IMPACT OF INDIAN PATENT REGIME & PRICING POLICY ON PHARMACEUTICAL SECTOR IN INDIA

BY

SAKSHATBANSAL

ID NO. 694

UNDER THE GUIDANCE OF

PROF. (DR.) T. RAMAKRISHNA

THESIS SUBMITTED IN CONFORMITY WITH THE REQUIREMENTS FOR THE DEGREE OF LL.M.

NATIONAL LAW SCHOOL OF INDIA UNIVERSITY, BANGALORE

ACKNOWLEDGEMENT

Writing a thesis with precision and in a meticulous manner poses a diverse range of challenges. This work is a sincere endeavor from my side which has got the present form as a result of the contribution given and support extended by my well-wishers. Firstly, I thank God, without whose grace, the goal of completing this thesis could not have been converted to the accomplishment in the present form.

My first obligation to express my gratitude towards the mortals has to start with expressing a deep sense of gratitude towards Prof. Dr. T. Ramakrishna, who guided me in every possible form. I am also grateful to my parents for supporting me and boosting my confidence every single time, I was in need of it. I am also thankful to my Sister and Brother in Law for helping me in the non-doctrinal part of this research work.

I am also thankful to Dr. Asha Jain, Dr. Gaurav, Dr. Uma, Dr. Vaibhav, Dr. Shishir and all the Chemists and Medical Representatives for the insightful discussions which helped me to get well acquainted with technical jargons and industry specific terminologies. I am also indebted towards Mr. Vivek and Sadhavi Mam(CIPRA, NLSIU) for their valuable suggestions. I thank Mr. Aditya Jain for helping me with chemistry and molecular arrangements of the drugs, which helped me immensely in understanding the concept of efficacy.

WITH PROFOUND GRATITUDE

SAKSHAT BANSAL

CERTIFICATE

This is to certify that this dissertation titled "IMPACT OF INDIAN PATENT REGIME AND PRICING POLICY ON PHARMACEUTICAL SECTOR IN INDIA", submitted by Sakshat Bansal(LL.M. Id no.694) as part of the degree of Master of Laws(Business Law) for the session 2015-2016 of National Law School of India University, Bangalore is the product of bona-fide research carried out under my supervision and guidance. This dissertation has not been submitted elsewhere for any degree.

Date: 28 · 5 · 2016

Place: Bangalore

Prof. Dr. T. Ramakrishna

(Dissertation Guide)

DECLARATION

I, Sakshat Bansal, a sincere student of LL.M. (2015-2016) of N.L.S.I.U., Bangalore, hereby declare that the research work titled "IMPACT OF INDIAN PATENT REGIME AND PRICING POLICY ON PHARMACEUTICAL SECTOR IN INDIA" is submitted by me as per the requirement for the degree of Master of Law in Business Laws. This work is an original and independent work done by me under the supervision and guidance of Prof. (Dr.) T. Ramakrishna.

I assert that the statements made and the conclusion drawn is the outcome of the said research work is my intellectual property. I declare that it is to the best of my knowledge and belief that the dissertation does not contain any part of any work that has been submitted for the award of any other degree in this university or any other university.

Place: Bangalore

Date: 28-May-2016

Sakshat Bansal

SAKSHAT BANSAL

ID No.694

LL.M. (Business Laws)

TABLE OF CONTENTS

CH. 1 INTRODUCTION TO THESIS

India is considered as the lifeline of patients for the patients in many countries all across the globe, especially the developing countries and poor countries. The Indian generic drugs are not only vital for patients in India but also in many countries with low income status of their citizens and the related problems with bearing out of pocket expenditure. Millions of people are dependent on the generic medicines provided by India which are comparatively much affordable that might disappear in case the strict parameters stipulated in Indian Law are diluted. This research work is a sincere endeavour that deliberates on strategies having the potent to ensure the availability of drugs at affordable prices along with the necessary incentives for the pharmaceutical sector so that they can invest in R&D activities.

> *"Indian pharmaceutical industry is by far the largest in the developing world and by volume it is the third largest and India exports to about 200 countries. India makes almost the entire range of the medicines including the essential medicines."*
>
> (Dr. Amit Sengupta, People's health movement)

> *About 10 million people in the developing countries are having access to generic drugs out of which 80% is coming from India which shows our Government's commitment towards health.*
>
> (Loon Gangte, Registered Coordinator, ITPC-south Asia and DNP)

In the present scenario, it is as clear as day light the Indian Government has a positive duty which calls for the intervention of the state to devise certain strategies having the potent to help the citizens of India with the most basic need, i.e. health. Pricing Policy is one such act that is sine qua non for the

affordability drive. The following points show the need of a putting price limits to the drugs.

I. India's substantial section of population falls under low income groups; it is important to note that around 21% of the world's poor are in India.
II. Indian citizens are more prone to diseases like malaria, dengue, diarrohea, due to the tropical climate.
III. In the light of the previous researches, it is a known fact that out of the total out of pocket expenditure, a substantial portion goes towards the health issues, which is 80%in some cases. "A large part of the money that the poor in India spend on healthcare goes to buy medicines, and this itself is the cause of 2.2 per cent of families going below the poverty line every year while combating medical emergencies, even though medicines in India are among the cheapest in the world."[1]
IV. India has highest number of people that falls under the working age group and stands next to China in this regard. Therefore, it is imperative to ensure that India has a healthy population which is also important for the economic growth of the nation as it adds to the GDP of the nation. Apart from the strategies in the Patent Act with regards to the sustained healthcare, Government's regulatory control on the prices is also an important one.

Apart from being affluent in the agriculture India is also known for abundance of natural herbs which is used for natural medication. In the light of previous researches it is very clear that the substantial portion of India's population along

1<http://www.business-standard.com/article/opinion/price-control-problems-114102701332_1.html>(visited 10 March 2016)

with many other countries is dependent on this traditional knowledge. In the recent past the infamous incidents of bio piracy heralded the wave of deliberations on the adverse impact on the indigenous communities and also on the easy availability of medicine to the mankind in general.

1.1 Statement Of The Problem

Intellectual Property Rights regime is primarily based on the notion of rewarding the innovators for the mental decision to come up with a work of creativity along with the labor and toil required to fructify the work. Patents in particular are granted as a form of acknowledgement given to the ingenuity exhibited in the form of invention, which satisfies the strict parameters enshrined under Indian Patent Act and TRIPS. It is worth mentioning that grant of patent facilitates, nay paves the way for making money through exclusivity. This research work is in the context of Patents vis-à-vis Pharmaceutical Companies and hence conferring exclusivity on patent holder or his assignee in absolute sense seems to have the potent of having serious repercussions on the aspect of accessibility to medicine. It is in the light of myriad of health right issues, that an amendment was introduced in the year 2005, as member nations of WTO can devise TRIPS+ provisions as the situation warrants.

It is axiomatic that health issues needs to be given utmost importance but at the same time the fact that pharmaceutical companies incur huge expenditures in Research and Development and even then the possibility of not getting patent in numerous cases, is also worth considering. It has also been seen in many nations where concerns have been raised on the point of accessibility and affordability of medicine due to the steep prices of medicines. The present research work, the researcher intends to research on the following issues:

(1)- Section 3(D) of Indian Patents Act 1970 and strict parameters for granting patent.

(2)-Regulation of Prices of Drugs and Issue of Parallel Imports

(3)- Traditional knowledge and India patent regime.

1.2 HYPOTHESIS

ISSUE 1

India's Patent regime exhibits in clear terms that endeavors to have consistency with western legal framework cannot be done by compromising the principles of equality and social justice, enshrined in the Preamble to the Constitution of India. India being a party to a plethora of human rights instruments has evidently incorporated the core of human rights in its IP framework. Taking into account the aspirations and needs of numerous patients dependent on the generic drugs manufactured by India, Novartis judgment appears to be a praiseworthy effort of the Supreme Court, where 'basic survival needs for human' has been viewed and considered as the key feature and hence any claim for grants of patent needs to satisfy the essential requirements of Section 3(d), so that generic drugs are not kept out of the common stock due to ever-greening, which becomes even more important in the light of India's unique socio-economic ethos and also the fact that several nations depend on India for getting cheaper drugs in the form of generic drugs.

ISSUE 2

The current pricing policy needs a revisit so as to achieve a balance between the need of access to medicine and sustainable model for pharmaceutical companies. At this juncture researcher is of the opinion that there are some

escape routes which can be devised by the pharmaceutical companies having the potent to give a blow on the very objective of NPPA. Also, there is a need of holistic approach as by merely putting reliance on the Pricing Policy, desired results might not be achieved..

ISSUE 3

TRIPS provisions with premium on development aspect, in particular Article 8 is a a\hortatory provision and it becomes highly imperative for a particular nation to come up with a an effective model so as to achieve the objectives enshrined under CBD and Nagoya Protocol. Also strict parameters need to be laid down in the patent regime so as to ensure that mere tinkering with the generic resources vis-a vis traditional knowledge does not qualify for patent protection.

1.3 RESEARCH QUESTIONS

1- *Whether section 3(d) of Indian patent act and Novartis Judgment are products of myopic contemplation which in their implantation bypasses the mandate of TRIPS?*

2- *Whether the present Pricing Policy of India with reference to pharmaceuticals, has the potent of striking a reasonable balance patient and patent?*

3- *Whether the scheme of Indian Patent Act 1970 provides an effective solution to the problem of Bio- piracy with reference to genetic or biological resources of country of origin or the traditional knowledge of its indigenous communities?*

1.4 Scope of Study and Limitations

Issue 1

In particular, researcher wants to deliberate on the point that whether provisions of TRIPS indicating towards development dimension are more of rhetoric and hortatory provisions leaving it to the discretion of the member nations to devise TRIPS + provisions so to ensure that the aspect of accessibility to medicine is taken care of?

The researcher intends to explore the conflict that exists between Section 3(d) of the Indian Patent Act, 1970 which keeps "mere increments" out of the ambit of from patent protection, and pharmaceutical companies putting premium on its recognition.

Issue 2

Researcher intends to deliberate on the point of need to strike a balance between accessibility to medicine and conducive environment for pharmaceutical companies to invest in the pipeline so that they are able to invest into bring new molecules into the market., which seems to be a herculean task in the absence of reasonable margin. Hence, threshold of reasonable margin needs to be asses and Indian market dynamics and share in the overall profits of a company needs to be considered. The researcher also intends to put premium on the repercussions of the present policy and hence the analysis of the market scenario holds utmost importance in this regard.

ISSUE 3

The Patent Act 1970- as Amended in 2002 and 2005, encompasses under its domain several provisions such as Sections 3(e)[2], 3(p)[3], 10(d)[4], 25[5]
Researcher intends to deliberate on the model adopted by India by including the above mentioned provisions in its Patent Act. Researcher intends to delve deep into the details of the question that whether these provisions have the potent of addressing the concerns raised by the scholars on the lack of any binding provisions in TRIPS

(1) to safeguard the interests of traditional communities and their special claims
(2) to ensure that mere tinkering with the genetic resources in the present form(which is the result of sincere endeavors of traditional communities in observing the natural milieu and then applying it to their use) does not get the patent protection, which would have the serious impact on the general health of the mankind including traditional communities.

It is important to note that this research work is not devoid of limitations and covers only specific areas abovementioned due to time and length constraints. The theme in itself is very broad in amplitude and hence an analysis of every component has not been done, but an endeavour has been made to touch as many areas as possible in the given word limit.

---

[2] It reads as: "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or process for producing such substances".
[3] It reads as: "An invention which in effect is TK or which is an aggregation or duplication of known properties of traditionally known component and components"
[4] It reads as: "The applicant must disclose the source of geographical origin of any biological material developed
[5] If the applicant does not disclose or wrongly mentions the source of geographical origin of biological material used for invention, then it becomes the ground for refusal of the patent

1.5 METHODOLOGY ADOPTED

The research methodology adopted in the completion of this thesis is based on the usage of:

(i) DOCTRINAL METHOD- Under this method, research is focused on the secondary data. Secondary Data encompasses under it ambit the material that has already been collected by a previous researchers and has passed through the rigmarole of statistical process. Reliance has been placed on sources like previous researches on the theme, newspaper information and Internet based information. An intensive research has been done to delve deep into the details of the problems related with the research topic.

(a) CASE STUDY- To have in depth understanding of the developments in the concerned area, case studies holds utmost importance. "Case study as a research method excels at bringing an understanding of a complex issue or objects and extends experience or add strength to what is already known through previous research."[6] Objective behind incorporation of case studies is based on the fact that 'case studies' focus on the particular aspect of a topic and hence the need of collecting the data from large set of data is done away with. In this study, I will draw on my conclusions based on the 'case studies' to understand the present trends and jurisprudence developed in the concerned area. In the penultimate sections of my research work, it will help me to put my views regarding the credibility and efficiency of the present legal framework.

(ii) NON DOCTRINAL METHOD- For the first two chapters, Field based investigations hold utmost importance. Therefore, interviews of Students with

[6] *See*, "The Case Study as a Research Method", 1997 Available at:
< http://www.gslis.utexas.edu/~ssoy/usesusers/l391d1b.htm > (visited on 10 March 2016)

science background, Doctors, Medical Representatives and Chemists are conducted.

(iii) COMPARATIVE METHOD- For the second chapter, that puts premium on Pricing Policy, a comparative study has been done so to get apprised with the different models adopted by different nations with regards to the pricing policy. It is done with an objective to assess the efficiency of these models in the Indian socio-economic ethos and to ascertain whether any model or mix of models with streaming as per Indian conditions, can be emulated.

1.6 STRUCTURE OF THESIS

I have written this thesis by pacing reliance on three broad lines of arguments. Common theme that runs out through the all the three chapters and subchapters is "*striking a balance between patents and patients*".

Thesis begins with **Chapter One,** which includes the introductory part of the thesis encompassing under its domain statement of the problem, Hypothesis, Research Questions, Scope and Limitations, Research Methodology and the structure of the thesis.

Chapter Two; "*A walk through Section 3(d) of The Indian Patents Act: A Weapon of Choice or a Shield of Necessity*" This chapter focuses on the finding an answer to the following:

The researcher intends to explore the conflict that exists between Section 3(d) of the Indian Patent Act, 1970 which keeps "mere increments or minor improvements" out of the ambit of from patent protection, and pharmaceutical companies putting premium on its recognition.

In this Chapter, the researcher has taken a holistic approach under which the veracity of the claims of pharmaceutical companies with regards to their R&D expenditure, technological transfer and local working of the patents in India, has been assessed. The researcher has also put premium on providing an answer to the allegations regard Low Investment in India and the prospects for domestic manufactures, post 2005 amendment.

Chapter Three; "***India's Strides Towards Pricing Policy in Pharmaceuticals: Issues and Challenges***". In the present scenario the Government controls the price of 348 essential medicines. 1995 policy has been replaced with DPCO 2013 which got implemented from MAY, 25 2014, under which 680 formulations are covered, while the previous rule of 1995 used to regulated only 74 drugs. The present pricing control mechanism warrants investigation from two angles. First is from the perspective of affordability to medicine and shortcomings of the present policy to ensure the same. Second is from the perspective of pharmaceutical companies which are of the opinion that Government is trying to pass its burden of ensuring accessibility and affordability of medicine on pharmaceutical sector. This chapter focuses on the finding an answer to the following:

Need to strike a balance between accessibility to medicine and conducive environment for pharmaceutical companies to invest in the pipeline so that they are able to invest into bring new molecules into the market, which seems to be a herculean task in the absence of reasonable margin.

Chapter Four; *"Indian Patent Regime Vis-A Vis Protection of Traditional Medicinal Knowledge".* Traditional Knowledge is the result of ingenuity of indigenous communities due to their symbiotic bond with the environment. The

sincere endeavors of communities are wide in the amplitude, ranging from the identification of genetic resources to their application in treating the diseases, and hence the particular environment and the genetic resources therein have a direct impact on the central plan of their lives.

The Patent Act 1970- as amended in 2002 and 2005, encompasses under its domain several provisions such as Sections 3(e)[7], 3(p)[8], 10(d)[9], 25[10]. Deliberation on the model adopted by India by including the above mentioned provisions in its Patent Act has been made with a view to find an answer to the following:

Whether these provisions have the potent of addressing the concerns raised by the scholars on the lack of any binding provisions in TRIPS

(1) to safeguard the interests of traditional communities and their special claims?
(2) to ensure that mere tinkering with the genetic resources in the present form(which is the result of sincere endeavors of traditional communities in observing the natural milieu and then applying it to their use) does not get the patent protection, which would have the serious impact on the general health of the mankind including traditional communities?

Chapter Five; ***"3(D) Implications and Pricing Policy: Assessing the Ground Reality"***, incorporates several observations based on the empirical research.

---

[7] It reads as: "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or process for producing such substances".
[8] It reads as: "An invention which in effect is TK or which is an aggregation or duplication of known properties of traditionally known component and components"
[9] It reads as: "The applicant must disclose the source of geographical origin of any biological material developed
[10] If the applicant does not disclose or wrongly mentions the source of geographical origin of biological material used for invention, then it becomes the ground for refusal of the patent

CH. 2 A WALK THROUGH SECTION 3(D) OF THE INDIAN PATENTS ACT: A WEAPON OF CHOICE OR A SHIELD OF NECESSITY

INTRODUCTION

A bare perusal of TRIPS indicates that an attempt has been made to strike a balance between incentives to be given to IP holder and public interests.[11] Previous researches indicate that TRIPS provisions when analyzed in a holistic manner, seems to be inclined towards protecting the interests of pharmaceutical companies even at the cost of public health which seems to fall under the ambit of "public interest". It is because of these reasons, previous researches in this aspect state in unequivocal terms that MNCs are aggressively asserting their patent rights not for getting genuine patents which they are entitled to but for preventing generic competition. Many claim that more people do not have access to life-saving drugs because of high prices and that patent rights both increase prices and stand in the way of getting treatment to those who need it.

India's approach towards the same is quite distinct from many countries. In 2005, Section 3(d) acquired its current form by an amendment, but it paved the way for deluge of controversies and criticism. The aim was to prevent the practice of ever- greening, and also to encourage improved level of innovation and enhanced efficacy so that the wealthy multinationals in pharmaceutical sector, do not obtain a dominant position by doing minor improvisations. Further, Novartis judgment heralded a wave of conflicting arguments, in which the chief

[11] See Articles 7 of TRIPS states the objectives of the IPR as "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".

issue was concerning the parameters set for patentability and the exclusion of 'incremental innovations'. Allegations have been leveled against Indian legislature for making a vague proposition of law and also against judiciary for analyzing the particular provision in a narrow and constrained manner. It has been a matter of debate that whether India has flouted international agreements concerning patent protection and intellectual property rights in order to keep their domestic pharmaceutical industries going and growing, at the expense of the innovative companies and individuals that have spent years and billions of dollars developing new medicines.

Specially from the perspective of India, being a leading manufacturer of 'Generic Drugs', it holds utmost importance to develop a balanced approach, so that in the process of ensuring the smooth flow of generic drugs, technological and development advancement is also not stifled.

