



INTERNATIONAL LAW
JOURNAL

**WHITE BLACK
LEGAL LAW
JOURNAL**
**ISSN: 2581-
8503**

Peer - Reviewed & Refereed Journal

The Law Journal strives to provide a platform for discussion of International as well as National Developments in the Field of Law.

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WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal providededicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

PATENT AND DRUGS

AUTHORED BY - ATHIRA R KURUP & JANE EYRE MATHEW

ABSTRACT

The initial phase of the research involves providing a concise introduction to the topic. The historical overview of the Indian Patents Act, 1970 including the changes and reforms made in it from time to time as India has been opposing the patents act being extended to all the fields of technology. The then Prime Minister Mrs. Indira Gandhi declared India's policy. In Indian Patents Act highlighting the protection of patents pertaining to drugs and medicines. There is a shifting change that has been brought in Indian Patents Act in the matter of patents on drugs and medicines from time to time. The testing of all the hypotheses is done by utilization of various research tools analyzing various provisions that were included in the three amendments were brought to the Indian Patents Act in compliance to TRIPs Agreement. It also deals with the various farmers' rights under the Intellectual Property Regime. It also proposes to examine the issues relating to farmers' rights in the context of Intellectual Property Rights, in genetically engineered (GE) crops and seeds, for which patents are increasingly available and their impact on the rights of the farmers. The conclusion of the research with certain suggestions to be addressed with on the basis of forgoing chapters, we can clearly prove that patent law has no concern whatsoever towards the issue of human right to health as there are no sufficient provisions for addressing this issue except flexibilities, the law is silent as to the disclosure of expenditure on Research and Development including the cost of developing the drug is not made public, on the other hand companies and the patent holder take all the benefits of tax concessions under various sections of Income Tax Act such as creating intangible assets and depreciating in the profit and loss account, charging research and development charges as revenue expenditure or capitalizing them and then amortizing it from companies profits.

Following are the points discussed in this paper:-

1. Introduction
2. Agriculture and ipr
3. Ipr laws in india
4. The indian patents act on drugs and medicines

5. The impact of product patent regime on price of drugs and their accessibility
6. Farmers right under ipr
7. Conclusion and suggestion

INTRODUCTION

The innovations and new techniques have been made in the modern scientific world giving a better way to live with all modern equipment which has made life easier and enjoyable to live who have been gifted with riches of wealth which enables them to lead a peaceful and enjoyable life giving them opportunities to afford whatever they require at their will. The have and have not's are the facets of the same coin the former having their own means to enjoy and the latter having their own sufferings and have to lead the life at the mercy of others and almighty God. India being a country which is rich with full of unutilized resources and the majority of the people are poor, illiterates and live with starvation due to unemployment and great dependence on daily wages and agriculture. Most of the people live in villages without much facility of road, communication, pure drinking water, shortage of electric power and lack of awareness as to the health and hygiene. This has led to the conditions that no appropriate means are available for them to even consult a doctor nearby even if they do so is with the registered medical practitioner (RMP) who is not so well versed in medical science. This has caused untimely death of poor people to worsen their life's causing another blow to their struggled living. It has been observed that many poor people are afraid of consulting a doctor for the purpose of diagnosis and prevention of the disease the only reason to such an attitude is the heavy cost involved in the process of diagnosis such as tests, CT scan, etc. There is also negligence on the part of the rural community not taking proper care towards their health. No proper care is taken for pregnant women and their child's growth due to lack of awareness and medical facilities many new born children suffer with ill health and ailment due to malnutrition, poor quality of food, water and living conditions in additions to the building pressures on the growing population with rapid pace. At the same time the modern technologies have made the world smaller in terms of space, time, distance and communications in urban areas by means of internet, mobiles, satellites, transport etc., which has led to globalization and liberalization of trade. India being a growing and developing country cannot restrain itself from being a member to the GATT/WTO which gave acceptance to the agreements to keep it with pace to other nations to facilitate trade, investments, transfer of technology etc. Hence, it was obligatory to the member nations to follow the norms of the agreements as a condition of membership in World Trade Organization (WTO) and the members not accepting the plurilateral

