate patents to gene editing.

3) At National level, in India the ICMR has already taken steps of issuing guidelines. This should be supported by a strong statutory legislation and monitoring mechanism of scientists, lawyers and doctors.

35 Pam Belluck, *Gene editing for "Designer babies"? Highly unlikely, Scientist say,* The New York Times, Aug 4, 2017(Jul.30, 2018, 2.33 P.M) https://www.nytimes.com/2017/08/04/science/gene-editing-embryos-designer-babies.html

PATENTABILITY OF STEM CELLS: A CRITICAL ANALYSIS OF INDIAN PERSPECTIVE

Aviral Vats[1]
and
Devang Gaur[2]

INTRODUCTION

"The glory of medicine is that it is constantly moving forward, that there is always more to learn. The ills of today do not cloud the horizon of tomorrow, but act as a spur to greater effort."

Late William James Mayo[3]

Stem cell research in contemporary times can be the most regarded field of research as it appears to have the promising means of human development and indeed sustenance. With the incessantly evolving capacity of science to progress human health and living, the exorbitant curiosity of man in understanding and manipulating the very fundamental unit of life, has now established itself as a recognized branch of scientific research. Stem Cells in most laymen's term are regarded as the fundamental, unspecialized cells that eventually results in making of human beings. Stem cells through the process of cell division can generate prolonged cell lines in which each cell has the capacity to either become a new stem cell or to develop into a specialized cell with specialized functions such as muscle cell, nerve cell, blood cell etc.[4] Stem cells are obtained majorly from inner mass of the blastocyst (a three to five day old embryo) termed as Embryonic Stem Cells or from specific parts of the body such as bone marrow,

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3 National Education Association: Proceedings and Addresses (1928)

4 Junying Yu & James A. Thomson, *Embryonic Stem Cells,* National Institutes of Health, (accessed on Jul 18, 2018), https://stemcells.nih.gov/info/Regenerative_Medicine/2006Chapter1.htm.

liver etc. called Adult or Somatic Stem Cells.[5] The immense interest in stem cell research is a result of the pluripotent nature of these cells. The idea is based upon theoretical claims that these cells can be manipulated into any human cell and even tissue. However the proposed claims are not 100% established but has highly substantial success rates.

Advancements in the field of stem cell research have come to present that medical therapeutic application of these cells can provide new scopes and horizons for the treatment of many diseases and illness which are deemed to be incurable. Stem cell researcher's find their use to be extremely potential when it comes to medical transplantation. This type of treatment could be used to replace neurons damaged by spinal cord injury, stroke, Alzheimer's disease, Parkinson's disease other neurological problems, produce insulin that could treat people with diabetes and heart muscle cells that could repair damage after a heart attack or replace virtually any tissue or organ that is injured or diseased and many more.[6] It is also believed that if process by which stem cells works could be understood then rehabilitation of harmed body parts will reach new heights. With such advancements, stem cells at large can achieve grave feats. Hence, these cells have invited multidimensional interests from sides of scientists, industrialists, politicians, human right activists, legal luminaries etc.

Stem cell research is surrounded by controversies since the induction of its research globally. The uses of stem cells, especially Human Embryonic Stem Cells [hESC], have seen to create many dilemmas in regards to the methods through which they are deduced. The common method practiced to obtain hESC is from inner cell mass of the Blastocyst, being the early stage pre-implantation embryo where around 150-200 stem cells are procured at a time. Embryo being the nascent stage for the development of human life makes the use of them for research a matter of ethical, moral as well as religious conflict resulting in many various diverse outlooks by different communities

5 *Id.*

6 *The Power of Stem Cells California's Stem Cell Agency* (2016), (accessed onJul 15, 2018), https://www.cirm.ca.gov/patients/power-stem-cells.

in regards to their conduction of the research, henceforth, the method of using left over surplus embryos from in-vitro fertilization [IVF] is often preferred to be used. The stem cells that are obtained are then stored in laboratories to create stem cell lines out of since the cells has a potential to replicate themselves in a perennial manner. These stem cell lines are then to become one of the most prominent sources for obtaining the stem cells. As far as patenting is concerned, stem cells have been recognized by the United States in order to promote science and innovation within the country. Despite of certain antithetical attempts, the United States has proved to be the major forerunner in regards to patenting of stem cells. On the other hand the European Union, who seems inclined towards providing funds for research purposes, holds a more contentious view towards the patenting of hESC.

GLOBAL NARRATIVE

Stem Cell Research and Patentability within the United States

Within the U.S. legal sphere many drastic vagaries have occurred on their viewpoint on stem cell research. The Dickey-Wicker Amendment 1996, disabled Federal Funding towards stem cell research on the basis that no research could attain grants on any research being conducted with "…activity involving: 1) the creation of a human embryo or embryos for research purposes; or 2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 C.F.R 46.208(a)(2) and section498(b) of the Public Health Service Act (42 USC 289g(b)."[7]The amendment included any human embryo "derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."[8] The Dickey-Wicker Amendment had increased the scope of disabling federally funded research from fetal stages to the embryotic stage of human cells. The National Institutes of Health (NIH),

7 *The History of the Dickey-Wicker Amendment*, Bedford Stem Cell Research Foundation (2014), (accessed onJul 17, 2018), http://www.bedfordresearch.org/the-history-of-the-dickey-wicker-amendment/.

8 *Id.*

in the year of 1999 had interpreted the Dickey-Wicker Amendment by providing guidelines in regards to the use hESC research but later with the change in Administration of the White House in 2001, federal funding was prohibited[9].

In 2005, the Stem Cell Research Enhancement Act was vetoed by President George W. Bush, had provided for the federal funding of hESC, although approval was granted by both houses. The bill had resurfaced around again on 2007 but again was vetoed by then President Bush but later on in 2009 was introduced again under the 111th Congress under President Barrack Obama's term[10]. Further, President Obama provided Executive Order 13505, uplifting the ban upon Federal funding of stem cell research of scientifically worthy manner. Order 13505 provided for the NIH to review its guidelines on hESC research and make it acquiescent with it[11]. In 2016, the 21st Century Cures Act came into action providing increased funding to research projects including the use of adult stem cells in the field of regenerative medicine[12]. In 2006, American scientists found an alternative of extracting

Within the United States, stem cells have been recognized as patentable with the Wisconsin Alumni Research Foundation (WARF) having three patents existing. Under the U.S. Patent Act, "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements" [35 USCS Sects. 1 et seq.]. An innovation cannot be

9 Joshua Whitehall, *Patenting Human Embryonic Stem Cells: What Is So Immoral,* 34 Brook J. Int'l L. (2009).

10 Stem Cell Research Enhancement Act of 2007 (2007 - S. 5), GovTrack. us, (accessed onJul 17, 2018), https://www.govtrack.us/congress/bills/110/s5.

11 Barack Obama, *Executive Order 13505—Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*, March 9, 2009. Online by Gerhard Peters and John T. Woolley, The American Presidency Project. (on Jul 20, 2018), http://www.presidency.ucsb.edu/ws/?pid=85830.

12 *21st Century Cures Act*, National Institutes of Health,(accessed on Aug 2, 2018), https://www.nih.gov/research-training/medical-research-initiatives/cures.

patented under the circumstances established by the United States Patents and Trademarks Office (USPTO) being those laws of nature, physical phenomenon, abstract ideas, artistic works, unhandy, and inventions that are disrespectful towards public morality[13]. The USPTO is the authoritative body in charge of issuing patents under its regulations and legally binding authority.

In the landmark case of *Diamond v.Chakrabarty*, the first instance of a patent being filed for human-made genetically engineered micro-organism, *Pseudomonas aeruginosa* bacterium, to be deemed patentable due to the differentiation of the bacteria developed in comparison to the one found in nature.[14] The landmark case opened the wide ability to patentable subjects of the biotechnology opening up the scope for the embryonic stem cells being first patented from birds and mice.[15] James Thomson from the University of Wisconsin with WARF had achieved the first ever patent on hESC seen globally.[16] The aforementioned patents held by WARF are held on the purified preparation of primate embryonic stem cells, purified preparation of pluripotent hESC, and replicating vitro cell culture of hESC.[17] The scope of these patents encompass a large portion of stem cell research causing many other institutes and research foundations to have issues occur with research being conducting in this field. These patents have been challenged on a significant basis, especially by the Foundation of Taxpayer and Consumer Rights (FTCR). The FTCR request for reexamination had been granted by the USPTO causing the existing

13 *Patents, Patent FAQs United States Patent and Trademark Office - An Agency of the Department of Commerce*, (Jul 20, 2018), https://www.uspto.gov/help/patent-help#1902.

14 Linda F. Hogle, Regenerative Medicine Ethics: Governing Research and Knowledge Practices (2014). PDF.

15 Id.

16 Jill Ladwig, *U.S. Patent and Trademark Office upholds key WARF stem cell patent*, The Wisconsin Alumni Research Foundation (WARF), (accessed on Jul 20, 2018), https://www.warf.org/news-media/news/releases-and-announcements/united-states-patent-and-trademark-office-upholds-key-warf-stem-cell-paten.cmsx.

17 *WARF Responds to the Patent Office on Its Re-examined Stem Cell Patents*, Patent Docs, (Jul 22, 2018) http://www.patentdocs.org/2007/06/warf-responds-t.html.

patents to gain amendments but still remained within the ambit of patentability and are still held successfully by WARF.[18] Ever since the WARF patents were granted, thousands of patents have emerged in relation to human genetic material and hESC. Patents exist within the U.S. on hESC on the basis of other novelties such as the methods to isolate embryonic cell populations, embryonic pluripotent germ cells, embryonic germ cell and methods of use, and an umpteen number more.[19]

In the U.S. after the cases of *Mayo Collaborative Services v. Prometheus Laboratories Inc.*and *Association for Molecular Pathology v. Myriad Genetics, Inc.*the USPTO has developed guidelines entitled "Guidance for Determining Subject Matter of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products" or commonly known as the Mayo-Myriad Guidelines. Under this, a three step analysis is created under which the claims to an invention have to satisfy. The Guidelines however do not distinctly mention stem cells under its ambit but the vague nature of document makes it fall under its ambit.

STEM CELL RESEARCH AND PATENTABILITY WITHIN EUROPE

Within the Europe, the United Kingdom's nascent stages of research on stem cells began in the 1970s at Cambridge University. Much like research being conducted in the United States, stem cells were successfully isolated from a mouse conducted by Nobel Laureate in Physiology or Medicine, Sir Martin Evans also known for successfully fertilizing the first human eggs outside of a body using in-vitro fertilization (IVF) technology[20]. Within the UK, the Warnock Report was conducted further on in order to determine the ethics regarding research upon human embryos concluding with endorsing them with strict supervision. The Human Fertilization and EmbryologyAct

18 Jill Ladwig, *U.S. Patent and Trademark Office upholds key WARF stem cell patent*, The Wisconsin Alumni Research Foundation (WARF), (Jul 22, 2018), https://www.warf.org/news-media/news/releases-and-announcements/united-states-patent-and-trademark-office-upholds-key-warf-stem-cell-paten.cmsx.

19 Linda F. Hogle, Regenerative medicine ethics: governing research and knowledge practices (2014). PDF.

20 Hans Clevers et al., Stem cells: scientific facts and fiction (2014).

(HFEA), 1990, provided for a statutory body to be constituted to enable provisions regarding research to be conducted such as the licences required for a laboratory to conduct research[21]. Further in 2001, the Human Fertilization and Embryology (Research Purposes) Regulations was implemented in order to befit the recommendations provided in the Donaldson Commission which prohibited reproductive cloning but was not worded concisely to do so causing other legislation to be invoked but successfully increased the reasons upon which licenses could be gained for research[22]. Again in 2008, HFEA is updated providing the regulation on the use of human-admixed embryos within research.

The patent system in Europe saw its early stages of unification with the European Patent Convention, 1973, coming into effect years later having the European Patent Office (EPO) established in 1978. Cases started occurring within Europe in the 1990s upon the morality and *ordre public* upon patents and bioethics. Later on within the 2000s the Trade-Related Aspects of Intellectual Property Rights agreement (TRIPS) had brought changes within the limitation of exception to patentability on the regards of inventions being uses for "commercial exploitation" adjusting Article 53a of the EPC to be as follows:

European patents shall not be granted in respect of:(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.[23]

The wider scope in Europe, in recent times sees different developments as the nations have different views upon the creation and use of embryos for research and other purposes while still supporting the development of stem cell research. The Council of Europe's Convention on Human Rights and Biomedicine had prohibited the creation of human embryos for research. With the European Court of

21 *Id.*

22 A. Sheared, *Patenting Stem Cell Technologies in Europe*, 5 Cold Spring Harbor Perspectives in Medicine (2014).

23 European Patent Convention, (1973).

Justice (ECJ) providing that the removal of hESC from the blastocyst of the embryonic stage is against public morality in terms of gaining patentability in the landmark judgment of *Oliver Brüstlev. Greenpeace*.[24] The case arose within the German federal court upon which the Non-Governmental Organization, Greenpeace, intimated the case on the University of Bonn on a hESC patent existing on ethical and immoral grounds. Unlike the U.S., many European nations recognize morality as a basis for not granting a patent unlike the USPTO which does not have the authority to do so and lies within the courts. Within the case the ECJ raised essential questions regarding the industrial use of human embryos, ethics and public policy, as well as German patent law, amongst the many quandaries emerging in the case. The Court had finally referred to the TRIPS agreement, which is an international instrument of the World Trade Organization (WTO), conclusively drawing that the use of totipotent or pluripotent hESC are recognized as human embryo. This conclusion drew that the patentability of the inventions could not be upheld as the destruction of embryo occurs during the extraction of the stem cells from the blastocyst. However, in Germany, the courts upheld later on in 2012 that the extraction of vitro cells from the blastocyst to be not considered human embryos as they were not in any means capable of developing into a human being.

Within Europe, the many dimensions of legislative bodies have brought in contrary and arbitrary outlooks to their view on the patentability of stem cells with the regional bodies such as the EPO having different views than the national courts. Research can be convoluted in the development of gaining a patent in the region which may hinder the hasty development but with some nations in the continent having lenient laws in relation to research, a near future of accessible therapeutic stem cells may occur.

ETHICAL CONTROVERSY SURROUNDING STEM CELLS

Potter Stewart, Associate Justice of Supreme Court of USA (retd.) once stated “ethics is knowing the difference between what you have a right

24 Linda F. Hogle, Regenerative medicine ethics: governing research and knowledge practices (2014). PDF.

to do and what is right to do."[25] This perhaps, can be regarded as a suitable definition for the rather ambiguous and differently interpreted term, ethics. One's understanding of righteousness is affected by several factors such as society, religion, culture, philosophy, etc. which themselves are rather dynamic in nature and are observed to exist in extremely diverse and non-uniform structures across the lands. People's notion of ethics may vary from place to place, time to time and especially from person to person, which clears draws an understanding that ethics is not a concept on which consensus could be provided easily.

Ethical controversy surrounding stem cells has differed in complexity as well as intensity in every other country of the world. In European countries only, a huge variation can be seen. The UK was among the primary countries followed by Belgium, Spain and Sweden to permitderivation of new hESC lines from supernumerary IVF embryos as well as therapeutic cloning, whereas countries like Denmark, France and Netherland allows derivation of new hESC lines from supernumerary IVF embryos but at the same time bans therapeutic cloning. Germany through a completely different approach, promotes stem cell research only if the hESC lines are imported.[26] The laws available are at much variation that even deduction of majority opinion does not seem as an easy task. An unending tussle between the conservative opponents and optimistic proponents stays on the rising.

Problem lies majorly in destruction of embryo which has been the common practice for obtaining stem cells. Those who raise such issues, argue that hESC research is a murder due to the destroying an embryo, in some religions and culture, is equivalent to the killing of a human beings.[27] Legalization of abortion can be regarded as a

25 Ethics for community planning, MSU Extension, (Jul 19, 2018), http://msue.anr.msu.edu/news/ethics_for_community_planning.

26 Elstner et al., The changing landscape of European and international regulation on embryonic stem cell research, Stem Cell Research 101–107 (2009).

27 M. C. Nisbet, *Public Opinion about Stem Cell Research and Human Cloning*, Public Opinion Quarterly 131–154 (2004).

clinch to the stem cell research advancement. To understand the very nature of this ethical fracas, it is precise to look initially into argumentation available for and against the abortion. In 2001, an ad hoc review committee on stem cell research made by UK, House of Lords concluded that moral status of an early embryo in Christian tradition has to deduced from the attitudes towards abortion.[28] To understand the very nature of this ethical fracas, it is precise to look initially into argumentation available for and against the abortion. Proponents of abortion presented somewhere similar argument as the proponents of stem cell research gives. They arguethat early stage of human development does not have equal rights and status as compared to that of a person, because the idea of beginning of life with conception is scientifically incorrect.[29]John Noonan, a US based conservative analyst, classified abortion as immoral act by saying that "it is morally wrong to kill humans, however weak, defenseless, or lacking the opportunity to develop. It is immoral to kill Infants and thus it is Immoral to kill embryos."[30] Noonan forms the base of his argument on sort of catholic religious belief that life begins at the time of conception. This idea was strongly rejected by Mary Ann Warren, an American writer, noted for her writings in support of abortion. She drew a line between what she called 'genetic humanity' and 'moral humanity'. Warren introduced certain criteria for a person to be given moral recognition i.e., consciousness; reasoning; self-motivated actions; capacity to communicate; and presence of self-concepts.[31] Warren's classification was pretty convincing but concept of 'potentiality' and 'continuity' stood as rigid obstruction. 'Non-

28 Committee Office & House of Lords, House of Lords, Stem Cell Research - Report House of Commons - Transport, Local Government and the Regions - Appendices to the Minutes of Evidence, (accessed on Jul 24, 2018), https://publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8314.htm.

29 Robert P. George & Christopher Tollefsen, Embryo: A Defense of Human Life 195 (2008).

30 John Noonan, *Abortion and the Catholic Church: A Summary History*, Natural Law Forum.

31 Mary Anne Warren, *Abortion and Human Rights*, Moral Status 201–223 (2000).

personhood' of fetus was established finally in *Roe v. Wade*, 1973 by Supreme Court of USA. Embryo being even earlier stage of human development, two decades post legalization of abortion smoothened the road for stem cell researchers.

Abortion was also backed by feminist activists as it being basic right of women. Also at the same time social activists supported it on the grounds of possibly devalued life of an unwanted child. Stem cells does not have any such backing, what it has is a non-confirmed, highly optimistic possibility of an extremely bright and elegant future. Perhaps the best description of what these cells are capable of doing was provided by former director of NIH, Harold Varmus in the congress when he stated: "There is no realm of medicine that cannot be touched through this innovation."[32] The question that arises here is that, to what extent individual rights can be compromised for betterment of the society as a whole? Killing of fetus to protect the rights of mother is seen to be reasonable enough, but doing the same to find probable medicinal cures for others may not. However answer is not really available till now but the debate is diluted by usage of leftover surplus embryos. Clinton administration, in 1999, for the first time, interpreted Dickey-Wicker amendment in a way that it does not include leftover frozen stem cell lines. However Bush, in 2001, reiterated the ethical concerns along with congress but ultimately in present scenario funding for stem cell researches got the green signal by Obama administration.[33] Since, surplus embryos usually remain frozen in laboratories or are ultimately destroyed to avoid maintenance, their usage for research purposes is acceptable to many. Later, legislations by UK policies of EU made this approach more sanctified.

Globally a diverse opinion on the ethical quandaries circumambient to the stem cells researches makes it difficult to achieve some concordant solution. On one side, the research is highly supported being a hope to humanity, while on the other side it is highly condemned on the

32 Roe v. Wade, 410 U.S. 113 (1973).

33 Stem Cell Research, Human Life Amendment NCHLA, Human Life Action, (accessed on Jul 24, 2018), https://www.humanlifeaction.org/issues/stem-cell-research.

ground of violating fundamental ethics of humanity. Ignorance to any kind of possibility that may help humanity is in itself immoral, but hope alone is not an outcome. It must be taken care that overwhelmed by the promises made by stem cell researchers, legislators shall not lose patience. Usage of stem cells for research purposes must be promoted without any doubt, but an unregulated industry of such kind can bring devastating consequences.

INDIAN NARRATIVE

Stem Cell Research and Patentability

India developing at a steady pace being the world's fastest growing economy has put in much investment towards biotechnology and biotherapeutics in order to be recognized at the global front for their developments in the field of medicine.

The Indian Council of Medical Research & Department of Biotechnology (ICMR-DBT) had issued in 2017 the National Guidelines for Stem Cell Research. These guidelines cover the scope of regulating the clinical and product development of research conducted, procurement of biological material with their banking and distribution, as well as the international collaboration. The priority of issuing these guidelines was to diminish the exploitations occurring and to ensure ethical and purely scientifically responsible research to be conducted.

Under the Ethical Considerations of the guidelines provides under Section 4.1.1.4 that under any potential for commercialization or development of Intellectual Property in relation to biological material procured by a donor does not provide them the necessary qualification to have property rights[34]. However, it is mentioned that fiscal benefits should have efforts to be provided to the donor or community whenever deemed feasible. Further, under Section 4.2.4 social responsibility is to be conducted in relation to Intellectual Property development through the research and be shared with the proper informed consent form with the expectations of returning benefits to the potential beneficiaries

34 Indian Council of Medical Research & Department of Biology (2017) https://icmr.nic.in/guidelines/Guidelines_for_stem_cell_research_2017.PDF.

including patients which have donated to creation of the invention.

The 2017 guidelines are the amended version of the 2013 guidelines issued on stem cell research and were to cover the lacuna present in order to provide order and efficacy within the field of stem cell research. However issues are being reported by the Union health ministry and the view of stem research in India a year after issuing the guidelines. Speculations arise with the Ministry proposing amendment to the *Drugs and Cosmetics Act*, *1940*, in order to include a definition for stem cells and cell-based products due to the lacuna present in present legislation to define them and term them as a drug.[35] Under Section 3 of the Drugs and Cosmetics Act the term drug includes:

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of (vermin) or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatin capsules;

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;

With the proposal of amending the definitions and including stem cells

35 Sumitra Roy, Govt seeks to define stem cells as drug, regulate use in therapy, TOI , July 28 (2018), https://timesofindia.indiatimes.com/india/govt-seeks-to-define-stem-cells-as-drug-regulate-use-in-therapy/articleshow/63776306.cms

within the ambit of a drug as it cordially fits within the term of a drug when used in a therapeutic manner but lacuna are still presented without having a concise definition inserted. If succeeded in falling under the definition of a drug under the act then it will be feasible for being licensed under clause (c) of Section 18 provided as:

(c) [manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale,] or distribute any drug [or cosmetic],except under, and in accordance with the conditions of, a license issued…;

The scope of gaining a license is deemed necessary in order to sell a drug much alike the patents law in India which requires a Compulsory License. The Patents Act, 1970 alongside the Patent Rules, 2003 are regarded as the contemporary legislations within India to gain patent protection on an innovation or process. An invention in India is to satisfy the criteria of having novelty, industrial step, inimitability, and an inventive step. Further, an invention should not fall under the criteria given under Section 3 and 4 of the act for inventions which are not patentable being obvious, contrary to natural law, scope of commercial exploitation, against public order/morality, discoveries of existing things, new forms of known substances, mixtures composite in nature of known substances, method of treatment on birds and animals, plants and animals wholly or a specific parts, essential procedures and other. In regards to stem cell research clauses (i) and (j) strike out the most from Section 3 being read as:

(i) Any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

(j) Plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.

Under these clauses it is provided that “animals in whole or any part thereof” would be the suitable extent for stem cells to fall within

the ambit of this definition, however, issues arise within the law in regards to the methods of extraction and of isolating and culturing of the stem cells can still be seen as patentable as long as the procedure of attaining the cells maintains within the guidelines. In 2009, Stem Cell Therapeutics Corp. had been issued two patents within the nation being Patent 229684 and Patent 229924, being "*Combined Regulation of Neural Cell Production*" and "*A Composition for Increasing Neural Stem Cell Number and In Vitro Method of Using the Same*", respectively.[36] The combination of the aforementioned patents pertains to the pharmaceutical composition of to cover the methods for using prolactin in neural stem cell culture.

Stempeutics Research, an Indian biotechnology backed by the Manipal Education and Medical Group and Cipla Inc., in 2015 gained a process patent within the United States by the USPTO for its stem cell based drug to help cure Critical Limb Ischemia[37]. The function of the drug is to enable functional tissues to help repair or replace tissues or organs which aren't working properly. Stempeutics shortly after gained a patent by the State Intellectual Property Office of the People's Republic of China for their drug.[38] These developments by Indian biotechnology firm in the field of Intellectual Property and stem cell research provide for massive consideration for the advancement occurring by the entities of the nation.

ETHICAL CONCERNS IN INDIA

India for long has been quite open to changes and reforms when it comes to scientific manifestations. For every scientific development in India a unanimous opinion can be seen to be formulated. Ethics are appraised wherever necessary, but, most of the time, not to an extent that progression may face an interlude. Moreover, Indian legislators

36 Alaan Moore, *Stem Cell Therapeutics Announces Issuance of Patents in India,* Marketwire, (Jul 29, 2018), http://www.marketwired.com/press-release/stem-cell-therapeutics-announces-issuance-of-patents-in-india-tsx-venture-sss-1015169.htm.

37 *Indian biotech firm Stempeutics Research gets US Process Patent for its novel stem cell drug*, ET, Aug 2 ,2015,(accessed on Aug 2, 2018).cms.

38 Ibid.

keep in mind the influence they are going to create on the society and the already existing stumbling blockades in their way. One such issue that is to be addressed while enacting stem cell regulations is the hardly regulated medical regime of India. India is developing at a higher pace than ever and hence its medical sector is also forming a rare combination of skilled doctors, advanced facilities and low cost treatments. Such availabilities are inviting a large number of foreign visitors travelling to India for helping their medical requirements. Then Minister of Tourism, K.J. Alphons, stated in Lok Sabha that the number of such tourists reached to a total of around 4.95 lakhs in 2017.[39] Usually people from less developed nations travel to a higher developed one for seeking proper medical attention but the trend is regarded to be in reverse now in a manner that people are travelling to gain access to many medical practices that are prohibited in their nation or even region.[40] India has already faced a legal complication regarding ban on commercial surrogacy recently. The mushrooming ART/IVF clinics all around the country are barely regulated. Presently such clinics are regulated through "*Pre-Natal Diagnostics Techniques (Prohibition of Sex Selection) Act, 2003, (PC & PNDT Act)*" or *guidelines given by Indian Council for Medical Research (ICMR)* which are not legally binding.[41] These circumstances led to a situation where ART/ IVF clinics functions arbitrarily and poverty stricken women acting as surrogate mothers were exploited financially as well as medically . Govt. taking the scenario into consideration banned commercial surrogacy in 2017.[42]

One of the major reasons behind these low-cost rendered services available in India is the access to cheap human resources within

39 Yuthika Bhargava, *Medical tourists flocking to India*, The Hindu, Aug 2 2018, https://www.thehindu.com/news/national/medical-tourists-flocking-to-india/article24497896.ece.

40 Shaun D. Pattinson, MEDICAL LAW AND ETHICS 238- 242 (1st ed. 2006).

41 SushmiDey, Only 20% IVF clinics, 2% ART units registered with ICMR , TOI, July 31,2017, https://timesofindia.indiatimes.com/india/only-20-ivf-clinics-2-art-units-registered-with-icmr/articleshow/60150184.cms.

42 One Hundred Second Report On the Surrogacy (Regulation) Bill, 2016.

a nation with the second largest population. In the medical sector, exploitation not only violates the rights of the victims but also generates vicious threats upon their health and prospective life. India as a hub of clinical trials creates some frightening possibilities that may occur if medical industry remains unregulated as it is.[43] In the words of Dr Ambujam Nair Kapoor, a senior scientist of the Indian Council of Medical Research (ICMR), "Unless we put in place systems that ensure safety of patients and good quality of trials, people will get away with whatever they can get away with."[44]

The medical sophistications that stem cells can gift the humanity will bring plight for many as a by-product, if regulation will not be well enacted and executed. The developments of stem cells have no surety as to what can be the repercussions and hence country like India needs a complete turnover in her policies relating to medical stream if she looks upon Stem Cells Industry as a direction in which she shall further proceed.

CONCLUSION AND RECOMMENDATIONS

The development within the field of stem cell research has seen to taken glorious strides in achieving many feats which weren't deemed feasible a few decades ago. The scope of future prospects within the therapeutic research with the application of stem cells makes for a promising future in regenerative medicine. A promise for a future where regenerative medicine is used to regain functioning to some nonfunctional organs lost due to age, disease, or accidents provides a positive outlook for humanity within our near future. Developments across the world have seen in major countries provide an ambit for

43 Ethics in occupational health and safety: case, (accessed on Aug 1, 2018), https://www.bing.com/cr?IG=ECB6F07F6C5142148DB6B83C0A16CB5E&CID=089E556E7390639818C15951726D62B8&rd=1&h=zy4XijiCjm44bHdLn7lZvj20g-2JDY7ba5b6_IjBFM0&v=1&r=https://www.researchgate.net/publication/315919605_Ethics_in_occupational_health_and_safety_case_studies_from_Gujarat&p=DevEx.LB.1,5068.1, PDF.

44 *Clinical trials in India: ethical concerns*, World Health Organization (2011), (Aug 1, 2018), http://www.who.int/bulletin/volumes/86/8/08-010808/en/.

expansion within the field but a lacunae of laws still provides for a vacuum created in existing legislation to have a positive environment for research.

Within India, the lacking of a definition for the term stem cell still by legislation creates for a giant hassle within the legal world. Even with notifications provided by the Directorate General of Health Services under Central Drugs Standard Control Organization, Biological Division to provide amendments to *the Drugs and Cosmetic Act* of 1940 to bring it under the term of New Drug, no rectification is seen. Further, the notification provided in February of 2014 by the Drug Controller General is still to find a system to be set up to properly monitor the licensing facilities in relation to stem cells and other cell based products as well as having entities such as hospitals, research institutes and companies to conduct clinical trials in a cohesive manner[45].

The field of Intellectual Property having a much promising scope for patentability of research inventions gives hope for the development of biotechnology within India. Although the Guideline for Examination of Biotechnology Applications for Patent have been issued by Intellectual Property India, a facet of the Department of Industrial Policy & Promotion under the Ministry of Commerce & Industry, these guidelines are noted to not be rulemaking guidelines and if conflict arises with the existing legislation for patentability then the existing Patents Act and Patent Rules will prevail over the issued guidelines. India still has a long way to go to in the field of patentability of biotechnology and should begin by issuing legislation in regards to bioethics. All the patents which are granted in the field of stem cell research should have stringent legislation created in order to provide benefits to the masses and beneficiaries while still helping the field to develop. Legislation should further be improved to not hinder the development and future of research fields due to intellectual property barriers and not cause for abuse or misappropriation.

45 Central Drugs Standard Control Organization Biological Division, Notice F. No. X-11026/65/13-BD F. No. X-11026/65/13-BD (2014).

The field of patentability is riddled with the goal of giving benefits to an inventor without having commercial exploitation existing. With stem cell products and procedures able to gain patentability, the issues arise with a persons' right to affordable healthcare due to royalties involved and expensive methods of treatment. The lacunae existing in bioethics and proper governance will bring to discussion the many dilemmas existing within the field of intellectual property and stem cells but will always be perforated with more than just a mere failure of laws and political dimension and the hopes for a future with therapeutic stem cells being accessible to the public at reasonable monetary values requires strenuous effort in the socio-legal and medical fields of India.

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OBSERVATIONS ON INTELLECTUAL PROPERTY VIZ-À-VIZ BIODIVERSITY

Devapreeti Sharma[1]

INTRODUCTION

The United Nations Convention on Biological Diversity ("UNCBD") and the Trade Related Aspects of Intellectual Property Rights Agreement, 1995 ("TRIPS Agreement") are two of the most influential conventions on biodiversity and intellectual property rights ("IPRs") respectively. As with other important legal instruments, they have generated great effects in national jurisprudence across the globe. The effects have been, largely, positive. But, in certain fronts, the duo diverges from each other along associated instruments. This is the front of biodiversity viz-a-viz IPRs. On this front, we have, along with the TRIPS Agreement, the International Convention for the Protection of New Varieties of Plants ("UPOV Convention") and other regional and bilateral treaties; and along with the UNCBD, the Whale Conventions, the Ramsar Convention and an extensive list of several others. It is not surprising therefore, that the front of biodiversity viz-a-viz IPRs is marred by a complex web of legal entitlements and obligations. Corresponding to the international regime, the Indian national scenario on tjis front too is equally blurred by the provisions of the Indian Patent Act, 1970 ("IPA"), the Protection of Plant Varieties and Farmers' Rights Act, 2001 ("PVFRA") and the Biological Diversity Act, 2002 ("BDA"). Demystifying this complex web, both at the international and national level is the objective of the present article.

This article is limited to a brief analysis of the linkages and differences between the TRIPS Agreement and the UNCBD on one hand, and that among the IPA, the PVFRA and the BDA on the other hand. Accordingly, it is divided into two parts. Part 1 contains a scrutiny of the global framework on IPRs and biodiversity whilst Part 2 contains a

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scrutiny of the Indian national framework on the same.

INTERNATIONAL FRAMEWORK FOR IPRS AND BIODIVERSITY.

This chapter presents an analysis of some important conventions in the international framework related to IPRs and biodiversity, in an attempt to point out the linkages and differences between the two.

The International Law on IPRs.

We know today, that the global regime of intellectual property comprises three elements: (a) multi-lateral treaties like the Paris Convention[2], the Berne Convention[3]etc; (b) regional treaties like the ASEAN Framework Agreement[4]; and finally (c) some bilateral treaties as well. However, amongst all, the most significant is the TRIPS Agreement. This is because the TRIPS Agreement is the only treaty which sets down some minimum standards for the protection of the most common kinds of intellectual property; and also because, these minimum standards are applicable almost universally. As a consequence, it seeks to achieve, and has achieved to a great extent, harmony in all national laws on intellectual property. There is yet another convention i.e. the UPOV Convention, which bears significance considering that it is the only instrument to deal with plant varieties comprehensively. Moreover, in the vast global regime of intellectual property protection, the TRIPS Agreement and the UPOV Convention are the only two instruments which contain provisions related to biodiversity. Hence, such provisions necessitate some deliberations.

- ***The TRIPS Agreement.***

The TRIPS Agreement came into being because of the growing role of IPRs in global trade. Since the 1970s, global trade came to be dominated largely by modern e-information processing, communications and biotechnology,[5] all of which have a large area of industrial application.

2 Paris Convention for the Protection of Industrial Property, 1883.

3 Berne Convention for the Protection of Literary and Artistic Works, 1971.

4 ASEAN Framework Agreement on Intellectual Property Cooperation, 1995.

5 R. Kaplinsky, *Industrial and Intellectual Property Rights In The Uruguay Round And Beyond*, 25(3) THE JOURNAL OF DEVELOPMENT STUDIES.

These industrial units remain in perpetual need of acquiring IPRs in order to boost, maintain and prolong increased profits and survive in industrial competition. It was due to industrial lobbying that IPRs were put in the agenda of the General Agreement on Trade and Tariff's ("GATT") Uruguay Rounds. Successfully negotiated, the TRIPS Agreement aimed that "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."[6] Based on these objectives, three features of the TRIPS Agreement can therefore be reduced:

a) It sets down some minimum standards which each World Trade Organization (WTO) must accord to IPRs. However, these standards have been criticized by many[7] and contested vehemently by the developing countries.[8]

b) It contains a set of measures for enforcing these minimum standards. These measures include principles, procedures, remedies and special measures which all domestic laws must adhere to.

c) The WTO dispute settlement mechanism automatically comes into play on any allegation of infringement on IPRs.[9] Thus, if a nation does not apply the TRIPS Agreement standards on IPRs or does not comply with it in other ways, the WTO can easily impose sanctions on that nation.

Having said this, it must be noted that the operative provision of the TRIPS Agreement with regard to biodiversity is Article 27. Under this

373-400 (1989).

6 TRIPS Agreement, art. 7.

7 FINK et al, INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH World Bank (2005).

8 India, against the W.R.Grace patent.

9 TRIPS Agreement, art 64(2) (cases involving the non-violation complaint shall not be applicable to the settlement of disputes).

Article, whereas all products and processes involving innovation, novelty and industrial application are patentable, however, two elements are excluded from patentability: (a) plants and animals, which are not microorganisms; (b) biological processes for the production of plants or animals which are not non-biological and microbiological processes. Thus, biotechnological products and processes, which are highly marketable today, are essentially patentable. Additionally, it must be noted that while plant varieties need not be accorded patents, yet they still need to be given some form of IPRs. This brings one to the essentially difficulty in distinguishing a plant from a plant variety. Reference therefore needs to be made to the UPOV Convention's definition of a plant variety.[10] This definition requires precision in categorising plants and plant varieties, and thus, draws a very fine line between the two. Therefore, controversies continue.

- ***The UPOV Convention.***

Administered by the Geneva based International Union for the Protection of New Varieties of Plants (UPOV), the Convention, and originally drafted in 1961 has been revised thrice since, with the latest revision in 1991. Purporting to protect new plant varieties, this convention protects only those varieties which are 'distinct', 'stable', uniform' and 'novel'[11]. Also, extending the ambit of the breeders' rights, the 1991 version of the UPOV Convention accords protection to all acts of –

> "(i) production or reproduction (multiplication), (ii) conditioning for the purpose of propagation, (iii) offering for sale, (iv) selling or other marketing, (v) exporting, (vi) importing, (vii) stocking for any of the purposes mentioned in (i) to (vi), above."[12]

It also extends the same protection to the harvested materials of the protected plant variety[13] and other essentially derived varieties[14]. Thus,

10 UPOV Convention, art 1(vi).

11 *Id,* art. 5(1).

12 *Id,* art. 14(1).

13 *Id,* art. 14(3).

14 *Id,* art. 14(5).

the 1991 revision of the UPON Convention confer a more patent-like protection to plant varieties.[15]

Also, more often than not, national legislations often uphold farmers' privilege in relation to these breeders' rights – something which is permitted by this convention itself.[16] This practise is followed in India as well, although she has not acceded to the same. Nonetheless, the farmers of India continue to breed plants traditionally and to what extent they have benefitted from the UPOV-type protection is debatable.

The International Law on Biodiversity.

The importance of biodiversity cannot be denied. The global community has tried, right from the twentieth century, to conserve and manage the earth's biological diversity, albeit it was done species by species; for example, the North Pacific Fur Seal Convention, 1911 and all the Whaling Conventions. Later, there sprang up habitat-specific conventions as well; for example, the RamsarConvention[17]. Then came up degradation-cause specific conventions, like the CITES Convention[18]. Finally, at the initiative of the United Nations Environment Programme ("UNEP"), the text of the famous UNCBD was opened at the Rio Earth Summit. Although welcomed graciously by the global community, the USA, after spending some six odd years negotiating the treaty, stayed away from it. The then President, George Bush, announced that the treaty with adversely affect the Americans' IPRs.[19] However, when American giants in pharmaceuticals and biotechnology changed their stand and spoke in favour of the treaty, the Clinton administration did eventually sign it.[20] This points at how delicate the links between UNCBD and IPRs are. A brief review of the

15 Graham Dutfield, *Intellectual Property Rights, Trade And Biodiversity: The Case Of Seeds And Plant Varieties,* IUCN Background paper(1999).

16 UPOV Convention, art. 15.

17 Convention on Wetlands of International Importance especially as Waterfowl Habitat, 1994.

18 Convention on International Trade in Endangered Species of Wild Fauna and Flora, 1983.

19 Peter T. Jenkins, *The United States And The Convention On Biological Diversity,* THE DEFENDERS, https://defenders.org/sites/default/files/publications/the_u.s._and_the_convention_on_biological_diversity.pdf.