2.1 HISTORICAL BACKGROUND

The Paris convention of 1883, which is considered as one of the foremost treaties related to the safeguarding of intellectual property rights (IPR), was quite liberal in safeguarding the IPRs.[12] As a result of which quite a few nations were apprehensive of the fact that such a liberal patent protection in pharmaceuticals sector will restrict the dissemination of the knowledge and thus thwart the way of making available the scientific innovations to general public, This is because, if a product gets patent protection (in cases of product patents), the particular

[12] "Under this convention, member countries were free to determine the standards of protection, the subject matter of protection and the period of protection and thus maximum divergence were observed in the case of protection of innovations in the pharmaceutical sector". *See* N.Lalitha, "*Trips And Pharmaceutical Industry:Issues And Prospects*" , Gujarat Institute Of Development Research, Ahmedabad, p.1, Available at : <https://www.google.co.in/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjdqJbL7srMAhWNCY4KHeUPDZUQFggbMAA&url=https%3A%2F%2Fwww.iprsonline.org%2Fictsd%2Fdocs%2FResourcesHealthArticleLalitha.doc&usg=AFQjCNHAsdH0B1vWWQYW2sw6brC5HhtW_g&bvm=bv.121421273,d.c2E>(visited 15 March 2016)

product cannot be manufactured even by an alternate mechanism for the stipulated protection period.

India's patent policy in 1950 was to make certain that drugs get locally produced. Till 1950, entire drugs delivery in India was done by foreign multinationals.[13] Drug prices then were exorbitant to an extent that in 1961, the US Senate Committee under the leadership of Senator Estes Kefauver opined that India was one of the top-most priced countries all across the globe for drugs. In the light of the same, Government of India devised the first five year plan to pave the way for India's development.[14]

Regardless of the fact that product patents in pharmaceuticals were acknowledged in India prior to 1970s and even after having liberal environment which was very much conducive for investment, MNCs did not make sincere endeavors to expand the industry. Rather, they used the patent system to their advantage as they were more inclined towards importing than that of manufacturing within India and in addition to it they were also charging exorbitant prices, which stifled the competition to a considerable extent.[15]

Finally to rectify all the above mentioned anomalies existing in the system, Justice Rajagopala Ayyangar committee Report emerged as a strong tool to

---

[13] Foreign multinationals controlled more than 90% of the Indian pharmaceutical industry and hence determined supply and availability of drugs. Drugs were manufactured outside India and imported for a higher cost. The cost of drugs in India was amongst the highest in the world. *See* Damanjeet Ghai, "*Patent Protection And Indian Pharmaceutical Industry*", Vol.3(2), (University Institute Of Pharmaceutical Sciences, Chandigarh – 160014, India, July-August 2010),P. 43, Available At :
<Http://Www.Globalresearchonline.Net/Journalcontents/Volume3issue2/Article%20008.Pdf> (visited 15 March2016)

[14] The first five year plan recorded that India was the largest reservoir of epidemic diseases. Poverty was also at its peak in India. Around 50% of India's population were living under poverty and were unable to afford the cost of drugs. Consequently, life expectancy was very low and mortality rate due to diseases was very high. *See* Damanjeet Ghai, as note 13 above. p.43

[15] Damanjeet Ghai, as note 13 above, p.44

overhaul the Indian patent regime.[16] One of the chief actions taken was to restrict the patent protection extended to pharmaceutical inventions to 'process patent', which is currently known as pre-TRIPS era. The Patent Act of 1970, encompassed under its domain a provision that prohibited the grant of 'product patents'; however, patents on processes for manufacturing pharmaceutical compounds was allowed, but with a shorter duration of protection in comparison to other categories of patents.[17] As a result of this system, India got recognized for producing generic drugs at a low price and also as a leading exporter of the same[18], as then it became possible to reverse engineer the foreign drug without inviting sanctions[19]. Therefore local industry actually flourished since the 1970s.

Impact of the above mentioned policy on the pharmaceutical industry was very much palpable and hence reversing this trend became the top most priority of US. [20] As per (Scrip's Year Book, Vol.2, 2000: 316). A loss of $500 million per year was assessed owing to the then India's intellectual property system regime.

Eventually on the request of India on the ground of being a developing nation, a period of 10 years was granted to India so that it can have the essential infrastructure to acquire the capacity of implementing the TRIPS mandate. Therefore after 10 years from 1994, i.e. from January, 1 2005, drug 'product

---

[16] *See* A.D. Damodaran, "*Indian Patent Law in the Post- TRIPS Decade: S&T Policy Appraisal*", vol.13, (Journal of Intellectual property Rights, 2008), p.3, Available at: <http://nopr.niscair.res.in/bitstream/123456789/2027/1/JIPR%2013%285%29%20414-423.pdf>, (visited 16 March 2016). Also See Report on Patent the revisions of the patent laws by Justice N Rajagopala Ayyangar, 1959

[17] Patent Act, 1970 section5 (a)-(b) and section 53

[18] Janice M. Mueller, "*The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*", (University of Pittsburgh School of Law, 2006), p.56, Available at : <http://law.bepress.com/cgi/viewcontent.cgi?article=1043&context=pittlwps>:(visited 18 March 2016)

[19] *See* Damanjeet Ghai, as note 13 above. p.44

[20] *Ibid*

patent' system was again introduced in India, as India decided not to opt out of the WTO purview ,owing to a panoply of reasons[21] Hence,India has to accept the TRIPS[22], as WTO is take it or leave it package without having any space for the introduction of any modifications suggested by the member nations. It is worth mentioning at this juncture that TRIPS does have some flexibility[23] and also the provisions dealing with the balancing of right to trade with other concomitant rights.

In the present scenario, patents are granted in all fields, which include pharmaceuticals as well having twenty years of protection, from the date on which application is filed.[24] With the adoption in its true sense(after the expiry of transition period) of TRIPS agreement in the majority of developing nations by 2005, a stronger patent system in the form of product patents seems to be

---

[21]"Several factors like the continuous advancement in science, new breakthroughs in bio-technology, the growing participation of the private sector in the cost intensive research and development in the knowledge based pharmaceutical sector and the relative strength demonstrated by the developing nations in adapting the results of the scientific innovations to the local environment have prompted the industrialised nations to seek stronger protection for their innovations in all the countries. As per the minimum standards mentioned in the TRIPS agreement, patent shall be granted for any inventions, whether products or processes, in all fields of technology provided they are new, involve an inventive step and are capable of industrial application without any discrimination to the place of invention or to the fact that products are locally produced or imported." *See* N. Lalitha, as note 12 above, p.1

[22] Trade Related Aspects of Intellectual Property Rights (TRIPS) were brought in with the prospects purpose of universalising the standards of Intellectual Property Rights and frame the rules of the game of the developing countries on par with the developed countries. *See* N. Lalitha, as note 12 above, p.1

[23]Article 27:1 of TRIPS states as follows: "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application

[24] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced". *See* Damanjeet Ghai, as note 13 above. p.45

unvaryingly applicable on innovations in pharmaceutical sector amongst all the member nations[25] of World Trade Organisation(W.T.O.).

2.2 Section 3(d) of Patent Act, 1970: A tool to prevent Ever-greening Patents and The Battle Over Glivec

It is a strategy of various companies to first take a patent on the first molecule, take a another patent on the polymorph, take a patent on the tablet, patent on the injection and so on and so forth. The second generation, the third generation and other formulations and other patents. It is a strategy through which many companies keep on taking patents on second generation and third generation kind of compounds or even variants of the same compounds.

India introduced major changes in the Law to provide patent protection, most notable amongst them is Section 3(d) of the Indian Patents Act, 1970 which says that new forms of known substances would not be patented unless they are significantly more efficacious than the known substance.

Novartis case was the first case which was on the drug called GLIVEC which is used to treat Chronic myeloid leukaemia (CML) and basically Novartis wanted the beta crystalline form of known substance which was the imatinib mesalyte or the imatinib base compound to be patented It is worth mentioning that it was only the polymorh, (the second generation) which Novartis was trying to get patented in India.

The generic product treating the same disease was available at a much cheaper cost than Glivec. When Novartis gained market exclusivity in India for its drug Glivec, it tried to enjoin the Indian generic drug manufacturer from the sale of Glivec copies in India, as a result of which the cost of the drug went up by ten

[25] In late '90s, as many as 140 countries were members of the WTO.

times[26]. In a country with little health insurance coverage and a per capita income below $1,500,[27] Novartis set the annual price for Glivec at a staggering $26,000.[28]

It is also important to note that Drug (GLIVEC) is very essential for the rest of the life of the patient, since it cannot be said with surety whether all the cells which contain this particular pathogenetic event have been completely cured or not and therefore drug is recommended lifelong for the patients who have been diagnosed with this disease[29]

Cancer Aid Association was the first group to oppose the same. Mr. Anand Grover was the lawyer. Novartis presented two broad lines of arguments at two different levels. First, Novartis argued that their claim for patent was valid and therefore they should be issued the patent. Second, Novartis challenged the key section of the Indian Patent Act, i.e. Section 3(d) on the ground that it sets the bar of patentability much higher than in most patent laws.

Novartis challenged the validity of Section 3(d)[30] on the following grounds:

---

[26] Ganapati Murdur, "*Indian Patients Go to Court Over Cancer Drug*", (BRIT. MED. J., 2004), Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi tool=pubmed&pubmedid=15321889> (visited 18 March 2016)

[27] World Dev. Indicators Database., World Bank Available at: <http://databank.worldbank.org/ddp/home.do?Step=12&id=4&CNO=2>(visited 18 March 2016)

[28] Mueller, Janice M., "*Taking TRIPS to India - Novartis, Patent Law, and Access to Medicines*". (New England Journal of Medicine, 2007) p. 541, Available at: < http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1397729> (visited 19 March 2016)

[29] Based on the interview of 5 oncologists, taken for this research work

[30] "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant"

A. Unconstitutionality With Reference To Article 14 And Also Violating The Mandate Of Honouring International Treaty Obligations

Explanation appended to Section 3(d) speaks in indisputable terms and therefore clearly rules out the possibility of the alleged conundrums, and also the authorities during the deliberation for granting paten have an obligation to act within the ambit of the explanation. With regards to the allegations of arbitrariness, in the light of celebrated Case Laws, it can be stated that for striking down a statutory provision on the ground of arbitrariness, it has to be within the contours of manifest arbitrariness[31]. A court solely and merely acting on its thinking cannot do so.[32] Hence, it can be safely stated that the inclusion of section 3(d) to the Indian Patent Act is constitutionally valid and grants no scope to the authorities to act in an arbitrary manner and hence misusing their discretionary powers. Also, the court opined that judiciary shall adopt a deferential approach with reference to the legislations dealing with the economic matters. The Court stated that encouraging the economic feasibility so as to ensure the affordability and accessibility was one of the chief objectives for introducing Section 3(d) behind and therefore the courts must exercise cautious while deliberating on these matters.

B. Contravention to the obligation undertaken by India under TRIPS

In the recent past, pharmaceutical MNCs along with their home governments have raised their concerns regarding the use of TRIPS flexibilities by Indian in a

---

Explanation - For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy

[31] *Bombay Dyeing & Mfg. Co. Ltd. V. Bombay Environmental Action Group*, (2006) 3 S.C. 434, 511

[32] *State of Andhra Pradesh v. Mc. Dowell and Company*. (1996) 3 SCC 709, 738-739

way that is contravention to WTO/TRIPS.[33] However, Indian government has unequivocally stated that that its laws are in consonance with the international obligations.[34]

A panoply of scholars have opined that Section 3(d) is in compliance with TRIPS.[35] , which is primarily based on the following factors:

(a) *INVENTION – DISCRETION WITH THE MEMBER NATIONS TO DEFINE THE SAME*

Article 27 mandates that "patents shall be available for any inventions, whether products or processes, in all fields of technology"[36], but it does not define the term 'invention'. Therefore, member nations can define the term in a way that furthers the public health objectives.

(b) DEFINING INVENTIVE STEP –

TRIPS provides no define of "inventive step" or non-obviousness (as used in TRIPS). Hence, the term is susceptible to diverse interpretations as per the distinct laws of member nations, which in turn could lead to a position where the same invention gets patent protection in one jurisdiction, and fails to get the same in another. No nation is mandated to follow the footsteps of another and hence India's approach with Section 3(d) can be taken as *refined "inventive step" or non-obviousness standard, which is not in contradiction to TRIPS*

---

[33] *See* Shamnad Basheer and Swaraj Barooah , "*Patent Error*",(Indian Express February 20, 2014), Available at:< http://indianexpress.com/article/opinion/columns/patent - error/99/ >(visited 20 March 2016)

[34] *See* Nayanima Basu, "India Play's WTO Card Against US" , (Business Standard April 28, 2014), Available at:< http://www.business – stand ard.com/article/economy - policy/india – plays – wto – card - against – us - 114042800008_1.html> (visited on 20 March 2016).

[35] *See e.g.,* Shamnad Basheer & Prashant Reddy, "*Ducking TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d)*", (National Law School of India Review 131-155, 2008)

[36] See Article 27.1 of TRIPS

It is worth mentioning that India is not the only nation which has denied patent protection to a drug which got the patent protection in other jurisdictions. An array of cases in the U.S. and other jurisdictions show the same trend. For example, in the famous case of *Escitalopram* case having enantiomer as a patented pharmaceutical drug[37], patent was considered valid by U.K.,[38] Canadian[39] , German,[40] and Australian courts[41], while it was held invalid on the grounds[42] of obviousness by the Dutch[43]

(c) NON DISCRIMINATION

It is quite clear that India sets high parameters of patentability, but can it be said on this basis that India is discriminating pharmaceutical inventions. 'Discrimination' under Article 27 has been interpreted by WTO Panel in the Canada- Patent Protection of Pharmaceutical Products case[44]as: "the unjustified imposition of differentially disadvantageous treatment."[45]

---

[37] *See* Jonathan J. Darrow, "*The Patentability of Enantiomers: Implications for the Pharmaceutical Industry*",vol.2, (STAN. TECH. L. REV, 2007) (discussing different aspects of enantiomers).

[38] *See Generics (UK) Limited and others v. H Lundbeck A/S*, [2009] UKHL 12.

[39] *See Apotex v. Lundbeck Canada Inc.*, 2010 FCA 32.

[40] *See Lundbeck A/S v. Neolab Ltd. et al.* (Escitalopram), invalidity proceedings, Federal Supreme Court, Germany, 10 September 2009, Docket number Xa ZR 130/07.

[41] *See H. Lundbeck A/S v. Alphapharm Pty. Ltd.*, [2009] FCAFC 70.

[42] The divergent conclusions on obviousness discussed above stem not only from a differential subjective assessment of the same facts, but can also be attributed to a difference in legal standards. As can be seen from the above discussion, Canada preferred a lower non-obviousness or inventive step threshold that would have found in favour of the patentability of a larger number of inventions than the U.K. regime. The US and other leading patent jurisdictions hold non-obviousness or inventive step to be a question of law, albeit one is that predicated heavily on underlying facts; for e.g., *In re* Kubin, 561 F.3d 1351, 1355 (Fed. Cir. 2009) ("Obviousness is a question of law based on underlying findings of fact.").

[43] *See* Alfred E. Tiefenbacher GmbH s. H. Lundbeck A/S, 312468 / HA ZA 08-1827 (District Court);

[44] Panel Report, The drugs in respect of which the CL was sought was Roche's "erlotinib" and Pfizer's "sunitinib" and Natco offered to pay a 5% royalty. *See* C. H. Unnikrishnan, "*Drug cos seek compulsory licensing*", (The Mint,2008), Available at: http://www.livemint.com/2008/01/29000742/Drug-cos-seek-compulsory-licen.html (visited 24 March 2016).

[45] *Ibid*, at 7.94

So it becomes palpable that it is not differentiation, but an unjustified differentiation, which would be hit by Article 27. In the light of the Mashelkar Committee report and the revolving jurisprudence around the same, it can be said that rational for introducing Section 3(d) lies in the importance of public health[46] and to prevent ever-greening through strict parameters of patentability. [47] In fact, even in countries like Brazil and Europe, it is quite difficult to get a patent for a POLYMORPH. The strategy to extend the life cycle of an expired drug is not encouraged in many countries of the world. So Indian Laws which are made in 2005 are in consonance with TRIPS.

With regards to TRIPS Compatibility, court on the basis of jurisdiction limitation opined that Dispute Settlement Body under WTO is the appropriate authority to settle dispute under TRIPS. Court adhered to jurisdictional point on the basis of outdated case Law from foreign Law i.e. "doctrine of incorporation"[48], but did not take into account number of Indian precedents . The Court placed reliance on contractual approach to justify lack of jurisdiction, i.e. 'held that TRIPS being a international treaty gives birth to a contract done between nations. Hence, it needed to be interpreted in light of normal contractual principles.

When looked from the Constitutional jurisprudence perspective, it seems that due to the adherence to dualistic approach by India , it could not have enforced the obligations imposed under TRIPS. Applicability of 'direct effect' theory is precluded by Indian Constitutional Jurisprudence.

---

[46] The medicines like imatinib mesalytes which is using for the treatment of Chronic myeloid leukaemia (CML), which is not available free of cost in Indian Public healthcare facility so thereof it is important that these medicines should be available at an affordable cost.

[47] Swaraj Paul Barooah, "*India's Pharmaceutical Innovation Policy: Developing Strategies for Developing Country Needs*", vol. 5(1) (Trade, Law and Development, 2013), p.150

[48] *Edye v Robertson*, 112 U.S. 580 (1884) [Supreme Court of United States of America].

C. NOVARTIS ALLEGED THAT LACK OF DESCRIPTION OF 'SUFFICIENTLY ENHANCED EFFICACY' AND 'ENHANCEMENT OF KNOWN EFFICACY'

Novartis was of the view that it opens the gate for vague interpretation which can result in granting unbridled discretionary powers to authorities, which is arbitrary and hence anathema to the concept of equality.

In response to the above mentioned allegation, it is worth mentioning that enhanced efficacy criterion can be viewed as refinement of principle of non-obviousness, i.e. 'most forms of existing pharmaceutical substances are deemed obvious, unless they demonstrate increased efficacy'[49]. It can also be understood as a refined utility test, where only those particular new forms demonstrating substantially different utility in comparison to what existed before (i.e. the form of "significantly enhanced efficacy") are patentable.[50]

There is also an important question about the sequence that is followed for grant of patents in India, in particular after the introduction of Section 3(d). Whether it moves from obviousness to Section 3(d) or first it has to satisfy the criterion of section 3(d) and then only the examination moves towards other factors like examining obviousness as such. On this point, light has been shed in a paper written by Mr. Firoz Ali Khader, in which he classifies the patents grant into two heads, i.e. radical innovation and incremental innovation. For the former, India follows the same method of examining the compliance with three prerequisites of novelty, inventive step followed by industrial application. For the incremental innovation, tt needs to be prove that his invention satisfies the criterion of enhanced efficacy. Even if the claim satisfies the other criterion but not the requirements of Section 3(d) and hence it makes more sense to start with the

---

[49] *See* Shamnad Basheer, "*Limiting The Scope of Pharmaceutical Patents And Micro-Organisms: A Trips Compatibility Review*" (Intellectual Property Institute , London, 2005)
[50] *Ibid*

same itself and then move to other criterions so that at a later stage the patent authorities don't refuse the same.