Agreements are not entitled to any of the rights emanating there from these rights¹. One of the important agreements of GATT/WTO was on protection of intellectual property rights (IPRs) namely the Trade Related Aspects of Intellectual Property (TRIPs) Agreement is the major concerns for the developing and under developed nations as there are harmful consequences in terms of certain issues such as patents, utilization of biodiversity, protection of the poor farmers and rural community. This was done by the developed countries under the threat of sanctions against the opposing country. The central importance was given to the economic development by means of contributing knowledge to the process of production by adopting modern technology sidelining the interests of the developing countries. The management of knowledge in IPR has become a very crucial issue, its adaptability and applications to the needs and requirements both at the national and international level satisfying the national interest and complying the WTO agreement was a difficult task. The TRIPs agreement facilitated trade by the mechanism of creating multilateral agreements on IPR which includes patents, trademarks, copyrights, geographical indications, industrial designs, layout designs and integrated circuits, trade secrets, breeder's right and utility models. The industrialized nations choose to reward innovators by giving exclusive right to use and market the product for a particular period in terms of patent rights, including the recognition of product patents to encourage further innovations in the field of science. Since the inception of TRIPs Agreement many developing countries have accepted the agreement and have brought the IPR laws to suit their own needs and all the developing countries were given transitional period to bring their laws at par with TRIPs agreement by bringing suitable amendments at the exit of the said transitional period. The last decade has witnessed a virtual revolution in protecting and enforcing of IPR laws in this part of the world. Almost all developing countries and underdeveloped countries have either replaced or substantially changed their IPR laws. Hence, India also in consonance with TRIPs has made amendments to its IPR laws especially the Patents Law in the year 1999, 2002 and 2005². Under the obligations of the TRIPs agreement which provides for patenting of inventions relating to pharmaceutical drugs including process and product patents a decision required for the countries to grant product patent for pharmaceutical innovations as a condition of membership in the WTO was very contentious. Almost 50 developing countries were not granting patent monopolies for drugs during the transition period when the Uruguay Round

¹ Agreement of WTO came into force on January 1, 1995-WTO in the New Millennium, edited by Arun Goyal, Noor Mohammad, 5th Edition, September 2001, Published by the Academy of Business Studies, New Delhi, p. 22.

² Amendments to the Indian Patents Act 2005, recognized for the first time the Product Patents in the field of Pharmaceutical Products, Drugs, Medicines and Food products including Chemicals - Universal's Bare Act on Patents.

of GATT was being debated these countries fiercely resisted the inclusion of this requirement claiming that drug prices would be higher which are associated with such patents. On the other side business interest in the west urged them to consider the beneficial effects of protecting innovations in pharmaceuticals would bring great fruits in Foreign Direct Investments (FDIs) in local research on Tropical diseases. Hence patents on pharmaceutical products and processes provide drug companies with monopolies over the production and marketing of the medicines, allowing them to fix prices at high rates to maximize profits³. The TRIPs Agreement under the WTO has come under criticism for facilitating the extension of these patent rights around the world. The obligation under TRIPs to implement high standards of IPR protection in recognizing product and process patent will effectively eliminate competition from generic pharmaceutical producers and allow for increased prices of medicines beyond the reach of more patients in the developing countries. Although developing countries succeeded in getting the WTO Ministerial Conference to issue a landmark declaration by stating that public health should take.

Agriculture and IPR

Agriculture plays a key role in India's economy from the point of view of employment generation as well for its share in GDP. Agriculture engages nearly 70 per cent of the population and it is a principal contributor to India's economic output. It was worth Rupees 2,925 billion (US\$ 61 billion) in 2002, accounting for nearly 25% of India's GDP (at constant prices basis 1993-94). This sector is vast in its coverage, consisting of food grains/ cereals, fruits, vegetables and several other commercial crops like oilseeds, cotton, rubber, spices, sugar cane, jute and tobacco. While India is a dominant producer of agricultural commodities, Indian productivity in almost all crops is far behind the world averages. There are two main cropping seasons: generally, crops harvested from July to December are known as Kharif crops and those harvested from January to June are Rabi crops⁴. A recent economic survey expressed concern on the decline in the share of the agricultural sector's role in capital formation in GDP.