20 *Id.*

convention is therefore needed.

- ***The UNCBD.***

The UNCBD started operating from 1993. Its objectives are three-fold: (i) the conservation of biological diversity; (ii) sustainable use of the same; (iii) fair and equitable benefit sharing.[21] Embedded within these objectives are the states' quiet realization of the economic value of biodiversity. At the negotiable table of the treaty, there were the biodiversity-rich developing nations on one hand and on the other hand, the biodiversity-poor developed nations. Needless to say, the UNCBD had to balance both the sides and provide some kind of harmony. Accordingly, we find several provisions in the treaty which are related to IPRs.

The UNCBD runs on the international environmental law principle of state sovereignty, which is premised on an assumption that every sovereign state has complete control over their own resources.[22] However, resources can be obtained only through prior informed consent and on mutually agreed terms.[23] Once accessed, the benefits of these resources are to be shared. Technology too, is to be accessed and transferred along the same lines;[24] and where such technology is protected by any form on IPR, the state parties need to ensure that such IPRs are supportive of the UNCBD objectives.[25] It also requires all state parties to –

> "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote the wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge,

21 UNCBD,preamble.

22 PHILLIPE SANDS, PRINCIPLES OF INTERNTIONAL ENVIRONMENTAL LAW 236 (2nd ed. 2003).

23 UNCBD,art. 15(4) & (5).

24 *Id,*art. 16.

25 *Id,* art. 16.5.

innovations and practices." [26]

Thus, the provision hints at some rights which the "holders" of traditional knowledge possess, regardless of whether these rights are IPRs or not. That these holders have some legal claims over their "knowledge, innovations and practises" just like companies and scientists have over their inventions, is further reinforced by the fact that all state parties are required to develop models of cooperation between the two seemingly opposite rights.[27]

This shows that the global regime on IPRs and biodiversity have some inherent synergies.

LINKAGES AND CONFLICTS IN THE GLOBAL REGIME ON IPRS AND BIODIVERSITY.

Overall, the IPR treaties and the UNCBD raise three grounds, presenting both linkages and conflict. All the three grounds revolve around three issues: (i) control over biological resources; (ii) impact of IPRs on conversation of biological resources and (iii) benefit sharing. One thread of scholarship argues that IPRs accorded to, and shared between, resources-providers and resource-users actually end up building national capacity to conserve and sustainable use those resources.[28] Another thread argues that IPRs are straightaway harmful for biodiversity.

With regard to control of biological resources, one cannot deny that in the pre-UNCBD period, access to life-forms are mainly regulated through the laws of international trade. Post-UNCBD however, a new scenario emerges. Questions of access to biological resources must now pave its path through new legal requirement. This has even created a huge North-South divide; the North being biologically poor

26 *Id,* art. 8(j).

27 *Id,* art. 18(4).

28 W. LESSER, SUSTAINABLE USE OF GENETIC RESOURCES UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY: EXPLORING ACCESS AND BENEFIT SHARING ISSUES (1998). *See also* REI et al, BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT (1993).

but technologically rich and the South, vice versa.[29] As a matter of fact, after the W. R. Grace neem patent, several environmental activists claims that the North's novelty and inventive step only exists as far as their ignorance in biodiversity stretches.[30]

With regard to the impact of IPRs on biodiversity conservation, the debates are endless. The pro-patent view understands that as long as patents are available for biological resources, the rich industries would be willing to invest in natural resources. When invested adequately, the avenues for conservation and sustainable development would automatically bear more fruit. The problem here is that for such avenues to be fruitful, these rich industries must not only invest capital but also technology, which is, sadly, they often do not do. Perhaps that is why, there an anti-patentview which under understand that patents only create monopolies and more often than not, lead to bio piracy. However, this anti-patent view is more fierce and critical when it comes down to patenting on traditional knowledge.[31]

With regard to benefit sharing, the most deprived of all are the indigenous communities and holders of associated traditional knowledge. Often the victims of bio piracy, these communities, though not exclusively, do not reap the benefits of investing on their local life-forms. Although there are treaties highlighting the need for the same, the hindrances occur in implementation. Difficulties occur in determining how the benefits can be shared effectively?[32]

As a result of these continuing issues, there emerges conflicts between the TRIPS Agreement and the UNCBD. The conflicts are fourfold:

a) The TRIPS Agreement can stand in the way of fair and equitable sharing of benefits arising out of biological resources and

29 Charles R McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology,* 76(1) WASHINGTON UNIVERSITY L.R. 255, 258 (1998).

30 Shayana Kadidal, *Subject-Matter Imperialism: Biodiversity, Foreign Prior Art and the Neem PatentControversy*, 37 IDEA 371, 375 (1997).

31 V. Reyes, *The Value Of Sangre De Drago*, 13(1) SEEDLING20 (1996).

32 Manuel Ruiz*, Intellectual Property Rights and Biodiversity: Processes and Synergies,* IUCN Background Paper 6 (2003).

associated traditional knowledge as required by the UNCBD. This occurs because patent offices across the globe often allow corporations to acquire access to resources without the prior informed consent of the local communities, due to which these communities do not stand a chance of reaping benefits. For example, the USA Patent and Trademark Office ("PTO") granted a patent to RiceTec over traditional *basmati* rice.[33] It also granted patent to a private individual over a type of Ayahuasca vine, which is used in the Amazon basin for healing purpose.[34] Similar was the case of the infamous W.R.Grace*neem* patent. Even if the prior informed consent mechanism is used, the resource-providing often fail to appropriate strong benefits. The benefits they receive are meagre, compared to the profits corporations acquires; and if more benefits are claimed, Article 30 of the TRIPS Agreement can be invoked for unreasonable prejudice. Repercussions are then felt in bilateral relations and the WTO dispute settlement body.

b) The TRIPS Agreement also can stand in the way of effectively protecting traditional knowledge. This convention does not explicitly ban IPRs on traditional knowledge – something which many have called against[35] - and only provides for an "effective sui *generis"* system for plant varieties. What an effective *sui generis* system means has not been defined and thus, states, almost always refer to the UPOV Convention for the same. The UPOV Convention, on the other hand, by subjecting farmers' rights to national legislations, often limit their rights.

c) The TRIPS Agreement can stand in the way of technology transfer. Firstly, IPRs can create technologies. The TRIPS Agreement inadvertently accords significance to market-based

33 *India Business,* TOIONLINE ,Jul 24, 2000, http://www.timesofindia.com/240700/24busi2.htm.

34 Rural Advancement Foundation International (RAFI), *Bio-piracy: Annual Update*, (1996), http://www.rafi.org.

35 H. LOCKHARM, HOW SHOULD WE "PROTECT" OUR TRADITIONS 65 (2003).

technologies while the UNCBD inadvertently does the same to technologies of conservation and sustainable use. Secondly, IPRs can also limit access to and transfer of technology along the lines of UNCBD's fair and equitable benefit sharing. For technology transfer, the TRIPS Agreement require that incentives be provided[36] but little has been achieved along this front.

d) The TRIPS Agreement can stand in the way of conservation and sustainable use of life-forms. IPRs created by the TRIPS Agreement may have negative impact of biodiversity; and cannot always be measured. Commercial priorities often become hurdles in conserving and sustainably using biodiversity.

Nonetheless, it needs to be agreed that the beauty of these conventions, no matter how conflicting, lies in the fact they are implemented through and sometimes, even subject to, national legislations. Hence, the national framework for IPRs and biodiversity are no less important than the international framework.

INDIAN NATIONAL FRAMEWORK FOR IPRS AND BIODIVERSITY.

The Indian national framework comprises three primary legislations: (i) the IPA (ii) the PVFRA; and (iii) the BDA. All the three legislations conflict with one another.

Conflicting Legislations.

The IPA excludes from patentability traditional knowledge[37]. Similarly, the PVFRA narrows down the scope of farmers' rights - the right to reuse, exchange, and sell protected plant varieties[38]; it does not provide for the protection of farmers' own varieties, mainly because the farmers' own varieties are akin to traditional knowledge and therefore are not likely to pass the rigorous tests of novelty, distinctiveness and inventive step. In this way, the PVFRA ends up promoting formal sector

36 TRIPS Agreement,art. 66(2).

37 IPA, S. 2(p).

38 *Id,* 39.

plant breeders alone.[39] Again, whereas the BDA explicitly provides for benefit-sharing measures with local communities, the PVRFB has no such provision. Whereas the BDA has a mechanism of prior informed consent, the PVFRA lacks it. As a result, farmers' own varieties can be easily accessed for research and other purposes, that too without according them any benefit from the same. Also, the BDA provides for impact assessments – something which the PVFRA does not require. Local communities, at least legally, play a proactive role in the BDA, but not in the PVFRA and IPA.

It must be acknowledged that the BDA envisages to harmonize IPRs and biodiversity. It takes a regulatory approach when it comes down to IPRs over biological resources. It does not, and perhaps, should not prohibit IPR per se. But Section 6 requires that every applicant (regardless of the applicant's nationality) applies over obtaining IPR for the National Biodiversity Authority's ("NBA") approval. The NBA can accept, reject the application or impose certain terms on an accepted application.[40] Furthermore, Rule 14 of the BDA Rules provide that the NBA consult local communities before deciding on such an application.[41] The NBA is also empowered to oppose a foreign grant on an IPR over any resource, or knowledge associated to that resource, from India.[42] It also an elaborate mechanism for access-benefit sharing ("ABS"). Section 19 and Section 20 of the BDA provide for the procedures of granting approval of access and IPR (under Section 3 and Section 6) and of transfer (under Section 4) respectively. However, Section 21 requires that while granting approvals, the NBA must ensure that the benefits of such access/transfer/IPR is equitably shared among the applicant, local bodies and other benefit claimers[43] along the lines of mutually acceptable terms and conditions. These benefits include – (i) joint ownership of IPRs; (ii) technology transfer; (iii) development

39 A. Kothari & R.V. Anuradha,*Biodiversity and Intellectual Property Rights: Can the Two Co-Exist?*2(2) JOURNAL OF INT'L WILDLIFE L & POL'Y (1999).

40 BDA, § 21(2).

41 *Id,* § 6(3).

42 *Id,* §18 (4).

43 *Id* (defined in § 2(a)).

of R&D and Production Centres in suitable areas; (iv) founding an association between scientists, local communities and benefit claimers for developing bio-resources; (v) establishing venture capitals and (vi) paying compensation or non-monetary benefits to the benefit claimers. Section 21 is further supplemented by theGuidelines on Access to Biological Resources and AssociatedKnowledge and Benefits Sharing Regulations, 2014 ("ABS Guidelines"). These guidelines provide an 18-step procedure of effecting access-benefit sharing. The procedure, in short, begins with a paid application to the NBA or State Biodiversity Boards ("SBB"), whatever the case may demand. These authorities have the discretion to clear the application if deemed fit. If thus cleared, an agreement of mutually agreed terms is made, for which the applicant will have to pay a royalty (the benefits of which will be given to benefit-claimers). A key feature of the ABS Guidelines is that the benefits have to be shared also with the SSB and BMC/benefit claimers[44], which is something the neither the BDA nor the BDA Rules provide for. [45] However, the picture is not as rosy as it appears.

Inadequate Synchronization Between Biodiversity Concerns And IPR Concerns.

NBA is mandated, under the BDA, to grant approval for access and benefit sharing; and one method of access-benefit is through IPR. In fact, the BDA explicitly mandates that the NBA grants approvals to IPR applications. What is interesting to note, however, is that IPR approvals of the NBA comprise 67% of all applications for access to biological resources (476 on 709).[46] Thus, it not be wrong to make a sweeping remark that the NBA has, in practise, become a screening office for granting IPRs. In addition to this undesired reality, the law itself is unclear - Firstly, NBA does not adhere to any objective standards for approving or rejecting requests for IPRs. Secondly, when

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44 ABS Guidelines, § 15.

45 Pankhuri Agarwal, *The Curious Case of the Indian Biological Diversity Act,* THE WIRE ,Nov. 16, 2017, https://thewire.in/environment/india-biological-diversity-act.

46 *Approval granted to Applicants,* NATIONAL BIODIVERSITY AUTHORITY, http://nbaindia.org/content/683/61/1/approvals.html.

it comes down to Plant Varieties Rights ("PVRs") and Plant Breeders' Rights ("PBR")[47], the NBA has no say. This is because PVRs and PBRs are under the control of the Protection of Plant Varieties and Farmers' Rights Authority[48]. This complete exclusion in favour of the aforesaid Authority is problematic since the preambular objectives of the BDA and PVFRA are in complete dichotomy and can, in consequence, disrupt the goals of the former legislation. Thirdly, traditional knowledge ("TK"), which comprise a big chunk of access-benefit of biodiversity, is principally unguarded as an effect of a looming legislative gap – on one hand, the NBA, in terms of technical legal implication, is empowered approve patents for TK but on the other hand, TK has been marked 'non-patentable'[49]It must be mentioned that efforts have been made to cover this legislative gap; the most significant of which is the Draft of the Protection, Conservation and Effective Management of Traditional Knowledge Rules, 2009, which sought to make TK patentable. However, these rules are not yet in force. Legislative gaps exists not just for TK alone; but also, sadly, for the NBA too – on one hand, the NBA empowers the NBA to oppose foreign IPR grants[50] but creates no forum for the NBA to do so. Interestingly, the Supreme Court of India, has observed that there is no necessity for such a forum[51] and this effectively renders the legislative enablementsuperfluous.

Deficient ABS Mechanism

The multi-faceted synergies between IPR and biodiversity becomes manifest in the ABS mechanism; but sadly, under the current legislative framework, this mechanism is deficient. Under the ABS Guidelines, benefit sharing need to be governed by ABS Guidelines and determined on a case-to-case basis[52]. But, practically, the ABS Guidelines is, by and large, a gigantic financial framework. This is

47 BDA, § 6(4).

48 PVFRA, § 3(1).

49 IPA, *supra* note 36.

50 BDA, § 18(4).

51 Research Foundation for Science, Technology, Ecology and Anr. v. UOI and Anr,WP (Civil) No. 64 of 2004.

52 Biological Diversity Rule, 2004, § 20(3).

because monetary sharing has been made the face of benefit sharing – most of the benefits need be shared in pre-fixed rates of monetary payment.[53]This raises questions not only regarding the efficacy of ABS mechanism but also that of the legislative policy itself; the latter arising due the apparent arbitrariness of the Guidelines. Firstly, there appears to be no objective stand for determining the prescribed rates of payment. Secondly, in certain specific cases of access (for instance, Commercial Utilization), the benefits directly accrue at the local-level (for instance, the Gram Sabha) but in some others (for instance, Transfer of Research Results)[54], the benefits accrue of the NBA first which later diverts the same to the SSBs and Biodiversity Management Committees ("BMC").[55] Thirdly, the ABS Guidelines do no provide for how the benefits are to be accrued in a "fair and equitable" manner. There is no prioritization and no conditions attached to the various modes of benefit-sharing[56], which can guide the applicant and the BMC as to which mode to apply in which situation. As a result, many of these modes are under-utilization or not utilized at all. Practise of the NBA has shown a preference for monetary benefits alone.[57] These issues are further complicated by the difficulties involved in identifying benefit-claimers.

The access-benefit sharing mechanism, due to its profitability, has also created controversy regarding the definition of 'biological resources'[58]. Practise of the NBA and SBBs has demonstrated a tendency to stretch the meaning of 'biological resources' so as to bring more and more resources under this mechanism and get more monetary benefits.[59]

53 *See* ABSGuidelines, § 3, § 4, § 7 & § 8.

54 *Id,* § 5.

55 *Id,* § 15.

56 *Id*, at Annexure (which lists various modes of benefit-sharing).

57 P. J. Singh & A. K. Tiwari, *Analysis of Status of Access and Benefit Sharing of Biological Resources and Associated Knowledge in India: The Path from Common Heritage of Mankind to Sovereign Right of a Nation*, SOCIAL SCIENCE RESEARCH NETWORK(Apr.29, 2015), https://ssrn.com/abstract=2666508.

58 *Id*, at § 2(c).

59 Kanchi Kohli & Shalini Bhutani, *The Legal Meaning of Biodiversity*, XLVIII:33 E.P.W. 33 (2013).

The matter reached the National Green Tribunal (hereinafter referred to as "NGT") in *Biodiversity Management Committee v. Western Coalfields Ltd. and Ors*[60] wherein the petitioner argued that coal, being formed from plant remains, is a biological resource and hence, access to coal for commercialization would require sharing benefits with the BDA authorities. However, the National Green Tribunal ("NGT") held that coal in not a biological resource and that coal, petroleum, natural gas etc. cannot come under the ambit of the BDA. In deciding whether a resource is a biological resource or not, the objective of the BDA is to be born in mind, which is but the conservation of living genetic resources.[61] Now, while the *ratio* of the NGT does make sense, it also points to the fact that if biodiversity is to be conserved, developmental projects such as mining also ought to be regulated, if not by the BDA but by other laws. This suggests the need of better coordination.

Given this situation, perhaps it would not be wrong to say that complete synchronization between the laws on biodiversity and IPRs is yet to be achieved.

CONCLUSION

The discussion in the previous pages reveal that the laws of promoting IPRs is directly in conflict with the need to conserve biodiversity. There are several national and international legislations which govern both IPRs and biodiversity. But governance is independent and separate. Therefore, there are a lot of conflicts. The major conflicts on this front have been highlighted in this article. But the undercurrent running through such highlights presents a pragmatic optimism – that implementation of the goals of UNCBD, through the provisions of the BDA or otherwise, cannot wait for an IPR free world; nor can those of the TRIPS Agreement or the UPOV Convention can wait for a biodiversity mobile world. Each is dependent on the other. As such, it would be much better to reform the existing systems to bring about more harmony between the duo. How exactly this can be achieved, is beyond the scope of this article and lies in the hands of our able policymakers.

60 MANU/GT/0169/2015 (India).

61 *Id*, at para. 40.

UNDERSTANDING INTELLECTUAL PROPERTY (IP) STRATEGY FOR ARTIFICIAL INTELLIGENCE

Digvijay Singh[1]

INTRODUCTION

The rapid technological growth is now providing alternatives to human cognition. Technologies, which are replacing human cognitive activities are generally, artificial in nature and thus, called artificial intelligence (AI).[2]Now, artificial intelligence technologies are intervening in every domain that was considered to be exclusive to human cognition or intelligence. However, AI technology-based machines performing such cognitive activities lacks the corporal existence and even not regarded as entities that may be considered as person either natural or juristic in the eye of jurisprudence.[3] The machines that are having artificial intelligence can themselves be owned by natural persons or legal entities and IP protection for such machines means IP protection for those entities. It also raises the question of ownership/authorship regarding works created by autonomous machines unanswered.[4] Julia Bossmann, says that the possibility of establishment of ownership over such systems may be open for debate in the future in regards to robot rights.[5]

Sundar Sarukkai argues that the real worry about this technology is the emphasis on intelligence rather other characteristic of human beings.

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2 GönençGürkaynak, Ilay Yılmaz, TürkerDoygun, and EkinInce, *Questions of Intellectual Property in the Artificial Intelligence Realm*, at 9, available at: *www.roboticslawjournal.com.*

3 R.W.M. Dias, JURISPRUDENCE,Chapter 12, pp.250-271,(LexisNexis, 15th Edition, 2013)

4 Gürkaynak, Yılmaz, Doygun, and Ince, *supra* note 1.

5 Julia Bossmann, *Top 9 ethical issues in artificial intelligence*, *World Economic Forum,* 2016, available at: *https://www.weforum.org/agenda/2016/10/top-10-ethical-issues-in-artificial-intelligence/*.

It is an attempt to reproduce super-intelligent humans and artificially magnifies it to an extent that allows the machines to do things far better that humans can and the success of these machines only reinforces the success of a particular view of human beings.[6] Stephen Hawking has warned that the efforts to develop artificial intelligence to create thinking machine poses a threat to the very existence of human race. The development of full artificial intelligence could spell the end of the human race.[7]The Panel at the WorldEconomic Forum, 2017 also focused on AI as a disruptivetechnology that will drive productivity as it continues to make its way into enterprise systemsand computing platforms.[8] However, at the same time AI is an increasingly relied tool for conducting business and according to Forbes, the AI market will grow from $8 billion in 2016 to more than $47 billion in 2020.[9] The current AI penetration in businesses is 38 *percent*, and its adoption is predicted to grow to 62 *percent* by 2018. This is precipitated by a greater than 300 *percent* increase in investment in artificial intelligence in 2017 compared with 2016.[10]

There are always two aspects of even a revolutionary technology. Supporters of first view focuses over its possible contribution to the humanity and on the other hand people having view against such technology because they simply focus over the possible detriment which may be posed by such technology. Even the Committee on Legal Affairs, European Parliament has noted that in a couple of decades, AI systems could surpass human intelligence in terms of

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6 *Is AI a Danger to Humanity*, The Hindu,March 2, 2018, available at: *https://www.thehindu.com/opinion/op-ed/is-ai-a-danger-to-humanity/article.*

7 *Artificial Intelligence Could Eliminate Mankind*, The Hindu, December 3, 2014, available at: *https://www.thehindu.com/sci-tech/science/artificial-intelligence-could-eliminate-mankind-hawking/article.*

8 World Economic Forum, Annual Meeting, System Initiatives Programme (2017), available at: www3.weforum.org/docs/Media/AM17/AM17_System_Initiatives.pdf.

9 Gil Press, *Top 10 Hot Artificial Intelligence (AI) Technologies*, *Forbes,* Jan. 23, 2017, available at: *https://www.forbes.com/sites/gilpress/2017/01/23/top-10-hot-artificial-intelligence-ai-technologies.*

10 *Ibid.*

performing functions, which uncontrolled, could pose challenges as to the manner in which these AI systems control and manage their own destiny.[11] In such a situation the need is to ethically regulate use of such technologies for the betterment of human kind as a whole.

Artificial intelligence has been evolving constantly, and having the potential to solve many our problems we are facing or will face in near future, the law sometimes has difficulty in keeping pace with such evolution and regulation of such technologies. AI enabled systems have transcended from performing simple calculation to producing poetry, art works and other complex creative works.[12] Inventor/owner of these technologies can take full advantage of such technologies if legal protection is provided to such technologies. There arises the question whether or not such work can be afforded any protection under Intellectual Property (IP) Laws?

The present paper focuses on understanding of suitable IP protection for such technologies to ensure freedom to operate without violating third-party IP rights, and protection of investments, research and development (R&D) in the field of AI technologies. It also examines completeness of the IP strategy which Government of India has recently adopted in its discussion paper on *National Strategy for Artificial Intelligence* in June 2018.

CONCEPTUALIZING ARTIFICIAL INTELLIGENCE

The modern artificial intelligence started with the aim of defining philosopher's system of human thoughts in 1884 when Charles Babbage started working on mechanical machine claimed to exhibit intelligent behaviour. He couldn't reach to a conclusion and was not able to produce a machine that would exhibit intelligent behaviour as

11 *Draft Report with Recommendations to the Commission on Civil Law Rules on Robotics,* 2015/2103(INL),Committee on Legal Affairs, European Parliament, 2014-2019, at 8, available at: *http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML%2BCOMPARL%2BPE-82.443%2B01%2BDOC%2BPDF%2BV0//EN.*

12 Swapnil Tripathi and ChandniGhatak, "Artificial Intelligence and Intellectual Property Law", 7(1) CHRIST UNIVERSITY LAW JOURNAL, 2017, pp.83-97, at 84.

a human being. Again, works on artificial intelligence got pace in 1956 when a conference on Artificial Intelligence was organised at Dartmouth College.[13] The term "Artificial Intelligence" was used for the first time in this conference wherein John McCarthy at the Massachusetts Institute of Technology defined it as science and engineering of making intelligent machines, especially intelligent computer programs.[14]This conference initiated a critical period in AI research from the 1950s to the 1970s. Early developments included experiential search and machine learning with the aim of achieving broader objectives such as computer vision, natural language processing, and robotics.[15] After this conference, research in the field of AI got new pace and direction and huge investment for research and development (R&D) in the field became order of the day. PwC research estimates that global GDP will increase by $15.7 trillion, a full 14%, by 2030 in the field of AI. But of this, $7 trillion is likely to accrue to China, $3.7 trillion to North America, and only $957 billion to India.[16]

An artificial intelligence machine is an autonomous entity and from what we have seen of such machines, they are like other human beings in terms of their capacities for decision and action.[17] AI may be best defined by analyzing the two components of the term i.e. artificial and intelligence.[18]Mrs. Younghee Lee says that technology

13 Bruce G. Buchanan, *A (Very) Brief History of Artificial Intelligence*, 26(4) AI Magazine, 2005, pp.53-60; Lee Spector, *Evolution of artificial intelligence*, 170 Artificial Intelligence, 2006, pp.1251–1253; and John Self, *Whoever Said Computers Would Be Intelligent?* (England,Drakkar Press Limited, 2005).

14 *The History of Artificial Intelligence*, University of Washington, 2006, at 4, available at: *https://courses.cs.washington.edu/courses/csep590/06au/projects/history-ai.pdf.*

15 Anne Bowser, Michael Sloan, Pietro Michelucci and Eleonore Pauwels, *Artificial Intelligence: A Policy-Oriented Introduction*, Wilson Briefs, 2017, at 2.

16 "Sizing the prize: What's the real value of AI for your business and how can you capitalise?", available at: *https://www.pwc.com/gx/en/issues/analytics/assets/pwc-ai-analysis-sizing-the-prize-report.pdf.*

17 *Supra* note 5.

18 "The Future is here: Artificial Intelligence and Robotics", *Nishith Desai Associates*, 2018, at 2, available at: *http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/Artificial_Intelligence_*

is dramatically changing our world. When we look at innovations through a humanistic lens, technology can become a powerful catalyst for creativity. It will transform creativity, for the better, by inspiring all of us to achieve the impossible.[19]AI is a science and technology-based discipline, which includes computer science, biology, psychology, linguistics, mathematics, and engineering. The major thrust of AI is in the development of computer functions associated with human intelligence such as reasoning, learning, and problem solving.[20] Now, artificial intelligence has established itself as one of the next digital frontiers of innovation world-wide.

IP PROTECTION FOR ARTIFICIAL INTELLIGENCE

Although artificial intelligence has been evolving constantly, the law sometimes face difficulty in keeping pace with such evolution so far as the question of its regulation is concerned. Eric Lavallée argues that inventor/owner of these technologies can get advantage of such technologies to its fullest sense if a comprehensive intellectual property protection is provided to them.[21]further, Frank A. DeCosta and Aliza G. Carrano argue that interface of artificial intelligence with intellectual property issues typically stem from two business objectives, *first* maintaining a freedom to operate, and *second* without violating third-party IP rights, and protecting investments in AI research and development.[22] The various forms of intellectual property that may be useful to provide protection to artificial intelligence based technologies may as follows:

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and_Robotics.pdf.

19 Younghee Lee "Will Technology be the Downfall or Saviour of Creativity?" 2018, available at: *https://news.samsung.com/global/editorial-will-technology-be-the-downfall-or-saviour-of-creativity.*

20 "Artificial Intelligence" *tutorialspoint*, 2015, available at:*https://www.tutorialspoint.com/artificial_intelligence/.*

21 Eric Lavallée,*Need to Know: Intellectual Property and Artificial Intelligence*, 2017 available at: *http://www.lavery.ca/en/publications/our-publications/3037-intellectual-property-and-artificial-intelligence.html.*

22 Frank A. DeCosta and Aliza G. Carrano, *Intellectual Proper_ Protection for Artificial Intelligence*, WESTLAW JOURNAL INTELLECTUAL PROPERTY, 2017, available at: *https://www.finnegan.com/en/insights/intellectual-property-protection-for-artificial-intelligence.html.*

Copyright protection to Artificial Intelligence

Copyright gives and protects exclusive rights of creator of original literary, artistic, dramatic and musical works. Nonetheless, the predominant subject matter of copyright is literary work and besides "originality"[23] of such work, it needs to be "fixed"[24] to claim copyright protection. Copyright is used to protect software, as computer software is copyrightable in all most all the jurisdictions under domain of literary work.[25] Thus, AI programmes are equally qualified to get copyright protection as any other software. However, creation of works by using such AI programmes would have very important implications for copyright law. If works in the domain of literature and arts are created by using AI programmes, the question which may pose serious problem is whether AI based machines have created works for what it has been given instructions or it goes beyond such instructions. It simply means the level of human intervention in creation of work must be examined to determine who would be given copyright protection. As the programmes have been developed by the humans, they should be given copyright protection. If the AI based machine performs certain acts for which it has not been given instruction in such situation also it would be difficult to say such machine per se will be given protection as person. Traditionally, the ownership of copyright in computer-generated works was not in question because the programme was merely a tool that supported the creative process. The Indian Copyright law also provides that in relation to any literary, dramatic, musical or artistic work which is computer-generated, the person who causes the work to be created is considered as author of the work and is given

23 The question of originality, the threshold standard of qualification for copyright protection, is at the core of copyrightability. Howard B. Abrams, *Originality and Creativity in Copyright Law", 55(2) Law and Contemporary Problems,* 1992, pp.3-44.

24 To understand the requirement of fixation under copyright law *see*, Elizabeth Adeney, *Authorship and Fixation in Copyright Law: A Comparative Comment*, 35 MELBOURNE UNIVERSITY LAW REVIEW, 2011, pp.677-696; and Evan Brown, "Fixed Perspectives: The Evolving Contours of the Fixation Requirement in Copyright Law", 10(1) WASHINGTON JOURNAL OF LAW, TECHNOLOGY & ARTS, 2014, pp.17-34.

25 The Copyright Act, 1957, Section 2(o).

protection accordingly.[26]

Creative works qualify for copyright protection if they are original, and definition of originality requires a human author as the creation always take place in the mind of humans. Thus, in most of the jurisdictions, only those works which are created by a human can be protected by copyright.[27] But with the latest types of AI, the computer programme is no longer a tool. Now, it actually makes many of the decisions involved in the creative process without human interventions.AI systems can also generate new works protectable by copyright, such as creating new artwork or music. However, most of the copyright statutes do not yet clearly define who owns machine-generated works.[28] It is a contention that though the work is generated by a machine, the role played by the humans in creation of the work should be recognised and to this end, one should attempt to clarify ownership. Further, an AI system may act or operate autonomously in a manner that infringes third-party IP rights. If existing laws do not extend liability to a machine, then a related stakeholder (such as the owner, developer, operator or another supply chain participant) may be responsible.[29]Andres Guadamuz, argues that there are two ways in which copyright law can deal with works where human interaction is minimal or non-existent. It can either deny copyright protection for works that have been generated by a computer or it can attribute authorship of such works to the creator of the programmes.[30]

Patent Protection to Artificial Intelligence

Patent law is more significant to provide protection to AI based technologies as it generally falls in the domain of invention which is

26 *Id.,* Section 2(d)(vi).

27 Andres Guadamuz, "Artificial intelligence and copyright", 5 *WIPO Magazine*, 2017, available at: *http://www.wipo.int/wipo_magazine/en/2017/05/article_0003.html.*

28 "Artificial intelligence and intellectual property considerations",*Financier Worldwide Magazine, 2018, available at:https://www.financierworldwide.com/artificial-intelligence-and-intellectual-property-considerations/#.W2CqNNIzY2w*

29 *Ibid.*

30 Andres Guadamuz, *supra* note 26.

exclusively a subject matter of patent protection, but it is very difficult to apply principles of patent law to AIs based technologies. As AIs based technologies have been used extensively in order to simplify the execution of basic functions and primarily reduce human effort. However, it functions in a much more complicated manner. Today, AI enabled systems are equipped to perform tasks based on their own key learnings, creating the possibility of them inventing something. Swapnil Tripathi and Chandni Ghatak argue that while this is a huge development from a technological standpoint, it poses new challenging questions from the perspective of patent law.[31] The subject matter of patent protection is invention and it has been understood to cover any product or process, which provides to the users a novel way of performing a certain action, including that which offers a new solution to an existing technical problem.[32]

AI enabled systems are equipped to perform functions and even create inventions, which ordinarily results as an outcome of the application of human cognitive processes. In fact, these machines are producing results which could qualify as patentable inventions.[33] Now in such a circumstance the question is whether such machines should be considered as true inventor? In all most all the jurisdictions inventor are natural persons and there is no scope for anyone besides humans to be considered as inventor. However, the increasing involvement of the AI systems in creation of invention needs to be clarified keeping in mind the above situation. The European Union has recently tried to clarified this question when it encouraged nations to expand their IP laws to accommodate copyrightable works produced by computer and other devices under the category of 'own intellectual creation'.[34]

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31 Swapnil Tripathi and ChandniGhatak, *supra* note 11, at 90.

32 To understand Basics of Patents, *see,* Lionel Bently and Brad Sherman, *Intellectual Property Law* (New York: Oxford University Press, 2001) pp.309-539.

33 Liza Vertinsky and Todd M. Rice, *Thinking about Thinking Machines: Implications for Machine Inventors for Patent Law*, 8(2) BOSTON UNIVERSITY JOURNAL OF SCIENCE AND TECHNOLOGY LAW, 2002, pp574-613.

34 *Draft Report with Recommendations to the Commission on Civil Law Rules on Robotics,* 2015/2103(INL),Committee on Legal Affairs, European

This is a progressive step to acknowledge creativity exhibited by these systems, while producing poetry, artwork *etc.*, due regard must also be paid to include inventions and application of patents by AI systems and robotics.[35]

The biggest challenge of time in obtaining a patent grant for the inventions invented by AI enabled systems/technologies, how far it satisfies the criterion of patentability? For indicating novelty, it becomes necessary for the invention to be different from whatever exists in the prior art. While an AI system will certainly have access to prior art, is it independent, is it capable to make a judgment on whether or not its invention can account for something novel? As to the question of an inventive step, Ronald Yu argues that the chances of making innovations on existing models which is not obvious to a person skilled in the art, is certainly difficult to achieve.[36] At present, AI is usually fed with pre-existing objectives which they are programmed to achieve. The technology must first advance to equip these systems with a human-like intelligence so that judgment calls on new situations can be made by them.[37] India has recently removed the rigid requirement that only computer programs embodied in hardware is eligible for patent protection.[38] If an AI enabled system creates a software which can be used on generic machines, it would entail practical utility, perhaps in more than one industry, which allows satisfaction of the industrial application requirement within the patentability test. Further, patent protection may suit to the nature of AI based technologies and such technologies may be give patent protection, if specification and claims

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Parliament, 2014-2019, at 8, available at:*http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML%2BCOMPARL%2BPE-582.443%2B01%2BDOC%2BPDF%2BV0//EN.*

35 Swapnil Tripathi and ChandniGhatak, *supra* note 11, at 91.

36 Ronald Yu, Should an Artificial Intelligence be allowed to Get a Patent?", 2017, available at: *http://robohub.org/should-an-artificial-intelligence-be-allowed-to-get-a-patent.*

37 Swapnil Tripathi and ChandniGhatak, *supra* note 11, at 92.

38 Intellectual Property Office, *Office Order No. 36, 2017*, (India), available at: *http://www.ipindia.nic.in/writereaddata/Portal/Images/pdf/Office_Order_No_36_of_2017_for_Revised__Guidelines_for_Examination_of_CRIs.pdf.*

of those technologies are drafted by the patent attorneys in such a manner which is conducive to the requirement of patent laws.

Trade Secrets protection to Artificial Intelligence

Trade secret (undisclosed information) protects economically valuable secrets including formula, methods, techniques, and business processes *etc.*[39]It doesn't even require registration to get protection and protection arises automatically provided that the trade secret owner demonstrates that the information creates a competitive advantage by virtue of its secrecy and reasonable measures have been taken to maintain its secrecy.[40] Unlike patents trade secret need not to be disclosed in order to get protection.[41] The disclosure requirement under patent may unnecessarily disclose valuable trade secrets to public as all the claims may be granted patent protection. Further, a patent grant only protects the rights of patentee in jurisdiction of state granting patent. Based on the disclosure of valuable information, invention may be practised in other jurisdictions. Frank A. DeCosta and Aliza G. Carrano argue that above shortcomings of patent system highlight potential advantage of trade secret for AIs.[42]

Trade secret protection may be well suited for rapidly developing and changing AI inventions. It offers advantage of avoiding disclosure requirement. When inventors rely on trade secrets to protect their AI inventions, they don't need to determine when an invention is ready for patent grant.[43]However, there would be no cause of action against

39 *See*, Abhik Guha Roy, *Protection of Intellectual Property in the Form of Trade Secrets*, 11 JOURNAL OF INTELLECTUAL PROPERTY RIGHTS,2006, pp.192-200.

40 "Protecting Artificial Intelligence IP: Patents, Trade Secrets, or Copyrights?",Jones Day Publications, 2018, available at: *http://www.jonesday.com/protecting-artificial-intelligence-ip-patents-trade-secrets-or-copyrights-01-09-2018.*

41 Patent protection requires disclosure of invention. It is based Faustian pact between inventor/owner and state agency.

42 Frank A. DeCosta and Aliza G. Carrano, *Intellectual Property Protection for Artificial Intelligence",* WESTLAW JOURNAL INTELLECTUAL PROPERTY, 2017, available at: *https://www.finnegan.com/en/insights/intellectual-property-protection-for-artificial-intelligence.html.*

43 *Ibid.*

competitors who have independently developed that technology or ascertained it by reverse engineering. Features such as neutral networks, training sets, software including AI code and AI-generated code, and learning *etc.* may get protection in the name of trade secret.[44] The broad scope of what may be a trade secret potentially allows for the protection of data sets that underlying the machine learning of AI. A trade secret protection strategy is also well-suited for the rapidly developing and changing marketplace of AI innovations.[45] If the marketplace shifts or an AI technology developed by a company proves unsuccessful, using a trade secret protection, instead of seeking patents, reduces the investment loss that may otherwise be incurred from pursuing patent protection and paying related patent prosecution expenses.[46]

NATIONAL STRATEGY FOR ARTIFICIAL INTELLIGENCE IN INDIA

Artificial intelligence-based machines are now enabling high-level cognitive processes like thinking, learning, problem solving *etc.* AI presents opportunities to complement and supplement human intelligence and enrich the way people live and work.India has a significantstake in the AI revolution and recognising its potential to transform economies, NITI Aayog, Government of India has recently established the National Programme on AI, with a view to guiding the research and development in new and emerging AI technologies. NITI Aayog has adopted a three-pronged approach particularly undertaking exploratory proof of concept of AI projects in various areas, crafting a national strategy for building a vibrant AI ecosystem in India and collaborating with various experts and stakeholders. Learnings from these projects, under various stages of implementation, as well as our engagement with some of the leading institutions and experts have given a better perspective to our task of crafting the national strategy for AI.[47] This strategy document is premised on the proposition that

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44 *Ibid.*

45 David A Prange and Alyssa N Lawson, *Re-evaluating Companies' AI Protection Strategies*, *ManagingIP.Com,* 2018, pp.37-38.

46 *Ibid.*

47 *National Strategy for Artificial Intelligence#AIFORALL,* Discussion Paper.

India, given its strengths and characteristics, has the potential to position itself among leaders on the global AI map with a unique brand of "AI for All". The approach in this discussion paper focuses on how India can leverage the transformative technologies to ensure social and inclusive growth in line with the development philosophy of the government.[48]

The discussion paper argues that Artificial Intelligence based technologies have the potential to provide large value to a wide range of sectors including health care, agriculture, mobility, retail, manufacturing, smart cities, energy, and education *etc.* globally. It further argues that in order to ride the AI innovation wave, Indian needs a robust intellectual property framework. Despite a number of government initiatives in strengthening the IP regime, challenges remain, especially in respect of applying stringent and narrowly focused patent laws to AI applications. To tackle these issues, establishment of IP facilitation centres to help bridge the gap between practitioners and AI developers, and adequate training of IP granting authorities, judiciary and tribunals may be a forward-looking step.[49] The present discussion paper should be seen as the government's first step in a drawn-out, and potentially transformative, policy.[50]

The Ministry of Commerce and Industry has set up a Task Force on Artificial Intelligence to kick-start the use of AI for India's economic transformation. However, the Task Force in its report submitted that the most important challenge is to collect, validate, standardise, correlate and distribute data relevant for AI and making it accessible to organisations, people and system without compromising privacy of people.[51]

NITI Aayog, Government of India, June, 2018, pp.1-115.