The Hon'ble Court opined that 'efficacy' means mere 'therapeutic efficacy'. 'Therapeutic'[51] delineates 'healing of disease and having good effect on the body' and 'efficacy'[52] implies 'the ability of a drug to produce the desired effect'. It implies that a drug is deemed to be capable of exhibiting increased efficacy, when effectiveness of the new drug is in terms of healing capacity is noteworthy and that too without having any lowered side effects.

The Court while equating efficacy with a therapeutic effect on the body, also accepted the argument of respondents that *"... petitioner is not a novice to the pharmacology field but it being pharmaceutical giant in the whole of the world, cannot plead that they don't know what is meant by enhancement of a known efficacy and they cannot show the derivatives differ significantly in properties with regard to efficacy".*

The nuances related to efficacy were to be decided by IPAB which came up with view that Imatinib mesylate qualifies to be novel and inventive, but does not qualify the test of ' sufficiently enhanced efficacy' [53]. Assistant Controller held it insufficient after examining pre grant objections, so as to fall under the ambit of "increased efficacy". Technical expert stated the following

> *"difference in bioavailability is only 30% and also the difference in bioavailablity may be due to the difference in their solubility in water. The present patent specification does not bring out any improvement*

---

[51] Medical dictionary meaning
[52] Oxford dictionary meaning
[53] *Novartis AG v. Union of India and Ors., Intellectual Property Appellate Board,* Judgment, June 26, 2009,Available at:<http://www.ipab.tn.nic.in/Orders/100-2009.htm>.,(Visited 27 March 2016)

in the efficacy of the beta crystal form over the known substances. Even the affidavit submitted on behalf of the Applicant does not prove any significant enhancement of known efficacy."

It is clear from the careful perusal of the observation made by the patent office that the observation is not very illuminating and devoid of detailed reasoning as to why beta crystalline lacked enhanced efficacy.

Against the decision of IPAB, Supreme Court was approached. 'The Supreme Court upheld the Madras High Court's "enhanced therapeutic efficacy" standard, and agreed with the IPAB's ruling that Novartis had not met this standard.[54] The Supreme Court further held that the "enhanced efficacy" standard complied with TRIPS, given that agreement's flexibility.[55]' There were high expectations from the apex court to provide clarity on the amplitude of section 3(d) with especial focus on term 'sufficiently enhanced efficacy' but the Court interpreted it in narrow terms and opined that it relates to therapeutic efficacy.

2.3 Need of Imparting Certainty

One of the most vexing problems in this area is the uncertainty that prevails in regards to the "quantum of enhanced efficacy" so as to set a benchmark and being considered significant. This is a complex issue as efficacy has not been defined concretely in any patent regime with reference to pharmaceutical sector. Experience shows that Indian patent authorities use the terms 'efficacy' and 'effectiveness' interchangeably[56] but there is a difference in the amplitude of these two terms as the later is a wider term and in special cases of effectiveness, there is a possibility of interpretation of efficacy. More importantly,

---

[54] *Ibid*, p.189
[55] *Ibid*, pp. 65-67
[56] Aditya Kant, "*An attempt at Quantification of 'Efficacy' Factors under Section 3(d) of the Indian Patents Act*", vol.18, (Journal of Intellectual Property Rights, 2013), p. 305

comparison with prior art becomes important in this regard, but when this aspect is minutely examined the result that come out is that this comparison is an effectiveness examination which is relative by nature, while the efficacy examination is absolute by nature.

After the Novarits Judgment, it is quite clear that Section 3(d) has been interpreted in narrow terms and further the court has put premium of therapeutic efficacy. Ohly[57] states that an interpretation where efficacy has been confined to therapeutic efficacy seems to be against the intent of legislature. He further states that the narrow interpretation given to efficacy seems to be based on certain wrong assumptions, which are as follows:

(a) Applicability of Section 3(d) to drugs and
(b) Applicability of Section 3(d) to human Beings only
(c) Applicability of Section 3(d) to pharmacology only

By any stretch of imagination the above mentioned assumptions (if any) doesn't seem to have the legs to stand on as there is nothing in the section which excludes its application to chemicals other than pharmacological drugs such as fertilisers and also to non human drugs. Moreover, drugs of such nature cannot be even tested on humans and hence their therapeutic value on humans cannot be derived. If the opinion furnished in Novartis is to be taken as carte blanche then it would result in non-patentability of such drugs.

It is worth mentioning that the current version of Section 3(d), is a unique provision and finds place nowhere in other jurisdictions. It is important to note that this provision has been taken from Article 10(2)(b) European Directive that relates to regulations on drug safety. Scholars have pointed that the borrowing

[57] *Ibid*, p.306

of a foreign provision per se to Indian Context creates certain difficulties for the concerned entities. From the perspective of drug manufacturing companies it becomes an onerous task to complete the phase three of the clinical studies related to the assessment of therapeutic efficacy of the drug. Also, because of this provision, very high parameters of patent eligible criterion are set.

I am of the opinion that vehement criticism for borrowing the foreign provision is not justified as Section 3(d) in its entirety entails other components which are necessary to ensure that innovations based on ever-greening does not get patent protection. It is the need of the hour to clearly set the threshold or yardsticks to measure the therapeutic efficacy.

The battle over Glivec was not only restricted to notion of enhanced efficacy in the strict sense and had other challenging issues. For example Mashelkar Committee opined that objective behind introduction of Section 3(d) is to provide impetus to inventions resulting in enhanced efficacy and hence committee in a way acceded to the introduction of this section as In India most of pharmaceutical inventions are by incremental inventions. Therefore, the judgment came out with focus on other aspects which were strong enough to negate the claim of Novartis, but the clarity on the notion of efficacy is still warranted

2.4 RECOMMENDATIONS

(a) In the light of the above mentioned discussion it can be safely asserted that there is a need of legal- institutional reforms in the area of efficacy as Indian System exhibits a mix where efficacy and effectiveness are used interchangeably.

(b) Secondly, the way in which therapeutic efficacy has been interpreted seems to be a problematic way as clear yardsticks are not present in

this area and it is strongly recommended that a ceiling or threshold limit in precise terms for ascertain the therapeutic efficacy must be given. The aftermaths of the introduction of this threshold limit would result in reducing the deluge of litigation due to uncertainty and secondly Companies will be well apprised with the quantification of efficacy as done by the Indian Patent system. Thirdly it will stop bringing international opprobrium to India as allegations have been levelled that the present outlook of Indian Patent authorities is against the interest of inventors.

(c) Section 3(d) puts premium on the comparison of the present work with prior work, but the problem arises in the cases in which there is no Prior Art. Absence of prior art cannot be a ground to reuse patent to an applicant who qualifies the essential criterion. Hence, I recommend that the views of a person skilled in art must be taken into consideration while evaluating the merit of a patent claim.

(d) Most importantly, Section 3(d) has not been drafted to be applicable on only human drugs. Reliance has been placed on therapeutic efficacy for which their efficacy has to be tested on humans. But there are certain drugs which cannot be tested on humans such as agricultural chemicals/ fertilisers. I strongly recommend that the views expressed in Novartis Case must not be taken in a broad manner otherwise the above-mentioned drugs or chemicals will outside the ambit of Patentability.

2.5 PATENTS FOR GENUINE INVENTIONS OR FOR PREVENTING GENERIC COMPETITION? NEED FOR REVISITING THE BASIC PHILOSOPHY FOR GRANT OF PATENTS.

India's take on IPR has been vehemently criticized by many companies of several countries, one of the most notable being United States of America. According to them India maintains a poor track record in the pursuit of honoring IP rights. [58]

Many claim that as a result of the above mentioned, signs of apprehension have been shown by the global pharmaceutical industry about entering into the Indian market which is turn seems to have the effect of indirectly affecting the pharmaceutical FDI. [59]

In the light of the abovementioned allegations leveled against India and also the fear of losing the FDI due to prospects of bringing International opprobrium to India, it becomes highly imperative to assess the veracity of these claims and allegations. To get apprised with the same, the researcher has tried to delve deep into the details of basic philosophy and jurisprudential spectrum dealing with the grants of patents.

---

[58] US Chamber's of Global Intellectual property Centre (GIPC), recently opined that India stands at the bottom for the handling of IP rights followed by China and Russia. *See* Varun Mishra, "*The Indian IPR Poilcy- Fitting Enough For The Pharma Industry?*", Available at:< http://stellarix.com/ip-news/the-indian-ipr-policy-fitting-enough-for-the-pharma-industry/>, (visited 30 March 2016)
On April 30 2015, the office of the USTR named India and China among 13 countries, which were placed on a priority list, requiring close scrutiny for their alleged IPR weaknesses in diverse areas including pharma, IT and publishing. The Office of the USTR is part of the executive office of the American President and apart from being the chief trade negotiator of the U.S. government has enormous clout over the conduct of trade across the world. *See* C.R.L. Narasimhan, "*Defending India's IPR*", (The Hindu, May 17, 2015), Available at: <http://www.thehindu.com/opinion/columns/C_R_L__Narasimhan/defending-indias-ipr/article7214559.ece>, (visited 30 March 2016)

[59] Varun Mishra, as note 58 above

It is as clear as day light in the present scenario that the intellectual labor infused within the innovation deserves due acknowledgement, so that public gets benefitted out of the same. Pharmaceutical companies often beat the drums of incurring huge research and development (R&D) costs[60] so as to come up with a new technology and to introduce the same in the market.[61]

But at the same it cannot be forgotten amidst the large hue and cry that Patent protection is given as a legal incentive to act as a catalyst in promoting technological innovation. [62]At its core, patent system envisages to promote new and non-obvious works of ingenuity (inventions) by the virtue of giving a limited legal monopoly.[63] The most prominent and often cited theory under the patent system is the incentive theory. [64] However, this theory cannot be taken as the final word as the veracity of the contents of this theory when tested on the

---

[60] Some previous researches show that the cost of introducing a new drug into the market may cost a company anywhere between $ 300 million to $1000 million along with all the associated risks at the developmental stage, no company will like to risk its IP becoming a public property without adequate returns. There is high cost attached to the risk of failure in pharmaceutical R&D with the development of potential medicines that are unable to meet the stringent safety standards, being terminated, sometimes after many years of investment. For those medicines that do clear development hurdles, it takes about 8-10 years from the date when the compound was first synthesized. See < http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/>(visited 30 March 2016)

[61] New Delhi: Department of Science and Technology (DST), Government of India; 2002. Anonymous. Research and development statistics.

[62] *See* Dan L. Burk & Mark A. Lemley, Policy Levers in Patent Law, 89 V A . L. R EV . 1575 (2003) ("Patent law is our primary policy tool to pro mote innovation, encourage the development of new technologies, and increase the fund of human knowledge. To accomplish this end, the patent statute creates a general set of legal rules that govern a wide variety of technologies.")

[63] *See* Hall, *Patents and patents policy* 18 (4) OXF. REV. ECON .POLICY at 568 (2007).

[64] This theory stipulates that patent rewards (in the form of a limited set of exclusive legal rights) incentivise prospective inventors to accelerate their efforts, more than would be the case without patents. In other words, patents are likely to increase the rate of generation of new and useful ideas for society. The US Supreme Court explained it thus : "The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare." *Mazer v. Stein*, 347 U.S. 201, 219 (1954).

touchstone of empirical investigation, have given diverse conclusions which are not uniform in nature.[65]

> *"Bronwyn H. Hall concludes that although a stronger patent system is likely to result in an increase in patenting, it is not clear if these changes will also simultaneously result in an increase in innovative activity".*[66]

There is very little evidence today that Patent system per se is the best driver of innovation. In fact there is a whole body of evidence that is now emerging that in many situations patent system puts the breaks on innovation rather than promoting it. You have a much larger number of patents issued to prevent others from working in a certain area rather than to protect one's own innovative activity, so these are called patents thickets.[67]

> *"The Patent System added fuel of interest to the fire of genius"*
>
> (Abraham Lincoln)

The activities such as 'patents thickets' are fundamentally against the above mentioned words of Mr. Abraham Lincon, and which was never the objective of

---

[65] *See* Andrew W. Torrance, & Bill Tomlinson, *"Patents and the Regress of Useful Arts"* (May, 28 2009); Columbia Science and Technology Law Review, Vol. 10, 2009. ("Despite the economic logic of the conventional view, there exists surprisingly little empirical evidence to support the key assumption that patents do actually spur technological innovation.").

[66] *See* Hall, *"Patents and patents policy"*, vol. 18 (4), (Oxford Review of Economic Policy 2007), p. 574

[67] Patent thickets means that an entity wants to have the patent protection primarily with a view to preventing others to come into that area.
See<http://eml.berkeley.edu//~bhhall/papers/HHvGR_Patent_Thickets_FIN_29Oct12.pdf>(visited 30 March 2016)

TRIPS also.[68] Absence of the definition the terms " new" and " inventive steps" provides some flexibility.[69] Developed countries, for example, the US, follow very liberal patent standards.[70]

It is worth mentioning at this juncture that developing countries are under no compulsion follow the footsteps of developed countries like U.S., and hence the developing nation are free to interpret the above mentioned terms in a way that can restrict the number of patents granted.

> "*The aim should be to ensure that patents are granted for true technical contributions and not for blocking innovation and legitimate competition by generic producers.*"
>
> (Correa 2000; Abbott 2001)

India during the process of streamlining its patent regime in consonance with the TRIPS opined in an unequivocal manner that patents are not to be granted for "a new molecular modification or a salt or ester or a derivative or a formulation or

---

[68] Under Article 27(1) of TRIPS, patents will have to be provided for inventions, which are 'new, involve an inventive step and are capable of industrial application'. The TRIPS agreement, however, does not define the terms " new" and " inventive step" .

[69] "The minimum requirements of TRIPS are not always clearly defined. While TRIPS has clear provisions on issues such as the minimum time length of protection, the range of subject matter to be protected, non-discriminatory treatment of foreign residents and the enforcement measures that should be implemented, the agreement does not codify rules on more technology –specific and subjective matters, like screening criteria in relation to novelty and inventiveness for patents or detailed definition of infringements to copyrights. In these complicated and ambiguous definitional areas there may be some scope to change local examination guidelines to suit national economic interests without violating the provisions of TRIPS". *See* R D Hunshyal & S S Biradar, "*Intellectual Property Rights (Iprs) In Pharmaceutical Sector*", vol.19, (Health Administrator Journal, 2005), p.49, Available at:
< http://medind.nic.in/haa/t06/i1/haat07i1p48.pdf>,(Visited 6 April 2016)

[70] Sudip Chaudhuri, "*Intellectual Property Rights And Innovation: MNCs In Pharmaceutical Industry In India After Trips*", (Institute for Studies in Industrial Development, New Delhi, 2014), p.7, Available at :< http://www.isid.org.in/pdf/WP170.pdf>, (visited on 6 April 2016)

dosage form of a known new chemical entity having the same or similar pharmaceutical activity' or new uses or new combinations of existing NCEs".[71]

India's framework for the grant of patents is mainly showcased in Sections 2 and 3 of Indian Patents Act, 1970. Based on the parameters stipulated in these provisions, patents are granted, but sometimes patent applications have also been rejected or being revoked at a later stage. Some of the recently denied patent applications are as following

(a) Imatinib Mesylate (Brand Name Glivec Of Novartis);
(b) Gefitinib (Iressa Of Astrazeneca);
(c) Peginterferon Alfa - 2a (Pegasys Of Roche);
(d) Formoterol And Mometasone Aerosol Suspension (Merck);
(e) Bimatoprost And Timolol (Ganfort Of Allergan)

A careful analysis of the above mentioned patent applications reveal the fact that main grounds for the denial of patent protection was that the claimed inventions were " obvious" (Section 2 (1)(j and ja)) and/or did not show enhanced efficacy (Section3(d)). A careful perusal of the claim specifications in the abovementioned patient applications were not a work of creativity to an extent that qualifies for grant of patent in Indian patent regime.

Previous researches have also shed light on the fact that pharmaceutical companies tried to use the patent protection to their benefit so as to ensure that generic drug manufactures remain out of the market. "Motivation clearly has been to prevent generic competition rather than to promote innovation".[72]

[71] Peoples' Commission on Patent Laws in India 2003, pp. 62, 76
[72] Sudip , as note 70 above, p.9

2.6 ASSESSING THE VERACITY OF THE CLAIMS BY PHARMACEUTICAL COMPANIES: A REAL CAUSE OF CONCERN OR A SHEER EXAGGERATION

D. A. R & D EXPENDITURE: EXPLODING THE MYTHS ASSOCIATED TO IT

While advocating the patent system in incentivizing innovation, scholars frequently say that noteworthy investments and considerable efforts are required to translate ideas of ingenuity into commercially valuable products.[73] It is also pointed out by many scholars that firms may be disinclined towards investment in R&D if there are no legal sanctions imposed on the generic drug manufactures protection that could reproduce the drugs at minimal cost.[74] The often cited study in this context(Di Masi study), estimated that generally it takes approximately a-whooping amount of U.S. $802 million and a time period of 90 months to manufacture a marketable drug.[7576] However, In the light of the reluctance of drug companies to publicly disclose the costs incurred in drug discovery and its development, therefore these costs are intensely debated on the point of its veracity, as a result of which Di Masi study has also been criticized.[77]

---

[73] *See* F.M. Scherer, "*Industrial Market Structure And Economic Performance*", (Houghton Mifflin, 2d ed. 1980), pp.440-441(The traditional economic justification for patents has likely always encompassed the promotion of development and commercialization efforts in addition to inventive activity).

[74] *See* Richard A. Posner, "*The Economic Structure of Intellectual Property Law*", (Belknap Press, 1st ed. 2003), p.315

[75] *See* Joseph A DiMasi, Ronald W Hansen, Henry G Grabowski, "*The price of innovation: new estimates of drug development costs*", vol. 22(2) (Journal of Health And Economics 2003), pp.151-185

[76] These estimates have increased, with the most recent figures ranging from approximately U.S. $1.3 billion to over U.S. $1.8 billion and durations of 10 – 15 years. *See* J. Mestre-Ferrandiz, J. Sussex, and A. Towse, "*The R&D Cost of a New Medicine*", (Office of Health Economics, London, UK, 2012)

[77] Illustratively, *see* Donald W. Light, "*Misleading Congress about Drug Development*", vol. 32(5) (Journal of Health Policy., Policy & Law 2007)., pp. 895, 897

Generally, corporations always inflate the costs incurred to develop a new drug. Basic research for drug development in most situations in developed countries for example, U.S. and Europe is done through public funded systems. In U.S. research organizations get public funding. For example in U.S. it is (National Institute of health for drug development) which is the major funder. Eventually, Corporations pick up the innovations from public institutions and commercialize it, so the calculation that big pharmaceutical companies project in the market, is highly inflated.