In the present era of liberalization, globalization and fast paced information technology, intellectual property rights have emerged as a new global phenomenon. An efficient and effective IPR regime is one which balances individual incentives and benefits with the wider needs of the society, while, IPRs

³ Cecilia oh, TRIPs, Patents and Access to Medicines, With Third World, Briefing Paper, June 2001, discussed at a meeting hosted by the Indonesian Mission, P.1

⁴ Government of India, 'Indebtedness of Farmer Households' Report No. 498 May 2005

are a well-established institution in the manufacturing sector, their application to agriculture is still in a state of evolution. The key issue in the agricultural sector is, quite simply, that some agricultural innovations are imperfectly appropriable. This imperfect appropriability may reduce innovators' incentive to invest in the improvement of such crops.

Several forms of IPRs employed in the sector of agriculture attempts to address this issue. Here it is relevant to mention the prevalent legal mechanisms including patents, plant varieties protection, trademarks, trade secrecy rights and plant breeders' rights.

India is among the first countries in the world to have passed legislation granting farmers' rights in the form of the Plant Varieties Protection and Farmers' Rights Act, 2001 (PVPFR). India's law is unique in that it simultaneously aims to protect both farmers' and breeders' rights. The Indian case assumes immense importance due to the country's lead in establishing a legal framework on Farmers' Rights and also significant as the Indian Gene Centre is recognized for its native wealth of plant genetic resources.⁵

The Plant Varieties Protection and Farmers' Rights Act, 2001, establishes a unique system by extending the concept of Plant Breeders Rights (PBRs), which is currently applied to new varieties of plants, held by farmers, NGOs and public sector institutions.⁵ The law emerged from a process that attempts to incorporate the interests of various stakeholders, including private sector breeders, public sector institutions, non-governmental organizations and farmers, within the property rights framework. While the Act is based on the important principle of distributing ownership rights in a fair and equitable manner, assigning of multiple rights could pose several obstacles to useful utilization and exchange of resources.

This study attempts to evaluate the potential implications of India's Plant Varieties and Farmers' Rights Act on stakeholder's access to genetic resources. The study focuses on two aspects: **firstly**, the scope of India's legislation as an attempt to satisfy various interests, and **secondly**, the possible implications of this process on utilization and the flow of resources among stakeholders. As the law is implemented recently and many aspects are subject to interpretation, the study is an exploration of possible outcomes. The potential implications of the Indian law has global significance, as many

⁵ Anitha Ramanna, Farmers' Rights in India - A case study, FNI Report 2006, Norway, p.vii.

developing countries are in the process of evolving similar legislations.

Innovation in the field of agriculture has been important to human civilization since farmers first began to cultivate crops. Increasing crop yields has long been the goal of agricultural research and development (R&D). Two recent trends in agricultural R&D are rather important to understand the ongoing debates concerning the scope of plant variety protection. The first is the biotechnology revolution brought about by the advances in genetic engineering. This new technology makes possible comparative rapid development of new plant varieties with larger yield and disease-resistance characteristics that might substantially relieve pressures on the world food supply. IP is often closely interlinked with social questions, and that IP issues must be considered in their social context.

In recent years IPRs are obtained by western scientists and corporations on traditionally used biological resources such as Neem, Turmeric and Basmati rice. This has made people aware of the threat and injustice to biological resources and related traditional knowledge coming under the control of private monopolies, preventing the legitimate use of those resources by others. There is also concern that existing IPRs fail to provide positive incentives to local and indigenous communities to preserve and to capitalize on their traditional knowledge. It is clear that patents are largely inappropriate to protect traditional knowledge. The assertion of IPRs and the resulting private monopolies over biological resources and related traditional knowledge have direct implications on the biological diversity, agriculture, food security, the protection of traditional knowledge and the rights of traditional communities such as farmers and forest dwellers.

IPR LAWS IN INDIA

India being a member of the various international conventions and agreements is bound to enact/amend relevant domestic laws to gear up and face the challenges of globalization. The IPRs related laws in India are undergoing changes in order to conform to the stipulations in the TRIPS Agreement.

Patent Act of 1970 is one of the important milestones in the history of IPR laws in India. The government brought amendments to the Patent Act in 1999, 2002 and 2005. The main changes brought through the amendments do not substantially affect traditional knowledge, farmers' rights and biodiversity. There are also few provisions, which attempt to reduce biopiracy. For instance, the scope of an 'invention' has been broadened to cover all aspects of new scientific creations. However,

new uses of known substances, including the duplication of traditional knowledge have been specifically excluded from patentability. In addition, the nondisclosure of the source of geographical origin of a traditionally known material has been made a basis for the challenge of a patent. The food sector in India is also facing new challenges in the new patent regime. Different processes and products will become patentable.