48 *Ibid.*

49 *Id.*, at 8.

50 R. Shashank Reddy, *Can India become an AI hub for the developing world?*, 27 June 2018, available at: *https://www.bbc.com/news/world-asia-india-44614802.*

51 *Report of the Artificial Intelligence Task Force,* Ministry of Commerce and Industry, Government of India, 2018, at 9, available at:*http://dipp.nic.in/sites/default/files/Report_of_Task_Force_on_*

CONCLUSION

Increasing investment in AI based technology needs appropriate strategy including IP strategy for its effective regulation. IP laws don't explicitly provide for protection of AIs; however, intellectual interpretation of provisions of copyright, patent and trade secret laws may provide IP protection to AIs to some extent. Recognition of IP protection for AI generated works would be a step forward keeping in mind the importance of technology to the humanity. Present laws and regulations need to be streamlined in a manner which may explicitly allow for IP protection to AI. Besides IP protection government should also adopt comprehensive strategy to maximize the utilization of artificial intelligence. The recent discussion paper titled National Strategy for Artificial Intelligence prepared NITI Aayog 2018 looks forward to meet challenges in the field of Artificial intelligence in the country. The Task Force on Artificial Intelligence is also focusing its potential use for the economic growth of the country. These affords may boost the revolution brought by AI based technologies.

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PROTECTING TRADITIONAL KNOWLEDGE IN INDIA AS INTELLECTUAL PROPERTY: A WAY FORWARD

Ipsita Kaushik[1]

INTRODUCTION

Since the primitive time, knowledge is regarded as power. However, with the evolving concept of knowledge-based economy, knowledge is no longer treated only as a sign of societal position rather as a property, which has great economic potential. Traditional knowledge is one of such knowledge which has drawn attention of various International fora, Policy makers and Researchers. The debate on the importance of protection of traditional knowledge has increased following various incidence of patent granted in the United States and European Union Patent Offices on the centuries old Traditional knowledge of indigenous people of India. Traditional Knowledge is a very broad term, referring to various knowledge systems, encompassing a variety of areas, held by traditional communities or to knowledge acquired in a non-systematic ways.[2]

Indigenous people are barely literate but amazingly intelligent in gathering wonderful ideas and information by keenly observing nature, that provide them all necessary assistance for their survival in absence of modern sophisticated facilities. Traditional Knowledge thus developed, discovered and invented by tribal and indigenous people is the result of long experience of their forefather since time immemorial, passed down from one generation to another generation, preserved in its virgin state or sometimes added value to the prevailing knowledge and thus it becomes their way of life. There is no universally accepted definition of Traditional Knowledge. Traditional knowledge can be defined as "a cumulative body of knowledge, know-how, practices and representations maintained and developed by people with extended

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2 R.G. Alvarez Nunez, *Intellectual Property and Protection of Traditional Knowledge, Genetic Resources and Folklore: The Peruvian Experience* ,12 MAX PLANCK UNYB 487,492 (2008).

histories of interaction with the natural environment".[3]

Traditional Knowledge typically distinguishes one community from another. For some communities, traditional knowledge takes on a personal and spiritual meaning. Traditional knowledge can also reflect a community's interest. Some communities depend on their traditional knowledge for their survival. Traditional people are knowledgeable enough to find out solution to most of the problems created by nature.

Some of the basic characteristics of Traditional knowledge are: *Firstly,* it is basically a community knowledge which is generally created, originated and held by a community. It is the result of collective effort of the community. *Secondly,* oral transmission is another characteristic of traditional knowledge which passes down from one generation to another orally. However, in some rare cases it may be found in written form also. *Thirdly*, Traditional Knowledge is not a myth, but the result of practical experience. It is the result of century long observation, experiment and research of the indigenous communities through trial and error method. *Fourthly,* Traditional Knowledge is not static but dynamic. It changes with the change in the nature of environment. *Fifthly,* it is holistic in nature which is inseparable from the people who hold it. It is deeply rooted in their spiritual beliefs and cultural identity.

India a paradise of traditional knowledge has not only witnessed cultural diversity but also has diverse age-old traditional practices. India is the one of the biodiversity hotspot of world. India has four major biodiversity hotspots and they are Eastern Himalayas, Western Ghats, Indo-Burma and Sundaland.[4] People of this region are very much familiar with the plant varieties of their ecosystem and their usages. Traditional medicine of India has global recognition. More than half of the population in India is dependent on traditional medicine,

3 BIBHASH DHAR, TRADITIONAL KNOWLEDGE WITH SPECIAL REFERENCE TO THE TRIBES OF NORTH EAST INDIA 8 (1st ed.2016).

4 P. Pushpangadan and Sharad Srivastava, *Traditional Knowledge, IPR, Value addition and Technology Transfer: A Case Study, in* BIODIVERSITY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE: UNDERSTANDING INTELLECTUAL PROPERTY RIGHTS (Aravind Kumar& Govind Das ed.; 2010).

due to their poor access to the modern medical science. Protection of traditional knowledge has received recognition only in recent decades, because earlier they were treated as unsophisticated with no scientific basis.[5]

Thus in the simplest form one can understand traditional knowledge as a vast expanse of knowledge, innovations and practices of indigenous and local communities embodying their traditional life style. This whole body of knowledge forms a part of cultural and ethnic identity of the indigenous people.

JUSTIFICATIONS FOR PROTECTING TRADITIONAL KNOWLEDGE

In developing countries where people are mostly dependent on nature, traditional knowledge plays an important role in healing ailment, food production, and in their other means of livelihood. Indigenous and local communities are mostly situated in areas which are biologically rich and diverse with abundant natural resources and hence they possess knowledge about many undiscovered biological compounds of plants which can cure various malady. Pharmaceutical companies as well as many other industries have realised the great value of such knowledge. The foreign health care industries which are constantly working on new technologies to assess the chemical makeup of plants have realised that by using the traditional knowledge of indigenous people they can make their research more efficient and less expensive.[6] Demand for medicinal plant is increasing constantly because they are non-narcotic, have no side effect and they are easily available at a cheap rate. Therefore, knowledge of indigenous about the beneficial use of plants, vegetables, flowers, fruits has great economic value. But due to their lack of awareness, they see traditional knowledge only as an identity of their community, and not as a pathway for social and economic development. Since no property right is assigned to the

5 Hui Tag, *Biodiversity Traditional Knowledge, Intellectual Property Rights and Benefit Sharing in the context of Northeast India*, *in* RESOURCES, TRIBES AND DEVELOPMENT: COMPETING INTERESTS AND CONTOURS OF POSSIBILITIES 259, 261 (M.C Behera & Jumyir Basar ed., 2014).

6 Jhon Reid, *Biopiracy: The Struggle for Traditional Knowledge Right*, 34 AMERICAN INDIAN LAW REVIEW 79(2010).

knowledge holder, such knowledge is often taken by unauthorised party without due recognition and benefit sharing and get patent on invention using such indigenous knowledge.

Apart from this, traditional communities regard natural environment as a way of life and therefore they contribute a lot to conserve the biodiversity. Tribal communities maintain some "Sacred Groves" in forest areas, where they consider some woods as sacred and it is a belief that if a person clandestinely enters such woods and cuts timber or collects orchids and other forest products without informing the custodian he is liable to be punished by the unseen power by making him fall ill. In India there are many Sacred Groves known by different local names. Such as in Maharashtra sacred groves are locally known as *Devrai, Devrahati, Devgudi*, in Kerala sacred groves are locally known as *Kavu, Sara Kavu,* in Rajasthan sacred groves are locally known as *Orans, Kenkris, Jogmaya* etc.[7] Indigenous people since the time immemorial have been making sincere efforts to save trees, shrubs, orchids, lifesaving medicinal plant, birds and animals. Traditional people have in-depth knowledge about our ecosystem, any they have realised well that a healthy ecosystem is essential for sustainability of mankind. But urbanisation and industrialisation has led to the shrinkage of some of the largest groves in the country. Therefore, protection of traditional knowledge of traditional communities will ultimately protect our biodiversity.

In respect of Artistic work, craft, textile, jewellery, terracotta, pottery, traditional dresses of indigenous people also have great economic value. Specially, such traditional items are on high demand for tourists who have great love for ethnic items. Ethnic items reflect their rich cultural aspects unique to their community. They not only portray their cultural uniqueness but also encourage the tourist to purchase these items commonly prepared out of organic resources and usually handmade. But the great threat they are facing now a days, is the misrepresentation of such valuable cultural assets by some dishonest

7 C.P.R Environmental Education Centre, *Conservation of Ecological Heritage and Sacred Sites in India*, (Nov.21, 2017, 12.00 A.M), http://ecoheritage.cpreec.org/innerpageof.php?$mFJyBfKPkE.

commercial operators.[8] Some machine made cheap qualities similar looking products are now competing with the authentic products, which poses a threat to the cultural integrity of a community.

Therefore, traditional knowledge deserves protection and recognition as the economic asset of knowledge holder. However, it is difficult to estimate the value of traditional knowledge in monitory term. But TK has the potential to improve the economy of developing countries by enabling greater commercial use of their biological wealth and increasing exports of TK related products. The future of a nation is not dependant only on new innovation and invention but also on the age-old traditional knowledge and practices which is the result of century long observation, experiment and research of the indigenous communities. However, if the traditional knowledge is overprotected it will hinder possible future discoveries because traditional knowledge about the beneficial compound within the millions of plant varieties has the potential to lead to medical advancement that can save the world.[9] Similarly, if the traditional knowledge remains unprotected any unauthorised person can exploit such knowledge to acquire monopoly right over such knowledge, which will be a gross injustice to the original holder and custodian of such resources. Therefore, it is necessary to strike a balance by which rights of indigenous people can be protected and promotion of future research and discoveries can also be served. Indigenous people have wide array of knowledge about the beneficial biological compound of plants, vegetables, flowers, fruits, spiritual therapies, manual exercise and techniques etc. but due to lack of financial resources could not conduct further research to get patent. In such cases they can permit the deep pocketed companies to use such valuable information to attempt new discoveries with due recognition to such indigenous community and benefit sharing. In this way Researcher could get valuable experience based information and Indigenous communities could get the most needed capital for the upliftment of their standard of life.

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8 Raguvaran Gopalan & Sindhu Sivakumar , *Keeping Cashmere in Kashmir: The Interface between GI and TK,* 12 JOURNAL OF INTELLECTUAL PROPERTY RIGHT 581(2007) .

9 Reid *Supra* note 8, at 78.

CHALLENGES IN PROTECTING TRADITIONAL KNOWLEDGE UNDER IPR SYSTEM

With the growing instances of acquisition of Intellectual Property Right by any party other than the traditional knowledge holder, over traditional knowledge based innovation and creations, protection of traditional knowledge under Intellectual Property Right regime is receiving significant attention. Protection of traditional knowledge as an intellectual property is not an easy solution. These growing concerns for protecting traditional knowledge as an intellectual property has raised a practical question regarding the adequacy of current IPR system to protect traditional knowledge.[10] Some characteristics of traditional knowledge are not at par with the requirements essential for granting protection under IPR regime. Challenges that the traditional knowledge is facing in respect of its protection are:

Traditional knowledge has been considered as a matter in public domain, accessible and exploitable by anyone from public at large. *Novelty* which is the paramount consideration for granting patent protection under IPR framework is said to be missing in Traditional knowledge because of its widespread availability and practice within a community. But to counter this claim various activists and researchers have claimed that, public availability of knowledge within a particular community does not necessarily mean that any third party can exploit such knowledge without any authorisation and compensation. Moreover, some knowledge of indigenous people is within the secrecy regime of the community, which has some sacred value.

Intellectual property Law regime is also not similar in all countries. Intellectual property protection granted in one country may not be recognised in other country. Although there are some international arrangements to harmonise the intellectual property protection, but there still exist differences in national laws.[11] The patent law of

10 Pamela Andanda, *Striking a Balance between the Intellectual Property Protection of Traditional Knowledge, Cultural Preservation and Access to Knowledge,*17 JOURNAL OF INTELLECTUAL PROPERTY RIGHT 547,548 (2012).

11 Silvia Salazar, *Intellectual Property and Right to Health, in* INTELLECTUAL PROPERTY AND HUMAN RIGHTS 65, 70 (WIPO, 1998).

United States draw a distinction between the knowledge that is foreign and domestic. In United States novelty requirement is not fulfilled if knowledge is available in any form within the United States, but knowledge outside the United States must be published or documented in order to prevent the grant of patent for lack of novelty.[12] As long as there is no written record, a company based in United States can easily obtain a patent on the indigenous knowledge of a foreign country. That was the main reason behind the Bio piracy case of Neem. The traditional knowledge regarding Neem was not published in India, and therefore didn't bar the novelty requirement to grant the patent and the patent was upheld in United States. Moreover if a Researcher collect any information about the traditional knowledge of indigenous people and publish the same in any academic publication as his own invention, this can also prevent the original knowledge holder to get patent.[13]

Traditional knowledge is mostly in undocumented and uncodified format. It transforms orally from one generation to another. So, there remains no solid prove against the patent obtained on traditional knowledge based invention and creation. Therefore, it is necessary to make proper documentation of traditional knowledge so that the IP officer can access the database in defending the rights of knowledge holder against the unauthorised exploitation by third party.

The very attribute of traditional knowledge is that it is collective rights, hold by an indigenous community. Traditional knowledge reflects the interest of whole community. On the other hand, Intellectual Property Right is an individual private right, which gives the owner exclusive proprietary right. But in traditional knowledge, it is impossible to identify the original creator as these knowledge and practices are century old.

Limited duration of protection under IP protection is another challenge standing on the way of protection of traditional knowledge. Traditional

12 Reid *Supra* note 8, at 89.

13 Aravind Kumar and Govind Das, Biodiversity, Biotechnology and Traditional Knowledge: Understanding Intellectual Property Rights, 201(1st ed., 2010).

knowledge which has become the way of life of a particular community demands for permanent protection. Protection for a short duration of time will not solve the problem of indigenous people.

These are some of the practical challenges that the indigenous people are facing in respect of the protection of their valuable assets, which gives the money minded people more opportunities to get benefits at the expense of poor disadvantageous people.

Figure 1- Challenges Surrounding the Protection of Traditional Knowledge under IPR

Intellectual Property Rights in Traditional Knowledge

Intellectual property right is the exclusive right given to persons over the creations of mind. Knowledge of indigenous and local people is their property and therefore deserves enjoyment of the rights in that property. If so, then there is no justification forthe totally discriminating treatment, ofinnovations using modern technology and Traditional Knowledge. Bothshould be given same legal status and recognition. The intersection of indigenous knowledge and IP comes about because of a number of factors, including the creation by indigenous people of global political networks in the second half of the twentieth century, the recognition of the economic value of indigenous knowledge and the increasing activism of developing countries around international IP rights.[14] It is true that, the concept of intellectual property right is

14 Vandana Shiva, Biopiracy: The Plunder of Nature and

rooted in western developed countries. But it is also an undeniable fact that, these sets of legal framework have been the primary vehicle for protection of artistic, literary and scientific work worldwide.[15] Therefore, to deprive the indigenous people from this legal regime is to deny the indigenous people a powerful legal shield. Therefore, it is necessary to find out the solution within this IP framework first. The protection of traditional knowledge in IPR is sought in two forms; defensive protection and positive protection. Which are discussed here:

A. Defensive Protection

The Defensive protection prevents the grant of intellectual property right protection on traditional knowledge based innovations and creations to any party other than the custodian of such traditional knowledge. Defensive protection includes regulatory measures adopted by various authorities to prohibit the unauthorised misappropriation of such indigenous knowledge. Misappropriation of traditional knowledge means acquisition, appropriation or utilisation of traditional knowledge for commercial benefits by illicit means such as theft, fraud, breach of contract, breach of trust etc. Various defensive mechanisms evolved to safeguard the traditional knowledge from being patented are:

a. Documentation of Traditional Knowledge

Many a time, due to lack of defensive mechanism western based companies can easily get patent on traditional knowledge based inventions. Therefore, some countries and communities have developed their Traditional Knowledge data bases, to defeat the grant of patent on such traditional knowledge. India has developed Traditional Knowledge Digital Library (TKDL), which can be used as a prior art in granting of patent. TKDL does not ensure any specific rights over the traditional knowledge holder but enables the protection of such knowledge against misappropriation by digitizing existing publicly available traditional knowledge. The IP officer can access the data base to check the novelty requirement before the grant of patent. As most of the traditional

Knowledge,101-105(1999).

15 Rajat Rana, Indigenous *culture and Intellectual Property Right,* 11 JOURNAL OF INTELLECTUAL PROPERTY RIGHT 132, 135(2006).

knowledge is transmitted orally and remains undocumented, it is therefore necessary to codify the traditional knowledge like codified Indian System of Medicine (ISM), and to make it available to the patent examiner in the form and language understandable to him.[16]

b. **Disclosure of Origin**

Another instrument of defensive protection of traditional knowledge is the disclosure of source of origin of genetic resources and associated TK, when such genetic resources are used in an invention. Some countries have already incorporated such requirement under their national law.[17] At international level some developing countries are constantly requesting to include this disclosure requirement in TRIPs agreement, to prevent the unauthorised grant of patent on traditional knowledge. Thus it many countries it has been made mandatory to disclose the source of origin of genetic resources and other associated traditional knowledge when it is used in an invention. In India, the Patent Act, 1970, as amended in 2002, under Section 10(4)(D) provides that, Patent applicants have to disclose the source and geographical origin of the biological material used in the invention, with complete specification. This is supplemented by a provision in Section 25(j) which makes the failure to disclose the source and geographical origin of the biological material used as ground for opposing the grant of patent.

c. **Prior Informed Consent (PIC)**

Prior Informed Consent (PIC) is one of the norms under Convention of Biological Diversity (CBD), which requires the approval in advance for the use of genetic resources and other associated traditional knowledge. Under this principle it is necessary to consult traditional knowledge holder before their traditional knowledge is accessed and used by third party. An agreement should be formulated in

16 Carlos M. Correa, *Traditional Knowledge and Intellectual Property: Issues and options surrounding protection of Traditional Knowledge,* Discussion Paper QUAKER UNITED NATION OFFICE 2001.

17 In India, Article 10(4) of Patent Act 1970, as amended up to 2005, provides for the disclosure requirement of genetic resources and other associated traditional knowledge when used in an invention.

appropriate terms between the traditional knowledge holder and third party, specifying risk and implications of the use of such traditional knowledge, proposed objectives, social, economic, environmental effects on the local community, potential commercial value etc.[18]. This principle has been incorporated in national laws of many countries. In Peru it is necessary to formulate a written agreement to use traditional knowledge.[19]

B. POSITIVE PROTECTION

According to WIPO, defensive protection is effective in preventing the illegitimate grant of intellectual property right, but some positive protection is required to prevent unauthorised use of traditional knowledge.[20]Positive protection of traditional knowledge grants the traditional knowledge holder rights to promote and protect traditional knowledge and to take action against and to seek remedies for misappropriation of traditional knowledge. Positive protection requires a legislative basis for the recognition and protection of the rights of traditional knowledge holders. Various instruments of positive protection of traditional knowledge are application of existing IP law and legal system (including law of unfair competition and trade practices), extended or adopted IP rights specifically focused on TK (i.e. Sui Generis aspects of IP laws) and new, stand-alone Sui-Generis systems. Apart from these some non IP legal mechanism can also act as a positive protection such as law of contract, customary law of indigenous people, law of civil liabilities, trade practices and Labelling law etc. Unfair competition and trade practices law allows for action to be taken against false and misleading claims that a product is authentically indigenous or has been produced or endorsed by or otherwise associated with a particular indigenous community. For example, unfair competition law can legally prevent a company

18 Ranjay K. Singh, *Implications of Prior Informed Consent for the Conservators of Indigenous Biological Diversity of Northeast India*, 7 INDIAN JOURNAL OF TRADITIONAL KNOWLEDGE 655,658 (2008).

19 Nunez *Supra* note 1 at 528.

20 WIPO, *Intellectual Property and Traditional Knowledge*, Nov.15, 2017, 3. 00P.M http://horseproject.wiki/images/1/1b/Wipo-traditional.pdf.

from falsely claiming a particular handicraft as "certified authentic" or as "Aboriginal craft", when actually such product was not made by aboriginal people and had not undergone any certification process.[21]

a. **Application of Existing IPR mechanism**

The existing IP laws such as the laws of patents, trademarks, copyright, geographical indications, industrial designs and trade secrets may be used successfully to protect TK, but in some cases with modifications may be required to work better. Possible intellectual property protections for traditional knowledge are:

a) Patent

Some elements of traditional medicine may be protected under *patent*. Patent system could be used to protect an invention that is new, involve inventive steps and have industrial application. Genetic resources as encountered in nature are not the creation of human mind and therefore they cannot be directly protected as intellectual property. But Patents may be granted for products isolated, synthesised or developed from genetic structures, micro-organisms and plants or animals or organisms existing in nature. Patent protection may also be obtained for processes associated with the use and exploitation of those resources. But there are several major obstacles to afford patent protection to traditional knowledge. Such as traditional knowledge is treated to be in public domain hence does not qualify novelty requirement. Moreover, applying for patent and enforcing the same is quite expensive for indigenous people. Collective ownership of traditional knowledge is another hurdle in the way of granting of patent.

The *Utility Models or petty patents* are some sort of patents designed to protect knowledge consisting less detailed inventive step for a limited period of time. In case of petty patent, criteria for protection are same to those of the patent but less strict than patent. Utility model or petty patent may prove to be useful in

21 Correa *Supra* note 16, at 11.

protecting traditional knowledge because it is not documented. Kenya has already passed the "Industrial property Act", 1989 as amended in 2001 incorporates petty patents for traditional medicinal knowledge.[22]

b) Copyright

Copyright can be a suitable instrument in protecting traditional cultural expressions (TCE) or folklore of traditional knowledge holders. Copyright is an exclusive right granted for a certain period of terms to an author, composer etc. to print, publish and sell copies of his original work. Copyright can be used to protect the artistic manifestations of Traditional Knowledge holders against unauthorised reproduction and exploitation. It includes traditional knowledge pertaining to literary works; such as tales, legends and myths, traditions, poems; textile works such as traditional fabrics, garments etc.; musical works; and other three-dimensional works, such as pottery and ceramics, sculptures, wood and stone carvings etc. But in order to get copyright protection there must be an identifiable author, which is difficult in case of traditional knowledge as it is hold by the community as a whole. Moreover, copyright protection requires fixation of work, which is also an obstacle for traditional knowledge, which is mostly in oral form passing down from one generation to another. Unfixed cultural expressions up to a limited extent can also be protected under performers' right where performances have been fixed without the permission of the original performers. Performances of singers and dancers and presentations of stage plays, puppet shows and other comparable performances of indigenous people can be protected by Performer's right. [23]

c) Trade Secrets

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22 At present the industrial property Act (ch.509) of 1989 in Kenya, has been replaced by the Industrial Property Act (Act 3 of 2001) 2001. Part x of the Act 1989 and part xii of the present Act 2001 deal with utility model.

23 Correa *Supra* note 16, at 11.

Sometimes traditional knowledge is within the secrecy regime of the community. In case of traditional medicine, many healers have the sacred beliefs that their medicine, techniques will work only when this remains in their secrecy regime. In such cases trade secrets can be used to protect the non-disclosed traditional knowledge, as well as the secret and sacred knowledge. Trade secrets will prevent the acquisition or unauthorised use of such knowledge by third party.[24] The principle criterion to get protection through this instrument, the information must be confidential. But in case of traditional knowledge this often happens that such knowledge is diffused among other members of the community, which makes it difficult to get protection through this method. But if the knowledge is kept by only one person as in case of traditional healer then this instrument may work.[25]

d) Geographical Indication

Geographical indication can be a suitable tool to protect the traditional knowledge in reputation, if their characteristics are attributable to their geographical origin. Sometimes product of a particular region reflects the traditional process and knowledge of one or more communities of that given region. The special characteristics of those products may be symbolised by the indication of source used to identify the products. Geographical indication also enhances the reputation and potentiality of local producer to sell their distinctive products directly to the final consumer, thus competing more effectively in global market. Geographical indications have significant potentiality as a tool to protect traditional knowledge and cultural expression because they are not transferable from one owner to another owner and are not subject to unconditional

24 Pacon Ana Maria, *The Peruvian Proposal for Protecting Traditional Knowledge*, *in*PROTECTING AND PROMOTING TRADITIONAL KNOWLEDGE SYSTEMS: NATIONAL EXPERIENCES AND INTERNATIONAL DIMENSIONS (Sophia Twarog & Promila Kapoor ed., 2004).

25 Nunez *Supra* note 1, at 520.

control by private owner. Moreover, it can be maintained as long as the collective tradition is maintained.[26]Geographical Indication however does not protect the specific knowledge and technology as such, but prevent the false use of geographical indication.

e) Trade Mark and Industrial Design

Indigenous people may also register indigenous names, signs or symbols to prevent them from being used by third parties without any authorisation. Some symbols and signs of indigenous people may have some religious significant, and its improper uses such as use in T-shirt, tattoo, postcards etc. may become offensive for them. In Canada, the First Nations peoples have registered a series of petroglyphs (ancient rock painting images) as 'official marks'to prevent their improper use by third parties, as it has some religious significance attached to it.[27] Similarly Industrial design can also protect the designs and shapes of ethnic jewellery, craft products such furniture, receptacle, articles of ceramic, wood, leather and other materials.

b. **Designing an IPR Sui Generis Regime**

In order to extend protection to traditional knowledge, various countries have adjusted existing intellectual property system to satisfy the needs of traditional knowledge holders through *sui generis* measures. Sui generis regime of IPRs is a legal regime "of its own kind" which is specifically adapted to the nature and characteristics of Traditional Knowledge. Sui-generis system is the modification of some of the features of intellectual property system so as to properly accommodate the special characteristics of traditional knowledge and the specific policy needs which led to the establishment of a different

26 Daphne Zografos Johnsson, *The Branding of Traditional Cultural Expressions: To Whose Benefit, in* INDIGENOUS PEOPLES' INNOVATION, INTELLECTUAL PROPERTY PATHWAYS TO DEVELOPMENT 147, 155-158 (Peter Drahos & Susy Frankel ed., 2012).

27 *Ibid.*

system.[28]In India, Patent Act has been amended in 2002 to clarify the status of traditional knowledge within Patent Law. *Section 3(j)* of the Patent Act rejects the patentability of seeds and plant varieties. Similarly, *Section 3(p)* of this Act says that an invention which in effect is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components are not inventions for grant of patents. Under Section 10(4) (D) of the Act, Patent applicants also have to disclose the source and geographical origin of the biological material used in the invention, with complete specification. This is supported by a provision in *Section 25(j)* which makes the failure to disclose the source and geographical origin of the biological material used as ground for opposing the grant of patent.[29] In New Zealand the trade mark law has been amended to exclude the trademark that causes offence and this applies specially to Indigenous Maori symbols. [30]

c. **Stand-alone Sui Generis System**

Many countries have considered that the actual intellectual property right regime, even after modification is not suitable enough to protect the unique characteristics of traditional knowledge. The object of this Sui Generis law is to protect the collective rights of indigenous peoples over their creations. Peru has adopted a sui generis law to promote fair and equitable sharing of benefits, to ensure that the use of knowledge takes place with the prior informed consent of indigenous people and to prevent misappropriation. Similarly in June 2000, Panama has passed a *Sui Generis* law by the name Panama's special system for collectiveIntellectual Property Rights of indigenous people, for protection and defence of their cultural identity and traditional knowledge and setting out other provisions.[31]

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28 Balavanth Kalaskar, *Traditional Knowledge and Sui Generis Law* International Journal of Scientific and Engineering Research, July 2012.

29 The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India).

30 *Supra* note 17.

31 Law on Special System for the Collective Intellectual Property Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and their Traditional Knowledge, 2000, Legislative Assembly Law No. 20, Panama.

Thus it can be said that, Intellectual property right is one of the possible tools to protect the traditional knowledge. But protection of traditional knowledge by Intellectual Property Right regime is not free from obstacles. Many requirements under Intellectual Property Right often come in conflict with many characteristics of Traditional knowledge.[32]The nature of Traditional knowledge is such that it might not necessarily fit into the sphere of intellectual property but might be guided by existing intellectual property laws. Apart from Intellectual Property Right regime there are some other non-IP measures also such as using customary laws and establishing contractual arrangements for benefit sharing etc.The shortcomings, however, in respect of customary law is that it is based on inadequate enforcement measures and adherence to them are seen as a voluntary matter.[33] Therefore it is the call of an hour to formulate a hybrid type of mechanism which in one side will protect the traditional knowledge from misappropriation and in other side will not hinder possible future research and development.

PROTECTION OF TRADITIONAL KNOWLEDGE: THE INDIAN EXPERIENCE

India is one of the twelve-mega biodiversity countries of the world, with only 2.4 percent of the land area and accounts for 7-8 per cent of the recorded species of the world. This number is based on the survey of 65 to 70 percent of total geographical area of the country. Over 91,000 species of animals and 45,000 species of plants have been recorded. Similarly, the flora of India is both rich and diverse due to wide range of variations in climate, altitude and ecological habitats. It is estimated that the floristic spectrum of India comprises of over 30,000 species, of which the flowering plants with about 17,500 species constitute the dominant group, representing 7% of the flowering species of the world.[34]

32 Graham Dutfield, Intellectual Property, Biogenetic Resources, and Traditional Knowledge,97 (2004).

33 Emmanuel KA Sackey & Ossy MJ Kasilo,*Intellectual property approaches to the protection of traditional knowledge in the African Region*, THE AFRICAN HEALTH MONITOR, (Aug. 2010) 89,97.

34 P. Pushpangadan and Sharad Srivastava, *Traditional Knowledge, IPR, Value Addition and Technology Transfer: A Case Study,in* Biodiversity,

India is also one of the twelve primary centres of origin of cultivated plant and is rich in agricultural biodiversity. India is equally rich in traditional and indigenous knowledge, both coded and informal.[35] In the recent past there have been several cases of Bio piracy of traditional knowledge from India. Patents were obtained in other counties on Haldi (turmeric), Karela (bitter gourd), Neem, Basmati rice etc. Many of these patents were successfully contested and patents were got revoked. Foreigners obtain patents on the traditional knowledge based on Indian biological materials, without acknowledging the source of origin and benefit sharing. These entire incidences have necessitated some concrete measures to prevent the misuse of age old traditional knowledge of indigenous people. Though, India lacks a specific sui generis legislation to protect such traditional indigenous/ local knowledge, some of the existing laws such as Biological Diversity Act, 2002; Protection of Plant Varieties and Farmers' Rights Act, 2001, Patent Amendment Acts etc. have some bearing on protection of traditional knowledge.

Constitution of India

India has a great diversity of people and cultures and the sustainable use and equitable sharing of benefit have been part of the traditional life styles and ethos of the people. This is reflected in Indian forms of worship, rituals, food habits, philosophy and culture. The constitution of India which is the guardian of the conscience of people also under Article 29(1) says that any section of the citizens residing in any part of India having a distinct language, script or culture of its own has the right "to conserve the same."[36] The Genetic and Biological resources could be considered as the "material resources of the community" which are capable of generating wealth for the community. Our constitution under Article 39(b) and (c) provides that States shall

Biotechnology and Traditional Knowledge: Understanding Intellectual Property Rights, 205 (Aravind Kumar and Govind Das ed., 2010).

35 Vinod Khanna, *Intellectual Property Rights and Traditional Knowledge: The Indian Scenario, in* BIODIVERSITY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE: UNDERSTANDING INTELLECTUAL PROPERTY RIGHTS, 205 (Aravind Kumar and Govind Das ed., 2010).

36 M.P. JAIN, INDIAN CONSTITUTIONAL LAW, 1221-1222 (5th ed. 2005).

directs its policies towards securing that the ownership and control of the material resources of the community are so distributed as best to sub serve the common good and to ensure that the operation of the economic system does not result in the concentration of wealth and means of production to the common detriment.

Article 51 (A) (f) of the constitution imposes a duty on every citizen of India to value and preserve the rich heritage of our composite culture. The traditional knowledge and cultural expressions nurtured and developed by the indigenous communities over generations are also an integral part of our composite culture. Thus, after a review of various provisions of Indian Constitution it can be said that indigenous practices and traditional cultural expressions are recognised and protected under Indian Constitution.

Legislative Attempts

India's strong concern to the continued misappropriation of its traditional knowledge deserves recognition. India is playing a lead role in the TRIPs-CBD negotiations. Moreover, in domestic level also, various measures have been taken to recognise and protect biological materials and other associated traditional knowledge. Some of the effective legislative attempts are:

a. Patent Act, 1970(As amended in 2005)

The Patent Act, 1970 comprehensively amended in 2002 and 2005 provides for protection of traditional knowledge. Section 3(p) provides that an invention which, in effect is traditional knowledge or which is an aggregation or duplication of known properties of the traditionally known component or components is not patentable.[37] Section 10 of the Act provides that while applying for Patent in India, disclosure of source and geographical origin of the biological materials used in invention is mandatory. Non fulfilment of this requirement is a ground for opposition under section 25 and revocation of patent, if granted under section 64.

b. Geographical Indication of Goods (Registration and Protection) Act, 1999

37 Khanna,*Supra* Note 50, at 209.

The Geographical Indication of Goods (Registration and Protection) Act, 1999 seeks to protect geographical indication registered under the Act. The protection is also available to authorise users. The Act permits any association of persons or producers or any organisation or authority established by law, representing the interest of the producers of goods to register a geographical indication. The holders of traditional knowledge in goods so produced and sold using geographical indication can register and protect their traditional knowledge under this law.[38]

c. Biological Diversity Act, 2002

India being a party to the Convention of Biological Diversity enacted the Biological Diversity Act, in 2002, which provides for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of benefits arising out of the use of the biological resources. This Act stipulates that, no person shall apply for any IPR, by whatever name called, in or outside India for any invention based on research or information on biological resources obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application. Provided that, if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the Patent Authority concerned. While granting approval the National Biodiversity Authority may impose royalty etc. [39]

d. The Protection of Plant Varieties and Farmer's Right Act, 2001

This Act provides for mandatory disclosure of the Geographical location from where genetic material has been taken and all such information relating to the contribution of farmer, village community, institutions or organisations in breeding, evolving or developing the variety. Non-disclosure or wrongful disclosure could lead to the cancellation of the registration. The Act specially provides that a farmer who is engaged in

38 S.K Tripathi, *Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore: International, Regional and National Prospective, Trends and Strategies,*8 JOURNAL OF INTELLECTUAL PROPERTY RIGHTS, 468,477(2003).

39 Khanna, *Supra* Note 50, at 210.

the conservation of genetic resources of land races and wild relatives of economic plants and their improvement through selection and reservation shall be entitled for recognition and reward from Gene Fund established under the Act. The Act also recognises rights of communities to claims attributable to the contribution of people in the evolution of any variety.[40]

e. The Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006

This Act was passed to recognise and vest the forest rights and occupation in forest land in forest dwelling Scheduled Tribes and other traditional forest dwellers who have been residing in such forests for generations but whose rights could not be recorded; to provide for a framework for recording the forest rights so vested and the nature of evidence required for such recognition and vesting in respect of forest land. Section 3(1) provides for forest rights of forest dwelling Scheduled Tribes and other traditional forest dwellers on all forest lands, which includes-

a) Right of ownership, access to collect, use, and dispose of minor forest produce which has been traditionally collected within or outside village boundaries;

b) Rights to protect, regenerate or conserve or manage any community forest resource which they have been traditionally protecting and conserving for sustainable use,

c) Right of access to biodiversity and community right to intellectual property and traditional knowledge related to biodiversity and cultural diversity; etc.[41]

OTHER MEASURES

a) Traditional Knowledge Digital Library (TKDL)

The Traditional Knowledge Digital Library (TKDL) is a scientific approach to develop a digital data base of traditional knowledge of

40 Tripathi, *Supra* Note 53, at 474.

41 Ministry of Tribal Affairs; Government of India, Forest *Rights Act, 2006: Acts, Rules and guidelines*, MINISTRY OF TRIBAL AFFAIRS, (DEC. 20,2019,1;00P.M), https://tribal.nic.in/FRA/data/FRARulesBook.pdf

India in the field of medicinal plants to check patenting of products based on such knowledge.[42] TKDL is a collaborative project of Council of Scientific and Industrial Research (CSIR), AYUSH, and as well as Ministry of Health and Family Welfare.[43]Traditional Knowledge Digital Library provides information on Traditional Knowledge in the language and format that the patent examiner at International Patent office can easily understand; by scientifically converting and structuring the available contents of the ancient texts on Indian Systems of Medicines i.e. Ayurveda, Siddha, Unani and Yoga, into five international languages, namely, English, Japanese, French, German and Spanish, with the help of information technology tools and an innovative classification system - Traditional Knowledge Resource Classification (TKRC). TKRC has structured and classified the Indian Traditional Medicine System in approximately 25,000 subgroups for Ayurveda, Unani, Siddha and Yoga.

At present, as per the approval of Cabinet Committee on Economic Affairs, access of TKDL is available to nine International Patent Offices that is European Patent Office, United State Patent & Trademark Office, Japan Patent Office, United Kingdom Patent Office, Canadian Intellectual Property Office, German Patent Office, Intellectual Property Australia, Indian Patent Office and Chile Patent Office, under TKDL Access (Non-disclosure) Agreement.As per the terms and conditions of the Access agreement, examiners of patent office can utilize TKDL for search and examination purposes only and cannot reveal the contents of TKDL to any third party unless it is necessary for the purpose of citation. TKDL is proving to be an effective deterrent against bio-piracy and is being recognized as a global leader in the area of traditional knowledge protection.[44]

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42 U.N. Rai and N.K Singh, *Intellectual Property Rights in Biodiversity Conservation, Biotechnology Transfer and Environmental Sustainability, in*BIODIVERSITY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE: UNDERSTANDING INTELLECTUAL PROPERTY RIGHTS, 205 (Aravind Kumar and Govind Das ed., 2010).

43 Pamela Andanda , *Striking a Balance between the Intellectual Property Protection of Traditional Knowledge, Cultural Preservation and Access to Knowledge,*17JOURNAL OF INTELLECTUAL PROPERTY RIGHT 547,548 (2012).