It is worth mentioning that during 1990s before the advent of TRIPS, Pharmaceutical MNCs spending on R&D was around 1% of their sales. As a matter of surprise, R&D expenditure of these MNCs has further declined to 0.3 % of their sales during 2012 - 13.[78] In absolute terms, R&D expenditure by these MNCs has shown a downfall which is depicted as following:

(a) Rs 570.2 million in 2009 - 10 (R & D expenditure)[79]

(b) Rs 246.7 million in 2011 - 12 (R & D expenditure)[80]

(c) Rs337.1 million in 2012 - 13 (R & D expenditure)[81]

In the light of the above mentioned data, it can be safely concluded that:

> *"The MNCs disprove the hypothesis that strong intellectual property rights are important for their investments in R&D. Rather than doing*

[78] *Source* for the study was CMIE Prowess database, in which calculation was done based on the Data of 8 MNCs. Glaxosmithkline Pharmaceuticals, Pfizer, Sanofi - Aventis, Abbott India, Novartis India, Wyeth, Merck, AstraZeneca Pharma India. These 8 MNCs accounted for 61 per cent of the MNC market in 2012 - 13 in India.
[79] *Ibid*
[80] *Ibid*
[81] *Ibid*

much R&D in India they are getting technology and R&D services from their parent organizations."[82]

"So far as innovation in India is concerned what is important is what they do in India."[83] If it is not done in India then India's interest is adversely affected, as their citizens have to bear the brunt of exorbitant prices of patented products and also, the absence of technological dissemination to India affects its capacity building.

In contrast to the R&D expenditure by these MNCs, Indian companies of substantial weight which is comparable to MNCs have been found to be involved in noteworthy expenditure over R & D.[84]

It has also been noticed that the operations of these MNCs in terms of their sale in India is around 1% or even less than that, when compared to their overall sales on global level. Therefore, the multinational corporations do not heavily depend on profits that they get from the Indian market in order to plough back into R and D cost. Their basic profits come from the European and US markets i.e. from the northern markets of the globe. Hence, the large hue and cry made about the India's policy on patent does not make a substantial difference, but one of the reasons for their reservations about the same might be to ensure that in future, the model of India cannot be emulated by others and if someone tries

[82] Sudip , as note 70 above, p.5
[83] *Ibid*, p.6
[84] In 2012 - 13, Natco Pharma which is a mid - sized Indian pharmaceutical company alone spent Rs 377.8 million which is more than what the 8 MNCs together spent in the same year (Rs 337.1 million). There are 22 other Indian companies each of which spent more than the 8 MNCs put together. The larger Indian companies spend much more. Lupin, for example spent Rs 71,507.8 (11.2%), Dr Reddys- Rs 83,946 (8.2%), Cadila Healthcare Rs 4,927 (15.9%) etc in 2012 - 13.(R&D and sales data obtained from the CMIE Prowess database.)

to do the same, they can use the same momentum against that country also, which they used against India.

B. Technology Transfer Vis- a-Vis Local Working Of Patents

Advocates of IPR opine that a patent rights framework has the potent to increase human welfare. Monopoly granted through patents help the companies in doing investments which in turn leads to the dissemination of new technology and novel products. It represents a quid pro quo situation in which the "social costs attached with monopoly rents that patent holders derive should be adequately compensated by the benefits of new technologies and products".[85]

"But if the benefits of technological progress which are supposed to follow from patent protection take place in developed countries, not in developing countries, then how does the latter gain? "[86]

Scholars like Penrose (1951), Vaitsos (1972) and Greer (1973), have deliberated on the need and rationale behind patent protection when the benefits of technological progress are not extended to the developing nations. Developing nations will be at the receiving end by granting patents because their citizens will have to pay high price for the drugs but the technological diffusion is not happening in their country. The issue of importing the drugs rather than manufacturing it in the developing nation seriously jeopardizes their interest. The absence of technological dissemination raises serious concerns[87] about the grant of patents as it goes against the jurisprudential spectrum of granting patents.

---

[85] *See* Calvin W.L. Ho, Klaus M. Leisinger, "*Intellectual Property and Access to Essential Medicines: A Tenuous Link?*",vol. 5(4), (Asian Bioethics Review, 2013), p. 377

[86] Sudip, as note 70 above,p.2

[87] The reason why patents are granted is not only that it will stimulate R&D for innovation. The expectation is that disclosing of inventions in patent applications and working of patents will lead to diffusion of technology and facilitate further progress. *See* Sudip , as note 71 above, p.12

In Indian Context, patentees are under an obligation to present to the Controller " the extent to which the patented invention has been worked on a commercial scale in India" [88]. Patent Rules, 2003 also stipulates the Form (no. 27[89]) that is to be filled and submitted for giving the information. According to a research conducted in November 2014, "out of the 1115 patented products for which information were available for 16 MNCs, only 140 were commercially worked, i.e., were marketed in India (12.6%)". Again out of the 140 patented products worked in India, information about whether these were manufactured in India or not were available for only 92 products. Only 4 of these were manufactured in India including one which involves packaging of bulk imports. The remaining 88 patented products were being imported and marketed in India."[90]

Molecule	*Brand/Unit*	*Therapeutic Group*	*MNC*	*Unit Price ₹*
Ixabepilone	Ixempra 45 Mg Injection	Anti-Neoplastics	BMS India	71175.00
Goserelin	Zoladex 10.8 Mg Injection	Hormones	AstraZeneca Pharma India	28320.00
Ixabepilone	Ixempra 15 Mg Injection	Anti-Neoplastics	BMS India	26569.35
Zoledronate	Aclasta 5 Mg Infusion 100 Ml	Pain / Analgesics	Novartis India	19516.00
Pegylated Interferon Alpha 2a	Pegasys 180 Mcg Injection 10 Ml	Anti-Neoplastics	Roche	18200.00
Ibandronate	Bondronat 6 Mg Injection	Pain / Analgesics	Roche	13950.00
Pegylated Interferon Alpha 2a	Pegasys 135 Mg Injection 0.5 Ml	Anti-Neoplastics	Roche	13884.00
Goserelin	Zoladex 3.6 Mg Injection	Hormones	AstraZeneca Pharma India	9754.00
Erythropoietin Products	Mircera 100 Mcg Injection 0.3 Ml	Blood Related	Roche	8821.00
Sunitinib	Sutent 50 Mg Capsule	Anti-Neoplastics	Pfizer	8714.78
Everolimus	Afinitor 10 Mg Tablet	Anti-Neoplastics	Novartis India	7217.60
Erythropoietin Products	Mircera 75 Mcg Injection 0.3 Ml	Blood Related	Roche	7207.00
Everolimus	Afinitor 5 Mg Tablet	Anti-Neoplastics	Novartis India	5052.30
Sunitinib	Sutent 25 Mg Capsule 7	Anti-Neoplastics	Pfizer	4357.39

[88] Section 146 of the Patents Act, 1970

[89] Form 27 is quite elaborate and requires the patentees to provide information on not only whether the invention is worked or not but if not worked the reasons for not working and if worked the quantity and value of the patented product manufactured in India and imported.

[90] Sudip , as note 70 above, p.13

Molecule	*Brand/Unit*	*Therapeutic Group*	*MNC*	*Unit Price ₹*
Liraglutide	Victoza 6 Mg Injection 3 Ml	Anti Diabetic	Novo Nordisk India	4315.00
Erlotinib	Tarceva 150 Mg Tablet	Anti-Neoplastics	Roche	4030.00
Dasatinib	Sprycel 50 Mg Tablet	Anti-Neoplastics	BMS India	3287.30
Dasatinib	Sprycel 70 Mg Tablet	Anti-Neoplastics	BMS India	2953.67
Long Acting, Crystalline Zinc Suspension (Ultra-Lente)	Novomix 30 Penfill	Anti Diabetic	Novo Nordisk India	2211.65
Long Acting, Crystalline Zinc Suspension (Ultra-Lente)	Novorapid Penfill	Anti Diabetic	Novo Nordisk India	2211.65
Sunitinib	Sutent 12.5 Mg Capsule	Anti-Neoplastics	Pfizer	2178.65
Long Acting, Crystalline Zinc Suspension (Ultra-Lente)	Novorapid 100 Iu Injection 10 Ml	Anti Diabetic	Novo Nordisk India	1450.00

Sources and Notes: Form 27 information submitted by companies to the Patent Office as explained in the text; price data from Sales audit data of AIOCD Pharmasofttech AWACS Pvt. Ltd. Out of the 24 molecules identified as products imported by MNCs, the table provides information for only those products with unit prices more than Rs1,000/-[91]

In the light of the above mentioned facts highlighted, it can be safely concluded that If patented drugs are not manufactured in India rather they are imported from a foreign country, India comes at a receiving end as their citizens get affected due to the high prices of patented products and at the same time, the absence of technological diffusion to India gives a serious blow to India's prospects of capacity building in the long run.

C. INVESTMENT SCENARIO AFTER THE INCORPORATION OF SECTION 3(D) IN INDIAN PATENTS ACT, 2005

As mentioned in the initial parts of this chapter that several allegations were leveled against the introduction of Section 3(d) and there were serious apprehensions with regards to the investment factor. The following analyses is an attempt to asses the veracity of the same.

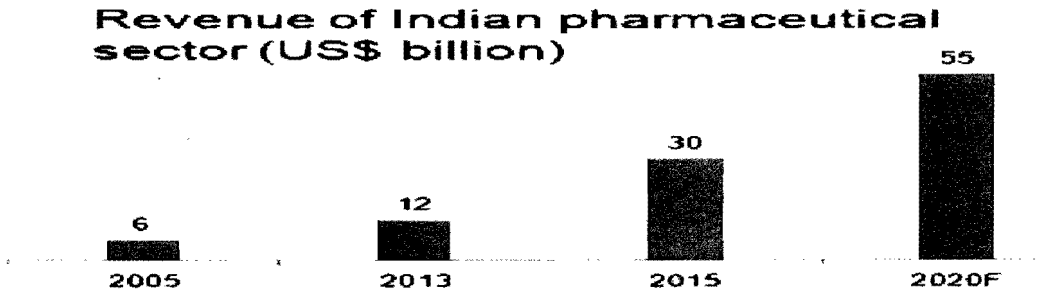
[91] Sudip , as note 71 above, p.15

INCREASING INVESTMENTS IN THE SECTOR

"The Indian Pharmaceuticals market increased at a CAGR of 17.46 % in 2015 from US$ 6 billion in 2005 and is expected to increase at a CAGR of 15.92 % to US$ billion by 2020"[92]

"By 2020, India is likely to be among the top three pharmaceutical markets by incremental growth and sixth largest market globally in absolute size."[93]

"India's cost of production is significantly lower than that of the US and almost half of the Europe. It gives a competitive edge to India over others."[94]



Source: Department of Pharmaceuticals, Pwc, McKinsey, TechSci Research

Notes: F- Forecast, CAGR- Compound Annual Growth Rate

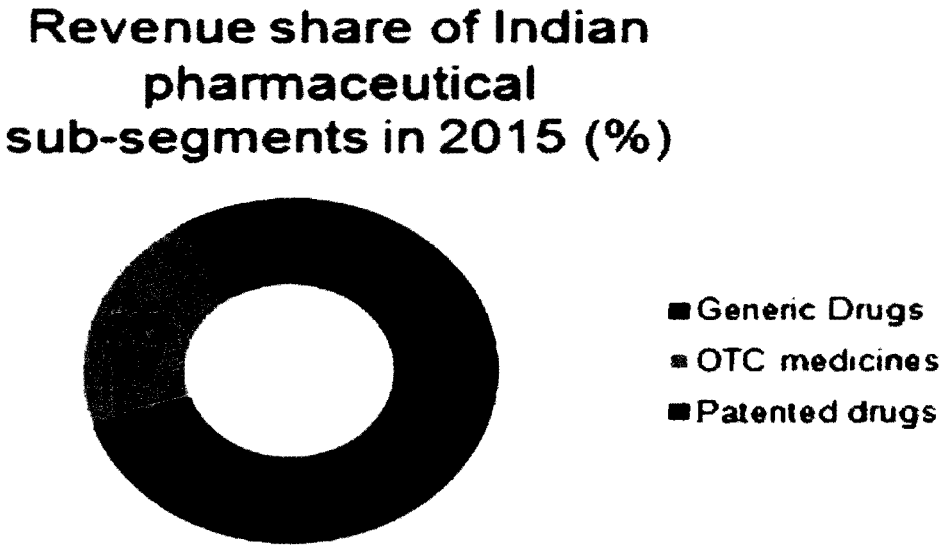
[92] See <http://www.ibef.org/industry/pharmaceutical-india.aspx>(visited 15 April 2016)
[93] *Ibid*
[94] *Ibid*

GENERIC DRUGS FORM THE LARGEST SEGMENT

(a) "With 70 per cent of market share (in terms of revenues), generic drugs form the largest segment of the Indian pharmaceutical sector."[95]

(b) "India supply 20 per cent of global generic medicines market exports in terms of volume, making the country the largest provider of generic medicines globally and expected to expand even further in coming years."[96]

(c) "Over the Counter (OTC) medicines and patented drugs constitute 21 per cent and 9 per cent, respectively, of total market revenues of US$ 20 billion"[97]



Source: Business Monitor International, FCCI Indian Summit 2014-15, TechSci Research

[95] *Ibid*
[96] *Ibid*
[97] *Ibid*

2.7 Indian Pharmaceutical Companies And Their Profit Making: Scope For The Same Amidst India's Ip Regime

In the TRIPS-compliant patent framework, reverse engineering skills of Indian pharmaceutical industry can no longer help them like before(prior to 2005). It is worth mentioning that by the end of 2005 India's domestic pharmaceutical companies attained a decent level of growth in technological capabilities, by the virtue of which they introduced two fundamental changes to their business models).[98]

The strategies adopted by India's leading domestic pharmaceutical companies consist of the following:

(a)Collaboration - Indian pharmaceutical companies carry out research to develop new molecules, but due to the presence of high parameters of patentability in India along with many regulatory stages, they license out their research work of creating new molecules to the foreign pharmaceutical firms.

(b)Competition with Western pharmaceutical MNCs- Indian firms has challenged big pharmaceutical companies the West Generics Market.[99] In order to expand and promote their generic drugs in the west, many Indian drug firms are entering into overseas acquisitions[100] also. [101] For example, the companies

---

[98] *See* Lanjouw (1997), Sampath (2005), and Chaturvedi et al. (2007) (which provides a detailed update on the strategies of Indian pharmaceutical firms before and after TRIPS). See also Ramanna (2005) on the emergence of a strong pro-patent lobby in the country prior to 2005.

[99] The high returns in the generic drugs market in North America and Western Europe is highly attractive to Indian drug firms. *See* Jayan Jose Thomas, "*Knowledge Economies in India and China: Challenges and Prospects in Pharmaceuticals and Biotechnology*", Available at : < http://www.networkideas.org/featart/mar2007/India_China.pdf>,p.26(visited 16 April 2016)

[100] To that end, some have already established production facilities and equipment that meet regulatory standards in the US and elsewhere. Some Indian companies have also begun purchasing foreign pharmaceutical firms to improve their access to overseas markets and develop new profit streams. *See* India Pharma Summit 2014-15, "*Policy Landscape Reforms for Strengthening Indian Pharmaceutical Industry, "Focus on Critical Verticals to Foster Access to Pharmaceuticals, Enhancing Production and Technology Adoption in Pharmaceutical*

like Ranbaxy, Dr. Reddy's Laboratories (DRLs) and CIPLA went outside and set up manufacturing facilities which are quite distinguished either through green field ventures of joint ventures or they acquired distribution market companies in the western markets.

> *"Thus Indian drug companies have started to invest more in research and development to produce their own patented formulations, or to affiliate themselves with large Western pharmaceutical companies and become outsourcing centres for some of those firms' activities, such as clinical trials."*[102]

2.8. Novartis Judgment: A Boon For India And Neighbouring Countries

What effect this judgment would have on Indian domestic manufactures and neighboring countries? This is the primary question that needs to be answered. An attempt has been made to answer as following:

This judgment again reinforces what the Indian Law has said for a very long period of time through Section 3(d) since 2005. Hence, important point is what would have happened if Novartis would have won the case? A lot of patent applications especially for HIV drugs and a few anti cancer drugs were rejected section 3(d), those could have opened up again. A lot of patent applications did not perceive through because of the presence of Section 3(d), because they thought that they would not qualify, those issues would have opened up. A slew of cases would have opened up for grant of patents, so that was the real danger.

Enterprises & Medical Devices and Diagnostics", Position Paper, (Ramada Plaza Palm Grove, Mumbai, 23 March 2015), p.14 Available at: <http://www.searo.who.int/india/mediacentre/events/2015/position_paper_pharma_summit_2015.pdf> (visited 16 April 2016)

[101] Information obtained from various issues of *Indian Industry: A Monthly Review* for the year 2007, published by Centre for Monitoring Indian Economy, Mumbai.

[102] *See* India Pharma Summit 2014-15, as note 100 above, p.14

It would have meant that supply line that the Indian Pharmaceutical companies provide for a range of countries across the world, especially poor people in poor nations, it would have been disrupted.

In order to understand it better, the acts of politicization done with the help of IPRs as a tool to further their interests, needs to be understood. The following shows the difference in what the developed nations do for themselves and what they say for the developing nations.

(a) India does grant patents but this judgment is about the non extending patent protection to a drug after 20 years in the absence of genuine innovation. India has the 3% per capita income of United States. It is also the case that 90% of Rand D was done by Non –Profit organizations in the United States. Big MNCs from developed nations often cite their R& D expenditures but they don't divulge that fact of their research being funded by public sectors or NGOs .

(b) It is also worth mentioning that Swiss Nations, European Union and U.S. decide not to challenge Section 3(d) of Indian Patent Act 1970 in dispute settlement body and hence the allegation that Novartis Judgment is not in compliance with TRIPS is undermined by the fact of not challenging it in Dispute Setllement proceedings. I think Developed countries have not taken India at the WTO dispute panel because of the simple reason that it opens the Pandora box for them. South Africa might want to think about it because they might want to change their law, Thailand might want to change their law and several other countries might want to think about it, why give unnecessary publicity to Indian Law which could indeed turn into a very big campaign in itself.

(c) Also, most of the generic drugs that are sold in U.S. are generic and large fraction of those are actually made in FTA approved plans in India and exported to EU and U.S. This seems to be a situation of Paradox, because at one hand the medical prescriptions in U.S. find generic drugs up to 80%, while on the other hand they want India to repeal or modify Section 3(d) to a considerable extent which has the potent of giving a boost to generic drugs.