The Biological Diversity Act, 2002 was adopted following India's ratification of the Biodiversity Convention (CBD). It aims to conserve biodiversity, sustainable use of biological resources and equitable sharing of benefits that arise from their use or traditional knowledge. It mandates the setting up of institutions at national, state and local levels, for the purpose of regulation of biological diversity.

For access and transfer of biodiversity data, foreigners and commercial establishments have to take permission from the national body, while the local body will conserve and document biodiversity and related traditional knowledge. Pregrant of all related IPRs has to be routed through the national body. The Act attempts to regulate access to biodiversity for commercial purposes, to fight biopiracy, and recognise community rights over traditional knowledge and biodiversity. However, it does not authorize local community, the actual owners, to decide on granting IPRs to others or sharing benefits, since all powers are vested with the national body. The Act having no clear position on IPRs is particularly unfortunate, especially when IPRs on biological materials are the single most vexed issue in the overall IPR debate today. Therefore, the legislation is not that participatory.

Plant Varieties Protection and Farmers Rights (PVPFR) Act, 2001 was enacted under the obligations set out in Article 27.3(b) of the Agreement on Trade Related Intellectual Property Rights (TRIPS) which mandates the protection of plant varieties either by patents or by an effective sui generis system or a combination of both. The Indian legislation on Plant Varieties Protection (PVP) is being perceived as a progressive legislation when compared to the PVP Acts adopted by the other developing nations. The PVPFR Act of India, in addition to offering protection to plant breeders in the form of plant breeders rights, also protects the rights of the farmers to save, use, sow, re-sow, exchange, share or sell farm produce including the seeds of any unprotected variety, with an exemption to prevent the sale of branded seeds. This law incorporates some principles of the Convention on Biological Diversity (CBD) like prior informed consent and sharing of benefits with farmers. However, the Act is heavily weighted in favour of breeders. The benefit sharing clauses in the Act are highly convoluted.

The Geographical Indications of Goods (Registration and Protection) Act, 1999 was enacted as a sui

generis system, post Basmati rice case (1997) in which India challenged the patent granted to the American Company Rice Tec, on its claim of producing basmati rice grains.⁶ The Act was brought in to protect the unauthorized use of geographical indications and the rules of origin with respect to agricultural goods, which bear Indian names. The name, Mysore Silk has been recently provided with protection under this Act. Thus, even domestic silk manufacturers from any region, other than the designated one, are legally prevented from using the protected name for their product.

The Seeds Bill, 2004 was proposed as a replacement for the existing Seeds Act, 1966. The stated objective of the proposed law is to regulate the seed market and ensure seeds of "quality". With the proposed changes, the seed law would be harmonized with other seed laws around the world and ensure that the Indian seed market is open to big business. The rationale for a new Act can be traced back to the relatively rapid changes that are taking place in the seed sector in the past couple of decades. These include in particular the growing role of private seed companies and the progressive introduction of transgenic seeds. It was enacted to confirm stipulations in the TRIPS Agreement which authorized the seed growers to get their seeds patented and the farmers will not be allowed to exchange their seeds without patents. The provisions of this Act are really a cause of concern.

These legislative instruments, as a whole make up the IPR regime for the use of biological resources and related knowledge. The government's response through these Acts is to harmonize IPRs and sovereign rights in the field of biological resources.

The Indian Patents Act on Drugs and Medicines

In Indian Patents Act highlighting the protection of patents pertaining to drugs and medicines. There is a shifting change that has been brought in Indian Patents Act in the matter of patents on drugs and medicines from time to time. The Patents Act, 1911 which was a British legislation modeled on English law introduced product patents in the field of drugs and medicines. The Patents Act of 1970 specifically prohibited product patents on "substances intended for use, or capable of being used as food or as medicine or drug" or "relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds)", while allowing the processes for the making of such substances to be patentable for a short period of between 5 to 7 years. The terms of all other types of patents (for e.g., mechanical devices) were 14 years from the date of the patent. In shaping its first indigenous patents regime, India made a deliberate choice to stimulate domestic manufacturing and reduce the prices of products deemed "essential", such as food and medicines.