44 TRADITIONAL KNOWLEDGE DIGITAL LIBRARY (Dec 19, 2017, 2.00 P.M)http://www.tkdl.res.in/tkdl/langdefault/common/Home.asp?GL=Eng.

b) People's Biodiversity Register (PBR)

Peoples' Biodiversity Register is a document which contains comprehensive information on locally available Bio-resources including landscape and demography of a particular area or village. These Registers shall be prepared by Biodiversity Management Committee, constituted under Biological Diversity Act, 2002 in consultation with local people. The Register shall contain comprehensive information on availability and knowledge of local biological resources, their medicinal or any other use or any other traditional knowledge associated with them. The National Biodiversity Authority and the State Biodiversity Boards shall provide guidance and technical support to the Biodiversity Management Committees for preparing People's Biodiversity Registers.[45]

c) National Intellectual Property Rights Policy

The Union Cabinet has approved the National Intellectual Property Rights (IPR) Policy on 12th May, 2016 to stimulate a dynamic, vibrant and balanced intellectual property rights system in India to foster creativity and innovation and thereby, promote entrepreneurship and enhance socioeconomic and cultural development, and focus on enhancing access to healthcare, food security and environmental protection, among other sectors of vital social, economic and technological importance. Some of the relevant excerpts are

a) The ambit of Traditional Knowledge Digital Library (TKDL) should also be expanded to include other fields besides Ayurveda, Yoga, Unani and Siddha.

b) Public research institutions should be allowed access to TKDL for further R&D, while the possibility of using TKDL for further R&D by private sector may also be explored, provided necessary safeguards are in place to prevent misappropriation.

c) Document oral traditional knowledge, taking care that the integrity of the said knowledge is preserved and traditional ways of life of communities are not compromised

45 Ghazala Javed, *Protection of Traditional Knowledge: Initiatives of India,*WIPO (Dec. 20, 2017, 2:00 PM)http://www.wipo.int/edocs/mdocs/tk/en/wipo_iptk_ge_2_16/wipo_iptk_ge_2_16_presentation_12javed.pdf.

d) Promote India's rich heritage of traditional knowledge with the effective involvement and participation of the holders of such knowledge. Traditional knowledge holders will be provided necessary support and incentives for furthering the knowledge systems that they have nurtured from the dawn of our civilization.[46]

CONCLUSION AND SUGGESTIONS

The protection of TK raises a number of policy issues, which are extremely complex, since there are broad differences about the definition of the subject matter, the rationale for protection, and the means for achieving its purposes[47]. Every community has their unique traditional expressions, with different values and objectives, which makes it difficult to adopt a uniform legal framework for the whole world. Although wide range of discussions for the protection of traditional knowledge is going on at regional, national, and international level but various issues such as the nature of such protection, rights of knowledge holder, scope of its implementation are still vague. Presently, traditional knowledge is an amorphous legal regime, which is predominantly protected under the Intellectual Property Law mechanism. However, active negotiation is going on about the suitability of Intellectual property law mechanism to protect traditional knowledge. Many discussions were taken place on the adaptation of existing form of IPRs to protect Traditional Knowledge. But it is not likely to work because of the inherent mismatch between the requirements under IPR regime to get protection and characteristics of traditional knowledge.

A *sui generis* system of protection has been adopted by many countries such as South Africa, Peru, Panama, Costa-Rica, Portugal, India and Thailand as the most appropriate alternative for the protection of traditional knowledge. The need for sui generis protection of traditional knowledge arises from the perceived shortcomings of the existing

46 Department of Industrial Policy and Promotion, *National Intellectual Property Rights Policy,* (Dec.20, 2017, 3:00PM)http://dipp.nic.in/sites/default/files/National_IPR_Policy_English.pdf.

47 Correa *Supra* note 16, at 27.

IP system. Normally *Sui-generis* laws are not entirely different from intellectual property laws. A Sui-generis law may be a combination of intellectual property law, customary law, benefit sharing provisions and contractual agreements. Indian Parliament has passed Sui-generis laws such as, "The Indian Biological Diversity Act 2002" and "Plant Verity Protection and Farmer's Rights Act 2001"[48]. Though this approach has received considerable attention but very little progress has been made in terms of actually implementing this kind of protection.

Some suggestions to take into account to protect Traditional Knowledge are as follows:

a) To provide effective protection, conservation and preservation of traditional knowledge proper documentation of oral traditional knowledge both manually and electronically is very essential. This would check the menace of Bio piracy, as this would constitute prior art. There is a need to ensure that all reasonable efforts are made to obtain consent from the relevant indigenous peoples as a condition for placing information in a database, whether that TK is in the public domain or not

b) The inconsistencies among international conventions such as CBD and TRIPs should also be harmonised in such a way to protect traditional knowledge without hindering the future potential development.

c) The importance of obtaining prior informed consent from the appropriate authority prior to accessing genetic resources and equitably sharing the benefits arising from the use of traditional knowledge and genetic resources should be recognised. We should take the instance from Peru where it is necessary to formulate a written agreement to use traditional knowledge.

d) Indigenous people treat traditional knowledge only as a mean of fulfilling their basic needs and not as a pathway for their social and economic development. Therefore, it is necessary

48 Sackey & Kasilo, *Supra* Note 32, at 100.

that some special campaign should be launched in form of Training programmes, Workshops, Seminars, Publication of small booklets in various languages for awareness of traditional knowledge and intellectual property rights i.e. Patents, Trademarks, and Copyright etc.

e) National governments should include indigenous representation on national delegations, and international bodies need to develop mechanisms to ensure increased indigenous participation in decision making processes through the development of participatory processes

f) While protecting traditional knowledge, integrity of such knowledge, traditional way of life of the community should not be compromised. If their traditional knowledge is confidential it should be kept in a separate register. The Peruvian law provides for three types of registers- a national public register, a national confidential register and local registers to be administered by communities themselves. By this way their community sentiments will not get hurt.

Thus, in brief it can be said that, whatever approach may be used, the ultimate purpose to protect traditional knowledge should be served, which has become the way of life many indigenous people in developing countries. Since every community has their unique traditional expressions, with different values and objectives, it is very difficult to adopt a uniform legal framework suitable for all. Therefore, a midway should be chosen or a hybrid legal mechanism should be adopted as per national requirements. However, adoption from the laws of other countries on the protection of traditional knowledge should be encouraged with necessary dressing up.

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THE UPSURGE OF *SHADOW LIBRARIES* – BRIDGING KNOWLEDGE DIVIDE OR SUBVERTING COPYRIGHT REGIME ?

Karthik Shiva[1]

"Where Knowledge is free….Into that heaven of freedom, my Father, let my country awake!"

\- *Rabindranath Tagore (Gitanjali)*

INTRODUCTION

In the post-globalization era, the education sector[2] has grown in gargantuan proportions[3] and the demand for books has expanded exponentially[4] worldwide. Equally, the increase in the cost of education and educational materials has created access barriers for academicians and students particularly from developing and under-developed nations around the world. Access to top-notch research content and material proves to be costly to the scholars and this has led to the emergence of shadow libraries also known as 'pirate libraries' which provide access to copyrighted books and research papers free of cost in the digital mode.[5]

Shadow libraries which emerged as a reaction to the copyright expansionism by way of stricter anticircumvention measures hindering fair use has slowly transformed into a free and open access movement

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2 The global expenditure on education is the second highest after the expenditure on healthcare.

3 HM Government, Industrial Strategy: Government and Industry in Partnership, *International Education – Global Growth and Prosperity: An Accompanying Analytical Narrative,* (July 22, 2018, 8.30 PM), https://goo.gl/VhCR3T.

4 Janja Komljenovic & Susan Lee Robertson ,*Making global education markets and trade,*GLOBALISATION, SOCIETIES AND EDUCATION, 15:3, 289-295, DOI: 10.1080/14767724.2017.1330140.

5 Some of the most prominent among them are Sci-Hub, LibGen, Bookfi, Bookzz, Gigapedia, etc.

which threatens to topple the very fundamentals of present copyright regime while attempting to create *"information and knowledge communism".*[6]

Hence, shadow libraries prove to be a persistent and problematic leakage in the information economy led by major publishing houses around the world. Major publishing houses have filed lawsuits[7] and are determined to shut down these libraries compelling a number of them to close operations while certain others tenaciously shift their web addresses to evade detection.[8]

In this background, this article makes an attempt to trace the development of shadow libraries and to evaluate the status of shadow libraries in the context of the copyright regime (both national and international) and fair use policy. It also posits whether emergence of shadow libraries has helped in bridging the knowledge divide or subverted the copyright regime. A reference will also be made to ethical and fiscal issues surrounding the use of shadow libraries.

AN INQUIRY OF THE ACADEMIC PUBLISHING INDUSTRY

Commercial Academic Publishing has grown by leaps and bounds from its humble origins. The advent of internet and technology tools have rendered the traditional publishing services offered by academic publishers redundant. The cost of value added services offered to the prospective authors has been reduced to a fraction. This in turn, has enabled commercial publishers to cut costs thereby paving the way for greater profits. Leading players in the academic publishing market such as Elsevier, Blackwell, Taylor and Francis, Thomson Reuters, etc. rake in profits that exceeds well over one third of their revenues.[9]

6 Milton Mueller, *Info–Communism? Ownership and Freedom in the Digital Economy,*FIRST MONDAY, Volume 13, Number 4 - 7 April 2008, http://firstmonday.org/htbin/cgiwrap/bin/ojs/index.php/fm/article/viewArticle/2058/1956.

7 Matt Kamen, *UK ISPs must block ebook pirate sites,*WIRED, (May 25, 2015), https://www.wired.co.uk/article/high-court-blocks-pirate-ebook-sites.

8 Quirin Schiermeier, *Pirate research-paper sites play hide-and-seek with publishers*, NATURE, (Dec. 4, 2015), https://www.nature.com/news/pirate-research-paper-sites-play-hide-and-seek-with-publishers-1.18876.

9 Jason Schmitt, *Can't Disrupt This: Elsevier and the 25.2 Billion Dollar A*

However, a study of pricing trends of academic publishers shows that the comparative cost advantage of the transition from the conventional mode of publication (books) to the contemporary mode (e-books and articles) has not been passed on the ultimate consumers.[10] On the contrary, the price of academic journals and books are increasing at an unprecedented rate which impedes access by making them prohibitively expensive.[11]

Public libraries particularly in developing countries do not provide access to digital content on par with the traditional paper content due to licensing issues and lack of funding for the same. Ironically, the cost of e-books even for libraries are on par with the traditional books or sometimes even costlier. Moreover, unlike traditional books, the e-content are not sold to the libraries but are rather licensed. The licensing regulations and fine print contracts indirectly impose fetters in the dissemination of the purchased content even for legitimate purpose and fair use in accordance with copyright law.[12]

Some writers draw the attention to the problem of 'double payment' towards the academic publishing industry because of the fact that most of the articles and papers written in academic journals are submitted by scholars, researchers and professors who are funded by various universities and research institutes.[13] Peer review is also done by them

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Year Academic Publishing Business, (Dec. 23, 2015), https://medium.com/@jasonschmitt/can-t-disrupt-this-elsevier-and-the-25-2-billion-dollar-a-year-academic-publishing-business-aa3b9618d40a.

10 Vincent Larivieret al.,*The Oligopoly of Academic Publishers in the Digital Era*, PLoS ONE 10(6): e0127502, https://doi.org/10.1371/journal.pone.0127502.

11 Ian Sample, *Harvard University says it can't afford journal publishers' prices,*GUARDIAN, (April 24, 2012), https://www.theguardian.com/science/2012/apr/24/harvard-university-journal-publishers-prices.

12 Matthew P. Chiarizio, *An American Tragedy: E-Books, Licenses, and the End of Public Lending Libraries?*VANDERBILT LAW REVIEW 66(2), 615-644, https://www.vanderbiltlawreview.org/wp-content/uploads/sites/89/2013/03/Chiarizio_66_Vand_L_Rev_615.pdf.

13 Adriane Macdonald & Nicole Eva, *It's time to stand up to the academic publishing industry,*UNIVERSITY AFFAIRS, (Feb. 28, 2018), https://www.universityaffairs.ca/opinion/in-my-opinion/time-stand-academic-publishing-industry/.

free of cost and once the article is published, the universities and research institutes are compelled to buy back the results in the form of premium subscription fee paid to these corporates thus creating a vicious cycle of paying for your own research.[14]

A HISTORICAL CONTEXT OF COPYRIGHT LAW

The extension of legal protection to works under copyright began in the early 18th century with the Statute of Anne which is the considered the earliest copyright protection law by recognising the authors of the work as its owner and providing a statutory period of protection. This was followed by the Berne Convention for the Protection of Literary and Artistic Works, 1886[15] which dealt with copyright protection in a comprehensive sense until the emergence of TRIPS[16] and WIPO[17] regime.

The ebb and flow of copyright law witnessed an intellectual and political challenge to the exclusive property rights over informational goods and the concept of openness in communication-information policy emerged. It is called by different names ranging from the "commons" movements, "free culture" movement, "openness movement", "guerrilla open access" movement and the latest "Access to Knowledge" (A2K) movement.[18]

The freedom of commons encompasses the creation of an Internet Commons, in other words, Communist Internet grounded as an association of free creators and consumers on the basis of principles of self-management, cooperation and non-surveillance irrespective of social class. This is to be supplemented with measures to encourage

14 Science Europe,*Workshop Report - Challenging the Current Business Models in Academic Publishing: Accelerators and Obstacles to the Open Access Transition,* (June 2018), d/2018/13.324/3.

15 The Berne Convention was revised a number of times on various occasions and the version we now follow is the 1979version to the Berne Convention.

16 Agreement on Trade Related Aspects of Intellectual Property Rights, 1994.

17 WIPO Copyright Treaty and WIPO Performers and Phonograms Treaty, 1996.

18 Mueller, *supra* note 5.

internet literacy paving the way for use of internet in more beneficial and productive purposes so as to sub-serve community and individual interests.Computer software, hardware and web access is provided to all humans without interference from corporations that own platforms and exploit communicative labours.[19]

The guerrilla open access movement is based on the fundamental premise that the existing efforts to encourage open access within the present copyright regime are insufficient to bring about radical reforms and stifles the realm of free culture.[20] It functions on the basis of rogue and radical principles underscoring the need to overthrow and subvert existing regime of copyright law by mass infringement with aim of 'content liberation'. A competing view point is that guerrilla open access advocates copyright abolitionism in the name of cultural expansionism and the damage done by academic Robin Hoods such as Aaron Schwartz and Alexandra Elbakyan will only serve to accentuate the problem underlying access by increasing anti-circumvention measures.[21]

THE DAWN OF SHADOW LIBRARIES

The dissemination of unauthorized digital copies of scholarly literature began to develop into online collections in the early 2000s. These collections which were generally small and limited in number and gradually grew over the years resulting in a slow osmosis of scholarly literature from the academic haves to the have-nots.[22]

Alexandra Elbakyan, a student pursuing her masters in neuroscience established *Sci Hub*[23]*,* devised an ingenious solution of collating and

19 Sylvain Firer-Blaess et al.,*Wikipedia: An Info-Communist Manifesto,*at 3, (Nov. 23, 2018), http://fuchs.uti.at/wp-content/Wikipedia.pdf.

20 *The Open Access Guerilla Cookbook*, Internet Archive, (Jan. 16, 2013), https://archive.org/details/open.access.guerilla.cookbook/page/n5.

21 Simon Oxenham, *Meet the Robin Hood of Science,*Big Think, (Feb. 9, 2016), https://bigthink.com/neurobonkers/a-pirate-bay-for-science.

22 JoeKaraganis,*Introduction – Access from Above, Access from Below,* in Shadow Libraries - Access to Knowledge in Global Higher Education1 (Joe Karaganis1 ed. 2018).

23 It is an unauthorised search engine that provides access to academic journals and it has a core archive of fiftymillion articles that are freely available and its basic search and archive features can be easily

consolidating a database for academic articles which were beyond the reach of many students by roping in university colleagues to share virtual private networks instead of the particular articles.[24] Every time a person searches for an article which is not available in the database of the shadow library, its institutional credentials are used to login and download the article with a copy being available to the researcher and another in the database for further use, thus perpetually expanding the size of the libraries.[25]

Shadow libraries employ a number of tools to circumvent the paywall of academic publishers and make them accessible to almost anyone having an internet connection. Most of them, are voluntarily uploaded by a large share of sympathetic users who help in the dissemination of protected articles by sharing them in these websites.

Shadow libraries are quickly turning into the world's de facto open-access research library by liberating 'protected' and 'copyrighted' content locked behind paywalls. It is quite interesting to note that recent research of the usage of shadow libraries has yielded startling results indicating that even students and researchers from developed countries are resorting to these methods despite having legal access simply for the sake of convenience rather than necessity.

Russia and USA continue to top the list of downloads and one-fourth of the user requests are made from the Organization for Economic Cooperation and Development (OECD) comprising of financially and academically well-endowed nations with greater access to such journals in the 'legal' channel. Other major nations that depend heavily on shadow libraries are India, China and Indonesia.[26]

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replicated.

24 John Bohannon, *The frustrated science student behind Sci-Hub*, SCIENCE, (Apr. 28, 2016, 2:00 PM), http://www.sciencemag.org/news/2016/04/frustrated-science-student-behind-sci-hub?IntCmp=scihub-1-11.

25 Joe Karaganis,Shadow Libraries - Access to Knowledge in Global Higher Education28(Joe Karaganis1 ed. 2018).

26 John Bohannon, *Who's downloading pirated papers? Everyone,*SCIENCE, (Apr. 28, 2016, 2:00 PM), http://www.sciencemag.org/news/2016/04/whos-downloading-pirated-papers-everyone.

Shadow libraries thrive most importantly because of two factors; the high price of legal content and the low price of unauthorised technology that serves the purpose. Another interesting point to be noted is that shadow libraries also host open access content in their platforms including books, monographs and articles.

The primary aim of the shadow libraries has been the development of its collection driven by a democratic approach to access on one hand and selectivity on the other in terms of the content. The shadow libraries show interest in non-fiction titles which aim at collecting humanity's valuable knowledge in the digital form. The underpinning altruism aims to share academic literature freely and build a community of people sharing knowledge, improving the quality of the books determined not to make money in the endeavour.[27]

Recently in India, the "Delhi University photocopying case"pitted Oxford University Press, Cambridge University Press, and other large academicpublishers against a university-based photocopying centre—triggering wider efforts tolegalize the zone of informal copying practices that shape much of Indian student life.[28] This judgment reopened the long side-lined debate regarding the broad contours of fair use in the Indian context, particularly having regard to the bourgeoning growth of student community and the consequent pressure on the infrastructure to ensure sufficient access to academic and scholarly works.

EXPANDING OR EXPOUNDING COPYRIGHT IN THE DIGITAL ENVIRONMENT

The primary objective of copyright law is to incentivise the creators of scientific and intellectual endeavours so as to ensure the benefits of the work reaches the general public after a specified period of protection during which the creators have a set of exclusive rights to exploit by

27 Balazs Bodo, *The Genesis of Library Genesis: The Birth of a Global Scholarly Shadow Library*, *in* SHADOW LIBRARIES - ACCESS TO KNOWLEDGE IN GLOBAL HIGHER EDUCATION28(Joe Karaganis1 ed. 2018).

28 KARAGANIS,*supra* note 16 at, 15.

translation[29], reproduction[30], performance[31], broadcasting[32], public recitation[33]and adaption[34] of the created work. It also incorporates a number of restrictions in the enforcement of the rights so as to ensure that the access to such works in a lawful manner is not hindered.[35] Thus, copyright law aims to establish a balance between the interests of the creators to profit from their work and the interest of the general public to have access to the aforesaid content.

Inthis background, the development of digital market for copyrighted products has infused significant changes in the praxis relating to copyright products. Though the digital content was dismissed as just another method of dissemination of copyrighted materials, later it was understood that the challenges posed by digital environment resulted in fundamental differences with the conventional mode of copyrighted products. The applicability and contours of doctrine of 'first sale', 'fair use' and 'infringement' has been subject to vociferous debate with one side of the argument being for greater control and restrictions having regard to the scope for piracy and copyright infringement in the digital environment and the other side being a reactionary approach that calls for discarding increased restrictions that will subvert access in the digital environment.

Earlier in the universities access was built around the last technological revolution viz., the photocopier rather than digital versions. E-books and the means of distributing and consuming them legally and illegally developed in the high-income countries and was not very prevalent in the middle and low-income countries. But later this mode of sharing content developed and flourished even in the latter set of countries.

It cannot be denied that there is a compelling public interest in

29 Berne Convention for the Protection of Literary and Artistic Works 1886, art. 8.

30 *Id*, art. 9.

31 *Id,*art. 11.

32 *Id,* art. 11*bis.*

33 *Id,*art. 11*ter.*

34 *Id,*art.12.

35 *Id,* art. 6.

fostering scientific achievement, and ensuring broad access is an important part of the endeavour. This is fulfilled in two ways, one being the "idea and expression dichotomy" which ensures that ideas, procedures, systems, method of operations, concepts, principles and discoveries as such do not become shackled by the copyright regime[36] and the fair use doctrine which allows use of copyrighted material for criticism, comment, teaching, research, etc.[37]

Hence, it is said that the public interest requirement is satisfied as every idea, theory and fact in a copyrighted work becomes instantly available for publication from the moment of its publication.[38] Similarly, under the fair use doctrine, copyrighted academic articles themselves may be taken and used, but only for legitimate purposes, and not for wholesale infringement.

FAIR USE IN THE AGE OF SHADOW LIBRARIES

The doctrine of fair use is facing a tumultuous time in the era of technology and digital environment with the line between fair use and infringement being narrower than ever before. Fair use is the right to make a limited use of another person's copyright subject to certain conditions and priorto creation of the fair use doctrine, others had what was effectively an unlimited right to use another's work in a differentform.

So much so that a second author could abridge or translate the first author's work and obtain a copyright. This was considered to be unfair and hence the courts limited the rights of the third parties by way of the doctrine of fair use. Thus, the doctrine of fair use which notionally appears to protect the generally public was actually devised to oust the doctrine of unlimited use and enlarge the rights of the copyright owner.[39]

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36 17 U.S.C § 102(b).

37 17 U.S.C. § 107.

38 Eldred v. Ashcroft 537 U.S. 186, 219 (2003).

39 L. Ray Patterson, *Understanding Fair Use,*Law and Contemporary Problems, Vol. 55, No. 2, Copyright and Legislation: The Kastenmeier Years 249-266, (Spring, 1992), http://www.jstor.org/stable/1191784.

The three factors were laid down in case of *Folsom v. Marsh* to determine fair use namely; (a). the nature of the work, (b) the amount of the work used, and (c) the effect of the use on the work's economicvalue.[40]Similarly, fair use should not be used to restrict the right of personal use-the individual's use of the work, for his or her learning.

In the words of Ray Patterson,"the greatest disservice of natural law to the jurisprudence of copyright is the emphasis it has placed on the individual's right to be rewarded for his or her creations". He argues that a creator who contributes to culture nearly takes a certain share from the culture which has to be factored.[41]

The legality of the ultimate end use of shadow libraries is dependent on the broad contours of how the doctrine of fair use is understood and expounded by the courts of law. The law relating to fair use particularly in the US has been drafted so as to offer guidance to users in determining when the principles of the doctrine apply rather than restricting the court's application to a rigid, multipart test.[42]

ACCESS TO KNOWLEDGE AS A HUMAN RIGHT

Access to knowledge occupies a pivotal place in the freedom of speech and expression narrative. Along with free speech, the global recognition of right to education both in constitutional, international law and human rights instruments has given a greater impetus to the importance of access to knowledge. The right to free speech, expression and education will be futile without ensuring equitable and fair access to information and knowledge notwithstanding that such material is copyrighted. However, the concept of access to knowledge has not been explicitly recognised as a human right but stems from the aforesaid human rights, though knowledge is envisaged in the universal declaration of human rights.

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40 *Id,* at 256.

41 *Id,* at 266.

42 Tyler G. Newby, *What's Fair Here Is Not Fair Everywhere: Does the American Fair Use Doctrine Violate International Copyright Law?*1633-1663, STANFORD LAW REVIEW, Vol. 51, No. 6, (Jul., 1999), https://www.jstor.org/stable/1229532.

In the words of Aaron Schwartz[43], who advocates Guerrilla Open Access, sharing of knowledge for the benefit of human kind is the imperative and duty cast upon all individuals particularly students, academics and the scholarly community.[44] The world's intellectual and cultural heritage cannot be permitted to be rendered inaccessible to the large share of our population. He argues that subverting the prohibition on access to such materials would be civil disobedience so as to prevent the private appropriation of public culture.[45]

Alexandra Elbakyan[46], the founder of Sci-Hub, a prominent search engine that provides access to scientific journal justifies the role of the website having regard to Art. 27 of the Universal Declaration on Human Rights, 1948 that, everyone has the right to freely participate in the cultural life of the community and to enjoy arts and share the fruits of scientific advancement and its benefits.[47] In the recent years, the European Union, US and UK have announced a policy decision stating all publicly funded and sponsored research will be openly available and accessible to the general public.

CONSTITUTIONAL PERSPECTIVE OF OPEN ACCESS

The Constitution of India in its preamble envisions an egalitarian society grounded on the principles of justice, democracy and socialistic values so as to ensure liberty of thought, expression and belief and

43 He was a computer programmer and activist who was arrested for downloading roughly 4.8 million articles from the *Jstor*database with a view to dump the same in the public file sharing network.

44 Aaron Schwartz, *Guerrilla Open Access Manifesto,* (July, 2008), https://archive.org/stream/GuerillaOpenAccessManifesto/Goamjuly2008_djvu.txt

45 Sarah Kendzior, *Academic paywalls mean publish and perish*, Al Jazeera, (Oct. 2, 2012), https://www.aljazeera.com/indepth/opinion/2012/10/20121017558785551.html.

46 The District Court of New York granted an injunction and awarded damages against Sci-Hub and Alexandra Elbakyan to the tune of 15 million dollars on a suit instituted by Elsevier in the year 2015 and she is believed to be in hiding Russia.

47 Ted Lockhart, *Sci-Hub: Stealing Intellectual Property or Ensuring Fairer Access,*Siam News, (Jan. 17, 2017), https://sinews.siam.org/Details-Page/sci-hub-stealing-intellectual-property-or-ensuring-fairer-access.

also underscores the importance of fraternity and equality. Free flow of information and diffusion of knowledge is a touchstone to gauge the maturity of a democratic setup. The absence of free flow of information and knowledge will lead to social suffocation. Thus, greater access to knowledge and information will promote good governance and rule of law.

Article 21-A confers a fundamental right on all children between the age six and fourteen the right to free and compulsory and education. The directive principles of state policy impose a duty on the state to ensure that the material resources of the state as employed so as to sub-serve common good. This principle holds good even with respect to the intellectual resources of the nation which should not be monopolised and muffled.[48]

To discharge the obligation imposed on the state by virtue of the aforesaid article, the government has enacted the Right of Children to Free and Compulsory Education Act, 2005 and its allied rules. Legislations impose strict restrictions to prevent the education sector from charging exorbitant fees[49] and aims to create a level playing field for students from marginalised and disadvantaged sections of society by providing 25% reservation[50] even in private non-minority schools.

This proactive approach of the government with respect to school education is not reflected in the higher education sector. Though, attempts have been made to regulate capitation[51] and other fees in education sector, the publishing sector has been largely ignored in the quest for ensuring equitable access to higher education. The decision of the Delhi HC in the *Chancellor and Masters, University of Oxford v. Rameshwari Photocopying Service*, *Delhi University*[52], wherein the doctrine of fair use was deliberated in background of photocopying of textbooks by the defendant and whether it amounted to an infringement

48 The Constitution of India 1950, art. 39 (b) & (c).

49 The Tamil Nadu Schools (Regulation of Collection of Fee) Act, 2009.

50 The Right of Children to Free and Compulsory Education Act 2005, § 12(1).

51 *Id,*§ 13.

52 CS(OS) 2439/2012,Judgement dated 16 Sep 2016.

of copyright of the plaintiff or whether it is covered by the fair dealing exception enunciated under section 52 of Indian Copyright Act, 1957 deserves special mention.

OPEN ACCESS MODEL AS A SOLUTION?

Openness plays a very vital role in higher education and there is underlying sense of altruism driven by the belief that education is a public good. The open access model has been subject to a various experimentation and adaptation largely as a result of the digital andnetwork revolution.[53] According to Robert King Merton, one of earliest advocates of the free access movement in research, "Each researcher must contribute to the 'common pot' and give up intellectual property rights to allow knowledge to move forward".[54]

Open education forms a part of the broader open movement and there is an active open data community which aims to make data particularly pertaining to governmental and corporation available openly.[55] Access to data is considered to be fundamental in accountability and engagement across a range of social functions including politics, energy, health, etc. as per organisations such as the Open Knowledge Foundation.[56]

In the recent years there has been a clarion call towards open access publishing particularly in academic research. Though, initially written off as a business model in its fledgling stage, the open access model has stood the test of time and is proving to be a highly inclusive yet sustainable model of publishing.

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53 Martin Weller, The Battle for Open – How openness won and why it doesn't feel like victory 3, (Ubiquity Press, 2014).

54 Marieke Guy, *Open Access to Research Data,* (April 30, 2015), https://access.okfn.org/2015/04/30/open-access-to-research-data-timeline/?utm_content=bufferde48c&utm_medium=social&utm_source=twitter.com&utm_campaign=buffer

55 Dan Weijers and Aaron Jarden, *The International Journal of Wellbeing: An Open Access Success Story,* in OPEN: THE PHILOSOPHY AND PRACTICES THAT ARE REVOLUTIONIZING EDUCATION AND SCIENCE, (Rajiv S. Jhangiani& Robert Biswas-Diener ed. Ubiquity Press, 2017), https://www.jstor.org/stable/j.ctv3t5qh3.18.

56 *Id,* at 3.

The different models of open access include the Green Open Access wherein the author himself makes his articles and research work in his own website or institutional repository, Gold Open Access under which the publisher charges a fee from the author for making the article openly available and the Platinum route where the journal operates for free.[57]

CONCLUSION AND SUGGESTION

In conclusion, it is very important to understand the academic publishing and copyright pertaining to it cannot be treated on the same footing as other commercial copyrighted works. The unequal bargaining power between the academic publishers and end users which comprise of universities, research institutes, academics and researchers has to be addressed. From a study of the pattern of ownership of publishing giants it is evident that market domination of a few players affects the entire sector. This has to be addressed by devising a model of business that is built upon equity and accessibility.

Another effective tool to curb the prohibitive pricing of academic literature is the use of the compulsory licensing regime. This is a step which a country like India can adopt in line with the continuing war against evergreening of patents and prohibitive pricing of lifesaving drugs and medicines. It also incumbent on the academic publishing industry to introspect on the growing concern of academicians and researchers and ensure that they voluntarily devote a share of profits and resources in creating content that is affordable, open and adequately accessible.

Open access movement though a commendable measure is not a panacea to the problem of academic journals which is in dire need of reform as a whole. This can be addressed only by coming up with a suitable regime of fair use in context of the digital environment. As the *Public Domain Manifesto* puts it, the public domain is the "cultural material that can be used without restriction", and which includes a structural core and a functional portion.

57 Laakso M, *et al.*, *The Development of Open Access Journal Publishing from 1993 to 2009,*PLoS ONE 6(6): e20961, doi:10.1371/journal. pone.0020961.

This is more imperative for a country like India which has one of the largest student population in the world but is not endowed with wide and rich resource like its European and Western counterparts.There is a need to adopt differential pricing of academic literature for developed and developing countries and similar dichotomy has to be drawn between professional, semi-professionals and non-professionals so as to ensure adequate informational penetration.

There is a need to create legal and legitimate digital libraries that are economically viable and sustainable model of digital libraries on par with conventional libraries that ensure access to the academicians and public. The advent of information and communication technology development such as artificial intelligence, block chain, data analytics and so on may soon render traditional libraries redundant.

To conclude with the thoughts of Christopher Kelty, we are witnessing a transition to a world where academic scholarship both in its content and organisation is directed towards the profitability of the platforms such as Elsevier that ostensibly serve it rather than being *vice versa*. This is an extremely worrisome trend with implications on life saving research in areas of modern medicine and bio-technology. Hence, there is an urgent need to address this growing menace of monopolisation of knowledge by corporate giants and ensure equity in access which is in the best interest of our community, nation and the world as a whole.

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TRIPS PLUS AND BIODRUGS: MODERN IMPERIALISM VERSUS BURGEONING PUBLIC HEALTH

Kanay Pisal[1]
and
Neha Rani[2]

INTRODUCTION

Bio drugs are complexly structured large-molecular drugs which are usually derived from metabolic processes of living cells for the treatment, diagnosis and prevention of diseases. It includes vaccines, insulin, monoclonal antibodies, therapeutic proteins and gene therapy products that are mostly developed from recombinant DNA technology. The advances in biotechnology and prevalence of bio drugs over other pharmaceuticals have triggered the need to protect the rights over invention by implementing "TRIPS plus"[3] patent[4] legislations by entering into bilateral or regional trade negotiations for broadening of IPR in return for market access.[5] Inspite of the fact that TRIPS provides necessary flexibilities to ensure public health and helps in its usage in domestic market[6], the recent failure to resolve the issue

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3 TRIPs Plus extends to provisions like patent life beyond 20 years, tightening patent protection (limiting parallel imports through contract and patent linkage), limiting provision of compulsory licensing in ways which are not required by TRIPs or limiting exceptions that facilitate prompt introduction of generics.

4 Indian Patent Act, 1970, § 2(n). A patent is an exclusive monopoly right granted to the inventor to make, use, license or sell the invention for a limited period of time which later on expiry, passes into public domain for usage.

5 Ruth Lopert & Deborah Gleeson, *The High Price of 'Free Trade': US Trade Agreements and Access to Medicines*, 41(1) JOURNAL OF LAW MEDICINE & ETHICS 199, 199-223 (2013).

6 Marrakesh Agreement Establishing the World Trade Organization Annex 1C, art. 31(f), April 15, 1994, 1864 U.N.T.S. 154.

of parallel imports and production and export of generic medicines to other countries might even indicate that the ecstasy and euphoria at 'Doha' was transient and premature.[7] These same reasons provide an easy ground for the developed countries to pressurize developing countries towards an even stricter IPR policy regime. The aspects of IP in Free Trade Agreements would rather augment monopoly while reducing competition since less than 1% corporations in India invest in R&D.[8] There has always been a disturbing relationship between IP regime, public health initiatives and consequent competition amongst the Pharmaceutical Companies.

This paper examines various options and strategies available before the global pharmaceutical industry from the perspective of public interest, particularly evaluating their importance in promoting trade and health by accessing the strengths, weaknesses and opportunities in context with TRIPS and FTA obligations. The paper concludes with the identification of salient interests at stake in the debate of drugs industry vis-a-vis IPR and re-evaluates the balance which presently favors the developed countries in the strategic policies of trade agreements.

LOOKING BACK: THE HISTORICAL PERSPECTIVE

The origin of patenting might be traced back to 500 BC Sybaris, Greece where new dishes were granted a patent for 1 year.[9] Sometimes it is even contended that the guilds in Rome were the origin of patenting where monopoly emerged in the form of communal property that was confined to a guild.[10] British roots of patenting go back to 15th century where King Henry VI granted a 20-year monopoly for manufacturing a previously unknown stained glass.[11] Even Queen Elizabeth granted

7 Ellen F.M' t Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines*, 3 CHICAGO INST. OF J.L 27, 29-30 (2002).

8 N. Lalitha, *IndianPharmaceutical Industry in WTO Regime: A SWOT Analysis*, 37 E.P.W. 3542, 3552-3553 (2002).

9 Vishwas Deviah, *A History of Patent Law*, ALTERNATIVE LAW FORUM,http://altlawforum.org/publications/a-history-of-patent-law/.

10 *id.*

11 *A Brief History of* Patents, CREATE IP (Sept. 29, 2014), https://www.createip.

patents for soap, iron, starch and paper.[12] Eventually, in 1624 came the Statute of Monopolies which talked about granting of patents for projects of new innovation. The principles of novelty, limited time and public interest earlier related to Statute of Monopolies, now formed the basis for the patenting laws in New Zealand, USA, and Australia. Parallely; in India, came the Act VI of 1856 followed by Act XV of 1859 and The Indian Patents and Designs Act, 1911. The 1911 Act saw a range of amendments and continued for a long time until 1970 when the Patents Act came into force.[13] Therefore, slowly yet gradually, almost all the countries started witnessing increased levels of IPR protection through various domestic policies and laws.

Asymmetrical Divide and Hypocrisy of Developed Countries

It is largely irrefutable that the established contemporary powers made their own existing levels of development as the focal point to view and decide, as to how and when to apply the 'stricter' and stronger standards of intellectual property. For that matter, in the early 19th century, Germany was labeled as the 'haven for plagiarists' by France. Similarly, it was only in the end of 19th and the start of 20th century, that Germany introduced legislation against unfair competition as it could afford the 'luxury of fairness' at that point of time. Even Japan, after the World War II was ill famous for copying almost everything produced in the western countries.[14] In contrast, these were the same regimes that subsequently emerged as the torch-bearers of IP fundamentalism a few decades later. Some countries and their historical perspectives are as follows:

The United States of America (U.S.A.)

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co.nz/brief-history-patents/.

12 *id.*

13 *History of Indian Patent System*, Comptroller General of Patents, Designs and Trademarks (Feb. 14, 2017), http://www.ipindia.nic.in/history-of-indian-patent-system.htm.

14 Walid Abdelgawad, *TRIPS Agreement: From Minimum Standards to Double Standards of Intellectual Property Rights Protection in North-South Relations*, (hal-01131407 v.1), https://hal.archives-ouvertes fr/hal-01131407.

The United States, now aggressively lobbying to ensure the world-wide stringent protection on Intellectual Property, was famous as 'pirate-nation' in its own early developmental days. Even when the U.S. proceeded with acts like the Chace Act, 1891[15] (to provide the safeguards to the foreign authors), it was only done when they consented to print in the U.S. itself and banned the import of editions published abroad.[16] Also US, the strongest advocate of TRIPS agreement in the present times, itself denied to sign the Bern Convention in 1861 stating that it being a developing country required freedom to copy in order to meet the socio-economic needs of its people.

The European Union (E.U.)

Many European nations like Germany, France, Switzerland and Russia have used the same methods of counterfeiting and copying to achieve the industrial prowess that they have today. France, Germany and Switzerland brought up the pharmaceutical patent legislations in 1960, 1968 and 1977 respectively.[17] In fact, towards the end of the 19th century, a number of European firms were set in Basel in order to imitate the German Products. The same event formed the plinth for the presently famous Swiss pharmaceutical industry.[18]

The TRIPS Agreement has mandated the developing countries to comply with its terms, even if not necessarily today, then upon the expiry of a certain fixed period of time. Thus, the irony lies in the same fact that the industrially developed and technologically advanced 'Big Daddies' of today are dictating to coercively put the 'one-sized' criterion upon developing countries in the present, the same policy measures that they refused to be put onto them when they themselves were in their initial stages of development.

Most of the supreme economic powers of today that preach free

15 Yu PK, *The Global Intellectual Property Order and Its Undetermined Future*, 1(1) The WIPO J.1, 13 (2009).

16 Bruce Willis Bugbee, Genesis of American Patent and Copyright Law 43 – 45 (Public Affairs Press, Washington D.C. 1967).

17 *Supra note* 12.

18 *id.*

trade to developing countries have actually risen to their position as a result of the protectionist policies in their 'developing' phase. This hypocrisy of developed countries can be summarized as that policy of these countries, where they wanted Developing and Least Developed Countries (hereinafter *LDCs*) to 'follow what they dictated, and not what they had themselves done!'

NARRATIVES USED BY DEVELOPED COUNTRIES TO PRESSURISE FOR TRIPS

Ignorance Narrative

It has largely been observed that the first world countries have incessantly alleged that the lesser developed countries are immensely ignorant about the importance of greater IPR protection during the TRIPS negotiations. Despite the fact that TRIPS Agreement has given the nudge to certain dormant countries; consecutively, since mid 1960s, reformation in the Berne and Paris Conventions had been asked for by the less-developed countries themselves.[19] This narrative can be best understood from the developed countries' assumption that the developing countries don't themselves know where the best interest lies for them and thus it is the developed countries who must decide for them.

Self-Interest Narrative

This sustains on the underlying assumption that the developing countries have the status-quo so pervasive in their behavior that they can't foresee and align with the best interest on their own. Additionally, the initial non-conformity with patents would lead to burgeoning of pirate industries that would ignore the internationally accepted standards and in the long run plague not just the International Patent System, but even the self-growth potential of the home nation. The developing countries henceforth peddle the narrative that negotiations like TRIPS are sometimes beneficial because they "place the larger interests of the nation at risk in the negotiations and invite

19 Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*,38 LOY. L.A.L. REV. 323 (2004).

participation from larger economic players who can offset the influence of the entrenched pirate groups."[20] However it appears that the said narrative is an exaggeration of the covert influence and representation that these pirate industries might have on the domestic policies[21] and that they deter the country from having an IP Protectionist attitude.