India's win on this case has the potential to help the WHO to push this agenda and ask and request the other countries to follow the same system which does not allow the new forms of known substance unless therapeutically efficacious.

A CHINESE PROVERB SAYS THAT "WHEN THE WISE MAN POINTS TO THE MOON, THE FOOL LOOKS AT THE FINGER OF THE WISE MAN." WHEN THE SUPREME COURT OF INDIA POINTED OUT PUBLIC HEALTH, NOVARTIS WATCHED ITS FINANCIAL BENEFITS.

CH.3 INDIA'S STRIDE WITH PRICING POLICY: ISSUES AND CHALLENGES

BROAD OVERVIEW OF THE NPPA POLICY

In this age of growing concern for human rights, when the notions such as cosmopolitanism has gained momentum, all the deliberations on global level seem to be a mere rhetoric, when the acts of developed nations and Pharmaceutical nations is tested on the touchstone of reality. One of the obvious for the same is TRIPS that encompasses under its domain strict patent rules with and elephantine impact on access to essential medicines. Currently the patent- patient approach has come to fore and the acts of pharmaceutical companies of making profits at the cost of life has received attention in an intense form after the Ebola breakout.[103]It is important to note that at the time of outbreak, US & Canada found certain cures in the very clinical stage and their alacrity for getting it patented is palpable by the fact that a search of word "ebola" showed more than 241 entries on the world intellectual property organization's patent scope.

Patent Laws framework has always put premium on incentivizing the intellectual contribution so as to make certain that innovators always get adequate motivation. But, the same reasoning is not absolute and cannot be stretched to such an extent that anyone's right to health get violated. Rawls in unequivocal terms has stated, "Each person possesses an inviolability founded on justice that even the welfare of society as a whole cannot override". "For this reason justice denies that the loss of freedom for some is made right by a greater good shared by other".[104]

---

[103]*See* Latha Jishnu, "*Patent issues delaying Ebola cure*", (Down To Earth),Available at: <http://www.downtoearth.org.in/content/patent-issues-delaying-ebola-cure> (visited 16 March 2016)

[104] Rawls J. (1971) "*A Theory of Justice*", (Cambridge: Harvard University Press)

It is axiomatic that scientific inventions are going on at a great pace and the developed nations have delved deep into the intricacies so as to found a preventive and curing treatment, but still deadly diseases such as HIV/AIDS, malaria tuberculosis (TB), Cancer continue to affect the vulnerable section of the global population. Access to medicine is still a far distanced dream for many and in fact, about thirty three percent of the world's population does not have access to essential medicines.

"*Access to drugs cannot depend on the decisions of private companies but is also a government responsibility.*"

WHO Commission on Intellectual Property Rights, Innovation and Public Health (WHO 2006)

Today, the bottom two-thirds of humankind have about four per cent of global private wealth[105] and six per cent of global household income. 1 person in the top 5 per cent has as much income, on average, as 300 people in the bottom quarter.[106] In the light of this statics it is very clear that if TRIPS is used to compensate the pharmaceutical companies by allowing them to reap benefits by selling it at a high price and also mark-ups that require blocking access to cheap

---

[105] *See* Credit Suisse, "*Global Wealth Report*", p. 3, and "*Global Wealth Databook*", both available at:
<https://responsibility.creditsuisse.com/app/article/index.cfm?fuseaction=OpenArticle&aoid=291405&coid=284071&lang=EN.> (visited 16 March 2016)

[106] The income data used here were kindly supplied by Branko Milanovic, Lead Economist in the World Bank's Research Department, in a personal e-mail communication of 25 April 2010, on file with the author. Milanovic is the leading authority on the measurement of economic inequality, and his published work contains similar albeit somewhat less updated information. *See* Branko Milanovic: "*True World Income Distribution", 1988 and 1993: First Calculation Based on Household Surveys Alone*", (The Economic Journal,2002), pp. 51-92; Branko Milanovic: "*Worlds Apart: Measuring International and Global Inequality*", (Princeton: Princeton University Press 2005); Branko Milanovic, "*The Haves and the Have-Nots: A Brief and Idiosyncratic History of Global Inequality*", (New York: Basic Books, 2011).

generic medicines, then it directly violates the fundamental right to health as enshrined in Article 25 of Universal Declaration of Human Rights[107].

In modifying the pricing policies to the drugs, Indian Government must strike a balance in its prime responsibility of protecting health and welfare of the citizens of India and also to ensure that India remains equipped with world class life sciences capability. This balance is vital to ensure that Indian citizens, in particular common man, get access to medicines at an affordable price for the treatment of the disease conditions. Right to health is an absolute right and not a qualified right and therefore Indian Government either at the Central Level or the State Level cannot shrug off his shoulders from entertaining this claim in a holistic spirit, especially in the light of constitutional mandates enshrined in Articles 39(e), 42, 47, 48-A, 242, 243-G along with the Eleventh Schedule (item 23)

As a result of liberal interpretation of the words 'life' and 'liberty' under Article 21, health has gained utmost importance and in *Parmanand Katara v. Union of India*[108], the Apex Court held that *"Every doctor whether at a government hospital or otherwise has the professional obligation to extend his services with due expertise for protecting life".*[109]

This has to be the core mission of any successful government. At this juncture, it also needs to be mentioned that in contrast to other nations including many of the OECD economies, India has emerged as the global competitor of advanced life sciences facilities. Indian pharmaceutical industry as a leader all across the

[107] Article 25 of the Declaration reads: "Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and the right to security in the event of sickness, disability..." Available at:< http://www.un.org/en/universal-declaration-human-rights/>(visited on 18 March 2016)
[108] AIR 1989 SC 2039
[109] Available at:<http://www.cehat.org/rthc/paper3.htm> (visited on 19 March 2016)

globe in generics markets at international level has introduced imperative inroads in the field of innovative drug discovery. Therefore, the pharmaceutical pricing policy should ensure that India's capability to be a leader of the world in pharmaceuticals does not get affected, so that the needs of Indian citizens and also the needs of the human beings in general should be taken care of[110]. Achieving this balance is not an easy task and a lot of deliberation goes into it and the same has to be viewed on continuous basis so as to match with the changing dynamics at nation and international level.

Drug Price Control Order (DPCO) was released by the India's Department of Pharmaceuticals in May 2013. The number of medicines has been increased on the National List of Essential Medicines (NLEM) from 74 to 348 and also offers a new approach for ascertaining and implementing price ceilings with premium on the aspect of ensuring stable drug supply. The previous method of fixing the price ceilings, i.e. on cost + basis has been replaced by the market priced linked cap for the drugs. For all the medications under NLEM, yearly price increases are permitted which have to be must be "in-line with or below the wholesale price index (WPI)". [111]

As per the previous researches in this regard, prices of 348 essential medicines including some life saving drugs will be cheaper on an average to 20-25%. These medicines fall under 27 therapeutic areas. [112]

---

[110] Health is so imperative to the very existence of a human being that keeping it restricted to the national frontiers, will be a myopic view which goes against the basic tenets of justice in a broader sense.

[111] Availableat:<https://www.simonkucher.com/sites/default/files/are_marketbased_pharmaceutical_price_controls_the_new_reality_in_india_simon-kucher_april_2014.pdf>(visitd on 19 March 2016)

[112] Renita Tisha Pinto, "*Good News: Medicine Prices In India To Be 80% Cheaper*", Available at:<http://www.indiatimes.com/health/buzz/good-news-medicine-prices-in-india-to-be-80-cheaper-240120.html>(visited on 20 March 2016)

This DPCO has substantial impact and notable repercussions and hence Pharmaceutical and biotechnology based companies doing business in India have a lot to analyse. Also it is important from the perspective of policy front so as to ensure that the present framework does not end up in overdoing which reduces the overall efficiency of the healthcare system in a broader perspective and long term.

The DPCO is to be analysed on the touchstone of its three primary aims:

(a) Expansion of National List of Essential Medicines (NLEM),
(b) Authority with the National Pharmaceutical Pricing Authority (NPPA) to monitor and regulate the prices of NLEM, and
(c) Authority with NPPA to regulate price hikes relating to non-essential medicines.

The DPCO uses market-based mechanisms to set price ceilings.[113]But as a matter of surprise, the NPPA, however, at present entails no mechanism for officially penalizing a manufacturer that offends the rules.

The Indian government reserves the right of mandating continuous production for up to a period of 12 months, quarterly drug production reports to be furnished

[113] It works differently, depending on how many products are in a category: If a drug is one of many drugs within a given product category, the price ceiling is the simple average of the prices of all drugs that have at least 1% of market share within that product category (plus a 16% pharmacists' margin). If a drug is the only drug within a given product category, the new price ceiling for that drug category will be a fixed percent, based on price reductions in similar product categories, of the current drug price. Moving forward, all drugs in a product category must be priced at or below the price ceiling or the manufacturer will face monetary penalties. In the case that a drug's price is already below the price ceiling, a price increase is prohibited. *See "Market-Based" Price Controls In India?*", (Pharmaceutical Executive Editors, 2014),Available at: < http://www.pharmexec.com/market-based-price-controls-india-0> (visited 21 March 2016)

It is also a requirement that the manufacturers have to send a notice of 6 months' before the production of a given drug is about to cease. One of the most notable features is that this regulation exempts the entire range of drugs which are patented and developed in India, from the rigors of price control so as to incentivize research and development to be done in India.

Three key implications of The DPCO are worth mentioning for pharmaceutical and biotechnology based companies in India and also for India as a viable place for pharmaceutical/biotech R&D activities in future.

1. Comparatively fewer "branded generics"

2. R&D investment of MNCs in India.

A. Case Studies

Implication 1: Comparatively Fewer "branded generics"- To understand the subtle nuances related with this aspect, the following three cases are taken.

#1: **Novartis' desferrioxamine mesylate** is the product which has no other similar biologics and hence it is the only one in the NLEM (in its class it belongs to monopoly category). As it is the only drug within its product class/category, it will experiences a fixed % of price reduction at its current price. In order to assess the price reduction for this product, the current NPAA framework considers the "average reduction in similar product categories"[114]. Therefore on the basis of this calculation, price reduction will be around 24.80%, it will be the average price for antidotes.

#2 For instance, **GSK's Hepatitis B vaccine**, this drug has branded alternatives and also the low cost generics are available in the market. As these kinds of

[114] As note 111 above

drugs are highly expensive in comparison to the alternatives they experience a greater decrease in the prices, which is expected to be around 75%. The reason being that in the current scenario, the price ceiling is determined on arithmetic basis, and not the earlier weighted average, as a result of which it forces the prices to go down to a considerable extent.

The unique aspect about the GSK's product is that despite being an expensive drug in comparison to other drugs, but still enjoys 26% of the market share. The reason is that price and market share are not always inversely related in this product class Therefore, this category exhibits the DPCO's success. But we need to remember that this success of the DPCO is attributed to the fact that this drug has a large market share. It gives a clear signal that complex economic angels are involved and anticipation by studying the market dynamics becomes really very important for the success of this Policy.[115]

#3: **A local manufacturer** (Pavior)

The current DPCO policy clearly stipulates that the drugs patented and developed in India will not have to face the mandatory price reduction. This aspect has been a matter of debate because through this provision it is believed by many that the aim of DPCO is to have an impact on the high-priced branded drugs only that are seen as competitors to generic and "branded generic" alternatives. Whatever be the% of the locally manufactured drug, it will not have to go through the price regulation process.

Scholars have taken the example of "Pavior's drug" with a staggering price tag of Rs 6000, keeping the same totally out of the price regulation in contrast to others raises many concerns which have to be deliberated with a broader vision.

[115] I thank Mr. Vikesh Garg, (Lecturer of economics) for helping with the economic aspects.

Implication 2: DPCO & MNCs investment on R&D in India

On the basis of the market dynamics and the strategy adopted by these MNCs, it can be said that the probability of adversely impacting the investment by MNC's is quite low, owing to the fact that R&D centers of these MNCs are also established outside India. Also there is one more important fact that the revenue generated by these MNCs from NLEM drugs in comparison to their global sales is minimal and hence it can be said that the said that the MNCs were anyhow not interested in establishing the new R&D centers in India and the DPCO policy cannot add to this.

3.2 Patterns of Pricing In Other Jurisdictions

Despite it being an area of cut throat competition in the present scenario, the socio-welfare effects of drug prices have been made a subject of the government regulations in almost all the jurisdictions, barring few and the most notable amongst them being United States of America. However, the ways of regulating the prices are different in different countries.

In some countries, it is the government bears the cost of a part of the total bill. Many governments adopt the process of listing the drugs, by setting up the qualifying criterion and the extent of its reimbursement. In most of the OECD member countries, therapeutic value of the drug is taken a conclusive factor for fixing the price along with the analysis of its production cost and the price of the similar drugs. It is also worth mentioning that the systems which are practiced in OECD member nations are integral to the universal health care and delivery system which gets is funded via different devices such as insurance, national budget and the employer benefits.

In France and Italy, social insurance programme is the key determinant for the manufacturers The UK system with regards to the patented drugs is of no price controls,but it has an inbuilt mechanism that seeks to monitor and regulate levels of profits by requiring annual disclosures to be furnished by the companies. It is also worth mentioning that price system of UK is favorable towards domestic firms with corporate headquarters and centers of R&D in UK. The positive outcome of the same is quite obvious in the form of capacity building enhancement.

It is important to mention that the multinationals substantial sales are to National Health Service in U.K., which means that a better distribution system is ensured due to the stocks availability with the governmental origination and at the same time the system of annual arrangements between companies and National Health Service regarding the total sum to be paid, also assures the companies with a reasonable rate of return. Reference pricing with regards to pharmaceuticals is followed by Germany. This is based on the system of classifying drugs belonging to similar therapeutic purpose into same groups with and setting "common reimbursement price" which has to be given to all belonging to a group similar in therapeutic purpose. The consumer is supposed to pay the difference between manufacturer's price and reference price as a result of which demand gets highly elastic at/above the reference price. One of the most notable features is that in all the above mentioned nations, substantial numbers of people are covered by one of the health security schemes. [116]

[116] The system adopted in Mexico, where public health care covers around 51% of the population, uses the weighted average ex factory price in the preceding calendar year in six countries that have contribut ed to the largest sales of the product. *See* S. Narayan, "*Price Controls On Pharmaceutical Products In India*",(ISAS, 2009), p.41

China's model has been widely discussed for its excellence in reducing the production cost. One of the most notable factors is that the health expenditure by Chinese Government is much more than that of the Indian Government. China follows a very good mark-up of the pricing for retailers and wholesalers, which has turned out to be a good economic model. China's value-based approach towards pricing and the focus on reimbursement to the off-patent initiators has also been a matter of deliberation. The use of Multiple Criteria Decision Analysis (MCDA) approach which puts premium on the methodical and orderly analysis of the current pricing trends and the reimbursement policy framework.

China's New Policy which has become effective from June 2015, puts premium on removing the twofold pricing control regime of the government with a view to to pave the way for decentralization, and to open the gates for prices to be determined by the market forces and medical insurance systems. Their current policy also focuses on tendering mechanisms whereby the hospitals can directly play a major role n the procurement of the drugs.

In absence of such security and insurance schemes along with low purchasing power of Indian people, Indian Government came up with its own model of bringing certain key essential drugs under the regime of price control. Based on India's experience post TRIPS Regime, and also the analysis of the major jurisdictions, it can be said with certainty that prices of the drugs had increased to a great extent after the protection. [117]

[117] *See* Iain M. Cockburn,"*Intellectual Property Rights And Pharmaceuticals: Challenges And Opportunities For Economic Research*", (The Economics Of Intellectual Property), P. 166, Available at: <Http://Www.Wipo.Int/Export/Sites/Www/IpDevelopment/En/Economics/Pdf/Wo_1012_E_Ch_5.Pdf>(Visited 23 March 2016)

India having a unique socio-economic ethos and a world renowned pharmacy industry, coupled with the obligations of a welfare state, poses a strong case where balance between incentives for pharmaceuticals and the need of ensuring accessibility and affordability of medicine has to be maintained. It is important that the latest drugs and formulations are available, that they can be reached to all, whether in the public health or the private health systems.

It is equally important that there be an environment for industry and research to grow, and that global firms are comfortable using the talent pool in India for R&D and drug discovery, assured of reasonable returns. In the light of income disparities , an array of "private care and public health systems, and freedom of choice, and the distortions likely to be caused by the price fixing for patented products, it is important to consider creative solutions that would suit a developing country like India."[118] "The drug prices in India were brought under control based on the recommendations of the Hathi committee, which observed that since the drugs industry has a social responsibility, it should operate much above the principles of trade for profit." [119]

3.3 CURRENT NPPA POLICY AND DPCO 2013: A SOLUTION OR NOT- A CRITICAL ANALYSIS

A. STANDING COMMITTEE PHARMACEUTICAL DRUGS (JUNE 2013)

Recommendations made by the standing committee on the functioning of ministries and their departments. (Report of Standing Committee on chemicals and fertilizers). Based on the 29th Report, the following are noteworthy areas of concern:

---

[118] S. Narayan, as note 116 above

[119] S.B. Puranik, MamataSangamesh & Mona Golshan S, "*Patent Laws In India And Its Impact On Pharmaceutical Industry*", v. 6(2)(International Journal of Pharma and Bio Sciences 2010)., p.9, Available at:< http://www.ijpbs.net/issue-2/117.pdf> (visited 23 March 2016)

Pharmaceutical companies use loopholes in DPCO of the Government and frequently change the composition of medicine. The report has pulled up the pharmaceutical company's strategies to use *dietary supplements in the original drugs* to avoid cost involved in the manufacturing. Committee has asked the Government to invoke the provisions of DPCO to curb malpractices adopted by the Pharmaceutical companies to increase their market share.

B. COMPANIES RANDOMLY FIX PRICES. LACK OF CONTROL OVER IT.

A careful analysis of the NPPA mechanism reveals that that the authorities have no powers to act against companies that failed to submit the price list of their products. The committee also found that there is no provision to book the companies that indulge in malpractices, they only ask for the penalties, the effect of which gets diluted to the quagmire of litigation that happens in Indian scenario. It has expressed concerns over the limited mandate of NPPA in fixing prices of scheduled drugs and said that even the state drug controller is helpless in dealing with defaulters. The essential commodities law does not provide any deterrence to malpractices. It is imperative that NPPA establishes an effective co-ordination between state drug controller and manufacturing units to ensure timely flow of data.

C. PRICE OF A DRUG VARIES IN DIFFERENT STATES.

We must have a centralized drug pricing system it must be followed by all states. Tamil Nadu and Kerala State Governments offer the medicine at a price which is 4000% less than what is offered in other states.[120] A survey conducted

[120] *Supreme Court Direction To Centre Over Drug Pricing Policy (July 16 2015)* The Supreme Court has directed the centre to reconsider the existing drug pricing policy for determing the prices of essential medicines. The apex court described the NNPA as unreasonable and irrational pointing out that price of certain medicines to have been found too much higher than

by the World Bank in 2002 with reference to the Indian pharmaceutical policy's impact on health sector, and it was found that there were significant variations in affordability, availability and also the quality of drugs in different states. States like Tamil Nadu have been successful in setting up reasonably strong pharmaceutical system, whereas states such as Uttar Pradesh are much behind.