India led the opposition to the inclusion of patent and intellectual property rights in a GATT accord. India and other developing countries viewed the GATT framework as a tool by which wealthy nations would impose strong IPRs as the cost of much needed access for the developing world to western markets. Members may, of course, choose to give effect to the rules of the TRIPs Agreement by the adoption of national legislation or administrative rules that specifically implement its provisions. However, not all legal systems require that the rules of treaties (or international agreements) be transformed into national law by the adoption of specific legislation. In some national legal systems, the constitution provides that treaties may be given “direct effect” by the regulatory authorities and courts by 1989; India had reversed its anti-TRIPs stance and agreed to serious negotiations over patent protection, while arguing for special provisions to be made within the framework of TRIPs for developing countries. Upon its signing the Uruguay Agreement along with 116 other countries in 1994; India became a member of the WTO from January 1, 1995 and became obligated to amend its domestic IP laws.

India was given ten years to implement its new laws.

TRIPs Agreement provided some transitional arrangements to developing country Members. Though the provisions of the Agreements are expected to be in force by 1st January 1996, developing countries which had process patent regimes were given time, if they wanted, to extend the period for further four years, i.e., till 1st January 2000. However, the Agreement required these Members to make provisions for receiving patent applications under Art 70.8 for developing countries which are obliged to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of the Agreement, i.e., 1st January 1996, could delay the application of the provisions for an additional period of five years, i.e., till 1st January 2005. India was having process patent regime in pharmaceuticals and agro-chemicals and had the time till 1st January 2005 to extend product patent rights in pharmaceuticals and agro-chemical products, though in other areas it had to meet its obligations by 1st January 2000.

India complied with its obligations under the TRIPs Agreement in three steps. The first step was the Patents (Amendment) Act of 1999, which provided for receiving of patent applications (mail-box applications) and for exclusive marketing rights. The Patents (Amendment) Act 2002 introduced comprehensive amendments to bring together various provisions of the Patents Act, 1970 into conformity with the TRIPs Agreement. The Patents (Amendment) Act, 2005 brought full-fledged compliance of the TRIPs Agreement by introducing product patent regime for the fields of food, medicines and chemicals.

Making Patent law with compliance to TRIPs Agreement had its own shortcomings hence Analysis of the amendment made with respect to third amendment granting patents on pharmaceutical products and types of components and compound that can be patented under different drugs and medicines are made. The important concern related to the introduction of product patent protection is the patenting of known substances. Various aspects of how often pharmaceutical companies misuse the patent protection to seek patents on known substances claiming incremental modifications as inventions the third amendment also introduced two more definitions, with an objective of limiting the scope of patent protection with special reference to Section 3 of the Patents Act which excludes 16 categories of inventions from patent protection, because they are not considered inventions within the definition of invention.

The Impact of Product Patent Regime on Prices of Drugs and their accessibility

This is the core of the research in which the testing of all the hypotheses is done by utilization of various research tools analyzing various provisions that were included in the three amendments were brought to the Indian Patents Act in compliance to TRIPs Agreement. The various aspects has been made as to the provisions of Article 27 to 31 inclusively so as to how exceptions can be utilized without infringing the patent rights and various stipulations are gone through so as to reveal whether in reality they work. The patent laws extending to pharmaceutical products have been analyzed taking into account the prices of various products that are currently in the market, The drugs are prescribed and their effect on affordability is made by making comparative tables making it easy to form a conclusion on the price effect and accessibility to life saving drugs.

The government's ability as to the utilization of various exceptions that are present in the Indian Patents Act to regulate the effect of prices on affordability, various steps have been taken by the government for free supply of medicines to the needy people and how the policy in respect of health is lacking in meeting the needs of the peoples demand is looked into to make a conclusion and bring out the deficiencies these policy suffer and lastly an analysis as to the remedy that are available under the Indian Constitution and relevant laws and policies are analyzed to seek whether the provisions under various laws and policies suffice to meet the needs of the people so as to enforce the "Right to Health" as of right and not as charity. Various provisions are interpreted taking into account the case laws to effectively analyze the current position that India is forced to pose to minimize the harmful consequences of the patent especially in health and pharmaceutical sectors.

Farmers' Rights under Intellectual Property Regime and PVP and FR Act, 2001

This deals with the various farmers' rights under the Intellectual Property Regime. This examines the issues relating to farmers' rights in the context of Intellectual Property Rights, in genetically engineered (GE) crops and seeds, for which patents are increasingly available and their impact on the rights of the farmers.