EVOLUTIONARY JURISPRUDENCE AND POLICY OF THE INDIAN PATENT LAW

The Law of Patent has witnessed a revolutionary change across the world. This Section focuses on the historicity of patent laws in India, justification for patent rights, International Conventions and related legislations while outlining recent developments and impacts in the field of patent. The first patent legislation in India was enacted in 1856 along the same lines as the British Patent Act 1852 with the objective to encourage inventions of new manufacturers and to induce them to disclose their secrets of inventions. The new Act was introduced in 1872 with a provision to protect the novelty of invention. Later, The Indian Patent Act, 1911 replaced all the previous Acts providing that a new drug was patentable by releasing all the related information and processes. In 1930, further amendments took place and the patent term was extended from 14 to 16 years and incorporated provisions related to grant of secret patents. After Independence, a need for a comprehensive patent law was desired owing to substantial economic changes in India. The patent law was reviewed under the chairmanship of Jurist Rajagopala Ayyangar in 1959 recommending amendments on the basis of socio-economic conditions of India. It observed that patent law must clear indications thereby ensuring that medicines and surgical devices are at easy access to public at the cheapest price while commensurately and reasonably compensating the patentee as well. In the early 1970s, India granted patent protection not to individual drugs but the manufacturing processes as well. The Patent Act of 1970 repealed the 1911 act, reduced patent year to 7 years and *abolished product patent regime*. This allowed companies to produce

20 Robert Merges,*Battle of the Lateralisms: Intellectual Property and Trade*,8 B.U. INT'L L.J. 239, 243-44 (1990).

21 *id.*

same drug using other processes and as it incurred less expenses on R&D and the medicines were available at more affordable rates. Indian companies became experts in reverse engineering and developed new processes for pharmaceutical production.[22] This reflected a consciously aware policy framework which stated that the advantages from low cost access to drugs were correspondingly greater than any deleterious impact of domestic patents on Research & Development of multinational companies. In fact, by 1990s, the Indian drug prices were amongst the lowest in the world till the signing of TRIPS. The Patent (Amendment) Act 2005 for the first time introduced product patents in Pharmaceutical Industry by deletion of Section 5 of the Patent Act 1970. This remarked India's concluding step towards achieving complete TRIPS compliance[23]; however, the safeguards and flexibilities of TRIPS have yet not been able to ensure affordable supply of medicines to the developing and even the least developed countries.

The philosophy behind Indian Patent Act 1970 hinges to Section 83 of the Act where it states that the object for granting patents is to ensure invention and its efficacious use for commercial purposes and it must not be granted to establish monopoly for the importation of patented articles. Indian patent policy focuses on balancing developmental concerns and views patents as a tool of public policy to stimulate innovation, encourage exploitation of new developments and ensure access to medicines at affordable prices. TRIPS require both product and process patents in all fields,[24] thus making India change its patent laws in 2005. This exacerbated the monopoly of industrialized countries and made drugs a costlier substance. India is a country with excess demand in the field but it being 'technologically-retard' requires incentives to 'independently develop' the R&D mechanism and the way out is a weaker IPR regime that TRIPS forbids. There is nothing trade related in TRIPS except for the purpose that it imposes restrictions for

22 Cornish W.R et al., Intellectual Property: Patent, Copyrights, Trademarks and Allied Rights305 (8th ed. Sweet and Maxwell Publication1989).

23 Patent (Amendment) Act, 1999; Patent (Amendment) Act, 2002.

24 Marrakesh Agreement Establishing the World Trade Organization Annex 1C, art. 27.1, Apr. 15, 1994, 1864 U.N.T.S. 154.

trade by developed countries and the sole purpose for the culmination of TRIPS by the triad, the U.S.A., Japan and Europe was to lower the losses made to them out of Reverse Engineering. India has been the chief exporter of cheap generic medicines to developing countries. India has been one of the most vocal opponents of TRIPS but eventually succumbed to include property rights in trade. Approximately 50% of essential medicines that UNICEF distributes to developing countries were manufactured in India and it controlled 80% of bulk drug market.[25] The factors of external trade threats and an interplay of domestic and international factors had a great influence which led to accession of India's patent regime by signing World Trade Agreement (Uruguay round) in 1994 to attune itself with TRIPS. The repercussions were suffered by Least Developing Nations who were dependent on Indian generic pharmaceutical industry. There is no clinching evidence to suggest that without strong patent regime, innovation cannot occur. What is required is a genuine innovation that subsists humanity. Now that the pharmaceutical industry itself is going through a paradigm shift from the small molecule drugs to those based on biotechnology, TRIPS compliance is a move that would certainly undermine the capacity of Indian Pharmaceutical Industry to thrive in biotechnology revolution.

POLICY INTERSECTION: IP FUNDAMENTALISM AND ACCESS TO MEDICINES

The emergence of biological medicine has raised challenges, mainly with the issue of regulating "bio-similar" follow-on products while incentivizing the originator at the same time. It is irrefutable that without an "incentive effect" of enforceable patent rights, even lesser number of new drugs would have possibly come into market without time limited restrictions on competition. However, there has been quite little difference by the introduction of product patent in terms of Research and Development expenditure and development of new

25 Martin J. Adelman & Sonia Baldai, *Prospects and Limits of Patent Provisions in TRIPS Agreement: The case of India*, 29 VAND J. TRANSNATL L. 507, 527 (1996).

and innovative products by domestic firms.[26] Hence, the effort to improve access to medicines and efforts to create R&D, can at times run contrary to one another.[27]

Arguments in Favor of IP Fundamentalism:

Protection of the First Inventor - TRIPS treat IP rights as commercial rights while recognizing the need to strike concord between inventors' rights and creation and protection of the rights of users of technology.[28] It is often argued by the IP fundamentalists that any nation cannot merely "free-ride" on the research and development endeavors of other transnational pharmaceutical enterprises."[29] It must be noted that basic reverse engineering skill (organic chemical skill) is quite different from skills needed to arrive at new drugs (medical chemistry skill)[30], and hence requires to be protected.

Encourages Investment **-** Without stronger patent protection, pharmaceutical companies cannot allure and attract the much needed investment for conducting the expensive and high risk research. The overall cost inflates even more, if the opportunity cost of such high investments (that too, for such a long time) with no guarantee is taken into account**.**

Augments further Innovation and R&D - Flexibility in patent regime limits the innovation on the margins of existing products such as process changes and new applications, instead of "breakthrough" innovations that create new market and demand. Due to lack of profit potentials, it is unlikely that TRIPS compliance shall motivate adequate

26 Scherer, F.M and Weinburst, 26(6) *Economic Effects of Strengthening Pharmaceutical Patent Protection in Italy*, International Review of Industrial Property and Copyright Law, 1009-24 (1995).

27 Jean O. Lanjouw, *IntellectualProperty and the Availability of Pharmaceuticals in Poor Countries*, *in* 3 Innovation Policy and the Economy 91, (Adam B. Jaffe et al. eds., 2002).

28 Marrakesh Agreement Establishing the World Trade Organization Annex 1C, art. 7, Apr. 15, 1994, 1864 U.N.T.S. 154.

29 Scherer & Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing* Countries, 5 Journal of Int'l Economic Law 913 (2002).

30 Jean O. Lanjouw & Iain M. Cockburn, *New pills for poor people? Empirical evidence after GATT*, 29(2) World Development J., 265-289 (2001).

Research & Development in LDCs[31] for diseases like tuberculosis and malaria. Therefore, the industry strongly relies on the patent system to recover its R&D costs, in order to generate profits and to fund research for future products.[32]

Leads to Technology Upgradation - Elimination of generic manufacturing ensures that a foreign technology supplier, licenses the production to a domestic local firm, instead of manufacturing itself, locally. This would lead to an indirect contribution to domestic technological capabilities.

Promotes and Protects Health – IP fundamentalists argue that IP protection ensures public health in the long run. Generic versions of patented complexly structured bio drugs might be hazardous in nature due to being of inappropriately sub-standard quality.[33] Compulsory licensing is often seen by industrialized countries as an impending threat to ensure greater public health by denying patients the future benefits of R&D activities and capabilities.

Absence of correlation between stricter regime and abuse of rights- An abuse of IP rights apply only if a patentee hampers development or refuses to grant license on reasonable terms or demand excessive prices for the product.[34] Infact, US limits the concept of anti-competitive practices to anti-trust violations.[35]

Arguments in Favor Of Access to Medicines

Violates Right to Health **-** Granting patents to Life saving drugs would violate right to health which is a derivative of right to life. This right

31 TheWTO recognizes the classification made by United Nations to declare countries as least developed countries. The list has 48 LDC members. See www.wto.org for the LDC MEMBERS of WTO.

32 Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy 29 (2002).

33 *India's Plague: Cheaper drugs may help millions who have AIDS – but how many will they hurt?*, The New Yorker, 17 Dec., 2001.

34 J. Reichman, *Implication of the draft TRIPs Agreement for developing countries as competitors in an integrated world market*,U.N.C.T.A.D. DiscussionPaper, Nov. 1993, 15.

35 J. Reichman, *Non Voluntary Licencing of Patent Inventions: Historical Perspective, Legal Framework under TRIPs and an overview of practice in Canada and the U.S.A.*, U.N.C.T.A.D.-I.C.T.S.D., Issue Paper No. 5, 2003.

must not be contracted but integrated with the rights of innovators.[36]

Access through Reverse Engineering - The dependence of domestic economy's market on transfer of technology as a basis for further innovation may not be sustainable. A weak IP regime can be comfortably used as a means for securing access to foreign technology and developing them through reverse engineering thereby further increasing their technological capability and capacity. However, TRIPS restricts the ability of developing countries to stride on this path.

Parallel Imports for Public Welfare - Parallel Import[37] of drugs at low prices could ease the accessibility of medicines to the public. Thus, it is of paramount importance to implement specific control measures in order to avoid consequent parallel exports of drugs which are imported at reduced prices.[38] It is a measure to circumvent price discrimination and market division on a regional as well as international scale.[39]

Impacts on Generic Medicine Industry - The countries which have adopted developed generic industry with a certain degree of competition are manufacturing medicines at lower prices. The strengthening of regime by increasing market power would result in significant costs to consumers due to reduced degree of competition and increased imports. India has proposed that the generic manufacturer shall provide a commercial benefit to the original innovator in order to assure access and harmonization of pharmaceutical patents.

Privatized Knowledge Concentration is not the objective - The privatization

36 Rahshree Chandra, '*3(d)'Effect: The Novartis-Glivec Case,* 46 E.P.W. 13, 13-15 (2011).

37 Parallel importation refers to a situation where a third party, without being authorized by the patent holder, imports a foreign manufactured product which is put on the market abroad either by the patent holder himself, his licensee or in some legitimate manner, in competition with imports or locally manufactured products by the patent holder or licensee.

38 F.M Scherer & J. Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, 5 JOURNAL OF INT'L ECONOMIC LAW 913, (2002).

39 Appellate Body, World Trade Organization, The U.S.- Section 211 Omnibus Appropriation Act of 1998, 72 (WT/DS/176/AB/R, 2002).

of knowledge restricts the research and innovation to those who can pay for it, giving right over invention of the subject. Developed countries representing 90% of the drug sale, represent only 10% of 14 million plus global deaths while developing countries account for 90% of death representing 10% of drug sale. This empirical evidence suggests that current system of providing incentives to industries have failed to ensure R&D priorities reflect health needs.[40]

Curtails usage of Compulsory Licensing - Although, the guidelines under Article 8 of TRIPS and Para 4 of Doha Declaration allow members to introduce measures that protect public health and foster innovation as well as transfer of technology in pharmaceutical sector but the affordable drugs have become largely dependent on compulsory licensing since the waiver of export constraints for countries to provide generic medicines to the importing country requires that the exporting country must have produced it under Compulsory Licensing. This does not solve the insufficient technology issue for manufacturing generics. The grounds for issuing compulsory licenses may include public health but Developing Countries are reluctant to initiate it in fear of adverse effects on FDI, initial threats from US and EC, and lack of sufficient administrative procedures to process such an issuance.[41]

HARMONISING IP, TRADE AND ACCESS: THE ROAD AHEAD

Innovation is largely knowledge intensive. The nation along with being socially and technologically in a situation to innovate (on globally competitive levels), is also supposed to have the knowledge and the technical know-how. In fact, in the present case of bio drugs, even greater levels of patent protections are upkept, (which calls for not just the end-product patenting but also the process patenting) and unless some proportion of concession or leverage is given to developing countries, any nation that is presently backward, shall viciously stay the same even later.[42] TRIPS has actually put out a race with lofty

40 MSF Access Campaign, Untangling the Web of ARV Price Reductions 11 (18th ed. 2001).

41 Fredrick M. Abbott, *The TRIPS Agreement, Access to medicines and the WTO Doha Ministerial Conference,* 15 Quaker Un Office (2001).

42 Peter K. Yu., *From Pirates to Partners: Protecting Intellectual Property in*

and high rewards for the first finisher, but what it does not consider is the different starting lines for different countries. The initial radical innovations that TRIPS cover require humongous investment outlays and long gestation periods. Firms in developing countries don't have such deep pockets and therefore, it is difficult for them to out-do the high capital and technologically savvy firms that have huge venture capital for the Research and Development.[43] This is against the healthy spirit of possibility of equity through IP Rights. The developing countries now focus on manufacturing off-patent products or soon to be off-patent products, partner with western firms or infact manufacture those products that the huge-capital based firms would not be willing to deal with, like the treatment of purely local diseases.

To strike a harmonious chord between enforcing greater IPR standards while maintaining public health, it has been often argued to link the prices of patented products with the overall financial standing or the per capita income of the country. The purchasing power and the economic standing must be the basis for a differential pricing of the same drug in different countries. For instance, a lung cancer drug Erlotinib HCL, sold by Roche holding by the name "Tarceva" costs Rs 35450 in India that is almost equal to Rs 1,21,085 in France and Rs 1,21,650 in Australia. But, if you consider the per capita gross national income, the drug that costs Rs 35,450 in India would respectively cost around Rs 11, 643in France while Rs 10.309 in Australia.[44]

Also, as the IPR preservation gained momentum, problem of 'evergreening of patents' emerged along with. Evergreening refers to harvesting the benefits of the patent even on expiry of its term by developing a portfolio of patents around a basic invention through certain minor changes in the product. However, different countries on having realized the speedy mushrooming of patents, devolved

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China in the Twenty-First Century, 50 AM U.L. REV. 131, 140-54 (2000).

43 Shyama v. Ramani and Augustin Maria, *TRIPs and its possible impact on the biotech based segment of the Indian Pharmaceutical Industry*, 40(7) E.P.W. 675, 680-83 (2005).

44 Editorial, *Link patented drug prices to per capita income: Panel,*THE INDIAN EXPRESS, Feb. 27, 2013.

accordingly suitable action-plans and made amendments in their domestic laws while encapsulating the solution for the same.

For instance, in India, the Patents (Amendment) Act, 2005 has provided within Section 3(d) that no patenting of drugs is allowed in case they emanate from "the mere discovery of a new form of a known substance which does not result in the enhancement of the efficacy of that substance" and introduced the 'single inventive concept' under Section 10(5). The Supreme Court of India's principle of no-novelty in the refusal[45] to grant Novartis[46] a patent for its new drug Gleevec was further upheld in 2012 by "India's Intellectual Property Appellate Board" (IPAB) while revoking Roche's (a pharmaceutical giant) patent of Pegasys, its drug for "Hepatitis C". Furthermore, the court's stand in a 2012 judgment while revoking Pfizer's patent on Sunitib and the Delhi HC's Cipla favoured ruling in a patent infringement case based upon Section 3(d) against Tarceva, the Roche's anti-cancer drug further provides clarity on the Indian stand and outlook on evergreening.[47]

As far as the aspect of health and ensuring access is considered, we must not forget the very reason for the establishment of the World Health Organization (WHO), mentioned under Article 1 as "the attainment by all peoples of the highest possible level of health". Even the Human Rights Council's Resolutions reinstate to use the flexibilities of TRIPS in the best possible manner (even through national legislations[48]) so as to ensure the right to health. The Human Rights Council's 2011 resolution on HIV/AIDS epidemic stated that IP agreements must not undermine the flexibilities of TRIPS and the concerns of Doha

45 Sarah Boseley, *Novartis denied cancer drug patent in landmark Indian case; Supreme Court ruling paves way for generic companies to make cheap copies of Glivec in the developing world*, THE GUARDIAN, April 1, 2013, at 40.

46 Editorial, *Patent Wars India: The Pharmacy Of the World*, THE INDIAN EXPRESS, April 7, 2013.

47 *id.*

48 Commission on Human Rights, Access on Human Rights, Access to Medication in the context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria, E/CN.4/RES/2004/26, 2006.

Declaration[49], WTO General Council decision (of 30 August 2007[50]) and the objectives of UN Millennium Development Goals. UN in its 2012 report on attainment of Millennium Development Goals concluded by saying that the "overall access of essential medicines in developing countries is still insufficient".

In order to harmonize the IP Fundamentalism demanded by the developed countries and the socialist policies of the national governments, it is quintessential to maintain poise between the two. The Developing and the Least Developing Countries might reap the most benefits from the extended transition period (1 Jan 2016) decided post-Doha declaration and the decision of TRIPS council for the test data protection for pharmaceuticals (enforcement procedure and remedies)[51] and the patent protection for the same. LDC members can push for further extension in the LDC transition periods; they shall not be pressurized to comply with TRIPS as long as they retain the status. In order to achieve these objectives, the LDCs shall have to come together and might even take help from the NGOs internationally thereby forming a strong coalition[52] that peddle their concerns and demands further rather than choosing to succumb to the international pressures.

SUGGESTIONS AND CONCLUSION

The developed countries have often contended that the faster legal unification that they push for would actually speed-up the Research and Development in the developing countries and the 'lash of the whip' would pull the developing countries out of the clutches of 'technological stagnation' and 'technological divide' that would have

49 World Health Assembly, Global health-sector strategy for HIV/AIDS, WHA 56.30, 2003.

50 Human Rights Council, The Protection of Human Rights in the context of Human Immunodeficiency Syndrome, A/HRC/RES/16/28, 2011.

51 Council for TRIPS, Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for the Least Developed Country Members for Certain Obligations with respect to Pharmaceutical Products, (IP/C/25, 2002).

52 JOHN H. JACKSON, THE WORLD TRADING SYSTEM 158 (2ded., The MIT Press, Cambridge 1989).

otherwise persisted for even longer periods. It is argued that stronger patent protection shall allow the developing countries to use the system to "leapfrog" their economies. However, it largely seems to be an exaggerated shimmering depiction instead of an empirical explanation as to how would the same be beneficial to the developing economies and ensure greater global welfare.[53]

TRIPS gives immense benefits to the first developers but the developing countries can't really compete to become the first developer due to absence of required deep pockets. What they are therefore confined to, is the manufacturing of the off-patented products, partnerships with western firms on own-friendly terms or to innovate in the lesser-interest areas of the bigger western firms like a local disease affecting a specific territory.[54]

TRIPS intend to cull-out a mechanism where countries give higher consideration to the intellectual prope rty and ensure incorporation of at least minimal patent protection. It is thus quintessential for countries to adroitly make the best use of the exceptions and concessions provided within the agreement. There exists some rudimentary flexibility in the agreement such as Compulsory Licensing, Exhaustion of Rights and likewise which can be intelligently exploited safeguard the objectives of larger public good with reference to essential drugs.[55] However, it is often alleged by the developing countries that the same has proven disadvantageous to the local pharmaceutical industry.[56]

TRIPS is pertinent in principle, but its interpretation might have life and death consequences for people from less developed countries. To an extent possible, the generics can come to the rescue. If the same is prohibited by TRIPS, compulsory licensing under specific array of

53 Carlos M. Correa*, Harmonisation of Intellectual Property Rights in Latin America: Is there still room for differentiation?,* 29 N.Y.U. J. INT'L L. & POL. 109, 126 (1997).

54 *supra note* 43, at 679.

55 Audrey R. Chapman, *The Human Rights Implications of Intellectual Property Protection*, 5(4) JOURNAL OF INT'L ECONOMIC LAW 861, 880-882 (2002).

56 Office of USTR, 2013 Special 301 Report 22 (2013).

conditions might be of help. For instance, Brazil has successfully used the same to pursue its National STD/AIDS Programme[57] It is agreeable that the WTO member nations must 'reasonably' compensate for the patents exposed to compulsory licensing and on precedents suggest anything greater than zero is reasonable. As far as Parallel Imports and Price Ceilings are concerned, the lesserdeveloped countries might get certain leverage but the same can be barred for the rich countries. Even the patent holders can adopt differential pricing,[58] that is lesser prices for developing countries with lesser per capita income and higher for the rich countries instead of having globally uniform prices as there exists weak correlation between wholesale prices and per capita income.[59]

In the present times, the problem is not only TRIPS, but instead the bilateral push for a stricter 'TRIPS plus'. The easily viable mechanism that the developing countries should consider of, is forming a veto-coalition against incessant ratcheting up of IP standards. Leading NGOs across the globe can step in and help form such an alliance. The fact that such an alliance has actually brought the attention of members to access to medicines in the special session of TRIPS, therefore suggests that it is a realistic possibility.[60] Such a veto would pose a challenge to the currently soaring networks of transnational activism. If not done, the developing countries can be assured about their picking-off by one of the broadly growing wave of US bilateralism.[61]

Therefore, greater IPR may augment the competitive advantage of certain countries or companies, but they might not be in favor of developing countries, small producers, and even civil society in

57 CIPR, Integrating Intellectual Property Rights and Development Policy 42 (2002).

58 F.M. Scherer & Jayashree Watal, *Post TRIPS Options for Access to Patented Medicines in Developing Countries* 45 (Commission on Macroeconomics and Health background paper, 2001), http://icrier.org/pdf/jayawatal%20.

59 *id.*

60 *Supra note* 52.

61 Peter Drahos & John Braithwaite, Information Feudalism 187-192 (Oxford University Press 2002).

large. The developed countries' double standards are much visible on the issue of IP protection and the same countries are largely using the system for using their deep pockets to hegemonize them in the markets and consolidate their positions. It must be ensured that the economically weaker countries do not succumb to the humongous pressure that the developed economies now exert upon them directly and indirectly. They must prioritize health and ensure cheaper access over aspects of trade using flexibilities in TRIPS to their advantage and while exerting due emphasis for their rights before bringing their domestic policies in-line with the international standards.

DECODING THE GENETICS OF IPR

Sai Prasanth[1]

"He, who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me."

Thomas Jefferson, Selected Writings[2]

INRODUCTION

Gone are the days when a product or process that was invented, fabricated and materialised as a result of long years of intense deliberation, intellectual thinking and hard work, benefitting the entire globe, was rewarded the least, with negligible amount of value and recognition to the creator. Ironically, the world's most major and ground breaking inventions were made at a time when their intangible and invaluable intellectual creativity had no monetary value or recognition. The driving force of those marvellous inventors of that era still remains and will remain a mystery. But now, times have changed and so has the legal system. As time passed by, many legal systems have matured to the extent of recognizing and adding value to the things created out of the box or the likes of the most famous "Eureka".

In this Modern world, the result of one's own intellectual labour is treated on par with owning a tangible asset with immense value. Intellectual Property (IP) is a breed of property that includes an intangible contrivance of the human intellect. It has primarily been encompassed in the form of copyrights, patents and Trademarks.[3] Intellectual Property Rights (IPR) is a bundle of rights, conferred on the owner of an intellectual creation which grants him exclusive

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1 Student, 4th Yr , B.B.A LL.B (Hons.) School Of Excellence In Law Tamil Nadu Dr. Ambedkar Law University, E-mail: saiprashanth915@gmail.com

2 Thomas Jefferson was an American Founding Father who was the principal author of the Declaration of Independence and later served as the third president of the United States from 1801 to 1809.

3 ANN MARIE SULLIVAN, CULTURAL HERITAGE & NEW MEDIA: A FUTURE FOR THE PAST, 15. Marshall rev. intell. prop. l. 604 (2016).

enjoyment over it.

This paper will proceed with three parts *Firstly*, enumerating the circumstance which brought about the evolution of Intellectual Property Rights and its importance in the commercial field and for benefit of the people at large. *Secondly*, the evolution of Biotechnology and Patent laws. And *finally*, a couple of case studies in brief and a suggestive conclusion.

HISTORY AND EVOLUTION OF INTELLECTUAL PROPERTY RIGHTS

The notion of Intellectual Property did not happen overnight. Rather, IP has come a long way till date. The idea and practice of Intellectual Property could be traced all the way back to 500 BC. This practice originated from the Greek state of Sybaris which granted its citizens to a right of patent for "any new refinement in luxury." Ever since, the laws relating to copyrights and trademarks have been subject to constant improvements. However, the aim and object of the law has always remained constant. The Intellectual Property laws were conceptualized to incite people's creativity and make it possible for inventors to reap the benefits of their original ideas. A full fledged law regarding patent, trademarks etc., was not mandated until the medieval times in Europe, when the Statute of Monopolies was brought about in 1623. During this time, various consortiums controlled all major industries. Every consortium exercised considerable influence on the process by which raw materials and products could be produced, and the manner by which it could be imported and sold.Those consortiums were also responsible for bringing new innovations to the marketplace. They had authority over inventions, even if they were not conceived by them. Hence, came in the Statute of monopolies, 1623.[4]

The Statute of Monopolies made it plausible for inventors to preserve the rights of their contrivance. It also ensured a 14-year period of exclusive rights for the inventors to regulate the usage of their

4 Robert Klinck, The *History of Intellectual Property*, KLINCKLLC (Jul.11,2018, 10:04 AM), https://www.klinckllc.com/ip-history/history-intellectual-property/.

inventions.

Later, the Statute of Anne was brought into force in 1710. It guaranteed 14 years of protection for an inventor. Under this statute, inventors were given an option to extend the term for another 14 years. It is also indispensable to note that authors were given power over the distribution and reproduction of their work under this statute. The innovations and creations of inventors were protected as well.[5]

During the year 1883, the Paris Convention was devised. This International agreement, to which India is a party, safeguarded the innovations of inventors, even if they were used in other Nations. The Paris Convention for the Protection of Industrial Property, signed in Paris, France, on 20 March 1883, was one among the first Intellectual Property Treaties. Pursuant to the convention a Union for the protection of industrial and intellectual property was established. The Convention is still in force at present. The substantive provisions of the Convention fall into three main categories: National treatment, Priority Rights and common rules.[6]

Later, in 1886, international protection of all forms of writing, songs, drawings, operas, sculptures and paintings came into existence due to the Berne Convention. In 1891, trademarks acquired wider protection due to the Madrid Agreement. Subsequently, the Paris and Berne Conventions had offices which later collaborated to establish the United International Bureaux for the Protection of Intellectual Property, which eventually became the current-day World Intellectual Property Organization (WIPO), an office of the United Nations.[7]

IMPORTANCE OF IPR

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5 *Ibid.*

6 WIPO, Summary of *the Paris Convention for the Protection of Industrial Property (1883),*WIPO (Jul.11,2018, 12:36 PM), http://www.wipo.int/treaties/en/ip/paris/summary_paris.html.

7 *Supra note* 3 at p.3. Om Prakash Gupta, IAS, Controller General of Patents, *Designs and Trademarks from the annual report 2016-2017*, IP INDIA (Jul.12,2018,10:36AM), http://ipindia.nic.in/writereaddata/Portal/IPOAnnualReport/1_94_1_1_79_1_Annual_Report-2016-17_English.pdf .

Strong IPR system in a country facilitates development of trade and commerce at both, the domestic and international levels, and provides an edge in the business over competitors.[8] Undoubtedly, Intellectual property is always and will be the most valuable asset of any business since it provides an edge against the competitors. An IP can be extremely crucial to the extent that several business concerns are solely identified by its IP, especially, for a patent, trademark, or design. Intellectual property contributes vehemently to the National and State economies. Countless industries across our economy pivot on the efficient enforcement of their patents, trademarks, and copyrights. At the same time, consumers use IP to ensure they are purchasing safe and guaranteed products.

(i) Benefits of IPR from the consumer's perspective:

Sturdy IP rights enable consumers to make an educated choice about the safety, reliability, and effectiveness of their purchases. It is no doubt that almost all consumers rely on the brand identity or the cutting edge technology patented by a company. Innovative methods have been employed by many business concerns in developing their own brand identity before going ahead with developing its market share. These kind of tactics are put into play because in this competitive world of ever-growing competition, customer retention happens to be a better recourse than customer attraction. For Example, many concerns have their own logos, designs, auditory identity and so on.

Authentic and high-quality products are guaranteed with rigid IP rights. In this world of ever-growing number of duplicate products which compromises on quality for price, or even worse such products are maliciously infused along with the products which are actually original with quality and sold at the same price. Therefore to eliminate this kind of chaos, the concept of IP rights comes into the picture. As in, once a product is patented, the consumers will unquestionably have a sense of security and confidence that the product or commodity to be purchased will meet their expectations in terms of standard, grade and class. IP rights foster the credence and ease of mind that

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consumers demand and markets rely.

IP rights induce free flow of information by sharing the protected technical know-how of the patented invention in the public domain. As an outcome, this process results in improving the existing ones and paves way for newer innovations.[9] Hence, the laws governing IPR not only protects a fresh invention but also protects the process or *modus operandi* by which an existing thing is commercially manufactured.

Lastly, if a competitor introduces an IP in a market, the other competitors will be forced and driven to bring a better substitute, thereby inducing the chain to create more cutting edge concepts. This would ultimately benefit the consumers since they would be exposed to newer and better technologies and advancements.

(ii) Benefits of IPR from the Industrialist's perspective:

Firstly, Protection against infringements by competitors, which ultimately empowers an IP holder to enforce before the court of law for his or her sole right to use, make, sell or export. But a person, who is not a holder of the IP in question, cannot claim the right of injunction. This step is taken so as to ensure non-misuse of the IP laws.

Secondly, Right to restrain others from exploiting the IP without the holder's permission.[10] For Example, once a product is patented, one cannot under any circumstance violate the patent within its duration, unless the patentee has granted exclusive rights by licensing. By licensing, the patent holder can claim royalties from the licensee which contributes to the patentee's pecuniary advantage.

Thirdly, an IP holder has the power to exploit his IP rights through strategic alliances.[11]A strategic alliance is a form of cooperative strategy whereby firms pool their resources and capabilities to achieve

9 *Why Are Intellectual Property Rights Important?*, GIPC, (Jul.12,2018, 10:36 AM), https://www.theglobalipcenter.com/why-are-intellectual-property-rights-important/.

10 *Protecting Intellectual Property*, NIBUSINESSINFO (JUL.12, 2018, 03:15 PM), https://www.nibusinessinfo.co.uk/content/importance-protecting-intellectual-property.

11 *Ibid.*

mutually beneficial outcomes. Alliances may be categorised as: joint ventures where firms combine selected assets to create an independent entity; equity allianceswhere the partners become shareholders in a new venture and; non-equity alliances, contractual agreements between companies relating to supply, distribution, manufacturing, R&D or any other dimension of the value chain.[12] But it is to be noted that out of all three aforementioned categories, it is joint venture that is germane to IPR in forming strategic alliance. Since the combination of selected assets can include intellectual properties too.

Lastly, as mentioned earlier, an intellectual property is on par with an actual tangible property. It can be sold or conveyed like any other property, henceforth, an IP holder can derive monetary advantages by selling his IP rights if he wishes to do so.

INDISPENSABLE UTILIZATION OF IPR

- Nearly 300 products on the World Health Organization's Essential Drug List were responsible in saving and improving people's lives around the globe. It had its origins from the R&D-intensive pharmaceutical industry that extensively depends on patent protections.[13]
- New products are developed to assist farmers to produce more and yield better to satisfy the world's hunger. Courtesy goes to the innovative agricultural companies.[14]
- It is anticipated that the discovery of alternative energy and greener technologies to tackle climate change and other hazards will be due to the reliance on IP protection.[15]

EVOLUTION OF BIOTECHNOLOGY AND PATENTS

Before we dwell into the aspects of biotechnology and patents, it

12 Guriqbal Singh Jaiya, *Managing IP in Public Private Partnerships, Strategic Alliances, Joint Ventures, and M & A*, WIPO (Jul.13, 2018, 11:15 AM), www.wipo.int/edocs/…/sme/en/wipo_smes…/wipo_smes_ge_2_06_www_63212.ppt .

13 *Supra note* 8 at p.5.

14 *Supra note* 8 at p.5.

15 *Supra note* 8 at p.5.

is pertinent to have a fundamental grasp as to what is technology. Technology is defined as the application of scientific knowledge for practical purposes, especially in industry.[16] The term "Technology" has a broad scope, and everyone has their respective way perceiving its meaning. We use technology to execute various tasks in our daily lives, in other words Technology can be elucidated as the products and processes used to simplify our daily lives. Technology is also an application of the field of science, used to solve problems. Technology is the human's erudition which involves systems, materials and tools. The application of technology typically results in products which can be tangible or intangible as that of any "service". If technology is judiciously applied, it will and continue to benefit humans, but on the other side of the coin, it can be used for malicious purposes too. Almost all business concerns use technology to stay competitive. They forge new products and services using technology, and they also use the same to deliver those products and services to their customers on time and within budget.[17]

Biotechnology refers to the use of cellular and molecular biology to make or modify products, processes or procedures. It encompasses scientific and industrial disciplines focused on understanding, handling and manipulating living or biologically potent material at the molecular level, often involving DNA techniques and the analysis of genetic information. Modern biotechnology is expected to lead to important breakthroughs in many fields, such as health, food, energy, and the environment.[18]

Modern biotechnological developments have posed new challenges before the existing patent laws of several countries, since biotechnological inventions differ remarkably from chemical and mechanical inventions that have been the traditional subject matter

16 Oxford dictionary, (Jul. 13, 2018, 16:10 PM), https://en.oxforddictionaries.com/definition/technology.

17 Karehka Ramey, *What is Technology – Meaning of Technology and Its Use*, USEOFTECHNOLOGY (Jul. 14, 2018, 08:45 AM), https://www.useoftechnology.com/what-is-technology/

18 Patents & Biotechnology, WIPO (Jul.14,2018, 01:30 PM), http://www.wipo.int/patents/en/topics/biotechnology.html

of patents.[19]

Albeit the adoption and ratification of the Trade-Related aspects of Intellectual Property rights (TRIPS), which has aimed to bring about a unified character to the patent laws of the member countries of the World Trade Organization (WTO) to a certain degree, these member countries have taken different paths regarding biotechnological patents in tune with their national policies. Accordingly, the ambit and realm of biotechnology patents vary from Nation to Nation.[20]

(i) Evolution of Biotechnology

The Contemporary developments are heavily influenced by the proclamation and dawn of DNA (Deoxyribonucleic Acid). The discovery made by an American biologist James Watson and English physicist Francis Crick in the year of 1953, of the double helix structure is what we all recognise immediately as DNA. It was a stupendous milestone. However, such a feat was achievable due to 100 years of scientific investigation, spanning across the entire globe. Other massive accomplishments in the past, includes the discovery of the chromosomes in the year 1888, pasteurisation in 1861 and, just before the break of this millennium, a rudimentary draft of the human genome map, revealing the location of over 30,000 genes.[21]

Biotechnology had its origins from the field of *zymotechnology or zymurgy*, which began as a quest for a better conceptualization of industrial fermentation, particularly beer. Beer was paramount industrially, and not just a social commodity. In the fag-end of the 19th-century, Germany's brewing contributed significantly to the Gross National Product as on par with steel, and taxes on alcohol

19 Singh& Kshitij Kumar,*Patentability of Biotechnology: A Comparative Study with Regard to the USA, European Union, Canada and India,* SPRINGER (Jul.14, 2018, 02:40 PM), https://www.springer.com/in/book/9788132220589

20 *TRIPS Agreement*, WIKIPEDIA (Jul.14, 2018, 05:25 PM), https://en.wikipedia.org/wiki/TRIPS_Agreement.

21 Gordon Hunt, *The evolution of biotechnology, a 10,000-year infographic,* SILICONREPUBLIC (Jul.14,2018, 09:30 PM), https://www.siliconrepublic.com/innovation/evolution-biotechnology-10000-year-infographic.

proved to be significant sources of revenue to the government.[22] From the 1860s, the object of several companies and firms were solely dedicated to brewing. The most prominent was Emil Christian Hansen of private Carlsberg Institute, established in the year 1875, who trail blazed the pure yeast process for reliably producing consistent beer. As time passed, the world war era arrived, undoubtedly, that was the time when the use of technology reached its all time high and the field of biotechnology too was not spared. Max Delbruck of Germany cultured yeast on large scales during the war, which catered to 60 percent of Germany's animal feed needs. Compounds of another fermentation product, lactic acid made up for the lack of hydraulic fluid, glycerol. On the Allied side, the Russian chemist Chaim Weizmann used starch to eliminate Britain's shortage of acetone, a key raw material for cordite, by fermenting maize to acetone. The industrial potential of fermentation was outgrowing its traditional home in brewing, and "zymotechnology" soon gave way to "biotechnology." [23]

But at the present, biotechnology as we see today has undergone drastic changes resulting in the materialisation and development of concepts which were once upon a time believed to be science fiction. The scope of biotechnology is now expanding in leaps and bounds. For example, the field of Genetic Engineering had started off with a bang with the discovery of synthetic insulin in 1978 which proved to be reliable and efficient. Ever since, the growth of the industry of biotechnology accelerated considerably. Every scientific discovery or invention became a media event designated to capture public support, and by the 1980s, biotechnology grew into a genuinely promising industry. In 1988, only five proteins from genetically engineered cells had been approved as drugs by the United States Food and Drug Administration (FDA). However this number had skyrocketed to approximately over 125 by the end of the 1990s. The branch of genetic engineering is a controversial topic of discussion in today's

22 Thackray, Arnold (1998). *Private Science: Biotechnology and the Rise of the Molecular Sciences*. Philadelphia: University of Pennsylvania Press. pp. 6–8. ISBN 9780812234282.

23 *Biotechnology,* WIKIPEDIA (Jul.15,2018, 11:45 AM), https://en.wikipedia.org/wiki/Biotechnology.

society with the emergence of stem cell research, gene therapy, cloning and genetically modified food (GMO).[24]

India occupies the top 12 biotechnology destinations in the world and has the third-biggest biotechnology industry in Asia-Pacific. India's biotechnology industry is evolving at a rapid rate thereby growing at a compound annual growth rate of 20%. The Indian biotechnology industry grew by 15.1% from 2012 to 2013, increasing its revenues to $3.81 billion.[25] This whirlwind growth is attributed to a range of factors, including a steep increase in demand for healthcare services, intensive R&D projects and strong Governmental initiatives. India is a vast market for biotechnology products and services due to its billion-plus population and increasing economic prosperity.[26]

(ii) Evolution of Patents

The word 'patent' insinuates *openness and accessibility*. The term patent is derived from the Latin term "*literae patentes"* which implies '*open letters'.*[27]As Aforesaid, in 500 BC the concept of patents arose from the Greek state of Sybaris which enabled its citizens to acquire a patent for "any new refinement in luxury." [28] The profits accrued using the patents can be enjoyed by the patentee for a fixed period. In the 1400s, the first formal legal institutions were developed in Venice. The Venetian statute of 1474 propounded that the inventors of new and useful devices would be protected from infringers and copiers for 10 years. During this time, Venetian inventors were granted patents for glass making and its process. Later, the concept of patents had

24 *Supra note* 20 at p.8.

25 Charul Yadav and Garima Kulshreshtha, *Patenting* in biotechnology – the Indian scenario, IAM (Jul.15, 2018, 01:45 PM), http://www.iam-media.com/Intelligence/IAM-Life-Sciences/2016/Articles/Patenting-in-biotechnology-the-Indian-scenario ref 14/07/2018.