> *"Most of the variations among the states are attributable to differences in the quality of human resources and institutions, with differences in socioeconomic development and political stability also contributing. The broad conclusion is that, despite the impressive growth in the Indian pharmaceutical industry over the last 25-30 years described above, problems with the availability, affordability, and rational use of good quality, cost-effective, essential drugs have persisted in most parts of India, and that these health-related issues need be addressed as apriority."* [121]

---

the prices fixed by some state governments(more than 4000 %). A bench headed by Justice TS Thakur has sought the analysis and explanation from the ministry of chemicals and fertilizers on this matter. Why the prices of essential medicines has been fixed so high, due to this poor people cannot purchase life saving drugs. Tamil Nadu and Keral State Governments offer the medicine at a price which is 4000% less than what is offered in other states. What kind of monitoring is this and why cognizance of this fact is not taken. Available at:< https://www.youtube.com/watch?v=P1Y5EN8QuGw>(visited 1 April 2016)

[121] *See* Ramesh Govindaraj, Gnanaraj Chellaraj, "*The Indian Pharmaceutical Sector: Issues and Options for Health Sector Reform*", (World Bank Publications, 2002), p.5 Available at: <https://books.google.co.in/books?id=lsUxvD4vULkC&pg=PR5&lpg=PR5&dq=Most+of+the+variations+among+the++states+are+attributable+to+differences+in+the++quality+of+human+resources+and+institutions,+with++differences+in+socioeconomic+development+and+political+stability+also+contributing.&source=bl&ots=Y0U2J9QFXP&sig=JS3oyhSYBCtftbmw73HqH9uUvpo&hl=en&sa=X&ved=0ahUKEwjpgP-WlcXMAhXHTI4KHQ-MBtgQ6AEIGzAA#v=onepage&q=Most%20of%20the%20variations%20among%20the%20%20states%20are%20attributable%20to%20differences%20in%20the%20%20quality%20of%20human%20resources%20and%20institutions%2C%20with%20%20differences%20in%20socioeconomic%20development%20and%20political%20stability%20also%20contributing.&f=false>(visited 3 April 2016)

In the light of the above problems, work at state level needs to be done with a focus on intensifying the regulation and implementation of already existing mechanisms in a better manner, rather than introducing new regulations. .

D. INFRASTRUCTURAL LAPSES LEADS TO LACK OF INVESTOR CONFIDENCE.

In India there is a lack of investor confidence, there is a concern by domestic players as well. For example, new projects are getting shifted outside the country. BIOCON decision regarding putting a new facility in Malasia attracted the worldwide attention. As per the T.V. interview given by Kiran MajumDar Shaw, Biocon could have done it in India but they thought that it is a risk in India and they believed that as a growing pharmaceutical company, they need to de-risk it by having a different geographical location. The biggest risk they see is that the infrastructure.

It is true that India has a huge infrastructure deficit in terms of roads and many other aspects industrial ecosystem, power deficit and if we don't fix that we become very unattractive for investment. It gives an advantage to the countries like Indonesia and Malaysia who are competing with India in the race for getting more and more investment.

It is not about the absence of the growth possibilities[122] , the bigger challenge is the regulatory framework, India does not have the optimal regulatory structure to

[122] There are still great opportunities for the Pharmaceutical companies and the need for affordable medicines is a spiraling task for all the countries. Indian Companies have the large opportunity to make a play at such a time. India is the lowest cost manufacturer of generics and generics today count 30% of 900 billion $ pharmaceutical market. In U.S.S 75% prescriptions are generic and 70% requirements are met by India. In India we have the concept of Branded Generic and unbranded generics while in U.S.S we don't have such a classification. In India we have such a diverse range of companies starting from small cottage level industries to very large pharmaceutical companies, we tend to have diverse prices because the larger companies intend to have premium on their products, whereas the small companies are intending to capitalize the low price generics.

move the things fast enough. We have been talking about implementing the Masehlkar committee report, but it hasn't been implemented. Revamping of whole regulatory system is all there in this committee report, and we are slow to take important decisions that is why we huge deficit in infrastructure, power, in regulatory reforms. If we want to be the big economy, we need to take quick decisions.

Second, the government needs to focus on the continued assessment of private health care markets, which entails private hospitals, expensive patented drugs and private insurance. Focusing on private market results in ensuring that India's middle-class which is burgeoning at a pace, which at present comprises around 200- 300 million people, will be having access to the sophisticated world-class health care, which in turn will ensure that the government's money reaches to that segment of our population which cannot afford private insurance and also find it difficult to bear the out of pocket expenses.

E. SUPPLY OF SPURIOUS DRUGS AND SUB STANDARD DRUGS

On many occasions, Government has been criticized for not ensuring the regular supply of medicines in all states which is must to satisfy the criterion of accessibility and at the same time NPPA must conduct frequent checks to put a check on the circulation of spurious drugs and substandard drugs in the market.

F. COMPLEX ADMINISTRATIVE PROCESS: MULTI TOUCH POINTS PROVIDING SPACE FOR DODGING THE PROCEDURE

As per the details published by the ministry of health, the quality of drugs is monitored by the drug controller of India which is under the jurisdiction of the

ministry of health and family welfare whereas, the pricing and availability of drugs falls within the purview of department of pharmaceuticals. Central Drugs Standard Control Organisation is under the ministry of health and family welfare. The presence of multiple monitoring bodies allows the pharmaceutical companies to skip the check procedures. Government must link the monitoring drug quality with the pricing and availability. According to Parliamentary Standing Committee, The department of pharmaceuticals must take up quality control and regulatory mechanisms under ministry of chemicals and fertilizers. The department should take necessary steps to make NPPA self sufficient and resourceful to monitor the prices of non-scheduled drugs independently and effectively.

G. Absence of non- scheduled drugs Essential commodities Act

Essential commodities Act, which is a principle Act in controlling drug prices does not include non- scheduled drugs. These scheduled and non- scheduled drugs must find a place into Essential Commodities Act so that it controls the pricing mechanism in a better way.

H. Inclusion of only Specific Drugs instead of class of drugs

New list included only specific drugs and not a class of drugs. Experts say that almost all the 348 drugs listed have effective alternative medicines available and pharmaceutical companies can escape the price control by selling these alternatives. For example, if A producer is producing Enalapril[123], which is used

123 Enalapril is an ACE inhibitor. ACE stands for angiotensin converting enzyme. Enalapril is used to treat high blood pressure (hypertension) in adults and children who are at least 1 month old. Enalapril is also used to treat congestive heart failure in adults. Enalapril is also used to treat a disorder of the ventricles (the lower chambers of the heart that allow blood to flow out of the heart). This disorder can decrease the heart's ability to pump blood to the body. <http://www.drugs.com/enalapril.html> (visited 20 April 2016)

in high blood pressure, then he will stop Enalapril and I will start peridopril[124], so that is how they will dodge the price ceiling.

I. COVERAGE OF SOME COMBINATION DRUGS ONLY

New Pharmaceutical Policy covers only some combination drugs. While the drugs listed under pricing control will have to sell for less but if the combination is changed, they can escape the price cap. Companies can actually circumvent or bypass the DPCO by actually changing the formulation and adding some irrelevant ingredient or a combination and again price it in the way they want it.

J. WHO PATENTS THE PRODUCT OVER WHAT IS PATENTED.

Some provisions under TRIPS indicate that price controls can be imposed on the products which are patented. However, exemptions to the products which are domestically produced by using the domestic Research and Development and are also patented in India are given by the government. Such exemptions to all the drugs falling under this category has the potent of keeping the prices very high which in turn makes the access to the drugs very difficult. It seems that 'who patents the product' carries more importance than what product gets patented.

K. NATIONAL LIST OF ESSENTIAL MEDICINES (NLEM) NEEDS EXPANSION

At present, prices of medicines which fall under the purview of the National List of Essential Medicines (NLEM) are to be regulated. The objective behind the

[124] Perindopril Erbumine Tablets are indicated for the treatment of patients with essential hypertension. Perindopril Erbumine Tablets may be used alone or given with other classes of antihypertensives, especially thiazide diuretics. < http://www.drugs.com/pro/perindopril.html> (visited 20 April 2016)

same is to ensure that medicines which are deemed 'essential'[125] or life-saving as per the definition given by the WHO, have a reasonable price and hence making it affordable for the substantial portion of the population. The 2013 order entails 348 molecules which are available as 650 formulations (injections, tablets, capsules and syrups of varying strengths). The question arises that is it enough to ensure the accessibility of the medicine for more than 1.3 billion people of the nation? The answers is no.

> For example, *"While 358 formulations of paracetamol are under price control, over 2,714 combinations (80 per cent of market share) are not (Sourirajan Srinivasan, 2013). Despite price controls, the Drug (Prices Control) Order, 2013 covers only 17-18 per cent of the domestic market (55 per cent is excluded combinations of NLEM drugs), with little impact."*[126]

Several Analysts in India have called for an urgent expansion of the essential medicines list. An independent evaluation of the current policy carried out by the Public Health Foundation of India and the Institute for Studies in Industrial Development has revealed that the current price regulation is limited to only 17% of the total drugs prescribed by the doctors in India. As a result of this,

---

[125] According to the World Health Organization, essential medicines are medicines that satisfy priority health care needs of a population, and they are selected with regard to disease prevalence, safety, efficacy, and comparative cost-effectiveness. In addition, they are intended to be available in functioning health systems at all times in adequate amounts, in appropriate dosage forms, with assured quality, and at affordable prices. *See (*Asian Bioethics Review December 2013) Vol. 5(4), p. 376.
Also *See* <http://apps.who.int/medicinedocs/en/d/Js4875e/5.2.html>(visited 21 April 2016)

[126] Feroze Varun Gandhi, "*Drug Pricing: A Bitter Pill To Swallow*", Available At: <Http://Www.Thehindu.Com/Opinion/Columns/Drug-Pricing-A-Bitter-Pill-To Swallow/Article8281282.Ece> (Visited 22 April 2016)

substantial market remains untouched and hence its provides only limited relief to the patients.[127]

The study also indicates that out of the 100 top most selling brands of India, 55 brands are outside the purview of the price control. In the top 20 acute brands, 8 remain outside, as a result of which researches have said that the Drug Price Control Order (DPCO) 2013 has been unsuccessful in bringing newly launched drugs under its purview.

L. Cost Based Method: Need of revising the same

It is highly recommended that the cost based formula needs to be reinstated.[128] Although, prima facie it looks fair as top 1% sounds fairly reasonable but in reality, brands having 1% of the market share have the highest sales and also have a substantial price difference among them , in some cases it is as high as 10-18 times. Therefore when the average is taken, the prices will remain high owing to this difference.

> *"As in the case DPCO, the new step will certainly bring down the prices of some diabetic and cardio vascular drugs; but it could have done better if it had based its price cap on the manufacturing cost because the difference between the manufacturing costs and retail prices often is huge - sometimes as high as 1000 percent."*[129]

---

[127] Available at: <http://isidev.nic.in/pdf/med_cov.pdf> (visited 23 April 2016)

[128] What the pricing policy did then was replacing the earlier regime, in which prices of drugs were calculated based on the cost of manufacture, with a regime that decided the prices based on existing market prices of top selling brands. The new regime took the average of the three brands that have one percent of the market share. See "*Not Just Price Caps: Here's How The Govt Can Make Essential Drugs More Affordable*", (Firstpost, 2014), P.2, Available at: <Http://Www.Firstpost.Com/Printpage.Php?Idno=2010689&Sr_No=0>,(Visited 24 April 2016)

[129] G Pramod Kumar, "*Healthcare: How govt can make essential drugs affordable*", (Firstpost, 2014), Available at:< http://www.firstpost.com/india/healthcare-how-govt-can-make-essential-drugs-affordable-1621655.html>

M. ESCAPE ROUTES

The rules relating to the price cap on 348 medicines are not free from the "escape routes" and therefore give only limited relief to the consumers. Though there are many instances of dodging the current DPCO 2013. However, for the purpose of this research work, two cases haves been included for the deliberation:

(a)GlaxoSmithKline (GSK) Consumer Healthcare had a price controlled product in the form of Crocin 500 mg, and was available at around Rs 14 for 15 tablets. Later on it launched new 'Crocin Advance' 500 mg having a high price tag of much higher price of Rs 30 for 15 tablets, and planned to slowly take out Crocin 500 mg. GSK Consumer Healthcare claimed the latest Crocin Advance to be a new drug and hence pleaded for keeping it outside the purview of price control system. According to IMS Health data, "Crocin Advance' was at that time the fifth largest brand among top Paracetamol branded generics, having a sales turnover of Rs 10.3 Crore for a window of 12 months".[130]

(b)The second instance where pharmaceutical companies evaded DPCO was related to anti-lipid drug Atorvastatin .Some companies were found selling the anti-lipid drug Atorvastatin[131] in the dosage forms ranging between 0 mg and 40

(visited 24 April 2016)

130 "*Is Drug Price Control The Key Growth Barrier For Indian Pharma Industry*?",(Pilman 2015),Available at:
<http://www.tapanray.in/is-drug-price-control-the-key-growth-barrier-for-indian-pharma-industry/>
(visited 25 April 2016)

131 Shardul Nautiyal, "*State FDA finds atorvastatin being sold at higher prices after tweaking prescribed dosage*", (Pharmabiz.com, 2014),Available at:
< http://www.pharmabiz.com/NewsDetails.aspx?aid=81220&sid=1>(visited 25 April 2016)

mg, which was the outside price control mechanism, as only 10 mg dosage form was under price control. [132]

Though the same was brought t the notice of NPPA by Maharashtra FDA on the account of absence of "proven additional therapeutic efficacy" for their product, but the important factor to note is that the claims get lost somewhere in the quagmire of the litigation and the time taken to reach to a conclusion is used to reap the benefits for the time being.

(c)Only specific strengths are covered in the NLEM. For instance, 1 ml of the Hepatitis B vaccine falls under the list, but 0.5 ml of the Hepatitis B of is not. It is worth mention that in some of the cases, the 0.5 ml vaccine carries more price than that of the 1 ml vaccine.

There are other ways[133] to dodge the same which indicates that the current system needs to be re- examined and the market dynamics and the strategies adopted by the pharmaceutical industries needs to be properly studied.

N. THE PARADOXICAL MOVE

DPCO "paradoxically" overburdens the drug companies already having their current prices below the price ceiling as they are forced to stick to the same price.

---

[132] *See "Is The New 'Market Based Pricing' Model Fundamentally Flawed?"*,(Pilman 2014),Available at:
< http://www.tapanray.in/is-the-new-market-based-pricing-model-fundamentally-flawed/>
(Visited 25 April 2016)

[133] Many FDCs(Fixed Dosage Combination) made their way into the markets which were medicines made from 2/more regulated drugs but since the FDC wasn't in the list, it wasn't under the regulation.

"This provision has an adverse impact on the small and medium scale pharmaceutical industry," "This provision punishes those producers who already charge less than that of the ceiling prices. It seems that the Government skipped the economic dynamics that can compel the manufactures to increase the price. For instance the fluctuation in currency and the volatile rates of the raw material may be the compelling factors.

3.4 A WALK THROUGH *NATCO V. BAYER*: ITS NEXUS WITH THE NOTION OF DIFFERENTIAL PRICING

Differential pricing structures is one unique way which has been considered as an effective way of ensuring better access to medicines without compromising on (R&D) incentives. This method holds utmost importance for the developing countries. Indeed, the rationale of this theory is deeply rooted in the economic theory itself. "Efficient recovery of fixed R&D out- lays calls for discriminatory pricing structures, whereby low-demand elasticity consumers pay more for drugs than high-demand elasticity consumers."[134]It has already been admitted in the prior researches that the free-market differential/discriminatory-pricing in segmented markets is not likely to approximate Ramsey pricing – "which are in fact regulated prices". It is worth mentioning that pricing-to-market helps the patients in affording the expensive patented medicines, at the same time the R& D costs are also taken care of. Some form of this system is prevailing in Mexico. [135] This way seems to have the potent of achieving the much desired goal of establishing a balance between helping the needy patients in affording the medicine and also ensuring the space of incentives for the R&D activities.[136]

---

[134] *See* Iain M. Cockburn, as note 117 above, p.150
[135] S. Narayan, as note 116 above
[136] *See* Iain M. Cockburn , as note 117 above, p.174

In the light of guideline 33 and 34[137], an endeavour has been made to set up mechanisms so as to hold pharmaceutical firms accountable when their acts as an impediment in ensuring the availability of medicines and thereby effecting right to health.

While examining this issue the Indian courts have indirectly referred to the right to health so as to guarantee that pharmaceutical firms do not use the patent exclusivity in a way that hinders the access to medicines. *Natco v. Bayer*[138] is an illuminating case on this aspect. [139]Natco asserted that drug was priced at exorbitant prices of Rs. 2,80,000/month and thereby making it unaffordable for the common masses (paragraph 11, p. 24). It is important to note that no

[137] Guideline 33 provides that a pharmaceutical company "...should give particular attention to ensuring its medicines are accessible to disadvantaged individuals, communities and populations, including those living in poverty and the very poorest in all markets. Guideline 34 provides that "the arrangements should take into account a country's stage of economic development, as well as the differential purchasing power of populations within a country. The same medicine, for example, may be priced and packaged differently for the private and public sectors within the same country"

[138] It involved the grant of a compulsory licence in March 2012 to Natco on Bayer's drug, Nexavar, which is a palliative medicine for kidney and liver cancer.

[139] "Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. In current public discussion, this is usually associated with pharmaceuticals, but it could also apply to patents in any field. Compulsory licensing enables governments to temporarily override a patent and license the use of a patented invention to a third party without consent of the patent holder. In other words, compulsory licensing authorizes the production of generic substitution of patented medicine in the public interest. Although article 31 of the TRIPS Agreement allows the use of compulsory licenses, there are a number of requirements that need to be respected." *See* Sidonie Descheemaeker, "*India, Pharmacy of the Developing World IP, Trade and the Access To Medicine*", (Jura Falconis 2012-2013), p.546, Available at:
< https://www.law.kuleuven.be/jura/art/49n3/descheemaeker.pdf> (visited 26 April 2016)
According to section 84 of the patents act, anyone can file a petition for the compulsory licensing of a patented technology/invention if it is not available at a reasonable price or if the reasonable requirements of the public are not met. *See* Varun Mishra, "*The Indian IPR Poilcy-Fitting Enough For The Pharma Industry?*", Available at:< http://stellarix.com/ip-news/the-indian-ipr-policy-fitting-enough-for-the-pharma-industry/>,(visited 30 March 2016)

differential pricing concept was implemented in India by Bayer. In assessing the prayer of Natco with reference to compulsory license, sale price of the drug in India was taken into consideration. Section 84(1)(b) , Indian Patents Act entails "reasonably affordable price" as one of the factors. Indian Intellectual Property Appellate Board (IPAB) stated that

> *"the right of access to affordable medicine is as much a matter of right to dignity of the patients and to grant stay at this juncture would really affect them..."*
>
> (paragraph 34)

I am of the opinion that had Bayer abided by differential pricing for selling Nexavar, the result of the case could have been different due to the compliance with the requirement of reasonably affordable price.