The concept of farmers' rights is basically contradictory to the principles of intellectual property.⁶ Intellectual property rights are intended to provide incentive for a limited period as a reward for the innovation. Farmers' right is a retrospective reward of unlimited duration for the conservation of plant genetic resources⁷. The rights provide reward for the innovations done on the field. The Keystone International Dialogue on Plant Genetic Resources between 1988 and 1991 offered suggestions for developing a recognition and reward system for informal innovation represented by the concept of farmers' right. Farmers' rights are the countervailing force to breeders' right and patents on seeds and plants. The knowledge and rights of local community has to be strengthened in order to conserve our biodiversity. The concept of farmers' right had its origin in the FAO International Undertaking on Plant Genetic Resources. The Resolution defines farmers' rights as "rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources, particularly those in centers of genetic diversity. These rights are vested in the international community as trustees for present and future generations." Innovation by farmers began from the time of settled agriculture. Though the process of innovation by the farmer may not conform to the strict terms of the distinctness, stability and uniformity requirement, they also have definite criteria to identify improved varieties they develop. But these innovations are rarely recognized. Farmers do not breed in ideal laboratory conditions, but on actual knowledge of the environmental conditions through natural selection and continuous evolving process. Indian farmers have evolved many varieties that are resistant to salt, flood, drought etc. If the breeders who develop a new variety from the existing genetic resources have a right of ownership and control by virtue of labouring to develop the new variety, the farmers also have a right for identifying, conserving and developing the traditional variety. It is the farmer who has safeguarded the tremendous biodiversity that breeders and

⁶ Suman Sahai, 2003, India's Plant Variety Protection and Farmers' Rights Act, 2001, Current Science Vol. 84, No. 3, Feb. 2003, p. 407.

⁷ Vandana Shiva, CED Documentation prepared for Bangalore Seminar on Women, Ecology and Health, 1991 and Sacred Seed, (2014) Global Peace Initiative of Women (GPIW) Editor, Daradhun. ⁷ Elizabeth Verkey, 'Law of Plant Varieties Protection' 2007, Eastern Book Company, Lucknow, pp. 171, 197, 204.

seed industries use as raw material. There have been various efforts at the international level for recognizing the contribution of the farmers.

Conclusions and Suggestions

The seventh chapter concludes the research with certain suggestions to be addressed with on the basis of forgoing chapters, we can clearly prove that patent law has no concern whatsoever towards the issue of human right to health as there are no sufficient provisions for addressing this issue except flexibilities, the law is silent as to the disclosure of expenditure on Research and Development including the cost of developing the drug is not made public, on the other hand companies and the patent holder take all the benefits of tax concessions under various sections of Income Tax Act such as creating intangible assets and depreciating in the profit and loss account, charging research and development charges as revenue expenditure or capitalizing them and then amortizing it from companies profits. The price of the patented drug is arbitrarily fixed without taking into account the cost of production. Companies have no obligations such as corporate social responsibility towards the poor sections of the society as no patented medicine is supplied to meet the demands of rural masses due to patent act the life saving medicines prices have shoot up exorbitantly to which access is possible only to rich class persons along with this a surprising fact is that even in district level places many of the patented medicines are not available in the market this is due to the reason that there are no proper cancer hospitals, diabetes specialty clinics, palliative care centers, and some of the tests for diagnosis are sent to metropolitan cities. Some treatments like chemotherapy, radiations are not available at the district centers. Surprisingly many of the government hospitals supply the medicines for communicable diseases and there is inadequate supply of medicines for diabetes. Blood pressure, nephropathy, neuropathy, anti-venom injections for snake bite, hemophilia etc.

From this it can be clearly made out that there is a conflict between patent rights and protection of public health and this has a negative impact on the country's public health policy. The patent flexibilities that exist within the patent act are not utilized properly because of the stipulations that are put forth for this purpose.

The sufferers right to have access to life saving drugs under Article 21 of the Indian Constitution which includes Right to health is not properly implemented as was required by a country like India being a welfare country it is expected that it protects the interest of its people upholding the largest democratic interest for the welfare of its people. Because of the reason that Right to Health is not enforced efficiently as a right as it is the discretion on the part of the government to provide health

care facilities either at central or state level to protect and provide the facilities for access to medicines in spite of having various Supreme Court judgments, which have upheld the Right to Health but due to government policy this right to health is inefficiently implemented without taking into account the needs of the people.

REFERNCE

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