26 Dr.Vijay Chandru, *Biospectrum's 11th annual Indian biotechnology industry survey,* ABLEINDIA (Jul.15, 2018, 04:45 PM),http://www.ableindia.in/pdf/reports24_10_survey.pdf .

27 *Evolution of patent laws,* (Jul.15,2018, 07:50 PM), http://shodhganga.inflibnet.ac.in/bitstream/10603/21666/5/chapter-ii.pdf .

28 *Supra note* 3 at P.3.

spread geographically, covering most of Europe.[29] In 1500s to 1700s the French and English monarchs, introduced the concept of patents with the sole intention of stimulating newer and efficient inventions. In the late 1500s nearly 50 monopolies were granted for starch, soap, salt, paper, etc. As expected, such arbitrariness attracted criticisms. By 1610, in light of the rising protests against those monopolies, the British Kingdom was forced to revoke the above monopolies.[30] In 1624, the statute of monopolies came into force which formally abrogated the practice of monopoly and restricted patents to only new inventions. In the 1700s, patents had a major turning point where the inventors were required to submit a written description of their patents in order to ascertain the nature of inventions and the manner by which it is to be performed.[31] Besides patents having been in its primitive stage, faced a few drawbacks. *Firstly*, due to weak enforcement, duplication of patents took place, which diluted the rights of the original patentee. *Secondly*, there was no systematic examination by technical experts which resulted in grant of frivolous patents. *Thirdly*, the patent laws were inventor and commercial centric rather than being biased towards the welfare of the common man and the society at large. *Fourthly*, the patent application fees were monstrously high, keeping patents only within the reach of the Elite.[32]

The law of Patents as we see today has indisputably undergone a sea change. In India especially, after the ratification of the TRIPS, several changes and refurbishments have been made to the existing patent laws, the most recent one being the Patents Act, 1970, last amended in 2017. The existing patent laws are more stringent and secured than that of its previous versions. There is a plethora of parameters and conditions to be satisfied in the patent office before getting patent rights granted. As per the annual report of the Indian Patent Office (IPO), as on 2015, there were 42,000 patent applications filed whereas

29 *Evolution of Patents,* STUDY (Jul.16, 2018, 09:35 AM), https://study.com.

30 *Ibid.*

31 *Ibid.*

32 *Ibid.*

only 5978 have been granted.[33] Hence, it can be deduced that a patent cannot be granted with ease. The applications will have to strictly conform to the standards encompassed.

In the contemporary world, the intent of patent laws has completely changed. Starting with vested interests and money making motives, Patents as we see today is granted for the sole purpose of encouraging innovation which would have long lasting effects on the economy which will ultimately reflect on the welfare of the people by and large. It was rightly observed by Lord Oliver, "The underlying purpose of the patent is the encouragement of improvements and innovation".[34]

(iii) Deciphering "Patents"

Any sort of invention, which has a unique way of operation and which has never been employed before, or any unutilized process, using which an already existing substance is procured are Patentable per se. Provided, *Firstly*, they are not a discovery of something which is already in existence and *Secondly*, it should be of industrial and commercial grade.[35]This monopolistic right is not perpetual. The duration is limited with a life time of 20 years (in India).[36] However, it can be extended on payment of fees for an amount prescribed. The owner of the patent is free to halt anyone within the jurisdiction of the patent from using the patented invention during the lifetime of the patent. The owner of a patent has the right to sell the whole or the part of the intellectual property and can also grant licenses to others. IPR being territorial in nature, a patent granted in one nation cannot be enforced in another nation unless the invention is patented in that country too. Whoever desires to exploit the contrivance disclosed therein, must obtain the necessary authorization of the respective person, who is essentially the owner of the patent. In case of contravention, he is deemed to have committed an illegal act resulting in infringement order passed by the court of appropriate jurisdiction against him and further liable to legal

33 *Supra note* 7 P.4.

34 Aerotel v. Telco Holdings, [1990] RPC 485 (HL).

35 Section 91(2)(ii), IndianPatents Act,1970

36 Section 53, Indian Patents Act,1970

action for paying damages to the proprietor of the patent.[37]

Henceforth, the conception of patent is a *creature of law* by which the State bars anyone within its jurisdiction from exploiting the invention for a fixed period. The economic reward from the invention is earned during this fixed period, thereafter it is streamlined into the public, for use.

Basic conditions to be fulfilled to get a patent granted in India:

Pursuant to the Patents Act 1970, the criteria for patentability of an invention are:

- Novelty – The invention given should be new and not disclosed to the public anywhere in the world in any medium or through any form.
- Non-obvious – The invention is not to be obvious to a person proficient in the relevant area of the given technology and it is supposed to be distinct from the previous innovations made in that particular field.
- Industrial application – The new product or process should be capable of being operable industrially, which in turn has economic significance.

PATENT LAWS AND BIOTECHNOLOGY: A COMPATABILITY TEST

As it can be deduced from the aforementioned paragraphs, it can be well inferred that the concepts of biotechnology and patents were not introduced yesterday or the day before, rather they have been prevalent in our society for a considerable amount of time. But the association between biotechnology and patent laws is something of recent origin. Such an association was possible ever since the commercialization of biotechnology. The sole reason which made it possible for biotechnology to enter into the commercial sector is the rapid advancement of technology which made it possible to bring the ideas and theories on the drawing boards into reality and practice.

37 N.R. SUBBARAM, PATENT LAW PRACTICES AND PROCEDURE 11 (New Delhi: LexisNexis India, 2nd ed. 2007).

Unquestionably, biotechnology has a monumental commercial production. And since its coming into the umbrella of commercial activities, it ought to be regulated by the Patent Laws.

ACCELERATING TECHNOLOGY- MOORE'S LAW

In 1965, Gordon Moore had observed that the number of transistors in a dense integrated circuit doubles about every two years.[38] This is known most famously, as the Moore's law. Moore's law has proved itself with textbook precision and is relevant even today. It is submitted that technology and semiconductors go hand in hand. They can neither be separated nor be isolated under any circumstance. Semiconductors are the bedrock and fulcrum of technology. Undoubtedly, any technology including the modern day biotechnology will have to either actively or passively rely on semiconductors and Integrated Circuits (IC). In this regard, bioinformatics is a great example. Therefore, with the rapid advancement of ICs, there is, and will be, a parallel and a swift development of technology in all fields. With such rapid augmentation of technology, the Patent laws too, must be able to catch up to be in consonance with this technology boom.

This calls for a robust legislature which is capable of making the necessary amendments to the patent laws as and when technology advances. This is to be done in order to harmonize Technology and patent laws and make them compatible with each other. Outdated laws for newer technologies would naturally inhibit the potential of inventors.

CASE STUDY 1:- STEM CELL TECHNOLOGY:

The contemporary era of Biotechnology has gone to the extent of regenerating and procuring not only plants but also human organs. This is possible, thanks to the stem cell technology. The advantage of using such organs is, on graft, there will be no autoimmune disorders since the organs procured matches the same genetic map of the given person.

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38 *Moore's law*, WIKIPEDIA (Jul.17, 2018, 03:25 PM), https://en.wikipedia.org/wiki/Moore%27s_law.

Now let's analyse the legal position in India. *Section 3(j) of the Patents Act 1970* propounds that, except micro-organisms, the following are non-patentable viz plants and animals or any part thereof, seeds, essential biological processes, and the discovery of any varieties and species.

Stem cells are reckoned to fall under the phrase "any part thereof" and hence are excluded from patentability. Nonetheless, *in-vitro* methods of differentiating, isolating/purifying and culturing of stem cells may be considered as patentable subject matter, provided that the modus operandi adopted is novel, possesses an inventive step and has industrial capability.[39]

In addition, inventions pertaining to stem cells may also be opposed under *Section 3(b)* of the act, which prohibits the grant of patent to any product or process, capable for commercial use, but which opposes public morality or prejudicial to the mankind or animals or plant life or the environment as a whole.[40]

Therefore, if critically analyzed, as of now, given the conditions of biotechnology in India, the legal system has struck a balance between science and morality. It may be observed that the potential to unduly exploit this technology was well anticipated, since, it has been enshrined that any process of stem cell technology which may be prejudicial, not only humans but also animals or plants, are Non-patentable. The best example that would fit in this case is non-consensual cloning.

CASE STUDY 2:- GENETIC ENGINEERING:

Genetic engineering is the process of altering the genetic makeup of an organism by inserting, deleting or modifying specific portions of DNA. Such organisms that have undergone alterations in their DNA are Genetically Modified Organisms (GMO). By doing so, we are

39 Sugandhika Mehta, *Patentability of Genes, Gene Sequencing and DNA based Primers*, KHURANA& KHURANA (Jul.18, 2018, 12:40PM), http://www.khuranaandkhurana.com/2015/10/09/patentability-of-genes-gene-sequencing-dna-based-primers/.

40 *Ibid.*

artificially creating a hybrid organism possessing favourable traits. This practice is very common in agriculture where over 25 countries grow Genetically Modified Crops on over 420 million acres of land. The crops that are commonly subject to genetic modifications are soybean, corn and cotton. By genetically modifying crops, it is possible to make them resist diseases, increase protein concentration, delay fruit ripening etc.[41]

Since Genetic engineering has lead to commercialisation, questions arose in several nations as to whether isolated genetic information is patentable subject matter? In the year 2013 the Hon'ble Supreme Court of U.S.A., in *Association for Molecular Pathology v. Myriad Genetics, Inc*[42] adjudged that genomic DNA was not a patentable subject matter.[43] This precedent was huge blow to the biotechnology start-ups, research labs and universities. Myriad contended that synthetic DNA primers are not naturally occurring because single-stranded DNA cannot be found in the human body. Rejecting the contentions, it was concluded that primers are synthetic and it makes no difference since synthetic primers "are structurally identical to the naturally occurring compositions" and function just like naturally occurring DNA by binding to complementary nucleotide sequences and separating DNA "from its surrounding genetic material is not an act of invention." However, this judgement was lauded on the ground that individual rights and privacy was salvaged.

In the Indian scenario, according to *sub-section 3(c), of the Patents Act, 1970*, mere isolation of naturally formed genes, fall under the category of discovery and not a novelty**.** Genes as they are isolated *in situ* are not patentable. For illustration, a patent can be granted for the isolated DNA sequence corresponding to the coding region of a human gene only, if the sequence is new and was isolated by a skilled person

41 *What is Genetic Engineering,* STUDY (Jul.18, 2018, 17:10 PM), https://study.com/academy/lesson/what-is-genetic-engineering-definition-benefits-issues.html ref 20/07/2018

42 Molecular Pathology v. Myriad Genetics, *Inc*, 569 U.S. 576 (more)133 S. Ct. 2107; 186 L. Ed. 2d 124; 2013 U.S. LEXIS 4540; 81 USLW 4388; 106 U.S.P.Q.2d 1972;

43 *Supra note* 37 at P.13.

and the method being employed should have been non-obvious, and it is to present unexpected, flabbergasting properties. At the same time, the sequence has to be disclosed in the patent office to prove that it has industrial application.

CONCLUSION

This is an era where the priority for technological advancements is at its peak. It is an age of information and of late the term "information" is rapidly expanding in scope. Ranging from actual facts to computer programs or even gene data are all considered as information. Therefore, the "information" that is conceived using one's own intellectual labour is crucial to be safeguarded. To protect any "creation" in this age of ever accelerating technology, it is paramount to have flawless laws which are dynamic and facilitative to cope up with rapid advancements. As previously mentioned, to achieve this, a robust legislature is the call of the day. The law makers are duty bound to be proactive in bringing about necessary changes to the statutes, in order to conform to today's technological standards. The aim of the IP laws should be to protect the current innovators and to encourage future innovators. Towards this direction, the laws should not only be updated to suit the emerging requirements, but should also be unambiguous. Any sort of flaw or lacuna can be easily exploited and there will be a delay in granting the designated IP rights. India has prudently performed its obligations, as the founding member of the TRIPS agreement by making suitable amendments to its intellectual property laws. But any lacuna in the law could derail its very purpose. For instance, the Indian Patents Act, 1970 has the provision relating to "Pre-Grant Opposition".[44] It enables anyone to challenge a patent, before it's even granted. Such a mechanism is not found in the laws of many countries. Though Pre-grant opposition has some positives, it cannot be denied that it won't be exploited with vested interests and ulterior motives by third parties. Frivolous oppositions can cause great prejudice to the bona fide patent holders, thereby de-motivating them. Hence it is submitted that the provisions like Pre-Grant opposition may cause more pain than gain.

44 Section 25(1) of Patents Act,1970.

It is finally concluded that Technology and IP laws are interdependent which cannot exist without each other, hence, the rapport between the technological Research & Development wing and the legal Research and Development wing stands indispensable

GOONDAS ACT VIS-À-VIS FREEDOM OF SPEECH AND EXPRESSION: A CRITICAL ANALYSIS OF THE RECENT AMENDMENT (BILL) IN THE GOONDAS ACT IN THE LIGHT OF IP LAWS

Sumedha Bhat[1]

INTRODUCTION

A person could now be arrested in Karnataka even before you commit an offense under the Information and Technology Act (IT Act), 2000. You could be in prison under the Goonda Act regardless of whether or not you are liable under the Indian Copyright Act. In the event that the government supposes you are intending to send an 'obscene' photograph to a WhatsApp gathering or sending a copyrighted tune, you can be arrested.

Have a cell phone? Keep running for cover. Peculiar as this may sound, the police will come after you on the off chance that you forwarded a tune to a companion. Disregard really doing it, any plans to do as such an act could land you in a bad position as well. You could be named a “goonda” according to the State and could wind up in a correctional facility.

At the point when the Legislature declared that it would correct the Goonda Act to bring corrosive assailants and sexual degenerates under its watchful eye, individuals of Karnataka wholeheartedly invited it. However, when the revisions were passed by the lawmaking body, even individuals who energetically supported it were left stunned. Where is the need to bring offenses under the IT Act and Copyright Act under the ambit of the Goonda Act with arrangements like preventive authority and disavowal of safeguard? It is starting to take note of that now and even posting remarks on contemporary issues will be considered as an offense under the Goonda Act.

The bill has been passed in the state assembly but isn't legitimately acknowledged by the legislature of India. This bill(Karnataka Goondas

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Amendment Act, 2014)is still pending for the President's consent as the bill is repugnant to numerous sections of Information Technology Act, Indian Penal Code, Code of Criminal Procedure and many others.[2]

GOONDA

"Goonda" is a term in Indian English, Pakistani English, and Bangladeshi English for an acquired criminal. It is both a conversational term and characterized and utilized as a part of laws, generally insinuated as Goonda Acts.

Historical Background

The word originates from the Tamil word goondan/goondar[3] or Telugu word goonda and in addition the Hindustani word guṇḍā.[4]There is likewise the indistinguishably spelled Marathi word with a comparative significance, originated in the seventeenth century, and with potential Dravidian roots.[5] Another hypothesis recommends that it starts with the English word "goon". Be that as it may, the principal English-dialect appearance of "goonda" (in British daily papers of the 1920s, with the spelling "goondah") begins before the usage of "goon" to mean criminal, a semantic change which seems to return just to the degree the 1930s clever toon character Alice the Goon. A related term is "goonda-gardi", generally signifying "spook kid tactics".[6] Another is "goonda tax", alluding to rewards or cash coerced into an assurance racket. [7]

Definitions

Numerous administrative bodies have passed "Goonda Acts" (an informal name, because of the long titles) giving lawful meanings of

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2 Karnataka Goondas (Amendment) Bill, 2014, Bill No.53, 2014 (India).

3 Tamil Lexicon; Vol II., Part I, University ofMadras, 1982, Page 978.

4 Grant Barrett, *The Official Dictionary of Unofficial English: A Crunk Omnibus For Thrillionairesand Bampots for The Ecozoic Age*, Mc.Graw-Hill Professional, 2006, at 148,149.

5 QaiserZohaAlam, *English Language Teaching in India: Problems and Issues*, Atlantic Publishers &Dist, 1998, at 120.

6 ArdeshirCowasjee, *No 'goonda-gardi'*, dawn.com, 11th May, 2008.

7 *Supra* note 2.

who constitutes a "goonda". A portion of these laws allows unforgiving treatment, for example, enabling the police to shoot them without hesitation.[8]

Bangladesh

Bangladesh's Control of Disorderly and Dangerous Persons (Goondas) Act (East Bengal Act IV of 1954), Section 13(1), gives seven grounds under which a court may announce a man to be a goonda and place him on the endorsed rundown of goondas:[9]

1. frequents for dishonest purposes houses or areas possessed by prostitutes; or
2. frequents resorts of unfortunate propensity, for instance, drinking or wagering alcoves, or spots 'where opium or other intoxicating medications are smoked or by and large ate up; or
3. by and large,show up in broad daylight while alcoholic; or
4. is dependent on smoking opium; or
5. utilizes vulgar or damaging dialect in broad daylight; or
6. makes false accumulation for the sake of philanthropy;
7. is associated with affray, rowdyism or demonstrations of terrorizing or savagery in wherever private or open to make caution the general population living or frequenting the area.

Section 13(2) also defines the class of "Dangerous goonda", giving in more than twenty further grounds on which a council may pronounce a man to be an unsafe goonda, for the most part, identified with viciousness, prostitution, and fabrication or offenses conferred by a man already announced a goonda under the Act. As per Section 14, goondas might be required to post a bond, and might be confined from going into betting houses; hazardous goondas may have substantially more extensive limitations set on their opportunity of development,

8 "*Kerala Goonda Act Minus Shoot-at-sight Clause*", FINANCIAL EXPRESS, 29th June, 2006.

9 The Control of Disorderly and Dangerous Persons (Goondas) Act, 1954, Act No. IV, Act of Parliament, 1954 (India).

and as per Section 18 moreover may have upgraded discipline forced on them for future offenses.

India

Numerous states of India have instituted uncommon laws to manage goondas.

Madhya Pradesh

Madhya Pradesh once had a goonda demonstration in the drive, known as the Central Provinces and Berar Goondas (Act X of 1946), altered by Act XLIX of 1950. Anyway, it was struck down in 1960 by the Supreme Court in the case *State of Madhya Pradesh vs. Baldeo Prasad***.** The court held that "the meaning of a goonda set around the Demonstration, which is of a comprehensive character, showed no tests for choosing whether the individual fell inside the initial segment of the definition".[10]

Uttar Pradesh

The Uttar Pradesh Control of Goondas Act (U.P. Act No. 8 of 1971, revised by U.P. Act No. 1 of 1985) Section 2(b) characterizes a goonda as a man who:

1. either without anyone else's input or as a part or pioneer of a pack, routinely confers or endeavours to submit, or abets the commission of an offense culpable under Section 153 or Section 153-B or Section 294 of the Indian Penal Code or Chapter XV, Chapter XVI, Chapter XVII or Chapter XXII of the said Code; or
2. has been sentenced for an offense culpable under the Suppression of Immoral Traffic in Women and Girls Act, 1956; or
3. has been sentenced at the very least thrice for an offense culpable under the U.P. Excise Act, 1910[11] or Public Gambling Act, 1867[12]

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10 The State of Madhya Pradesh and Anr. v. Baldeo Prasad, AIR 1961 S.C.293(India)

11 United Provinces *Excise* (Amendment) *Act*, 1914, *Act No.* III of 1914, Act of Parliament, 1914(India).

12 The *Public Gambling Act*, *1867*, *Act No.* 3 of 1867, Act of Parliament, 1867(India).

or Section 25, Section 27 or Section 29 of the Arms Act, 1959[13]; or

4. is by and large presumed to be a man who is edgy and perilous to the network; or
5. has been constantly passing obscene comments or prodding ladies or young ladies; or
6. is a tout; or
7. is a house-grabber.

Section 3 enables the region justice to arrange a goonda in writing to expel him from the award or to report his developments, for times of up to six months.[14]

Rajasthan

The Rajasthan Control of Goondas (Act No. 14 of 1975), in Section 2(b) characterizes who is a "goonda" for purpose of the Act[15]. Like the comparative Act in Uttar Pradesh; it gave that goondas the right to request to leave the region ("externment") for up to six months.[16] Be that as it may, the Rajasthan High Court struck down the externment arrangements as illegal in 2001.[17] Specifically, the Court called attention to the plight of a man detained under the Act. He must be given private convenience and subsistence to the detriment of the state government, under the Control of Goondas Act, in any case, no plan for a goonda under externment to be outfitted with private settlement was done, putting him in a moderately more horrible condition than a prisoner; this was held to abuse the right to life ensured under Article 21 of the Constitution of India.[18]

Tamil Nadu

The Tamil Nadu Prevention of Dangerous Activities of Bootleggers,

13 The *Arms Act, 1959*, Act No. 54 of 1959, Act of Parliament, 1959(India).

14 Brahma Prakash Singh v. State of U.P. & Others(India)

15 Devendra Jain v. State of Rajasthan and anr, AIR 2001, WLC 540(India)

16 *Supra,* note 11 & 13.

17 Sukhmani Singh,"*HC Gives Goons a Reason to Smile*", THE INDIAN EXPRESS, 1st May, 2002.

18 *Supra,* note 11.

Drug-offenders, Forest-offenders, Goondas, Immoral Traffic Offenders, Slum-grabbers and Video Pirates Act (Tamil Nadu Act 14 of 1982; "Video Pirates" was not added by Act 32 of 2004, Section 2(f) states "goonda implies a man, who either without anyone else's input or as an individual from or pioneer of a group routinely submits, or endeavours to confer or abets the commission of offense, culpable under Chapter XVI or Chapter XVII or Chapter XXII of the Indian Penal Code (Central Act XLV of 1860)".[19] As indicated by a 2011 decision of the Madras High Court, even a solitary offense under the Demonstration grants detainment of a man as a goonda.[20]

Karnataka

The Karnataka Prevention of Dangerous Activities of Bootleggers, Drug-Offenders, Gamblers, Goondas, Immoral Traffic Offenders and Slum-Grabbers Act (Act 12 of 1985), as amended by Act 16 of 2001, in Section 2(g) states "goonda implies a man who either without anyone else's input or as an individual from or pioneer of a posse, routinely submits or endeavours to confer or abets the commission of offenses culpable under Chapter VIII, Chapter XV, Chapter XVI, Chapter XVII or Chapter XXII of the Indian Penal Code (Central Act XLV of 1860)". As of not so long ago, individuals with a background marked by offenses like bootlegging, medicate offenses and shameless trafficking could be taken into preventive authority. Be that as it may, the legislature, in its excitement, while including corrosive assailants and sexual stalkers to the law, has likewise included 'digital offenders', signifying "any individual who knowingly or deliberately disregards, for business purposes, any copyright law in connection to any book, music, film, programming, aesthetic or logical work and furthermore incorporates any individual who illicitly enters through the personality of another client and wrongfully utilises any Personal Computer(PC)/advanced system for monetary pick up for himself or some other individual or

19 The Tamil Nadu Prevention of Dangerous Activities of Bootleggers, Drug-offenders, Forest-offenders, Goondas, Immoral Traffic Offenders and Slum-grabbers Act,1982, Act No. 14, Act of Parliament, 1982 (India).

20 K. T. Sangameswaran, "*Tamil Nadu: Single Case Enough To Detain Person Under Goondas Act",*THE HINDU, June 25th, 2011.

submits any of the offenses indicated under areas 67, 68, 69, 70, 71, 72, 73, 74 and 75 of the Information Technology, Act, 2000".[21]

Kerala

The Kerala Anti-Social Activities (Prevention) Act (Act 34 of 2007), Section 2(j), states "goonda implies a man who enjoys any against social action or advances or abets any illicit movement which are destructive for the upkeep of people in general request specifically or in a roundabout way and incorporates a peddler, a forger, a depredator of condition, a computerized information and duplicate right privateer, a medication guilty party, a hawala mobster, a procured hoodlum, rambunctious, an improper activity wrongdoer, an advance shark or a property grabber".[22]

Punjab

The Punjab Control of Goondas Ordinance (W.P. Law XXXV of 1959), Section 13, builds up a rundown of in excess of twenty offences (for the most part identified with brutality, open tipsiness, sexual wrongdoings, and ongoing falsifying or carrying) under which a court may proclaim a man a "goonda" and place his name on the endorsed rundown of goondas, after which he may be obligated to redesigned teach for any future offenses. It superseded the before Punjab Control of Goondas (Act XIV of 1951).[23]

IMPACT OF GOONDA ACT ON THE IT ACT, 2000

In a totally incomprehensible move, the vast majority of the offense is raised by Karnataka under Information Technology Act, 2000[24], and Indian Copyright Act, 1957[25], under the sphere of the Goonda

21 Shyam Prasad,*We the goondas"",* THE CENTRE FOR INTERNET AND SOCIETY, August 4th, 2014.

22 The Kerala Anti-Social Activities (Prevention) Act, 2007, Act No. 34, 2007 (India).

23 Punjab Control of Goondas Ordinance, 1959, West Pakistan *Ordinance No.* XXXV.

24 Information Technology Act, 2000, No. 21, Acts of Parliament, 2000 (India).

25 The Copyright Act, 1957, No. 14, Acts of Parliament, 1957 (India).

Act. Until now, individuals with a background marked by offenses like bootlegging tranquilize offenses and unethical trafficking could be taken into preventive care. Be that as it may, the legislature, in its excitement, while including destructive aggressors and sexual stalkers to the law has additionally included 'computerized guilty parties'. While it was believed to be against sound and video privateers, Bangalore Mirror has discovered it could be used against each individual who visit Facebook, Twitter and the other social media, posting easygoing remarks and responses to events unfurling around them.

So in the event that you are masterminding a propelled 'offense'— which could be a harmless sentiment like the young ladies' in Mumbai after the bandh announced on Bal Thackeray's demise[26] — it could draw in the provisions of the Information Technology Act. You could even be taken into preventive authority like a 'goonda' would. Indeed, even those given exemptions under the Indian Copyright Act can end up in prison for a number of years without being brought before a judge. In fact, in the event that you forward 'indecent' images and pictures to a WhatsApp contact/s or send a 'copyrighted' tune/PDF, you can be rebuffed under the Goondas Act[27].

The administrators obviously did not harp much on the suggestions while bringing most of the masses inside the ambit of this law. On July 28, 2014, the Karnataka Governing body passed (it took hardly a minute from tabling to voice vote) 'The Karnataka Prevention of Dangerous Activities of Bootleggers, Drug-offenders, Gamblers, Goondas, Immoral Traffic Offenders, Slum-grabbers, and Video or Audio Pirates, (Amendment) Bill, 2014[28]. The revision includes, "Acid attacker, Depredator of Environment, Digital Offenders, Money Launderers and Sexual Predators", to the title. In the like manner, this law is known as the 'Goonda Act'.

The move has come as a stun to the legitimate network which has

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26 Sherya Singhal v. Union of India, AIR 2015 S.C. 1523(India).

27 Shyam Prasad S, *We the Goondas*, BANGALORE MIRROR BUREAU, August 4th, 2014.

28 Karnataka Goondas (Amendment) Bill, 2014, Bill No. 53, 2014 (India).

pummelled it, naming it an endeavor by the state to usurp focal forces. The administration had before included 'robbery' under the Goonda Act. In any case, it was pertinent just to those pilfering film DVDs. Presently, this will incorporate books, film melodies, and music, programming or anything huge corporate and multinationals guarantee they have copyright on.

Sunil Abraham, official, Network for Web and Society, opines that the new law is "a horrible thing". "It is a tragic improvement. It isn't simply bringing the arrangements of the IT Act[29], yet in addition the Copyright Act[30], that will hurt the normal man," he said.

'Digital Offenders' signifies "any individual who intentionally or purposely disregards, for business purposes, any copyright law in connection to any book, music, film, programming, masterful or logical work and furthermore incorporates any individual who unlawfully enters through the personality of another client and illicitly utilizes any PC or advanced system for monetary pick up for himself or some other individual or submits any of the offenses indicated under areas 67, 68, 69, 70, 71, 72, 73, 74 and 75 of the Information Technology Act, 2000." [31]

Section 67 of the IT Act will be the most hazardous for the normal man with the easy availability of cell phones now. The area, "Distributing of data which is vulgar in the electronic frame," incorporates "any material which is licentious or offers to the lustful intrigue." This could have an exceptionally expansive translation.

CRITICAL ANALYSIS OF DISPROPORTIONATE PUNISHMENT UNDER GOONDA ACT

Sunil Abraham gives two cases by which the corrected Goonda Act will turn into a heartless bit of enactment. "On the off chance that I distribute a picture of a bare body as a feature of a logical article about the human body, is it indecent or not?[32] It won't be profane and,

29 *Supr*a, note 20.

30 *Supra,* note 21.

31 *Supra*, note 20.

32 *Supra*, note 26.

in the event that I am captured under the IT Act, I will be produced before the judge within 24 hours and can disclose it to him. In any case, now, I will be captured under the Goonda Act and need not be produced before a judge for 90 days. This could extend to a number of years. So for multiple years, I will be in prison regardless of whether I have not presented any off kilter. Another illustration relates to bringing offenses under the Copyright Act under the Goonda Act. In the Copyright Act, there is a special case for revealing, explore, instructive and individuals with a handicap. An outwardly debilitated individual, for instance, can, without paying eminence, change over a book into another configuration like Braille or sound and offer it to another outwardly hindered individual on a non-benefit premise. Be that as it may, on the off chance that he is captured under the Goonda Act, he will be in prison for multi-year, even before he does it."

ANALYSIS OF GOONDA ACT

The meaning of 'digital offenders' is essentially funny. I don't imagine that whoever requested that the state government incorporate 'digital offense' under the Goonda act has deliberately perused the Constitution of India. Under the Constitution, both copyright and media communications are selective focal subjects. This implies that states basically can't make any law regarding these matters. Dhananjay(Supreme Court Advocate) gives the case of installment of pay charge. You know as of now that exclusively the focal government can request and gather your wage charges. Could any state government say that it will make another law to rebuff its occupant who defaults in an instalment of salary charge? You would just giggle at any such law. This new meaning of 'advanced wrongdoer' is no less diverting. Offenses under the IT Act, 2000[33], are solely deserving of the local government as it were. State governments have no capacity to state that an Act will turn into an offense when it doesn't have the ability to direct such an Act.

As stated by senior advocate, MT Nanaiah: “This law will be excessively unforgiving. There are MLAs who don't have the foggiest idea about the

33 *Supra,* note 20.

importance of digital wrongdoing. We (advocates) will be kept occupied at the cost of blameless individuals on account of this progression. It accommodates capturing any individual who might supposedly want to accomplish something. Discovering him blameworthy or not generally comes later. What happens if your telephone is lost or some individual sends something from your telephone without your insight? For an initial couple of years, innocents will go to prison. At that point, the courts will most likely mediate and call for altering what is an awful law. A comparative circumstance emerged with Section 498(A) of IPC[3435] and Sections 3 and 4 of Dowry Prohibition Act[36]. It was abused to such a degree, to the point that courts needed to venture in".

Senior advocate and former State Public Prosecutor HS Chandramouli, claims that even social enactments have been abused. Furthermore, for this situation, a great many people are unskilled about what digital wrongdoing is. It is, for the most part, young people and understudies who will feel the warmth. These are the general population who for the most part forward material thought to be profane. It is important to instruct individuals through exchanges, workshops in the bar affiliations, law school and with specialists. The correction has been passed in the Assembly without exchange, which is a catastrophe. In any event now, before it is gazetted, individuals ought to be cautioned about what is being brought into the Goonda Act. I don't know how reasonable including 'computerized wrongdoers' in the Goonda Act will be to people in general, yet the odds of abuse are more. There are no riders or indictment for abuse. Furthermore, what a number of policemen think about digital wrongdoings? Amid the notorious 'kidney' case (where individuals were conned and their kidneys evacuated) numerous policemen did not know the distinction amongst kidneys and scrotum.

GOONDA ACT- IMPOTENCE OF POLICE TO VANQUISH INTERNET

34 The Indian Penal Code, 1860, Act No. 45, Acts of Parliament, 1860 (India).

35 B. M. GANDHI, INDIAN PENAL CODE 83 (K.A. Pandey ed., 4 th ed. 2017).

36 The Dowry Prohibition Act, 1961, Act No. 28, Act of Parliament, 1961 (India).

CRIMES

The move of the Karnataka State Government in bringing the specific act of the Information Technology Act, 2000 under the Goonda Act is subjective, inconceivable and would have genuine implications. The vital part to take note of is the repercussions of such offenses. With the move of the general public to e-administration, the greatness of the Digital Offences has become complex with no particular solution in sight.

The Karnataka state government has passed a follow up on July 28th, 2014, to the "The Karnataka Prevention of Dangerous Activities of Bootleggers, Drug-offenders, Gamblers, Goondas, Immoral Traffic Offenders, Slum-grabbers, and Video or Audio Pirates, (Amendment) Bill, 2014'. The amendment adds, "Acid attackers, Depredator of Environment, Digital Offenders, Money Launderers and Sexual Predators" A Digital Offender means –

"Any person who knowingly or deliberately violates, for commercial purposes, any copyright law in relation to any book, music, film, software, artistic or scientific work and also includes any person who illegally enters through the identity of another user and illegally uses any computer or digital network for pecuniary gain for himself or any other person or commits any of the offences specified under sections 67, 68, 69, 70, 71, 72, 73, 74 and 75 of the Information Technology Act, 2000".[37]

The Goonda Act enables the administration to detain a manfor to one year with a view to keeping him from acting in any way against public order. However, the Legislature has the ability to obstruct the sites for causing harm to a public order under Section 69A of the Information Technology Act, 2000[38] yet the same have infrequently been utilized to hinder the obscene sites. Furthermore, there are views taken by different courts that the transmission of an explicit substance through such sites does not constitute the infringement of public order. Indeed,

37 *Supra,* note 1.

38 Information Technology Act, 2000, No. 21, Acts of Parliament, 2000 (India).

even the section 67/67A/67B enables the police to enlist a case 'suo motto' against each site/blog/online production distributing obscene substance, however the same has not been utilisation by the police till date thus how are we to ensure the proper utilized of Goonda Act.

Presently the issue is conveying the offenses identified under the Goonda Act regardless of whether it is adequate or inadequate under the Information Technology Act, 2000 and the inefficiency of the police in dealing with the same. There is no debate that the technological advances are required to be managed quickly as digital offenses are expanding at an even faster rate. The digital offenses like hacking, information robbery, phishing fakes, online threats, data fraud, digital psychological oppression, youngster smut, DDoS assaults, email fakes have increased exponentially to the degree that an individual's current location is not secure. Furthermore, the multi-jurisdictional nature of the offenses, the authority's neglect to seize the digital culprits and many other issues has made these digital offenders the uncrowned rulers of the digital world.

The Information Technology Act, 2000 has repeatedly been scrutinized for its toothlessness in managing digital offenses and one of the fundamental reasons behind such a view is the fact that the majority of the offences have been made bailable under the Information Technology (Amendment) Act, 2008[39]. Without custodial cross-examination, the police has turned out to be incapable in gathering evidence regarding the escape of digital offenders from the indictment process and this fact added to the developing trend of digitalisation has become a major problem for which the legislature has scarcely made any arrangement while the European countries too are yet to discover an exit plan. Despite the fact that recently, a couple of judgments of the US court have enabled the police/court to order the digital lawbreakers to decode their digital actions or continue to serve their sentence, unnecessary the law on the issue is yet to be developed.

The present situation obviously shows that there is a serious lack

39 Information Technology (Amendment) Act, 2008, Act No. 10, Act of Parliament, 2008(India).

of talented police efficiency in examining the cases and identifying the digital offenses in the nation. The victims of these digital offenses have no cure in spite of them making active use of different dispute resolution systems. With the progression of time, the computerized proof vanishes and wrongdoer is let off. No probability of recovering such a situation appears to be in sight as the legislature has not found a way to manage it yet. To misuse this circumstance, for the sake of managing these activities, digital labs are being set up and crores of exchequers' money is being spent. These equipment/virtual products are being sold at impossible rates and nobody is dealing in such contraptions thus no rest seems probable for the digital victims in the not so distant future.

In spite of so much shout with regard to digital offenses, the administration has not notified even a solitary body under Section 79A of the Information Technology Act, 2000 as the "Inspector of the Electronic Archives" and even our FSL/CFSL's perspective does not qualify the demands of Section 45A of The Evidence Act[40] and accordingly not allowable. Indeed, even in this FSL, the people initially from different domains are dealing with the cases of computer/ mobile/network forensic and their result is constrained to the use of legal programming and they are not able to deal with the instances of complex advanced confirmation. The arrangement of question redressal through the instrument of Arbitrating Officer as gave under Chapter IX in Information Technology Act, 2000 isn't yielding the outcome and Cyber Appellate Tribunal is headless for most recent two years.

The utilization of Goonda Act to the digital offenses engages the police to make a preventive arrest on negligible doubt yet the issue is of its requirement. By what method can the police come to realize that a man sitting on the PC will submit the digital offenses and especially when the police offices are deficient with regards to the investigative abilities to associate the offense with the guilty party in the advanced medium? Indeed, one of the reasons for a spurt of digital offenses is

40 The Evidence Act, 1872, Act No. 1, Act of Parliament, 1872 (India).

the nonenlistment and examination of digital offenses by the police. The utilization of the Goonda Act by the police who needs the capacity to explore the Digital Offenses would make the risky circumstance for the nation of the state.

The hacking of the email account, online records, long range interpersonal communication destinations, however, the utilization of Spyware, Trojans have turned into the normal exercises and if a wrongdoer hacks a record and submit a digital offense which is secured by the Goonda Act, the result would be badgering of the blameless residents as police does not have the capacity to track the impression of hacking through Spywares/Trojans. The programmers are utilizing the PC as bots to submit DDoS assaults and different offenses which may embroil pure nationals and consequence would obliterate as neither the police have arange of abilities to acknowledge or to explore the same. Indeed, even the blameless nationals would not have a solution for bringing the confirmation of bots/ spyware/ Trojans on record and courts are likewise not cordial to the extent digital offenses are concerned.

The inadequacy of the law authorization offices in dealing with the digital offenses combined with the tolerant arrangements of the Information Technology Act, 2000 has made the holes in taking care of the quickly expanding digital wrongdoings. The conjuring of Goonda Act would not exclusively be inadequate to manage such holes yet, in addition, would be counterproductive. It would not make the clumsy police organizations capable to explore the digital offenses and secure the conviction without the proper computerized confirm. The main attainable arrangement is to set up the police organizations equipped for taking care of such offenses combined with appropriate alteration in Information Technology Act, 2000 perfect with the adjustments in the innovation.

CONSTITUTIONAL VALIDITY OF GOONDA ACT

The Act enables the legislature to preventively detain people who have not yet committed an act against public-order and a considerable lot of these actions deal with a subjects' fundamental rights (Right

to Freedom of Speech and Expression)[41]. This is known as "prior restraint", under free speech law.

At the point when this standard is connected to free speech, it is, for the most part, unlawful i.e. unconstitutional. There are two explanations for this. The earlier limitations i.e. prior restraint is for the most part impermissible (unless exceptional circumstances obtain).

This has been the uniform position in Old English American Law (Anglo-American Law) since the eighteenth century. According to the Schedule of 1765, the eminent English jurist Blackstone opined that "the liberty of the press… consists in laying no previous restraints upon publication."[42] The American Transcendent Court has held more than once that "any prior restraint on expression results in these present circumstances Court with a `heavy assumption' against its protected legitimacy."

There are numerous reasons why prior restraint is considered particularly harmful to the freedom of speech and expression. It puts the censorial power in the hands of an administrative or executive authority (rather than a Court). It makes it significantly simpler for the legislature to blue pencil material (than it would be on the off chance that it needed to take upon itself the weight to approach a Court and exhibit to it the reason the said material should be censored). At the end of the day, it gives the administration selective control over what material that can or cannot be permitted to enter the commercial center of thoughts.

Consequently, the Indian Supreme Court has repeatedly held that prior restraint as unconstitutional.