3.5 PRICE REGULATION FOR THE PHARMACEUTICAL INDUSTRY: DOUBLE EDGED SWORD

Price regulation for the pharmaceutical industry has the potential to act as a double edged sword. Policymakers typically focus at making drugs economically cheaper and affordable; at the same time, price control may have an adverse impact on availability of medicines. The prospects of firms exiting from producing the category put under regulation owing to low profit cannot be negated. Less profits is also seen as an obstacle for the entry of new firms. [140]

I am of the opinion that extensively well thought healthcare policy is the need of the day. Overburdening Pharma industries should not be to such an extent that

---

[140] *See* Arvind Sahay & Saravana Jaikumar, "*Does Pharmaceutical Price Regulation Result in Greater Access to Essential Medicines? Study of the impact of drug price control order on sales volume of drugs in India*"?, (Indian Institute of Ahemdabad, 2016), p.5

either they stop producing the drugs falling under the regulated category or they dodge the rigors of pricing policy by finding escape routes. In the light of the above mentioned peculiarity of the current pricing policy, it becomes imperative to see that whether the present price regulation model has any adverse impact on the sales volume of drugs in India.

A recent study suggests that "while some molecules had an increase in sales volume that can be attributed to DPCO, overall the impact has been negative."[141] In this study the event window was July 2013 to June 2014. The data used for this study was taken from IMS Health (India) database. [142]

"The event study indicated that, while few of the molecules analyzed (37) had an increase in sales volume attributable to DPCO, majority of the molecules (52) had a negative impact on their sales volume due to DPCO. Overall, the DPCO may have had a negative impact in terms of sales volume of oral solid molecules, with the average change in sales volume to be -33,931,992 units "[143]

In the light of the above mentioned outcomes, it is as clear as day light that price control is resulting in decreasing access to the those drugs which are essential as price ceiling is put only on essential drugs. It is the need of the hour that government re-examines the model and operation of the current price control in India. It is important to note that the drug in India are already sold at a very low cost and also the profit margins are lower for Indian pharmaceutical firms than that of the gigantic pharmaceutical firms of the west.

---

[141] *Ibid*

[142] IMS primarily records secondary data, i.e., sales data from stockists to retailers. All the oral solids (105 molecules) that come under the DPCO regulation are included in the analysis (few very low volume oral solids that are under NLEM 2013 are not covered by IMS due to insignificant data).

[143] Arvind Sahay & Saravana Jaikumar, as note 140 above, P.16

My own field based research results are note worthy in which I go to know that for some medicines like medicines or syrups which are not frequently used but very important for health are not easily available. According to the chemists I interviewed that the objective for them to stock these medicines is to earn enough margin, but when they can't get the same it becomes difficult to stock them. Anti rabies serum, TB syrups are the examples of the same.[144] Many pharmaceutical manufacturers stopped manufacturing the drugs which fall under the regulated list which in turn resulted in causing severe shortages. For instance: owing to the reduction of Human albumin serum, which is used in diseases elated to Kidney & liver, etc) from Rs. 4000 per 100 mL to Rs. 1650 per 100 ml, resulted in its severe shortage in the market.

3.6 Challenges And Issues Related To The Pharmaceutical Sector: Is The Government Exercising Crude Wisdom That Is Devaluating The Pharmaceutical Sector

It is as clear as daylight that the balance between accessibility to medicine and incentives for the Pharmaceutical sector is of vital importance. Accessibility to medicine is important but pharmaceutical companies must be able to invest in the pipeline so that they can bring new molecules into the market. They can't do that if they don't have a reasonable margin. "The primary question of investigation that emerges is that whether the Pharmaceutical Sector is overburdened?"

> *"The government seems to confuse its social objectives with the market economics of the pharmaceutical industry. Government seems to have abdicated his responsibility to ensure health care and is basically trying to pass the responsibility on to Indian Industry."*

[144] Based on the interview of the chemists

Kiran Majum Dar Shaw[145]

One of the most important reasons behind a statement of this nature may be that Government needs to understand that it should focus on providing universal healthcare and in that there are several mechanisms available to the government to make sure that drug prices are at their lowest. This is already happening in many state governments like Kerela, Tamilnadu, Karnataka. Further, shrinking of prices through other mechanisms which are very strict in nature ends up devaluing this important sector. Indian Industry needs to invest in this sector, it needs to compete globally because this is one sector which has the potential of becoming a very large provider of drugs to the world market and apart from the prospects of creating huge manufacturing base.

A. Impact dues to softening of prices

The Current pricing system does soften the prices, but at what cost? Indian Pharmaceutical Industry faces lot of challenges from Chinese manufacturers. Many drugs have been stopped manufacturing in India because it is just not cost effective for Indian companies to manufacture this drugs and hence they are importing these drugs from China. Dual Ceiling price is another hard move, as it provides different standards for the domestic manufacturers and the foreign manufacturers. This is strange that the imported insulin from the China enjoys higher prices in comparison to that of the Indian drugs.

Does the current system intend to say that it is batter to import insulin than to manufacture insulin? Isn't this move really devaluing the industry? This is quite surprising to note that the imported insulin from the china enjoy higher prices.

[145] She is the Chairperson & Managing Director, Biocon Limited.
<http://www.biocon.com/biocon_press_kmprofile.asp?subLink=down>(visited 27 April 2016)

B. Percentage of Expenditure on the Medicines In Comparison to That of the total Expenditure: Does that really help in ensuring affordability?

I am of the opinion that the Government needs to be understand that Drugs today only constitute around 35-40%.[146] Now where is the price control on the other aspects that covers 60 % of the expenditure on health? Do we have any controlling measure for the fees charged by the doctors for consultation hospitals cost, diagnostic centers? Also, the logistic component of the health care is a whopping 20 %. If we can work on logistics, affordability issue can be tackled in a most comprehensive manner. If one actually looks at what drug constitute as a % of the total healthcare spending, it is only 40%(oncology), so even if the government keeps on hammering away at drugs, the cost factor in totality cannot be changed by only focusing on drugs.

In the light of the same one pertinent question that emerges is that, has Drug Industry become a soft target and is that all the Government has gone after?

C. Has the Government done its bit

Private sector has created large opportunities. 80% of healthcare infrastructure is by private sector in India. It is a growing business and it is expected to be a 50 billion $ business by 2025. The area of concern is that the government has not done its bit. Today we spend a meager percentage of our GDP on our healthcare and this is the lowest in the world. *Despite of the fact that India has signed the Alma Ata Declaration 1978 which aimed at 'Health for All' by 2000,*

---

[146] Based on the interview. See contra, Healthcare access in India is affected with 70:70 paradox; 70 per cent of healthcare expenses are incurred by people from their pockets, of which 70 per cent is spent on medicines alone, leading to impoverishment and indebtedness. *See* Mahaveer Golechha, "*Healthcare Agenda for the Indian Government*", vol. 141(2), (Indian Journal of Medical Research, 2015), Available at:
< http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4418149/> (visited 28 April 2016)

the Government of India spending on health has been very low. We haven't been able to fulfill the same even in 2016. Increase in public health spending to 2.1% of GDP is expected by the end of by the end of the 12th five year plan.

Now, the Government has started taking essential steps, like freely distributing essential drugs. The way they are planning to do is through getting into e-procurement mode. They have also said that they will start reimbursement model for hospital care through accredited hospitals, nursing homes and diagnostic centers where they have pre agreed understandings with these accredited hospitals.

3.7 IT IS NOT A SOLUTION IF IT IS NOT AFFORDABLE: SUGGESTIONS FOR MAKING THE PRICING POLICY MORE EFFECTIVE

.....It's not a solution if it's not affordable.[147]

A. YESHASVINI SCHEME IN BANAGALORE

Indian are known to be genetically 3 times more vulnerable for heart attack. Indians develop heart attack at a younger age. (Average Age on Global Level - 65, In India, it is 45 years). As per the estimates, 2 million heart surgeries should be done a year, while only 120,000 heart surgeries are done a year. Remaining people perish in the process of time. "In India, a large number of children are born with a heart problem (600-800 per day)," adds Dr Shetty. He further says that, of these, 90 per cent perish gradually without ever getting any type of care."[148] It is because our government spends around 1.1% GDP on the health

[147] It's not a solution if it's not affordable: Dr. Devi Prasad Shetty at TedxGateway 2013, Available at:<https://www.youtube.com/watch?v=C3CXhwJjnk4>(visited 28 April 2016)

[148] Neelam M Kachhap, "*Breaking Ground on the way to success*",(Financial Express, March 2015),Availableat:<http://www.financialexpress.com/article/healthcare/cover-story-healthcare/breaking-ground-on-the-way-to-success/52795/> (visited 30 April 2016)

care (slightly more than sub Sahara African countries). So there is a great need of an Alternative for healthcare funding.

One of the most notable amongst them is the Yeshasvini scheme. It was around 2003, when Karnataka Government's Health Insurance- Yeshasvini was introduced. 1.7 million Farmers were asked to contribute Rs 5 a month and Government agreed to become the reinsurer. In 10 years over 4.5 lakhs of needy people had variety of surgeries and 50 thousand farmers had heart operations.

According to Dr. Devi Prasad Shetty, India has already crossed the mark of 850 million mobile phone subscribers, who are spending Rs 150/month, if Rs 20 are taken from every person cover health of 850 million people can be covered. In 2000 the concept of health city in Bangalore (Narayana Hrudayalaya Health City in Bangalore) took a definite shape. In the present scenario, Yashisvini's Scheme is recognized as huge success[149] which can be emulated on the national level.

The importance of Insurance is immense. "*The government's push for low cost "in-patient" insurance, while encouraging, should also incorporate out-patient expenses. Low-cost diagnostic capabilities, generic drug stores (Rajasthan's*

[149] It conducts 40 heart surgeries every day, It has expertise in liver transplants on babies less than 10 kg weight with 95 per cent success rate, It is the first heart hospital in Asia to implant an artificial heart, It has performed combined kidney and pancreas transplant, offers formal training programme for paediatric cardiac surgery, Thrombosis Research Institute, Bangalore a division of Narayana Health is working towards discovering a vaccine to prevent heart attack. The Institute has come up with markers to diagnose heart disease early, Two units of NH, Narayana Institute of Cardiac Sciences, Bengaluru and Narayana Multispeciality Hospital, Jaipur are JCI-accredited and four others are NABH-accredited. See Neelam M Kachhap, as note 149 above

"Life Line" drug stores) and low-frills hospitals that provide affordable care (Vaatsalya) can be considered."[150]

If the lessons from the above mentioned instances can be taken than it will not be exaggeration to say that India can become the "first country in the world to disassociate health care from affluence, India will prove to the world that wealth of the nations has nothing to do with the quality of health care its citizens.

B. VIABLE SUSTAINABLE MODEL

It is the need of the hour to have a viable-sustainable model having the potent of providing access to every citizen in terms of delivering a decent quality of healthcare. It is about creating a healthy environment, in which range of factors have a major role to play. For instance, sanitation plays such an important role. 50% of our population defecates in open.[151] We cannot let our people fend for themselves when they fall ill. 80% of expenditure on health happens out of pocket[152]. Today world debate is about OBAMA CARE[153], because they also clearly recognize that people cannot be left in exclusion to fend for themselves when they fall ill. We need to develop proper sustainable economic development model that does provide healthcare to all. It is a big challenge because it is a huge economic burden; it starts with preventive health care. In our pursuit of

[150] Feroze Varun Gandhi, as note 126 above

[151] *See*<http://www.dnaindia.com/india/report-over-50-people-in-india-defecate-in-the-open-government-2182295> (visited 1 May 2016)

[152] *See*<http://infochangeindia.org/agenda/access-denied/the-out-of-pocket-burden-of-healthcare.html>(visited 1 May 2016)

[153] ObamaCare (the Affordable Care Act) is a US healthcare reform law that expands and improves access to care and curbs spending through regulations and taxes. The Affordable Care Act's main focus is on providing more Americans with access to affordable health insurance, improving the quality of health care and health insurance, regulating the health insurance industry, and reducing health care spending in the US. The law contains hundreds of different provisions that address different aspects of "the healthcare crisis" in the US.
See http://obamacarefacts.com/whatis-obamacare/(visited 1 May 2016)

achieving the same we need to devise the policy framework with reference to the peculiar conditions of India. For instance, 70% of our population is in villages. Sanitation, proper water supply, hygiene, etc.,all these things are required to be improved.

C. ESTABLISHING RESEARCH INSTITUTES

We must have our own research institutes. It will help us in getting indigenous medicine at cheaper price. Research Centre will provide alternative medicine information which in turn will lead to the more usage of drugs that come at lesser price. It will also help in comparing the drug price among all listed companies.

There are 7 National Institute of Pharmaceutical Education & Research, institutes in India. There is a need of establishing more institutes.

In the light of the immense importance of R&D activities in the like pharmaceutical sector, there is an imperative need of establishing a close nexus between academic/research institutes and the industry. One of the major reasons that contributes for the western world's authority and dominance in R&D activities lies in the face of strong research collaboration between the "universities and the industry where the research lead provided by the university is taken up for further research by the industry both to explore new areas as well as to work on the existing knowledge available in the public domain."[154] This is highly imperative for India, which has been putting sincere efforts for opening up

[154] *See* N. Lalitha, "*Trips And Pharmaceutical Industry: Issues And Prospects*" , Gujarat Institute Of Development Research, Ahmedabad, p.11, Available at : <https://www.google.co.in/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjdgJbL7srMAhWNCY4KHeUPDZUQFggbMAA&url=https%3A%2F%2Fwww.iprsonline.org%2Fictsd%2Fdocs%2FResourcesHealthArticleLalitha.doc&usg=AFQjCNHAsdH0B1vWWQYW2sw6brC5HhtW_g&bvm=bv.121421273,d.c2E> (visited 1 May 2016)

its frontiers now, so that research is conducted on areas having vital importance for the welfare of people.

In the current scenario, very few foreign pharmaceutical firms are investing in India for R&D, which has to be improved with sincere efforts. The Pharmaceutical Research and Development Committee (1999) gave a valuable suggestion of mandating the "collection and contribution of 1 per cent of MRP of all formulations sold within the country to a fund called pharmaceutical R&D support fund for attracting R&D towards high cost-low-return areas and be administered by the Drug Development Promotion Foundation"[155].

One of the most frequently observed reasons put forth by the "Commission on Health Research Development" is that Ninety percent of R&D expenditure is undertaken in the better-off countries, with a nominal flow of technical know-how towards the developing nations. It is also to be noted that currently, approximately 80 percent of the world's population lives in developing countries with consumption of less than 20 percent of all pharmaceuticals. There option of establishing a nexus between domestic universities and foreign academic institutions in the form of contract research organizations (CRO) has to be explored with urgency on a greater level, so as to ensure the dissemination of the technical know-how along with skilled manpower.

D. Role of State Government in regulating drug prices

It is highly imperative that the State Government should take charge of Price Control and quality management of drugs. It is because NPPA and Central Drug Control organization as well as the ministry of health leaves space for the Pharmaceutical companies to increase the price without informing the

[155] *Ibid*, p.20

government. State G Government will definitely bring some kind of transparency in the total price control mechanism.

E. PUBLIC PRIVATE PARTNERSHIP(PPP) MODEL

There has to be PPP model where Public sector has to partner with private sector for affordable healthcare. The R&D agenda does not echo the majority of public health priorities in developing nations. Also, innovations in drugs with capacity of enormous benefit to developing nations are priced in a way that they become unaffordable for majority of the population. Several view this situation as immoral and in contrast with the best long-term interests of the human community as a whole.

Kantian moral philosophy's recognition of human dignity amid rational autonomy by putting premium on equivalent respect for each and every person and not treating another person as a means to an end, is of great relevance. Numerous partnerships[156] have emerged in recent times. Considerable ones are the Alliance for Microbicide Development, The Clinton Foundation HIV/AIDS Initiative, The Global Alliance for TB Drug Development, The International AIDS Vaccine Initiative, The Malaria Vaccine Initiative and the Medicines for Malaria Venture.

[156] The seed funding and some or much of the administrative costs is provided by public and philanthropic agencies. Many partnerships have charismatic leaders and spokespersons, e.g. the Clinton Foundation that is backed by former US president Bill Clinton and the icon of the anti-apartheid struggle, Nelson. Mandela. The foundation's HIV/AIDS Initiative is focused on supporting large-scale prevention & treatment in Caribbean & African countries. It develops country-level 'business' plans; and then presents these to donors and partners to mobilize resources. It has been very successful in reducing drug prices. It has been able to procure WHO-endorsed generics for ARV for as low as US$140 per year. Such low prices are now available to over 100 countries. In return, countries have to guarantee payment & secure drug distribution.

It is beginning to happen, (accredited hospitals, getting bulk procurement, getting into tendering). All this is going to drive down the cost of health care and it is going to build national healthcare system.

F. A Mix of Strengthening the Infrastructure and Continued Evaluation of Private Healthcare Markets

Strengthening the Infrastructure-For devising long term solutions, it requires a two-track system. First, the government needs to strengthen the public health infrastructure so as to make sure that poor people from rural and urban background have universal access to the treatment. Such an approach revolves around purchasing in bulk quantity of the low-cost generic medicines, by medicines.

G. Patented Drug and Generic Drug- Role Played by Doctors

This issue is related with the use of generic drugs which are cost effective. It is important to note that in US and in some parts of the Europe, pharmacists have been authorised "to dispense generic drugs in the place of a prescription drugs, which will cost less than the prescription drug."[157] It provides options to the consumers to consume either the generic drugs or the branded drug. This system can't be misused because in case the doctor writes `dispense as written' in that case, the pharmacist cannot suggest the generics. In India, researches have shown that '*Over the Counter*' market is confined to a handful of common medicines and most of the prescriptions don't have generic drugs. It has been seen in India that the consumers don't question the drugs prescribed by the doctors and simply adheres to the drugs prescribed by the drug prescribed by the doctor. Due to the special conditions that exist in India, the physicians and

[157] See N. Lalitha, as note 154 above, p. 5

experts have a crucial role to play to prescribe the drugs which are apt for the treatment and also prescribe the cheaper alternative drugs, so as to save the consumers from getting exploited from market forces.

H. UNETHICAL AND UNFAIR DRUG SELLING PRACTICES, SUCH AS HOLIDAY TRIP OFFERS AND FANCY GIFTS, USED TO INFLUENCE DOCTORS AND KEY BUREAUCRATS, NEED TO BE CURBED.