It did as such at an opportune time—in 1950—in the cases of *RomeshThappar*[43] *and BrijBhushan*[44] and as recently as *R. Rajagopal*

41 INDIA CONST. Art.19, cl. 1(a).

42 WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS OF ENGLAND, A FACSIMILE, (ED. 1ST, ED. 1765-1769).

43 Romesh Thappar v. The State of Madras, AIR 1950 SC 124(India)

44 Brij Bhushan & another v. The State of Delhi, AIR 1950 SCR 605 (India)

v. Province of Tamil Nadu [45](which was, but, a defamation case) which took into consideration extensive American Jurisprudence on prior restraint, before holding that "there is no law engaging the State or its authorities to forbid, or to force a prior restraint upon the press/ media."

Aside from the general unconstitutionality of prior restraint, the Goonda Act is conflicting with the Supreme Court's comprehension of freedom of speech and expression.

Under Article 19(2) of the Constitution, the State may apply "reasonable restrictions… in the interests of public order…" [46] upon the freedom granted in Article 19(1) (a) rights to freedom of speech and expression[47]. In the 1950s, the Court interpreted the expression "in light of an honest to goodness worry for" widely, allowing the organization a great deal of sagaciousness in making speech confining laws that were tied in with keeping public order.

There has not yet been a movein this position.

In Ram Manohar Lohia[48], for example, the Supreme Court demanded that the connection between the culpable speech and public disorder must be "proximate" and not remote or unrealistic. Resulting judgments have cleared up the importance of proximity: S. Rangarajan compared the vital association amongst speech and result to a "start in a powder barrel".[49]

Recently, in *Arup Bhuyan (2011)*[50], the Supreme Court has received the exceptional speech defensive "Brandenburg Test" for public order, which limits State obstruction with free speech to situations where there is an act of "prompting to approaching uncivilized activity."

These cases exhibit that the Supreme Court requires the State to

45 R. Rajagopal v. Sate of T.N, AIR 1994 SCC (6) 632(India)

46 INDIA CONST. Art.19, cl. (2).

47 *Supra,* note 36.

48 Dr. Ram Manohar Lohia v. State Of Bihar & Others, AIR 1966 SCR (1) 709(India)

49 BhatiaGautam, "*Goondagiri of the Goonda Act",*OUTLOOK..

50 Bhuyan Arup. State of Assam, AIR 2011 SCC 377(India)

show a high standard before it can legitimize limiting speech on 'public order' grounds. The purpose behind this is clear as keeping up public order is the errand of the State. By keeping a resident from exercising his right to free speech without fulfilling such a standard, the State infringes upon protected rights. This is the reason public order restrictions are constrained to situations where speakers are inducing effectively aroused crowds to prompt savagery ("start in a powder barrel"), since now and then the outrageous criticalness of that sort of a circumstance may require the State to make prompt move against the speaker, both for his own and for general security.

The Goonda Act, with its colossal preventive detainment laws for an entire host of offenses (295A[51]& 153A IPC[52], 67 IT Act so on) fails to assess the Supreme Court's deliberately made test on freedom of speech and its effect on public order. Thus, it is over-expansive. This makes it unconstitutional. At this point, it is to be believed that the Act will be quickly tested under the watchful eye of the Courts, struck down or possibly the unconstitutional sections shall be separated from the rest.

CONCLUSION

The absence of consideration regarding preventive detention enactment in India stays astounding. Particularly at time when there is renewed attention for the growing extent of detainment without preliminary over the globe. The legal endorsement of these statutes has stemmed discussion to a specific degree, and has therefore brought about encouraging states to constantly extend preventive detainment laws. While preventive activity in itself isn't an issue, Indian laws (both government and state laws) show a glaring absence of proportionality in their approach. Recommending conceivably year-long detainment's for potential copyright infringement, when the offense itself is bailable, is obviously unjustified and unlawful.

Right when the Governing body proclaimed that it would redress the Goonda Act to bring destructive attackers and sexual harassers under

51 *Supra,* note 29. "*Details of IPC Sections 153A, 295 & 295A",*ADRINDIA.ORG.

52 *Ibid.*

its careful gaze, people of Karnataka wholeheartedly welcomed it. But however, when the corrections were passed by the lawmaking body, even people who enthusiastically upheld it were left staggered.

If govt assumes you are expecting to send a 'vulgar' photo to a WhatsApp group, or sending a copyrighted song, you can be caught. It is beginning to observe that now and notwithstanding posting comments on contemporary issues will be considered as an offense under the Goonda Act.

It is to be trusted that the Act will be quickly tested under the watchful eye of the Courts, and struck down or if nothing else, the culpable bits separated from the rest.

RESTRICTIVE IPR CONDITIONS AND TECHNOLOGY TRANSFER FROM FDI: POLICY CONCERNS IN INDIAN CONTEXT

Swati Verma[1]

INTRODUCTION

Technology flows from an MNC parent to an affiliate located in a developing economy is considered as a prime source of technology transfer and a key contribution of FDI to the host economy by the policymakers in various developing regions today. The necessity of acquiring technology from developed regions for fostering development has always been recognized as a marked policy objective in India as well. In fact, this has been the major expectation of policy framers behind initiating a sequence of trade and foreign investment liberalisation reforms so vigorously since 1991.

Undoubtedly, majority of technology linked transactions across national frontiers still involves MNCs today and involves technology collaboration contracts with specified terms. Due to stronger bargaining position of technology supplier, the terms of contract may be heavily biased and a number of restrictive intellectual property conditions may be exercised by the licensor to ensure continued control on the intangible asset. Hence, the process of technology transfer via this arrangement may remain inadequate or less than expected as far as any degree of control is exercised on technology itself by the supplier.

Practical observations on this issue suggest that in these specific two party agreements involving financial and technology collaboration, the transferor of technology mostly exercise continued control of technology through various restrictive clauses and these contracts usually comprise conditions like tie-in agreements, vague forms and modes of transfer, terms of contract heavily biased towards the licensor

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including those related to renewal or termination of contract, as well as onerous charges paid for technology mostly in perpetuity over several following years. Various studies have identified the presence of these unfair clauses, costs and conditions in technology purchase process, especially in the case of foreign affiliated firms located in developing regions. The evidence however, remains very limited in the Indian context especially for recent years, due to unavailability of information on the actual terms of technical collaboration contract in the public domain.

Among the range of different parameters of the license, certain specific clauses mentioned in the technical collaboration contract may particularly restrict the extent of technology transfer to the licensee. Ordinarily, these restrictions placed on use or dissemination of technological knowhow and design may be present irrespective of the fact that the licensee may be an arm's length buyer of the technology or even an affiliated enterprise to the licensor. In fact, an affiliated enterprise that has an element of 'extra-territoriality' in its decision making process may have limited say or may be in a much weaker position to negotiate or bargain over the terms of technology transfer precisely due to its financial relationship with the licensor, and may agree to onerous costs and unreasonable terms of contract as has been indicated by various studies. Such a mode of restricted technology transfer can have significant adverse implications for a host developing economy like India where FDI is largely perceived as a sure source of technology transfer through the local affiliate and the policy framework has been designed and altered in due course to especially encourage the purchase of technology through this particular route.

The specific terms of technical collaboration contract that may reasonably limit the technology transfer extent from the technology supplier or licensor to the affiliated or unrelated licensee and eventually to the host developing economy where the licensee is located are particular direct clauses linked to non-transferability and indivisibility of license, strict confidentiality or secrecy of intellectual property or knowhow, restrictions placed on use of technology and geographical territory of its application, strict duration of contract, stringent

termination and post-expiration requirements, restrictions on research and development and grant back provisions. In addition, the terms pertaining to non-exclusivity of license, export restrictions, tying-in clauses linked to sales or imports, provisions for quality control, non-competition clauses and other unfair terms reflect the control that the licensor may directly or indirectlyexerciseon technology or intellectual property. In effect, these prohibitive clauses collectively ensure that the purchased technology or knowhow remains an exclusive asset of the licensor with a very limited scope for eventual 'real acquisition' or 'absorption' by the licensee either during the duration of the agreement or even after the expiry or termination of contract.

Additionally, owing to its primary ownership and control on technology, the supplier/ licensor has a superior bargaining power in the transaction of technology that may be conducted through an intra-firm or open market licensing arrangement and this aspect may also lead to high or unfair price for technology that the licensee may agree to pay.Indeed, such unreasonably high payments may continue on a perpetual basis particularly in the case of within-firm purchases, as has been observed in various instances in the Indian case[2]. It is obvious that the local affiliate has very limited say in drafting of such one-sided terms of contract due to its technological dependence or financial relationship with the parent MNE network supplier. Where the capacity to extract rents may be exercised more gainfully in an internalized set-up by the supplier, the extent of real technology transfer may be quite dubious under several prohibitive IPR conditions that may exist in the contract. In this backdrop, it can be inferred that the within-firm technology transactions are more prone to abuses related to unfair costs and conditions of technology purchase. The special case of technology transfer via FDI route in India shall be critically understood in this context of a susceptibility to perpetual drain of resources for technology purchase coupled with very limited scope for real technology transfer under commonly applicable restrictive terms

2 Swati Vermaand K.V.K. Ranganathan,*FDI, Technology Transfer and Payments for Know-how : A Case Study of Automobile Sector,*Working Paper No. 190, ISID, March2016

of collaboration agreement.

Indeed, a rising importance of financial-cum-technology collaboration contracts has been observed in recent times in India. The recent surveys on foreign collaboration in Indian industries by RBI (Table 1) indicate that among the surveyed sample of Indian firms reporting any foreign technical collaboration in different years, the share of foreign subsidiaries and associates has been quite high (approx. 84% to 94%). This roughly reflects the rising importance of foreign investment linked technological collaborations in India recently. In contrast, the share of companies reporting pure technical collaborations has been quite low (0% to 6%) in these recent years. Also, the survey results show that the share of foreign technical agreements involving transfer of knowhow has been quite significant (more than two-thirds) especially in recent years compared to other forms of asset transfers like trademark or brand name and patents. In fact, a very negligible share of the total agreements involved any transfer of patents.

TABLE 1

Survey on Foreign Collaboration in Indian Industry , RBI (No. of Companies)						
Year (press release date)	*TOTAL Firms reporting FTC*	*Foreign subsidiary*	*Foreign associates*	*Foreign Equity less than 10 per cent or only Outward investment*	*Pure Technology collaboration*	*Transfer of know-how (share in total agreements)*
2007-10 (July 11, 2013)	158	129	19	17	10	38.1%
2010–2012 (April 1, 2014)	244	144	83	17	0	45.8%
2012–2014 (March 24, 2015)	303	160	94	40	9	66.9%
2014–2016 (March 22, 2017)	306	185	75	35	11	68.6%
FTC : Foreign Technical collaboration ; Foreign subsidiaries : single foreign investor holding majority equity , >50% ; Foreign associates : foreign investors' equity holding ranging between 10-50 per cent. (Source : Press releases , www.rbi.org.in)						

In view of the distinct significance of the various terms of technical collaboration agreement in influencing the eventual transfer of technology to the licensee located in a resource constrained developing economy like India, it is crucial to analyze the various restrictive IPR conditions present in the technology collaboration agreements of Indian firms over recent years. The present paper studies the various restrictive IPR conditions and terms in technology collaboration

contracts of Indian firms in recent years. The study focuses on a set of FDI invested firms having financial-cum-technical collaboration with parent network technology supplier as well as few domestic firms having pure technical collaborations. Mainly manufacturing firms have been analyzed. The information on terms of technology collaboration agreements of Indian firms is not available in public domain. However, a number of cross-border technology payments have been legally disputed in India recently. The main grounds of these disputes have been related to transfer pricing of technology transactions and income tax deductions claimed on royalty payments by the companies by accounting them under 'revenue expense' head. In an increasing number of these cases, the benefit aspects of technology payments like actual technology transfer extent have been appraised and questioned by revenue authorities in India. Several of the case documents of judgments delivered on these disputes have made reference to the initial terms of technical collaboration agreements. These case documents are available on few legal databases like www.indiakanoon.org and www.itatonline.com. The information on specific terms of technical collaboration agreements of Indian companies has been procured from these data sources by searching for individual companies. About 50 cases of companies having technical collaborations have been studied in this paper and their respective terms of collaborations have been identified.

The following sub-sections (1 to 12) discuss the various restrictive terms of transfer of Intellectual Property Rights (IPR) and technology present in the foreign technical collaboration contracts of Indian firms that maydirectly or indirectly limit the transfer of technological know-how to the Indian licensee company. The specific Indian companies or foreign affiliate having a particular type of restrictive conditions of technology transfer in their collaboration agreements are discussed in every sub-section. Certain other conditions indicating the high degree of foreign control on technology are discussed as well. The analysis is followed by concluding remarks.

RESTRICTION ON FIELD OF USE, VOLUME, TERRITORY

Field of use restrictions are applied in clauses of contractual license to

limit the use of technology to a specific technical field of application and may restrict the forms in which the industrial property/ intellectual property may be used. Conditions pertaining to usage of technology may specify the product or output volume requirements which are associated with the application of the licensed technical knowhow and may reasonably limit the manufacturing activity to a very specific production or distribution process. The information may have to be used as per the terms specified in the agreement. Hence, these clauses allow the supplier to control or regulate the production or marketing of the licensee beyond what is necessary for the protection of his right under the act in question. The presence of this condition may restrict the transfer of technology to a licensee to a considerable extent, in so far as the contract allows only access to technology or intellectual property for a very specific time period and for production of a very specific product in a particularly indicated territory. In fact, such restrictions may also ensure that the technical knowhow of licensor cannot be used by the licensee for manufacture of any other product including its own products.

A number of technical collaboration contracts of companies in India carry specific conditions pertaining to the field of use. In the case of Fag Bearings (I) Ltd. (ITA no. 793 & 817/Ahmedabad/2006), the contract merely provided the right to use the knowhow for specifically defined purpose and time-period and the transferred knowhow never became an asset of the licensee. Similarly, Maruti Suzuki India Ltd. (ITA 5120/ Delhi/2010 & 2441/Delhi/2012) was not allowed to use licensed information directly or indirectly in connection with the manufacture of any product other than those agreed under the agreement. In the case of Hero Honda Motors Ltd. (372/ITR 481/ Del &2148/del/2009) also, the Intellectual Property rights and the Technical Information was not allowed to be used for manufacture or sale of any product or purpose other than the one expressed in the terms of the agreement under Article 18. Similar restrictions were imposed in the case of J.K. Synthetics Ltd. (ITR 139/1988 & ITR No. 202/1989) under Article 8 of the agreement and in the case of J. L. Morison (India) Ltd. (ITA Nos. 912 & 913/Kolkata/2011). A licence was obtained by Bajaj Tempo Ltd.(I. T. A. Nos. 271 and 272/

30 December, 1995/ PUNE) to manufacture only in accordance to the designs and process specified by the foreign collaborator namely Daimler Benz.

Different clauses in the collaboration agreement of HondaSiel Cars India Ltd. (2007 109 ITD 1 Delhi, 2007 111 TTJ Delhi 630) indicate that the licensee company had very restricted rights to use the technical information for manufacture of its own products. Similarly,the technical assistanceand know how was required to be used only for IMACO'S own manufacture of products in its own factories in India as per the contract terms in the case of Panasonic Home Appliances India Company Ltd. (ITA No. 82/Mds/2009).

In a number of collaboration contracts, territorial restrictions specifying the geographical territory of production, distribution, sale or assembly activity are imposed on the licensee. Specific territory was specified for the application of technology in certain cases like Honda Siel Cars India Ltd. (2007 109 ITD 1 Delhi & Civil Appeal no. 4918 of 2017) and Yamaha Motors (India) Pvt. Limited (2005 (186) ELT 161 Tri Delhi & 2006 3 S T R 665) under Article 2 of the agreement. In the case of Saraswati Industrial Syndicate (ITA No. 150 & 906/Chandigarh/2014, No. 929/ 2015), the use of equipment of only a defined capacity was allowed in a particular territory 1 in the agreement.

SECRECY/ CONFIDENTIALITY OF KNOWHOW

Restrictive clauses related to maintenance of the secrecy or confidentiality of the licensed or transferred knowhow by licensee especially with respect to divulging of information to any third party are introduced in the collaboration contracts to ensure that the control on the technology remains with the licensor. However, such restrictive conditions on inventions, drawings, documents, designs and specifications supplied by the licensor may reasonably limit the actual transfer of technology or intellectual property to the licensee over time, and may restrict the possibility of absorption by the buying entity and development of forward and backward linkages in any developing economy buying such technology from a foreign licensor. Such a restrictive practice can also lead to a continued dependence on the licensor for technology purchase.

The common clauses used for this purpose are towards strict confidentiality (Article 3.10 of agreement in case of Maruti Suzuki India Ltd., ITA 5120/ Delhi/2010 & 2441/Delhi/2012), secrecy(Kirloskar Tractors Ltd. ,98 / Taxman/ 112/Bombay), non-partibility of information, non-disclosure to unauthorized person or entity (Hero Honda Motors Ltd., 372/ITR 481/ Delhi &2148/delhi/2009), information not being communicated to any person other than the responsible employees of the licensee company(Fag Bearings (I) Ltd. (ITA no. 793 & 817/Ahmedabad/2006) , being barred from assigning the informationto any third party (Honda Siel Cars India Ltd. (Civil Appeal No. 4918 of 2017) or from making any copies of technology without licensor's consent(J. L. Morison (India) Ltd. (ITA Nos. 912 & 913/Kolkata/2011).

Varied forms of such secrecy clauses are mentioned in technology collaboration agreement of a number of companies like Bajaj Tempo Ltd. (I. T. A. Nos. 271 and 272/ 30 December, 1995/ PUNE), Kirloskar Cummins Ltd. (202 ITR 36/ Bombay/ 1993/ 27 January, 1993), Nestle India Ltd. (94 TTJ Delhi/ 53/ 2005), Cabot India Ltd. (ITA No. 8495/ Mum/2010), Shriram Pistons and Rings Ltd. (CIT /Delhi/ 24 April 2008) , Alembic Chemical Works Co. Ltd. , Ciba of India Ltd. .(1968/ 69 ITR 692), Hewlett Packard Ltd. (CIT(A)-I/ Delhi/ 1993, 14 August 2001), Saraswati Industrial Syndicate (Clause 10 of agreement , ITA No. 150 & 906/Chandigarh/2014, No. 929/ 2015), J.K. Synthetics Ltd. (ITR 139/1988 & ITR No. 202/1989), I.A.E.C (Pumps) Ltd. (1998/232/ ITR/316), Ramkumar Pharmaceutical Works (1979/ 119/ ITR/ 33) , Polyformalin (P.) Ltd. (1986/ 161/ ITR/ 36/ Kerala) and Syngenta India Ltd. (IT (TP) A No. 1373/Mumbai/2014).

In certain cases like Panasonic Home Appliances India Ltd. (ITA No. 82/ Madras/2009) and B.N. Elias & Co. (P.) Ltd. (1987 168 ITR 190 Calcutta), the technology was required to be kept strictly secret, and/ or suitable secrecy or non-disclosure agreement was to be signed by staff and employees of the licensee company. In the case of Triveni Engineering Works Ltd., written consent of collaborator was required before disclosing of data to anyone by the licensee.In the case of Mikuni Corporation (2008 (1) ARBLR 503 Delhi), both parties were required not to disclose the information to any third party.

In the particular case of Lg Electronics India Pvt. Ltd. (ITA No. 5140/ Del/2011), the confidentiality clause mentioned in Para 11.4 of the Agreement prevented the direct or indirect disclosure of technical information during the continuance as well as after the expiry of the contract. The transfer of technology through an intellectual property license under the above stated conditions of secrecy remains very limited in scope. These limiting conditions may also be present in the case of within firm transactions, as indicated by many cases listed above.

TRANSFERABILITY / INDIVISIBILITY/ SUB-LICENSING

Specific clauses indicating the rights under the license to be indivisible or non-transferable ensure that the licensee is not authorized to permit another person to have access to the technology. Under this term, the licensee is not having any right to sub-license, transfer, assign or convey the know-how to any third party. This condition out rightly limits the possibility of usage of the technology by any third party and may particularly inhibit the transfer of technology to any entity beyond allowing a restricted access to the licensee itself.

In a number of cases, indivisible and non- transferable rights and license was granted by the licensor to an Indian company. Some of these companies are Hero Honda Motors Ltd. (372/ITR 481/ Delhi &2148/ delhi/2009, article 2 in agreement), Honda Siel Cars India Ltd. (2007 109 ITD 1 Delhi, 2007 111 TTJ Delhi 630),Maruti Suzuki India Ltd.(ITA 5120/Delhi/2010 & 2441/Delhi/2012), Kirloskar Tractors Ltd. (98 / Taxman/ 112/Bombay), Toyota Kirloskar Motor Pvt. Ltd. (C/231/04 and C/949/04), Cabot India Ltd, (ITA No. 8495/Mum/2010), Lg Electronics India Pvt. Ltd. (ITA No. 5140/Del/2011) , Wavin (India) Ltd. (1996/236 ITR 314 (SC)), Reebok India Co (ITA No. 1137/Delhi/2014), Yamaha Motors (India) Pvt. Limited (2005 (186) ELT 161 Tri Delhi & 2006 3 S T R 665), B.N. Elias & Co. (P.) Ltd. (1987/168 ITR 190 Calcutta), Panasonic Home Appliances India Ltd. (ITA No. 82/ Madras/2009) , Saraswati Industrial Syndicate (ITA No. 150 & 906/Chandigarh/2014, No. 929/ 2015), J.K. Synthetics Ltd. (ITR 139/1988 & ITR No. 202/1989), Syngenta India Ltd. (IT (TP) A No. 1373/Mumbai/2014), Samsung India Electronics Private Ltd. (ITA no. 5316/Del/2011) andMunjal Showa Limited (ITA 149/2011 & ITA 150/2011/ Delhi).

In a particular case of Saraswati Industrial Syndicate Ltd. (ITA No. 150 & 906/Chandigarh/2014, No. 929/ 2015), licensee was not allowed to enter into license agreement with others for similar technology as licensedor utilize licensed technology in combination with other similar technologies. In certain other cases, sub-licensing was allowed only after prior approval or written consent by the licensor {For example :Eicher Motors Ltd. (82 TTJ Indore 61/ 2004), Shriram Pistons and Rings Ltd. (CIT /Delhi/ 24 April 2008), Ciba of India Ltd. (1968, 69 ITR 692) andHindusthan Motors Ltd. (192 ITR 619 Calcutta/ 1991)}. These restrictive terms ensure the control of licensor on intellectual property on one hand, while amply hindering the transfer of technical knowhow to the buyer entity over time.

DURATION OF AGREEMENT

The clause related to duration of the grant of intellectual property under a legal contract or license specifically indicates whether the license has been granted for a definite term or for a limited time. The duration clause is specified in every collaboration contract and it considerably defines the scope of the agreement. In various cases, the license is renewed over time or is of a perpetual nature especially in the case of marketing intangibles like trademarks or brand names. The terms of agreement that imply a strict period of contract are designed to provide a very limited access of the intellectual property to the licensee, and poses special limitations on technology transfer to the licensee. However, the terms of transfer may be specifically designed to restrict the scope of technology transfer even in the cases of any perpetual license. In the case of Eicher Motors Ltd. (ITA no. 533/Indore/1995), Hero Honda Motors Ltd (2148/delhi/2009) , Bajaj Tempo Ltd.(I. T. A. Nos. 271 and 272/ 30 December, 1995/ PUNE), the licensee had obtained limited right to use the technology of the collaborator during the currency of the agreement. The initial agreement period was ten years, that was extendable to further five years after necessary government approval in the case of Kirloskar Cummins Ltd. (202 ITR 36/ Bombay/ 1993/ 27 January, 1993). In the case of Lg Electronics India Pvt. Ltd. (ITA No. 5140/Del/2011), the license was of a perpetual nature.

Termination

The presence of stringent terms of termination of a collaboration contract (usually in the event of a default by any party) specially limit the possibility of technology transfer to the licensee, in so far as the further use of technology is prohibited and the buyer is required to promptly return all assets, residuary rights, relevant documents, tangible property or information belonging to the supplier on termination of the agreement. In the case of Samsung India Electronics Private Ltd. (ITA no. 5316/ Del/2011), licensee was required to stop using the technical know-how and to return the technical information to licensor on termination. Similar conditions were specified in the technical collaboration agreements in the case of Honda Siel Cars India Ltd. (2007/ 109/ ITD 1 Delhi & Civil Appeal no. 4918 of 2017), Fag Bearings (I) Ltd. (ITA no. 793 & 817/ Ahmedabad/2006),Maruti Suzuki India Ltd. (ITA 5120/Delhi/2010 & 2441/Delhi/2012), Honda Siel Power Products ltd.(ITA no. 5713/ Delhi/2011, Para. 33.6 of agreement) , Bajaj Tempo Ltd.(I. T. A. Nos. 271 and 272/ 30 December, 1995/ PUNE, article 16 of the agreement), Saraswati Industrial Syndicate (ITA No. 150 & 906/Chandigarh/2014, No. 929/ 2015, Clause 11.3.1 of agreement), Hero Honda Motors Ltd. (2148/del/2009, Article 33.3), Kirloskar Cummins Ltd. (202 ITR 36/ Bombay/ 1993), Shriram Pistons and Rings Ltd. (CIT /Delhi/ 24 April 2008) and J. L. Morison (India) Ltd. (ITA Nos. 912 & 913/Kolkata/2011).

In the case of Toyota Kirloskar Motor Private Ltd. (C/231/04 and C/949/04), all technical knowhow was to be sent back to the licensor even during the terms of agreement as soon as licensor requested so. Limited scope was there for the licensee to seek the termination of agreement in case of LG Electronics India Pvt. Ltd. (ITA No. 5140/Delhi/2011, Article 11 of the Agreement).Also, in the case of Motherson Sumi Systems Ltd. (ITA No. 3728/2009/ DELHI), assessee was not left with any asset or residuary right on termination of agreement and even inventories were to be sold within 150 days. Similarly, Hindusthan Motors Ltd. (192 ITR 619 Calcutta/ 1991) was required to return the technology related property within 90 days of the termination of the agreement and was not entitled to deal with even after the period of the agreement.The agreement in

the case of Hewlett Packard Ltd. (CIT(A)-I/ Delhi/ 1993) specified that the licensee cannot use the technology beyond a limitation of 5 years. In a very special case of technical collaboration of Warner Hindusthan Ltd. (1986/ 160/ ITR/ 217), USA collaborator had a right to terminate the agreement if its shareholding in the assessee company fell below 40%. It is evident from these cases that the termination clause is susceptible to be heavily tilted in favour of the licensor for ensuring the absolute control of technology by it.

Restrictions after expiration of agreement

In various instances, the restrictions on usage of technology were imposed by licensor even after the expiration of the term of the contract. For example, all technical details and materials were to be returned to the foreign collaborator after the expiry of the agreement in the case of Arvind Fashion Ltd. (ITA No. 1037/ Ahmedabad/2005). The confidentialyor secrecy clause was applicable even after the expiration of contract period in the case of Lg Electronics India Pvt. Ltd. (ITA No. 5140/Del/2011), Indian Oxygen Ltd. (1996/218 ITR 337 (SC)), Hero Honda Motors Ltd. (2148/delhi/2009) and in the case of Mikuni Corporation (2008 (1) ARBLR/503/Delhi) where secrecy obligation was applicable until such information was made public by any third party. These instances show that the licensee has very negligible rights over the licensed technology that remains an exclusive asset of the licensor even after the agreement ends.

GRANT-BACK PROVISIONS/ RESTRICTION ON RESEARCH AND DEVELOPMENT

In some particular cases, the technology collaboration agreements comprise clauses related to grant-back provisions under which any discovery or improvement with respect to the product or parts by the licensee during the agreement period is required to be transferred to the licensor. Similar grant back provisions are indicated in the technical collaboration agreements of Maruti Suzuki India Ltd. (ITA 5120/Delhi/2010 & 2441/Delhi/2012), Honda Siel Power Products ltd. (ITA no. 5713/Delhi/2011, Article 18 of contract) and Saraswati Industrial Syndicate (ITA No. 150 &

906/Chandigarh/2014, No. 929/ 2015). In the case of Saraswati Industrial Syndicate, grant back of intellectual property by the licensee was required to happen through a non-exclusive, royalty free, irrevocable license under clause 7.3 of the technical collaboration agreement. Such clauses directly place restrictions by the licensor on the research and development made by the licensee with respect to the purchased technology and fairly impede the local technology development or absorption process. However, such restrictions are imposed in a very limited number of cases.

Exclusivity arrangements

In an exclusive license, only the licensee has a right to utilize the technology that has been licensed and is quite similar to an assignment of Intellectual Property. However, in a number of customary cases, the licensor prefers to grant a non-exclusive license under which it can license the technology or IP to as many licensees as it may want. This mode of licensing may ensure the absolute control of the licensor on the intellectual property and also indicates the negligible rights of the licensee over the licensed knowhow. Such clauses considerably restrict the scope of technology transfer to the buying entity.

The Survey on Foreign Collaboration in Indian Industry published by RBI over few recent years indicate that the share of foreign collaboration agreements with exclusive rights has been within the range of 23 % to 38 % in the studied recent years.[3] This shows that the extent of sole licenses in technical collaborations is still fairly limited. Indeed, a number of technical collaboration agreements indicate that the license is on a non-exclusive basis today. Licenses of a non-exclusive type were observed in the cases of Maruti Suzuki India Ltd. (ITA 5120/Delhi/2010 &

3 Shares are 22.5% (2007- 2010 survey of 158 companies, July 11, 2013); 27.5% (2010- 2012 survey of 244 companies, April 1, 2014); 38.4% (2012- 2014 survey of 303 companies, March 24, 2015) and 35.9% (2014- 2016 survey of 306 companies, March 22, 2017), Source: Survey on Foreign Collaboration in Indian Industry, Press Releases, www.rbi. org.in.

2441/Delhi/2012), ToyotaKirloskar Motor Pvt. Ltd. (C/231/04 and C/949/04) , Wavin (India) Ltd. (1996/ 236 ITR 314 (SC)), Lumax Industries Ltd. (ITA No.4715/Delhi/2010 & ITA No.6086/ Delhi/2010) , Abb Ltd (112/MCH/AC/SVB/2011), Motherson Sumi Systems Ltd (I.T.A No. 3728/Del/09), Reebok India Co (ITA No. 1137/Delhi/2014, clause 2) and Panasonic Home Appliances India Ltd. (ITA No. 82/ Madras/2009). In few cases like Kirloskar Cummins Ltd. (202 ITR 36/ Bombay/1993) and B.N. Elias & Co. (P.) Ltd. (1987/168 ITR/190/ Calcutta), a non-exclusive license was granted to sell the specified product. For Yamaha Motors (India) Pvt. Limited (2005 (186) ELT 161 Tri Delhi & 2006 3 S T R 665), the license was on an exclusive basis (Article 2) , while trademark license was granted on a non-exclusive basis (Article 6).

Export restrictions

In certain technical collaboration contracts, specific restrictions on exports or sales are stipulated, which also signify a direct restrictive control on the use of technology by the technology supplier. For example, in the case of Honda Siel Cars India Ltd. (2007 109 ITD 1 Delhi & Civil Appeal no. 4918 of 2017), prior consent of the licensor was required to sell or export any product or part to any place outside Indian territory. The Survey on Foreign Collaboration in Indian Industry published by RBI for some recent years show that nearly 30 % of foreign collaboration agreements contained export restrictive clauses in recent years.[4] The export restrictive clauses are observed in a fair number of collaboration agreements in Indian case.

Tying in arrangements/ Exclusive sales

Restrictive terms linked to tying of imports or exclusive sales are usually present in some collaboration contracts. In some cases in

4 Shares are 16.3% (2007- 2010 survey of 158 companies, July 11, 2013); 27.5% (2010- 2012 survey of 244 companies, April 1, 2014); 30.3% (2012- 2014 survey of 303 companies, March 24, 2015) and 32% (2014-2016 survey of 306 companies, March 22, 2017).Source: Survey on Foreign Collaboration in Indian Industry, Press Releases, www.rbi.org. in}.

India, technology payments were found as being tied up with imports by revenue authorities. In such cases, a lump-sum payment has been made to the import supplier as a consideration for technical know-how, mostly under technical collaboration agreement. Some of these disputed cases are Gem Telegron Switchgears (P) Ltd. (Appeal No. C /221/2003), Hi-Tech Arai Ltd. (Appeal No. C/ 07/2004), HabonimVaas Automation (P) Ltd. (Appeal No. C/174/2003), GEC Alstom Ltd. (Appeal No. C./189/2004), Boss Profiles Ltd. (Appeal No. C/139/2004), TVS R&M Ltd., D. M. Walls Co.(P) Ltd. and Simpson & Co. Ltd. An undue influence of the licensor on the terms of technical collaboration is suggested in these above cases. In the case of Toyota Kirloskar Motor Pvt. Ltd., the licensor Toyota Motor Corporation had made it mandatory on the part of the importers to use the technical assistance agreement. Also, Royalties and licence fees were found to be related to the imported goods for Ferodo India Pvt. Ltd (Commissioner Of Customs , 2008).

Use of Quality Controls

In a fair number of agreements, the licensee was required to maintain the quality standards of the Products and the Parts in accordance with the specification and standards set by the licensor. For ensuring this, a Quality Control Director may be appointed by the licensee/ licensor. Similar conditions have been specified in collaboration agreements of Hero Honda Motors Ltd. (2148/delhi/2009, Article 20), Hindusthan Motors Ltd. (192 ITR 619 Calcutta/ 1991, Clause (xix)), Kirloskar Cummins Ltd. (202 ITR 36/ Bombay/ 1993) and Keihin PanalfaLtd(ITA Nos. 3287/ Del/2011 & 5546/Delhi/2012). Such terms also represent the direct restrictive conditions imposed on the use of technology by the licensor.

Non-competition Clauses

In some collaboration agreements, a non-competition clause may be introduced to ensure that the licensee, usually the affiliated company, does not manufacture or sell a similar product in the specified territory as the licensor. Clauses related to this are noted in few case like

Hero Honda Motors Ltd. (2148/Delhi/2009, Article 30) and Mikuni Corporation (2008 (1) ARBLR 503 Delhi). Such conditions may be imposed to exert a control on the usage of technology by the licensee and restrict the sale of technology.

CONCLUDING REMARKS

In view of the prevalence of a range of restrictive conditions on the use and dissemination of intellectual property or technical knowhow in a number of customary technical collaboration agreements that may substantially limit the transfer of technology to any licensee located in a developing economy in present times, a closer review of the terms of technical collaboration contracts is imperative. This is critical also because a rising number of such foreign collaborations involve financial relations with the technology supplier under FDI route. The aim of this paper is to identify the various significantly restrictive terms and conditions specified in the technology purchase arrangements under open market or within firm licensing routes that may limit the scope for technology transfer. This analysis is undertaken from the special perspective of possibility of technology transfer via the FDI mode of technology purchase in a developing host economy.

Through a closer evaluation of the specific terms of collaboration contracts of a set of Indian firms where majority have an FDI link, it is observed that several key clauses have been imposed on the Indian licensee of technology in a vast number of agreements by the licensor that effectively restrict the use or transfer of technology to the Indian licensee and substantially limit the dissemination of technology through various local linkages to the domestic economy. These clauses and terms ensure that the technology remains an exclusive asset of the licensor, while the licensee has very limited say in either the drafting of the terms of the contract or has very limited access to the technology per say. The observed cases clearly indicate that the payments for technology have been made only for restricted use for a limited period and, the purchased technology has not led to the acquisition of any asset over the contractperiod. The control over technology has been exercised by the licensor through direct clauses

pertaining to the usage and access to technology, as well as through a variety of indirect clauses to ensure the continued control of licensor on the technological asset over duration of agreement. Some of the common conditions used for continued control on technology pertain to clauses specifying indivisibility, and non-transferability of the license, strict confidentiality and stringent termination requirements imposed on the licensee and a range of indirect clauses that effectively control the usage, sale and dissemination of technological knowhow. Such restrictive pattern of transfer has been noted in various cases of foreign affiliated firms as well, which shows that the FDI route of technology transfer is equally vulnerable to inadequate levels of technology acquisitions when compared to pure technology collaboration route.

From the special policy viewpoint, it is worth noting that the pattern of technology purchase in the customary collaboration contracts may not lead to any valuable transfer of technology eventually. This is so because no secret formula or knowhow is sold under these collaboration arrangements, and the rights of the licensee are hedged in with all sorts of restrictive conditions so that it effectively has negligible ownership right over the technology beyond the right to limited use. Due to the weak bargaining power of the local affiliate or licensee in the negotiation process for technology purchases, it is difficult to ensure a deeper level of real acquisition of technology in the licensing route. Moreover, the non-absorption of technology by the local affiliate and continued dependence on foreign collaborator for technology in these technology purchase arrangements is a serious issue from a purely policy perspective in India seeking real technology transfer in this set-up.

It is to be noted that the control of restrictive practices in transfer of technology in various developing countries is undertaken through policy instruments which are exclusively designed for the regulation of technology transactions which generally have specific provisions to administer such practices.[5] In the Indian case, serious policy

5 See *Control of restrictive practices in transfer of technology transactions*, Report by UNCTAD secretariat , United Nations Publication, New York 1982.

intervention is required to ensure that these restrictive intellectual property licensing conditions in any technical collaboration agreements are minimized and deeper levels of technology acquisitions could be realized through FDI or open market purchase route. A strict monitoring of the negotiated terms of contract, strengthening of the bargaining power of the local licensee and regulatory supervision of technology transfer and its eventual absorption in economy over years is crucially needed in Indian context if higher level of technological upgradation is desired.

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WTO PRINCIPLES ON FREE TRADE AND CONCEPT OF INTERNATIONAL EXHAUSTION WITH SPECIAL REFERENCE TO THE NATIONAL TREATMENT PRINCIPLE

Vishnu Sankar P.[1]

INTRODUCTION

WTO, established in 1994 replacing GATT, is an international organization with common agreements binding its members to establish international free trade.[2] The theory of free trade through international arena, arose after the failure of protective market strategies prohibiting exchange of goods between nations in order to increase national production and subsequent results in economic rescission. Modern international law seeks to increase global welfare by lowering barriers to trade and encouraging competition. The first step towards this was instituted through the GATT agreement 1947 which sufficiently lowered the trade barriers to facilitate free trade and subsequently in 1994, GATT was revamped and WTO was established with GATT agreement, 1994 as an agreement among the various agreements which incorporated similar free trade agreements.

Exhaustion of rights in the intellectual property regime refers to the loss of the right of intellectual property owner to control the movement of the IP containing product once it is sold by the IP holder. This implies that the purchaser of the IP product can resell the same to any person or do whatever he intends to with the product so bought. Thus, exhaustion is an inherent mechanism within IP which allows unrestrained movement of goods after its first legal sale. However,

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2 Thomas Cottier and Matthias Oesch, *Direct and Indirect Discrimination in WTO Law and EU Law*, (NCR Trade Regulation, Swiss National Centre for Competence in Research, Working Paper No 2011/16 | April 2011, p.1,(23rd Nov 2018, 21:35 P.M, available at http://www.nccr-trade.org/fileadmin/user_upload/nccr-trade.ch/hi/CottierOeschNCCRWP16.pdf.)

even though the concept *per se* is not disputed, countries failed to reach a consensus regarding the kind of exhaustion that needs to be followed uniformly. Basically countries have recognised three modes of exhaustion namely, national, regional and international. The classification of exhaustion has taken place practically to suit the economies of each country.[3]But the practice of following different modes of exhaustion has created barriers to free trade at the borders of countries. The concept of regional and national exhaustion prohibits the movement of goods beyond certain territories. Thus it goes against the free trade theory propagated by the WTO regime, in which TRIPs s forms a part of the agreements.

This paper aims to analyse the principle of free trade as enshrined under GATT and whether international exhaustion furthers this free trade principles. The paper is divided into five sections. The first part deals with the general free trade theory while the second part explains how IPR exercises a restriction upon the free movement of goods across the borders. The third part explains the aim of GATT and its connection with the free trade. The fourth part deals with the GATT principles on free trade in which GATT articles are analysed for understanding the free trade notion of WTO. Even though this part deals with the main principles of GATT, principle of national treatment is given a more elaborate analysis. The WTO agreement contains the principle of national treatment as one of its basic principles. The national treatment principle of GATT 1994, under WTO, at the same time mandates that place of origin of products cannot be a ground for prohibiting the international movement of goods.[4] Adopting national exhaustion or regional exhaustion indeed differentiates the goods based on the origin or country of origin of goods. It is upon these prongs of arguments that the author argues for a uniform model of international exhaustion to be followed by all the nations. The last part of the paper concludes that the free trade principle enshrined in

3 Lazaros G. Grigoriadis, *Trade Marks and Free Trade – A Global Analysis*, p.88 , (2014).

4 Article III of the GATT 1994.

the WTO and GATT supports the notion of international exhaustion and encourages the parallel imports. The basic question which is addressed in this research paper is can the WTO principles apply differently to TRIPs agreement alone or in other words, can the issue of exhaustion be addressed from the perspective of national treatment and other free trade principles enshrined under GATT principles of WTO or not.

GENERAL NOTION OF FREE TRADE

The globally accepted free trade principle is driving the international free movement of goods and the global prosperous economy. [5] The goal of GATT is to liberalise trade in goods. The classical trade theory was based on the theory of absolute advantage in which the imports of goods are limited or prohibited as to encourage the local production of goods, thus, bringing about development in the local level.[6] This theory was propounded to be of great advantage to the economy as it generates employment and more goods. Later one sees a shift in the notion of trade theory to that of theory of comparative advantage wherein more goods are imported which are costlier for local production while those goods which are cheaper to produce locally are produced more so that it may be exported to international market. As Adam Smith has put in his words"*if a foreign country can supply us with a commodity cheaper than we ourselves can make it, better buy it from them with some part of the produce of our own industry employed in a way in which we have some advantages. Thus encourages the importation of good on a larger scale*"[7]

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5 Chung-Lun Shen, *Intellectual Property Rights and International Free Trade: New Jurisprudence of International Exhaustion Doctrine under the Traditional Legal System*, Journal of International Commercial Law and Technology Vol.7, Issue 3 p.176-211, (2012).

6 Smith, *An Inquiry into the Nature and Causes of the Wealth of Nations,* Book IV, Section ii, 12 , (1776). Also see: Sunanda Sen, *International Trade Theory and Policy: A Review of the Literature*, Levy Economics Institute of Bard College, Working Paper No. 635, November 2010.

7 Adam Smith, *An Inquiry into the Nature and Causes of the Wealth of Nations*, Book IV, Section ii, pg. 12 , (1776).

The modern theory of international free trade is based on the theory of comparative advantage.[8] It compels the countries to take part in the trade so as to gain access to different products. The idea behind the theory of comparative advantage is that if a country produce some set of goods at a lower cost than a foreign country and if the foreign country can produce some other set of goods at a lower cost than the local producers of the country, then clearly it would be the best for us to trade our relatively cheaper goods for their relatively cheaper goods.[9] In this case both countries may gain from trade and thus compels the countries to take part in the trade so as to gain access to products.

The theory of comparative advantage plays a critical role when we talk of IP products. As it is known, IP puts restrictions on the free movement of goods creating private ownership and monopoly over a particular product. Technology has always been aloof to the developing countries due to economic and social factors. Therefore developing countries always depended on developed countries for the access to it and often it is the situation when developing countries cannot afford the price of it. It is in order to fight this situation IP has in built mechanism for limitation of IP rights and one of them being exhaustion of IP rights. Even though different countries follow different modes of exhaustion, international exhaustion grants more access to developing countries.

Elimination of barriers to movement of goods across and within the national boundaries encourages specialization and efficiency in production and distribution and results in increased output of goods. Free trade enhances productivity and it is from this ground that elimination and reduction of tariffs and barriers of trade in goods arose. One of the positives of free trade or comparative advantage theory is that it can increase the standard of living and consumer welfare of the local people of a country as they make maximum use of

8 ReinhardSchumacher ,*Deconstructing the Theory of Comparative Advantage*, World Economic Review 2: 83-105, 2013.

9 David M Gould, *The Theory and Practice of Free Trade*, Economic Review — Fourth Quarter, 1-2, 1993, (23rd Nov 2018, 21:59 P.M., https://www.dallasfed.org/~/media/documents/research/er/1993/er9304a.pdf.)

the local resources for their own advantage. It can also lead to better distribution of goods and resources.

A good if produced and sold in a country for a cheaper price, it may be imported into another country where the price of the good is high. This can happen only if IP rights on products get exhausted upon the first sale and wherein international exhaustion is followed. Thus once IP right on the products gets exhausted the cheaper products of one country will be imported by another country which is called as parallel imports. Hence a parallel import furthers the comparative advantage theory and free trade.

INTELLECTUAL PROPERTY AND FREE TRADE

Free trade and IPR prima facie seems to be in conflict as one creates a limitation on movement of goods through the creation of private property regime while free trade aims at unrestricted movement of goods. IPRs are fortified by national borders while free trade aims to diminish the relevance of borders. IPRs reduces the quantity of movement of goods across the borders. On the one hand IPRs provides incentive for innovation while on the other hand it can lead to reduced access to the products. Even though these facts exists, IPR protection in critical and sensitive areas of goods can increase development in countries of free trade and who have comparative advantage over those areas. In addition to it, one of the goals of IP is wide spread dissemination of knowledge at the same time encouraging innovations. So, free trade based on comparative advantage theory helps in achieving the same. The complete incorporation of free trade into IPR can go against the basic IPR incentive collapsing the very structure of IP. Therefore limited exceptions need to be recognised by the IP system itself and exhaustion is one among them. As ECJ has quoted "*unification of market cannot be achieved if distributions of goods are limited on the sole ground that it was produced outside a national territory*" .The enquiry should be as to whether the first sale of a product exhausts the right of the IP owner to control the movement of goods across the border. In fact the basic conflict that arises is between the free movement of goods and the

selling right of the IP owner. It is to be found out whether the right to sell includes the right to control the movement of good even after the sale of the good. If it is accepted that it is so, then it would go against free trade notion. Therefore,a line has to be drawn between the right to sell and distribute the product which is an IP right from becoming over monopolistic to the extent of hampering free movement of goods. It should also be noted that there is no dispute as to the fact that upon the first sale exhaustion of rights takes place but dispute arises upon the fact of the territorial extend of this phenomena. The issue of parallel imports needs to address to conflicting issues- the interest of free trade reflecting the benefit to the consumer and intellectual property rights of the IP owner.

WTO PRINCIPLES ON FREE TRADE

The basic principle of WTO upon which it functions is by reducing trade barriers between countries so as to facilitate free trade. WTO aims at achieving increased exchange of goods for which substantial reduction of trade barriers should be made.[10] Also it is also the aim of the WTO to facilitate trade and access to developed countries for their economic upliftment.[11] Even though many literatures are available on WTO principles on free trade, author found it interesting that the analysis of the WTO articles on free trade was limited. Therefore it is the aim of this paper to bring out many other important Articles of WTO and other important aspects of it.

GATT 1994

Article XI: - Much of the discussion of the WTO principles on free trade circles around Article XI of the GATT principle of WTO[12] which is commonly called as the free trade principle of WTO. Article XI talks about the elimination of quantitative restrictions.[13] This is the most

10 Preamble of WTO Agreement, 1994.

11 Ibid.

12 Article XI of GATT 1994.

13 No prohibitions on imports other than duties, taxes or other charges made effective through licenses or other measures shall be made on

important Article of GATT and even WTO which talks about free trade wherein the Article makes it clear that no prohibitions on imports shall be placed by any member country other than duties, taxes or other charges or "other measures". Therefore it is evident from the Article that importation has been given due importance in the GATT agreement and only restrictions like duties, taxes charges etc can be limitation on the imports. The important query here is about the ambit of the words in the Article XI "other measures".

In *U.S. manufacturing Case*, [14] WTO panel examined whether the words other measure includes the banning of imports to a country. In the case, U.S. banned the importation and distribution of books into the country those books which were printed outside U.S. under section 6 of Title 17 of U.S. code. Panel found the ban on importation of books merely on the ground that it was not manufactured in U.S. violated Article XI.[15] Panel further held that even Import restrictions through state trading import monopolies are inconsistent with Article XI. Thus it is pretty clear that banning imports will not be covered under measures allowed against importations under Article XI. In another Panel report on U.S. "Restrictions on import on Tuna",[16] held that prohibition on imports of fish from Mexico was also violative of Article XI.[17]

Parallel import is an importing act. Under free trade principle parallel imports of products cannot be restrained under quantitative

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imports.

14 Report of the Panel,*The United States Manufacturing Clause*, *(L/5609 - 31S/74), May 15/16, 1984.*

15 Report of the Panel,*The United States Manufacturing Clause*, 34-42, *(L/5609 - 31S/74), May 15/16, 1984.*

16 Report of the Panel, *United States – Measures Concerning The Importation, Marketing And Sale Of Tuna And Tuna Products*, (complainant Mexico) WT/DS381/R, 15 September 2011.

17 Report of the Panel, *United States – Measures Concerning The Importation, Marketing And Sale Of Tuna And Tuna Products*, (complainant Mexico) WT/DS381/R, 5.67, 15 September 2011.

restrictions.[18] Report of the working Party on the use of quantitative restrictions for protective and commercial purposes, 1950, examined the use of both export and import restrictions. The report addressed that total prohibition on imports of products which are in direct competition with the domestic product on the disguise of balance of payment exception and concluded that they are inconsistent with Article XI. Thus it is clear that the aim of the quantitative restrictions is not to ban parallel imports and that Article XI furthers the concept of parallel imports as it encompasses even the competitive mechanism that imports can bring in. Parallel imports can bring in intra-band competition.

Also Article V of the GATT, 1994,[19] deals with the freedom of transit. Except for the non-compliance of customs laws and duties, no goods shall be unduly detained by a contracting party. Freedom of transit: "… includes protection from unnecessary restrictions, such as limitations on freedom of transit, or unreasonable charges or delays (via paragraphs 2-4), and the extension of Most Favoured-Nation (MFN) treatment to Members' goods which are "traffic in transit" (via paragraphs 2 and 5) or "have been in transit" (via paragraph 6)".[20]

Often is seen the case wherein the parallel imported goods which are destined to other countries, which was in transit are detained by the countries on request of IP owners. This is inconsistent with Article V.

RESTRICTIONS ON IMPORTS

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18 Chung-Lun Shen, Intellectual Property Rights and International Free Trade: New Jurisprudence of International Exhaustion Doctrine under the Traditional Legal System, Journal of International Commercial Law and Technology Vol. 7, Issue 3, 176-211, (2012).

19 Goods (including baggage), and also vessels and other means of transport, shall be deemed to be in transit across the territory of a contracting party when the passage across such territory, with or without trans-shipment, warehousing, breaking bulk, or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the frontier of the contracting party across whose territory the traffic passes. Traffic of this nature is termed in this article "traffic in transit".

20 Report of the Panel, *Colombia – Indicative Prices and Restrictions on Ports Of Entry*, 7.387, Wt/Ds366/R, April 27 2009.

WTO even though encourages free trade to a large extend, it doesn't mean that there are no restrictions on the importation of goods to a country. There are several restrictions upon the free import of goods which are listed below:

Article XI (2): Import prohibitions on the basis of not meeting standards or regulations: - Article XI (2) says that import and export prohibitions or restrictions necessary to the application of standards or regulations for the classification, grading or marketing of commodities in international trade shall be placed by the parties. However standards and regulations placed by a country on an imported product shall not exceed to an extent to unduly restricting trade.[21] The Review Working Party on "Quantitative Restrictions" in 1954-55 considered various proposals to amend Article XI: 2. [22] It commented that "Restrictions related to the application of standards or regulations for the classification, grading or marketing of commodities in international trade which go beyond what is necessary for the application of those standards or regulations and thus have an unduly restrictive effect on trade, would clearly be inconsistent with Article XI."[23]Panel report on Canada- - Measures Affecting Exports of Unprocessed Herring and Salmon, L/6268, held that any import or export restriction to protect domestic industry would not be covered under the standards or marketing regulations under Article XI (2).[24]

Article XII: Import restrictions to safeguard balance of payments: A party may restrict importation of certain goods in order to safeguard

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21 ANALYTICAL INDEX OF THE GATT, on Article XI (2) (B), GENERAL ELIMINATION OF QUANTITATIVE RESTRICTIONS.

22 ANALYTICAL INDEX OF THE GATT, ARTICLE XI ,GENERAL ELIMINATION OF QUANTITATIVE RESTRICTIONS, p..314.

23 Report of the GATT Special Sub Group, *" Working Party on Quantitative Restrictions- Relations between GATT and International Monetary Fund*, 67, L/332/Rev.1 and Addenda, adopted on 2, 4 and 5 March 1955, BISD 3S/170, 189-190.

24 Report of the Panel, *CANADA - MEASURES AFFECTING EXPORTS OF UNPROCESSED HERRING AND SALMON*, 4.2-4.3, March 22 1988 (L/6268 - 35S/98), 112.

the balance of payment.[25] Members confirm that restrictive import measures taken for balance-of-payments purposes may only be applied to control the general level of imports and may not exceed what is necessary to address the balance-of-payments situation.[26] However restrictions are placed under Article XII (2) upon Article XII. [27] The restriction placed on importation shall not exceed other than that is necessary to combat a threat or serious decline in monetary reserves. It should also be noted that it has been agreed by the parties that these restrictions on the grounds of balance of payment shall be of temporary nature and shall be lifted as soon as the contingency is over.[28]

Article XII (3) (c) (III): This article stresses that import restrictions shall not be placed which allows non-compliance of IP laws. Interpretation of the Article stresses the point that restrictive measure which is used under this Article should be the one which has least effect on trade distortion.[29] The Article also does not deal with general ban of imports from other countries but only on those goods which are critically important for the economy of the country due to a serious economic situation.

Article XVIII: Governmental Assistance to Economic Development: -

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25 Article XII (1), Notwithstanding the provisions of paragraph 1 of Article XI, any contracting party, in order to safeguard its external financial position and its balance of payments, may restrict the quantity or value of merchandise permitted to be imported, subject to the provisions of the following paragraphs of this Article.

26 Paragraph 4 of the Understanding on the Balance-of-Payments Provisions of the GATT 1994

27 Article XII (2) (a) : Import restrictions instituted, maintained or intensified by a contracting party under this Article shall not exceed those necessary:

(i) to forestall the imminent threat of, or to stop, a serious decline in its monetary reserves, or

(ii) in the case of a contracting party with verylow monetary reserves, to achieve a reasonable rate of increase in its reserves.

28 UNDERSTANDING ON THE BALANCE-OF-PAYMENTS PROVISIONS OF THE GENERAL AGREEMENT ON TARIFFS AND TRADE 1994, ARTICLE XII - RESTRICTIONS TO SAFEGUARD THE BALANCE OF PAYMENTS.

29 Article XII (3) (c) (III)

Article XVIII of GATT empowers the member countries to ban imports for the economic development of those economies which are in the early stages of development.[30] Clearly the Article aims at the developing nations and its empowerment. But even that case these measures can be sustained only for a temporary period.[31] Also developing countries may for protecting their financial position and in cases of balance of payment issues, may restrict the quantity or value of goods to be imported.[32]According to India, Article XVIII: B was the most important expression of the principle of special and differential treatment of less-developed countries in the GATT.[33] Subsequently there are certain restrictions on Article XVIII thorough Article XVIII (B).[34] According to Article XVIII(B) import restrictions shall be placed based upon three conditions :

(a) must determine the class of products the imports of which are to be restricted

(b) Must not unreasonably impair the regular channels of trade.

(c) Import restriction should not be applied as to prevent noncompliance of IP laws

Article XX: General Exceptions: General Exceptions to the WTO

30 Article XVIII (1), GATT, 1994.

31 Article XVIII(4) (a), GATT,1994.

32 Article XVIII :B, GATT,1994.

33 Report of the Panel, *India - Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products*, 3.205,WT/DS90/R, 6 April 1999.

34 In applying these restrictions, the contracting party may determine their incidence on imports of different products or classes of products in such a way as to give priority to the importation of those products which are more essential in the light of its policy of economic development; Provided that the restrictions are so applied as to avoid unnecessary damage to the commercial or economic interests of any other contracting party and not to prevent unreasonably the importation of any description of goods in minimum commercial quantities the exclusion of which would impair regular channels of trade; and Provided further that the restrictions are not so applied as to prevent the importation of commercial samples or to prevent compliance with patent, trade mark, copyright or similar procedures.

principles is given in Article XX . The most important exception which regards our query is under Article XX (d).[35] The words in the Article makes it clear that no IPR policy shall be inconsistent with the general principles of free trade enshrined in the WTO which implies that unreasonable restriction on imports shall not be placed by members.

Article XX IV (4) provides for creation of customs union[36]. But even the creation of the same should be to increase trade and reduce trade barriers.Although this provision has not been interpreted by the Appellate Body, the negotiating history offers some indication. The original text contained in Article 33 of the United States Draft Charter (1946) reads as follows: a union of customs territories for customs purposes shall be understood to mean the substitution of a single customs territory for two or more customs territories, so that all tariffs and other restrictive regulations of commerce as between the territories of members of the union are substantially eliminated and the same tariffs and other regulations of commerce are applied by each of the members of the union to the trade of territories not included in the union.[37]

The other relevant provisions of the GATT such as Article VIII (fees and formalities), Article VIII (c){minimized formality for imports} and ban on imports in emergency situations sheds light into the nature

35 Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

(d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices.

36 Art. XXIV:8(a) states that a customs union shall be understood to mean the substitution of a single customs territory for two or more customs territories.

37 Reference contained in Article XXIV and the General Agreement, Note by the Secretariat, MTN.GNG/NG7/W/13/Add.1, 10 August 1988, (2).

of restrictions that the WTO aims to have on importation of products. Also the principles of WTO i.e. the most favoured nation and National Treatment. Article 1 of the GATT deals with most favoured nation treatment.[38]

The restrictions imposed under most favoured nation are of the like duties, charges, formalities and rules. It's a trace towards the kind of restrictions that the GATT encompasses on importation of goods. MFN principle has several benefits like encourages international trade like minimising distortions in the market, allows nations to get goods from neighboring nations at a low price making it cost efficient.MFN basically aims at reducing trade distortions on the basis of origin of goods. MFN thus expects and encourages the importation of goods to take place in any economy.

CONCEPT OF NATIONAL TREATMENT

As a general matter, the principle of national treatment means that under a nation's laws, a foreigner enjoys no lesser rights and benefits than a citizen of that nation receives, subject to the specific terms of the relevant international conventions.[39] National treatment is basically a non- discrimination principle adopted into the international treaties mainly to combat the territorial nature of IP laws which can create differential treatment of persons of domestic and foreign

38 With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports, and with respect to the method of levying such duties and charges, and with respect to all rules and formalities in connection with importation and exportation, and with respect to all matters referred to in paragraphs 2 and 4 of Article III,* any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.

39 Manzoor Elahi Laskar and Narang, Chetan, *National treatment and efficient protection as adopted in IP treaties.*, (16 Aug, 2017http://ssrn.com/abstract=2410404.)

nationality.[40]National treatment provides for the complete assimilation of foreigners to nationals, without condition of reciprocity.[41] National treatment originated basically from trade agreements during the 1800's[42]. When it comes to the intellectual property regimes, the principle of national treatment was first adopted in the Berne and Paris conventions.

Later own the preamble of the Marrakesh Agreement establishing WTO and also GATT 1947, list the elimination of the discriminatory treatment in international trade relations as one of their goals.[43]Accordingly one of its main principles was national treatment principle which requires treatment of members' goods on a footing not inferior to the treatment granted to domestic goods. Thus the principle of national treatment got extended to even goods.

National treatment principle as enshrined in GATT

National treatment principle is enshrined in Article III of the GATT agreement[44] of the WTO agreements. The Article aims to provide equal treatment of goods of domestic and foreign origin.[45] For the same it mandates that taxes and laws and regulations etc. which affects the internal sale or sale or transportation etc. of a good shall not be applied differently to similar goods irrespective of domestic or foreign origin.[46]Within the context of GATT, National treatment principle

40 Ibid.

41 Paul Goldstein, International Intellectual Property Law : Cases and Materials, p. 12, (2008).

42 The principle of national treatment was laid down for the first time in Belgian-American Diplomacy Treaty of Commerce and Navigation concluded on November 10, 1845, under Article 1. National treatment derives its roots from the 'calvo doctrine' which was rule which prevailed in the Latin American countries which aimed to prevent discrimination between a country's own national with that of foreign national.

43 John H Jackson, *The Jurisorudence of GATT & THE WTO, Insights on treaty law and economic relations*, pg. 367-397, 2000.

44 National Treatment on Internal Taxation and Regulation, Article III of GATT agreement.

45 Article III of GATT.

46 Article III:1 :-The contracting parties recognize that internal taxes

requires that internal taxes, charges, laws and regulations must not be applied in a manner that treats imported products less favorably than domestic ones. the national treatment obligations of Article III of the General Agreement do not apply to foreign persons or firms but to imported products.[47] It aims at doing away discrimination of goods based on origin of products. Once imports into a member have cleared customs, they have to be treated no less favorably than like products originating in that member.[48] Therefore, even though national treatment principles are regarding internal regulations and not regarding border measures, differentiation based on territorial division is narrowed through national treatment principle.[49] While it is clear that measures could not be adopted against imported products so as to protect the domestic market of a product, even if right of importation is granted under the IP regime, this could not be used to ban parallel imports as it goes against the national treatment principle. This is because national treatment principle under WTO presupposes a right to import into any other country since free trade is advocated under the regime.[50]This implies that an exclusive right to import cannot be granted under any law to any goods to the extent that it can block the entry of any genuine goods produced abroad.[51] This

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and other internal charges, and *laws, regulations* and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products, and internal quantitative regulations requiring the mixture, processing or use of products in specified amounts or proportions, should not be applied to imported or domestic products *so as to afford protection to domestic production.*

47 Report of the GATT Panel *"Canada - Administration of the Foreign Investment Review Act"- 5.8, L/5504- 30 S/ 140- 1984.*

48 National treatment applies to goods which have been cleared by the customs to enter into the market of the importing country. Goods cannot be blocked under the border measure rule unless It is a prohibited category under WTO rules.

49 John H Jackson, *World Trade and the Law of GATT*, Lexis Law Pub, 1969.

50 Article XI of GATT,1994- No prohibitions on imports other than duties, taxes or other charges made effective through licenses or other measures shall be made on imports.

51 Import restrictions can be placed only in accordance with the provisions enumerated above which does not cover parallel imports.

forms the crux of the principle and thereby prima facie the practice of following different modes of exhaustion in different jurisdictions goes against the national treatment principle. In fact the compromise achieved between nations through the incorporation of Article 6 of TRIPs too is in violation of GATT principles.

Further Article III: 4 mandates for equal treatment of products of foreign origin imported into another territory[52] with that of like domestic product.[53] This implies that no discrimination shall be made on the ground of place of origin of goods. This provision, thus, is in direct conflict with the theories of national and regional exhaustion which in fact differentiates the goods based upon the origin of goods.

In Japan- Alcoholic Beverages case[54], the appellate body of WTO panel decided that the main purpose of Article III is to avoid protectionism.[55] Further in EC Asbestos case Panel held that "in endeavoring to ensure "equality of competitive conditions", the "general principle" in Article III seeks to prevent Members from applying internal taxes and regulations in a manner which affects the competitive relationship, in the market place, between the domestic and imported products

52 Import restrictions may be placed on goods of foreign origin only when :Article XI (2): Import prohibitions on the basis of not meeting standards or regulations, Article XII: Import restrictions to safeguard balance of payments,Article XVIII: - Governmental Assistance to Economic Development, Article XX: General Exceptions. None of these conditions is applicable for banning parallel imports. Article XX is the only provision which could be relied on for banning parallel imports about which will be dealt in detail in the following sections.

53 Article III:4 :- The *products* of the territory of any contracting party *imported* into the territory of any other contracting party shall be accorded *treatment no less favourable than that accorded to like products of national origin* in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use.

54 Appellate body report, *Japan - Taxes on Alcoholic Beverages, (WT/DS8, DS10, DS11),* October, 4,1996.

55 Appellate body report, *Japan - Taxes on Alcoholic Beverages, (Complaints by the European Communities, Canada, and the United States), para F(pg.16), (WT/DS8, DS10, DS11),* October, 4,1996.

involved , "so as to afford protection to domestic production."[56]It serves to protect the interests of producers and exporters established on the territory of any contracting party.[57]Therefore in order to attract Article III, there must be a law or regulation or requirement which affects the internal sale or offer for sale etc of the imported and domestic product, wherein the imported and domestic product are like products and the imported products are accorded less favorable treatment than the domestic product.[58] It is not in dispute whether the parallel imported goods are like products or not as they are the same kind of product. WTO panels have established that "when origin is the only factor distinguishing between imported and domestic products, there is no need to conduct a likeness analysis….In these cases, imported and domestic products may be considered to be alike under Article III: 4".[59] Therefore in the case of parallel imports too the only difference which exists would be based on the origin of goods, which cannot be a ground of differentiation under Article III: 4 of GATT and thus national and regional exhaustion cannot be sustained. Practically what national and regional exhaustion does is indirectly protecting the domestic industry by banning competing foreign products. This is exactly what national treatment principle tries to curb. The aim of the same is to prevent indirect protection of domestic production which countries may try to provide through internal mechanisms and to avoid protectionism and to ensure equality of competitive conditions between imported and domestic products.[60]The intention of the drafters of the Agreement

56 Appellate Body Report, *Measures Affecting Asbestos and Asbestos-Containing Products,by European Communities* – 98, WT/DS135/AB/R , April,5, 2001.

57 *GATT Report of the Panel,"Canada - Administration of the Foreign Investment Review Act"-, 6.5, L/5504- 30 S/ 140- February, 7, 1984.*

58 Robert E. Hudec, *GATT/WTO Constraints on National Regulation: Requiem for an "Aim and Effects" TestThe International Lawyer* , Vol. 32, No. 3, pp. 619-649, Symposium on the First Three Years of the WTO Dispute Settlement System (FALL 1998).

59 *Reports Of The Panel,* Argentina – *Measures Affecting The Importation Of Goods,6.274, WT/DS438/R , WT/DS444/R, WT/DS445/R*, August 22 2014.

60 ArtilclII:1 of GATT AGREEEMENT.

was clearly to treat the imported products in the same way as the like domestic products once they had been cleared through customs .[61] Otherwise indirect protection could be given.[62]

National treatment provisions are mainly invoked when a member's internal measure explicitly discriminates against products with regard to their origin.[63]Where a measure bans both the import and sale of a product, the whole measure should be examined under the scrutiny of national treatment.[64] The National treatment provisions also obligate the parties to create a competitive condition between domestic and foreign products within their national markets.[65] It was also noted that the rationale of the Article III and Article XI (free trade provision) of GATT are the same, namely to create a competitive condition between foreign and domestic products. Thus the GATT panel has clearly equated the national treatment provisions with that of free trade and thus making it a inseparable part of free trade. Thus, the national treatment provision covers only measures applied to imported products that are of the same nature as those applied to the domestic products, such as a prohibition on importation of a product which enforces at the border an internal sales prohibition applied to both imported and like domestic products.

In the case of parallel imports, by banning parallel imports the basic law and aims of the national treatment are completely destroyed. Parallel imports are foreign originated goods and are banned merely on that ground which goes against the national treatment principle of

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61 Clearance through customs is mandatory unless it falls under any of the express exceptions provided through GATT mechanism See *Suprafoot note* 14.

62 *GATT Report of the Panel, Italian Discrimination against Imported Agricultural Machinery", (Complainants United Kingdom),), 11, L/833 - 7S/60, October 23 1958* .

63 Article III of GATT agreement.

64 Appellate Body Report, *Measures Affecting Asbestos and Asbestos-Containing Products, by European Communities*– 31, WT/DS135/AB/R , April,5, 2001.

65 *GATT Report of the Panel, "United States - Taxes on Petroleum and Certain Imported Substances", 31 , (L/6175 - 34S/136), June 17, 1987.*

discrimination based on the origin of goods. The blockage of parallel trade hampers the foreign producers while protecting the domestic industry and thus kills the intra- band competition in the market. All these reasons point to the fact that only international exhaustion can co-exist with the principle of national treatment enshrined in the GATT philosophy.

CAN ANY POSSIBLE JUSTIFICATION BE MADE FOR NATIONAL OR REGIONAL EXHAUSTION?

The proponents of national exhaustion and regional exhaustion try to justify their stands by taking protection under Article XX (d) of GATT which provides for adoption of measures which might be against the national treatment principle. Article XX (d) provides for General exceptions to the GATT agreement. The provision states as follows: Article XX (d) : "*Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures…….*

(d) "necessary" to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trademarks and copyrights, and the prevention of deceptive practices."

Thus Article XX (d) of GATT provides an exception to all the obligations under GATT agreement enabling States to take import restrictive measures which are 'necessary' so as to secure compliance with laws or regulations which are not inconsistent with the other provisions of the agreement, including those of the Patents, trademarks and copyright. However such measures should not be such that they form disguised restrictions on international trade. The making of the

exceptions under Article XX created immense discussions among the member countries. Many opined that the exceptions could be misused for indirect protection which is undesirable. This provided for the formation of the words incorporated in the preamble- arbitrary or unjustifiable discrimination between countries or disguised restriction on international trade. Thus it forms the primary limitation upon application of the exceptions to the GATT agreement. The exception is important as it also forms an exception to the national treatment principle of the agreement and thus the application of the same should also be careful and sparingly applied i.e. when they are absolutely necessary. The provision also stresses the importance or supremacy of international trade over the exceptions provided and therefore any unnecessary restriction on free movement of goods.

The 1989 Panel Report on "United States - Section 337 of the Tariff Act of 1930"- panel held that in order for a measure to be "necessary" under the Article XX (d) certain conditions have to be met which are given as under :

(a) 'laws or regulations' with which compliance is being secured are themselves 'not inconsistent' with the General Agreement;

(b)measures are 'necessary to secure compliance' with those laws or regulations;

(c) measures are 'not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade' .The above limitations should be complied when a country adopts a measure invoking Article XX

(d). This makes it clear that for banning parallel imports through any measure under IP law, it must be shown that the measure is necessary for effective enforcement of the IP law and that the measure should not be an arbitrary or unjustifiable discrimination between countries or a disguised restriction on international trade. The Panel noted that each of these conditions must be met if an inconsistency

with another GATT provision is to be justified under Article XX(d). Further addition was made by another GATT panel whereby it was stated "Clearly, Article XX(d) is susceptible of application in respect of a wide variety of "laws and regulations" to be enforced. It seems to us that a treaty interpreter assessing a measure claimed to be necessary to secure compliance of a WTO consistent law or regulation may, in appropriate cases, take into account the relative importance of the common interests or values that the law or regulation to be enforced is intended to protect. The more vital or important those common interests or values are, the easier it would be to accept as "necessary" a measure designed as enforcement instrument."[66]

Thus various factors are necessary so as to make a measure under Article XX (d) a necessary and justifiable under Article XX (d) which includes the importance of the measure implementing the law, the social welfare encompassed by the law and its effect on imports and exports. It is important at this stage to analyse what is the implication of these exceptions under Article XX (d).

ANALYSIS OF LIMITATIONS ON ARTICLE XX (D)

(a) Disguised restriction on international trade: The measure adopted by the contracting party to the agreement in pursuance of Article XX (d) should not be such that it indirectly acts as an restriction on international trade. International trade is the order of international relations and economic rule of the era. Therefore any kind of restriction either direct or indirect is prohibited. Thus, applying IP law in a manner which in effect restricts trade cannot be upheld under Article XX (d). In the Panel report of EC- Asbestos case, the panel held that it must be examined whether a measure that formally meets the requirements of the Article XX is in fact designed to pursue a protectionist and trade-restrictive objective.[67] The 1983 Panel Report on "United States

66 Appellate Body Report, *KOREA – Measures Affecting Imports Of Fresh, Chilled And Frozen Beef,* 162, WT/DS161/12 WT/DS169/12, April 24 2001.

67 Appellate Body Report, Measures Affecting Asbestos and Asbestos-Containing Products, by European Communities – 172, WT/DS135/

- Imports of Certain Automotive Spring Assemblies" examined a ban on imports, under an exclusion order of the U.S. International Trade Commission, of certain automotive spring assemblies which the Commission had found under Section 337 of the Tariff Act of 1930 infringed United States patents. Even though the panel found that the measure adopted by U.S. to prohibit goods which infringe U.S. patents was not a disguised restriction on trade, panel found that the exclusion order would not prohibit the importation of automotive spring assemblies produced by any producer outside the United States who had a license from patentee to produce these goods. And it was on this ground the panel upheld the provision.[68]Panel thus clarifies that measures under Article XX (d) can be invoked to protect IP against infringed or counterfeit goods but not genuine products. The conclusion to be drawn from the above observation of the GATT panel is that is that the right of import recognised under any patent law could not be used to ban the genuine imports of legal goods. Thus the ambit of right to import recognised under U.S. law should be questioned.[69]Thus ban on parallel imports would amount to disguised restriction on international trade as they are produced legally outside the territory.

(b) Necessary to secure compliance with laws / protection of IP laws.

The measure adopted under the exception of Article XX (d) should be as to protect or enforce a national law. The measure adopted should be necessary in the absence of which the law cannot be properly enforced. In The 1983 Panel Report on "United States - Imports of Certain Automotive Spring Assemblies"- The Panel considered whether or not the exclusion order was applied in a manner which would constitute a disguised restriction on international trade. Measure against Patent

AB/R , April,5, 2001.

68 *GATT Report of the Panel, United States - Imports Of Certain Automotive Spring Assemblies,56, (L/5333 - 30S/107) May 26 1983.*

69 Similar decision was arrived in the recent U.S. case, *KIRTSAENG v. JOHN WILEY & SONS, INC. 568* U.S. (2013) wherein Supreme Court opined that the right to import conferred upon a copyright owner does not guarantee the right to block genuine goods made lawfully outside U.S.

infringement by people outside the country was a necessary measure to be adopted. The Panel further held that the exclusion orders under U.S. Trade Act was 'necessary' within the meaning of Article XX (d) since there was no other efficient alternative for the patent holder for a remedy. If any other least trade distortive method was available, then the measure would have been inconsistent within the GATT provisions.[70] This points out to the fact that the word necessary refers to a situation where there is no other means of method other than the measure adopted by the party which could justify the measure as covered under Article XX (d).However, one when an alternative method is available which will not disturb the international trade, then such least distortive method should be used. The 1989 Panel Report on "United States - Section 337 of the Tariff Act of 1930"- It was clear to the Panel that a contracting party cannot justify a measure inconsistent with another GATT provision as 'necessary' in terms of Article XX(d) if an alternative measure which it could reasonably be expected to employ and which is not inconsistent with other GATT provisions is available to it- the least trade restrictive trade measure should be adopted. [71]The panel further held that Patents were the few areas specifically mentioned in Article XX (d) of GATT which allows parties to take measures which ordinarily would be against the spirit of the agreement but necessary for the enforcement of the law.[72] However, it does mean that if a contracting party could reasonably secure that level of enforcement in a manner that is not inconsistent with other GATT provisions, it would be required to do so.[73]The panel further found that it is up to the contracting party seeking to justify measures under Article XX(d) to demonstrate that those measures

70 GATTReport of the Panel, *United States - Imports Of Certain Automotive Spring Assemblies, 55 , (L/5333 - 30S/107) May 26 1983.*

71 Report by the Panel, *United States - Section 337 of the Tariff Act of 1930*, 5.25-5.26, (L/6439 - 36S/345), 7 November 1989.

72 GATT Report of the Panel, *United States - Imports of Certain Automotive Spring Assemblies, 53, (L/5333 - 30S/107), May 26 1983.*

73 Ibid, para 52.

are 'necessary' within the meaning of that provision.[74]Article XX is a limited and conditional exception from obligations under other provisions of the General Agreement, and not a positive rule establishing obligations in itself.[75]

In the case of parallel imports, even in the Uruguay round the arguments against international exhaustion was that the same would lead to inflow of counterfeit goods into markets of the IP owner which destroys his market. When it comes to the IP scenario, it is clear from panel decision in U.S. Automotive Spring case that restriction on trade could be made only to fight counterfeit goods and not genuine goods. Even when that is the case, the least trade distortive method should be used. From the above analysis it is clear that the least trade distortive measure should be used to fight the counterfeit goods rather than banning genuine goods as a whole from other countries merely on the ground that it originated in another territory and that for the effective enforcement of IP laws banning parallel imports is not a necessary condition.

(c) Unjustifiable discrimination between countries : The last condition attached to the section is that it the measure adopted under Article XX should not be such that it is not applied uniformly to all the countries. In the 1982 Panel Report on "United States - Prohibition of Imports of Tuna and Tuna Products from Canada"- Panel found that prohibition of Tuna was not merely of that of Canada but also from many other countries such as Peru, Costa Rica and Mexico and for same reasons.[76] Therefore was not unjust discrimination. Similar dictum was found in The 1983 Panel Report on "United States - Imports of Certain Automotive Spring Assemblies"- Panel held that the exclusion order under Section 337 of Tariff Act was not directed

74 Ibid, para 58.

75 GATT Report of the Panel *"United States - Restrictions on Imports of Tuna", (complainants European Economic Communities) , DS29/R/1994* June 16 1994.

76 GATT Report of the Panel, *United States - Prohibition of Imports of Tuna and Tuna Products from Canada,* 4.8, (L/5198 - 29S/91), 22 February 1982.

merely against Canada but to all foreign sources which infringed U.S. patents.[77]This limitation negates the adoption of regional exhaustion. Even if banning parallel imports is justified, the ban must be equally applied by the nation to all the countries and cannot be applied differently to different countries. Under regional exhaustion one could entertain goods which are sold once in any of the region while does not permit to import from a nation outside the jurisdiction of the region even though they are similarly placed.

CONCLUSION

Thus it is clear from the above analysis that free trade through encouraging imports is what is enshrined in the WTO framework. The kinds of restrictions imposed on imports are not complete ban on imports but restrictions in the form of taxes and duties. Imports are banned only on the contexts of situations either favoring developing nations or in the cases of balance of payment cases which are of temporary in nature. From the analysis of the above said provisions in the WTO agreement, it is clear that WTO works on the comparative advantage theory of free trade and thus encourages maximum production of goods which could be cheaply produced locally for exportation and imports of those which are disadvantages for local production. Even though exceptional circumstances do provide for affecting these imports, restrictions like duties, taxes etc are favored rather than prohibitions on imports. Besides, preamble of TRIPs aims at desiring to reduce distortions and impediments to international trade and taking into account the need to effective protection of IPR and ensure that measures and procedures to enforce IPR do not themselves become barriers to legitimate trade. TRIPs is also subject to the basic principle of GATT 1994.[78]Also interpreting the national treatment provisions under GATT agreement, it is clear that following regional or national exhaustion will not be consistent with the same. National treatment, presupposing the importation right under WTO

77 *GATT Report of the Panel, United States - Imports Of Certain Automotive Spring Assemblies, 59, (L/5333 - 30S/107), May 26 1983.*

78 Preamble to TRIPs, 1994.

framework, imposes the nations to treat all genuine goods, foreign or national to be equal. Further the exceptions provided to national treatment and to the importation of gods too do not justify national or regional exhaustion. Thus banning imports of genuine goods merely for the reason that it originated in another territory goes against the basic notion of free trade under WTO. Thus from the analysis of WTO principles it could be safely concluded that, WTO principles favor international exhaustion.

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