I. REVISION OF NLEM

The NLEM should be revised every 2-3 years, with price regulation based on the therapy considered, instead of a focus on formulation. It has already been mentioned that in most of the OECD member countries, therapeutic value of the drug is taken a conclusive factor for fixing the price along with the analysis of its production cost and the price of the similar drugs. Indian system also needs to consider this aspect as a matter of topmost priority.

J. FOCUS ON INCREMENTAL HEALTH BENEFITS

In India, there is lack of clarity to determine the price of patented drugs on the basis of incremental efficacy/benefit of patented drug vs existing standard of care. In west, the incremental health benefits of the patented new drug are closely assessed before deciding the price of the newly launched drug. It becomes important as governments in many western countries follow the practice of reimbursing pharmaceutical expenses. The higher the incremental efficacy of the drug, the larger the amount of reimbursement is. The basic objective behind this is to ensure real innovation and not just minor tweaking with the already patented formulations.

K. Role in Universal Healthcare

The debate over the effectiveness of the price control mechanisms has been going for a very long period of time. Tamil Nadu and Kerala models are often quoted as the successful models, but .I am of the view that these two are not the only models. Successful examples of a developing country like Brazil in establishing a successful regime of universal healthcare should be carefully studied.

In Indian Context, The Jan Aushadhi Scheme that provides NLEM drugs and other important drugs is definitely an imperative step towards universalization of healthcare. But, the poor implementation and its failure in attracting the pharmaceutical companies is a matter of serious consideration and serious revamping is much required. In my humble opinion, an independent expert committee having members from states industry representatives, private and government hospitals, medical practitioners, and also civil society should be appointed.

L. Innovative Models

To keep price control under control, the government needs to study the present status of pharmaceutical sectors and a workable model can be adopted. Previous researches have shed some light in this regard. The need of the hour is that of the political will to move ahead in this direction with a serious outlook in the broader perspective.[158]

[158] "The government can act in two areas where it has not done so far. There are several public sector pharmaceutical companies that are either half or virtually dead. The government can revive these either through a change in management or the ownership pattern so that these companies can manufacture all the essential medicines that are needed. This will be relatively easy, as they are not under patent and the process chemistry for them is well known. If it is

M. Bulk Procurement of Medicines

Another important tool with the government is "bulk procurement of medicines for the public health services". The problem that exits in this area is that of the corruption and state governments in particular are largely responsible for the same. If we analyze the position in other countries, it is very clear that these costs in public health services are kept low, in particular, Western Europe that is widely recognized for the best public health services all across the globe, has achieved this recognition through efficient and strict processes of the procurement of medicines. If sincere action is taken in this area, it will be one of the most important to ensure the delivery of affordable drugs to the needy people.[159] We require encouraging the centralized procurement system, currently adopted and utilized by Tamil Nadu for the purchase of drugs. "A Tamil Nadu government tender for the antiparasitic Albendazole (400 mg) tablets attracted prices of 35 paisa per tablet; retail prices are quoted at Rs.12 (AIDAN 2009)."[160]

In Tamil Nadu, drugs to be purchased for the public hospitals through government are purchased by the negotiation done with the companies. Each tablet that is purchased through this mode has a distinctive mark and separately label is given on the strips to indicate not for sale in the retail market as they are meant only for the public health care system. The very same drug is available at

---

argued that the government is inherently incapable of running such manufacturing facilities efficiently, then the government can float tenders to select competent private firms to come forward and run them as contractors on a cost-plus basis." *See "Price control problems: Get drug procurement right, boost domestic production"*, (Business Standard, 2014), Available at: <http://www.business-standard.com/article/opinion/price-control-problems114102701332_1.html> (visited 2 May 2016)

[159] *Ibid*

[160] Feroze Varun Gandhi, as note 127 above

market prices in the open market. A twin pricing system entails the benefit of providing drugs at a low cost to public health care system without having a distorting effect on the overall market mechanism.

Under this approach, the concerned Department is expected to finalize the list of drugs which are patented and they intend to use them in the public health system. Under this approach, the drug producing companies are invited to submit the prices for the Government run public health system. Those drugs are to be specifically packaged along with a distinctive labeled and then supplied to respective health departments of the states. Outside the government run public health system, firms would be under no restriction to charge normal prices, and hence full IP protection will be enjoyed by them. Such a mechanism would require certain concrete steps to be taken with their proper monitoring:

(a) Identification of the government/publicly supported hospitals that are eligible for lowered prices putting in place a complete procurement system for each state that would cater to the needs of these hospitals
(b) Supplies to be made direct to the hospitals
(c) Creating a special packaging for supplies to these hospitals
(d) Setting up tracking and monitoring system that confirm end use and detect diversions if any clear commitments on payments

3.8 Exhaustion of Rights

It is important to find a solution which provides a balancing as right to health should not be jeopardized due to patent regime. TRIPS afford nations with measures to protect its social and economic circumstances.[161] Apart from the

[161] Exceptions to Rights Conferred-Article 30, Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably

above mentioned factors another important facet related to the efforts made for ensuring affordability is that of the principle of exhaustion of rights also known as parallel trade. To state this concept in precise terms, the patent owner no more holds the right once the concerned product becomes a part of the market or in cases where the patent owner sells his innovations. This doctrine imposes certain restrictions on the exclusive rights granted to the patentee as this doctrine puts premium on the fact that the initial authorized sale of the patented item has the effect of terminating all the patent rights of the sold product.[162] Therefore, the patentee cannot control the resale or the redistribution of an already sold good.[163] The rationale for the same is that the patentee has already been incentivized and rewarded at the time of the first sale and to reap profits repeatedly over the same product by putting restrictions on its resale and redistribution is something that does not appear to have the legs to stand on.

TRIPS provides the discretion with the respective countries to adhere to any of the three types, i.e. national[164], regional[165] or international exhaustion. India follows the system of International exhaustion which results in the patentee losing his rights once the product has been sold anywhere all across the globe.

---

conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

[162] *See* Chandra Nath Saha & Sanjib Bhattacharya, "*Intellectual property rights: An overview and implications in pharmaceutical industry*", vol. 2(2), (Journal of Advanced Pharmaceutical Technology & Research 2011), Available at:
< http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/), (visited 2 May 2016)

[163] *See* Iain M. Cockburn, as note 117 above

[164] The US adopts a national exhaustion principle whereby the patent owner will have no control over the product once it is placed in the domestic market. But he can exercise his rights outside the US market regarding the price and quantity of the product. *See* N. Lalitha, "*Doha Declaration and Public Health Issues*",vol.13, (Journal of Intellectual Property Rights, 2008), p.404, Available at:
<http://nopr.niscair.res.in/bitstream/123456789/2026/1/JIPR%2013(5)%20401-413.pdf>(visited 3May 2016)

[165] The European Union applies the regional exhaustion principle whereby the rights are exhausted within the EU region. See N. Lalitha, as note 164 above, p.404

It is worth mentioning that international exhaustion is in consonance with the broad goals mentioned in the Article 7 of Trips. International exhaustion entails certain advantages, for instance" developing countries such as India can scout for cost advantages of the patented product and also make use of the price differentials".[166]

Article 6 of Trips reads as "... *nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.*"[167] The meaning of this article is further cleared by Article 5(d) of the Doha Declaration which stipulates that " *the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge...*"[168]According to the Doha Declaration, members can apply the principle importation as per their wisdom owing to the national discretion so as to make sure that their domestic policy objectives are promoted. [169]

In Indian Context, the relevant section in this regard is Section 107(A)(b), the objective for the introduction is said to "ensure the availability of the patented product in the Indian Market at minimum international market price"[170]Section 107(A)(b) now reads as: "*importation of patented products by any person from a*

---

[166] *Ibid*

[167]See <https://www.wto.org/english/tratop_e/trips_e/t_agm2_e.htm> (visited 3 May 2016)

[168]*See*https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (visited 3 May 2016)

[169] Paragraph 5(b) and 5(d) Doha Declaration; "Fact sheet: TRIPS and pharmaceutical patents", WTO Secretariat, 2006.

[170] Shamnad Bashir & Mrinalini Kochupillai, "*Exhausting Patent Rights in India: Parallel Imports and TRIPS Compliance*" vol. 13, (Journal of Intellectual Property Rights 2008), p. 489, Available at:<http://www.manupatra.co.in/newsline/articles/Upload/56BF7AA8-6A64-4630-AF64-5EC5BE9F4E6E.pdf> (visited 3 May 2016)

person who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as a infringement of patent rights."[171]

This section was amended in the year 2005 so as to overcome the shortcomings of the 2002 Act in which the focus was on the first sale to be authorized by the patentee. The 2005 amendment has removed this requirement of authorization by the patentee and rather puts premium on the aspect of 'duly authorized under the law'. The exact meaning of this phrase has not been given in the Indian Patent Act, but it could be understood as making a reference towards a specific statute, which can be any Indian Legislation having the force of law which entails Indian Patents Act as well.

It is important to note that Indian law by placing reliance on this provision cannot extend its operation outside India. Similarly, foreign Jurisdictions through their law cannot allow the sale and distribution in India. To state in precise terms, importation of the products in India through this provision , which would have been viewed as infringement of the rights belonging to patentee under Section 48, is now deemed as non-infringing because such acts fall under the domain of the phrase "due authorization under Indian law."

[171] See<http://ipindia.nic.in/IPActs_Rules/updated_Version/sections/ps107.html>(visited 3 May 2016)

CH. 4 INDIAN PATENT REGIME VIS-A VIS PROTECTION OF TRADITIONAL MEDICINAL KNOWLEDGE

INTRODUCTION

Traditional Knowledge is the outcome of ingenuity by indigenous communities owing to the symbiotic union with the environment. The endeavors of communities are broad in the amplitude, starting from the discovery of genetic material to their practical application so as to treat the diseases, and therefore the particular surroundings and genetic resources therein direct impact central plan of their lives directly. Previous researches reveal that traditional knowledge and the genetic resources belonging to a community are susceptible of being paralyzed, owing to the bio-piracy issues, either owing to misappropriation or commercialization with no consent of the indigenous communities and nonexistence of beneficial sharing arrangements. By a careful perusal of Article 29 of TRIPS, it can be stated that requirements of mandating a patent applicant to comply with disclosure requirement, is outside the domain of Article 29 of TRIPS and hence it all depends on the discretion that lies with member nations as a result of which they can mandate the applicants to adhere to disclosure requirements contemplated in CBD.

When a practical analysis of the nexus between IPR & CBD is done, the obvious outcome is that IPR framework contemplated in TRIPS does not have working safeguards with the potent to ensure ABS scheme under CBD in every case. In fact owing to the practice of reverse engineering, patents are sometimes granted which affects the developing nations to make the most of their resources, [172] which is not in consonance with Article 3 of CBD.

---

[172] *Art. 28 of TRIPS provides:*
1. A patent shall confer on its owner the following exclusive rights:

In the light of the same, there is a dire need of the use of flexibilities given in TRIPS, by the member nations. India's endeavor in the same direction has received worldwide attention and therefore the success of India's system and the scope for the improvement is a matter of investigation in this research project.

4.1 TRADITIONAL MEDICINE, BIO-DIVERSITY AND PUBLIC HEALTH

Traditional knowledge is a holistic notion, having unique attributes in the form of intertwined spiritual and practical elements of Traditional Knowledge which makes them inseparable[173]. Traditional indigenous communities 'generate knowledge as a response to a changing environment'[174] and hence traditional knowledge(TK) is an ever expanding pool of knowledge with incessant incremental improvements.TK entails different fields, ranging from cultural expression to technical domains. It is worth mentioning that the creation of this knowledge is not based on an established procedure.

> *"Traditional medicine often goes beyond the purely 'physical' and aims at a holistic integration of the 'physical, mental, social and ecological aspects of well-being."*[175]

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

[173] "It is in this sense that every element of TK serves as an inherent part of the cultural identification of its holders". *See* Charles R. McManis, "*Biodiversity and the. Law Intellectual Property, Biotechnology and Traditional Knowledge*", (Earthscan 2007), p. 260 , Available at: < http://www.planta.cn/forum/files_planta/biodiversity_and_the_law_107.pdf> (visited 9 April 2016)

[174] *Ibid*

[175] Charles R. McManis, as note 173 above, p.127

Traditional medicine(TM) deals with natural botanical products which play an important role in human health care in several developing countries and also in developed countries, which in turn bolsters the commercial value of TM. Previous researches show that 60-70% of India's population[176] and up to 80% of the Africa's population makes use of TM.[177] As per some of the estimates, even in the developed countries '90% of Germans, 70% of Canadians and 50% of the European and North American population have used traditional medicines in one form or the other.'[178]

Moreover, traditional medicine contributes by providing the herbal leads to be used in active ingredients which are a part of numerous allopathic prescription drugs.[179] In the light of importance that TM holds, it is surprising to note that for a very long period of time, scant attention was given which lead to the numerous cases of bio-piracy.

As a matter of fact, medicines based on purely traditional knowledge should not qualify for patent protection, but people often claim the same. In particular, after introducing slight modifications pharmaceutical companies have the tendency of claiming IPR over the same. [180]Therefore, Medicinal plants and products related

---

[176] Report by the Secretariat, *Traditional medicine*, A56/18, 2003, WHO, Available at : <http://apps.who.int/gb/archive/pdf_files/WHA56/ea5618.pdf>(visited 6 April 2016); Ashok D.B. Vaidya & Thomas P.A. Devasagayam, "*Current Status of Herbal Drugs in India: An Overview*", vol. 41(1),(J Clin Biochem Nutr. 2007), pp. 1–11, Available at: < http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2274994/>(visited 6 April 2016).

[177] It is estimated that in China, traditional medicines constitute upto 50% of total medicine consumption Traditional Medicine, Fact Sheet No. 134, WHO, 2008, available at http://www.who.int/mediacentre/factsheets/2003/fs134/en/ (visited 7 April 2016).

[178] *Ibid*

[179] *See* A. Gray, "*Between the Spice of Life and the Melting Pot: Biodiversity Conservation and its Impact on Indigenous Peoples*",(International Working Group for Indigenous Affairs IWGIA 1991), Doc. 70.

[180] The fast growth of patent applications related to herbal medicine shows this trend clearly. The patent applications in the field of natural products, traditional herbal medicine and herbal medicinal products are dealt with own IPR policies of each country as food, pharmaceutical and

to them have become targets of patent precisely because of the fact that they are of great relevance to the herbal drug and cosmetic manufacturers.[181]

In the recent years, the functioning of IPR regime has become a matter of serious deliberation due to the numerous evidences showing misappropriation of TK and using genetic resources in the absence of authorization. These issues are of great concern to developing countries as most of them are in rich in biodiversity, and also the local communities share a symbiotic bond with the surrounding environment. [182]

In the light of this background, an important question arises: how to prevent the misappropriation of these resources without due acknowledgment and credit to the pertinent indigenous community i.e. 'defensive protection'? Second is the need of 'positive protection' owing to the unique nature of TK system as such.

4.2 NEED FOR THE PROTECTION OF TMK

The knowledge developed through generations within a particular community gets deeply rooted in personalities of local people in several forms, for instance, cultural, spiritual & moral identity, acknowledged as 'communal heritage' belonging to the whole community and hence barring the scope for its privatisation. Bio-piracy adversely impacts communities' cultural because of the

---

cosmetics purview, whichever appropriate. *See* Murat Kartal, "*Intellectual Property Protection in the Natural Product Drug Discovery, Traditional Herbal Medicine and Herbal Medicine Products*",vol.21(2), (Phytotherapy Research 2007), Available at :<https://www.researchgate.net/publication/6681428_Intellectual_Property_Protection_in_the_Natural_Product_Drug_Discovery_Traditional_Herbal_Medicine_and_Herbal_Medicinal_Products > (visited 9 April 2016)

[181] *Ibid*

[182] See Christoph Antons, "*Sui Generis Protection for Plant Varieties and Traditional Knowledge in Biodiversity and Agriculture: The International Framework and National Approaches in The Philippines and India*" (NLSIU Bangalore - Indian Journal of Law and Technology, 2010)

interference in the milieu that is the focal point of their life plans and also the imposition of a culture alien to the communities, which seems to be at odds with human rights jurisprudence.

CBD and Nagoya Protocol give an indication towards world health that is largely reliant over genetic resources. Many official reports state that around 80% of the population in several countries is dependent over the biological/genetic resources. In this perspective it becomes pertinent to note that the self centered motives of few entities will act as an impediment in realizing the goal of healthcare for all.

From the perspective of Global distributive justice, Sufficientarianism justice focuses on ensuring that everyone has access to resources having the potent of satisfying the need of subsistence (health issue is a certainly a facet of subsistence issue). Egalitarian justice puts emphasis on moral person-hood of every individual and the right to equality also indicates towards the conservation of genetic resources and more importantly the right of every individual to get benefited of the same.

4.3 Traditional Knowledge Protection through International Platform

Intense deliberations on IP law with regards to life forms were made all across the globe, especially in industrially advanced nations, but the issues related to the misappropriation of TK got the due attention much later. It was in the 1992 Convention on Biological Diversity (CBD) which gave nation states "the sovereign right to exploit their own resources pursuant to their own environmental policies" (Article 3, CBD) and stipulated that "the authority to determine access to genetic resources rests with the national governments and

is subject to national legislation". It was a remarkable provision which changed the earlier position. [183] (Article 15(1), CBD) dealing with access to genetic resources and benefit sharing is also a noteworthy provision. [184]

It is worth mentioning that the CBD does not discourage biotechnological research (Article 19, CBD) , but at the same time the need of maintain coherence between IPR and CBD is also contemplated. (Article 16(5), CBD). It is expected from Resource-rich parties to "endeavour to build conditions so to facilitate access to genetic resources for the uses that are environmentally sound which is conjunction with benefit sharing also " (Article 15(2), CBD), while Article 16 puts premium on the aspects of access to and transfer of technology .It also need s to adverted that the Access to genetic resources shall be on "mutually agreed terms" (Article 15(4), CBD) along with "prior informed consent" (Article 15(5), CBD) , which in turn shall lead to 'fair and equitable sharing of benefits' owing to the commercialization of genetic resources or their utilization in other forms." (Article 15(6), CBD).

While the parties to the convention are of course nation states, the CBD foresees an important role for indigenous and local communities. The domain of CBD is much broader than that of International Undertaking on Plant Genetic

[183] While the non-binding International Undertaking on Plant Genetic Resources of 1984 still regarded plant genetic resources as "heritage of mankind" and as freely accessible and exchangeable *See* Michael Blakeney, "*Intellectual Property Aspects of Traditional Agricultural Knowledge*",(IP In Biodiversity And Agriculture, Peter Drahos & Michael Blakeney eds., 2001), p.44

[184] The shift in the CBD was preceded by similar resolutions at the FAO conferences in 1989 and 1991 that added Annexes to the International Undertaking on Plant Genetic Resources. *See* Gregory Rose, "*International Law of Sustainable Agriculture in the 21st Century: Resources for Food and Agriculture*," vol.15 (Georgetown International Environmental Law Review 2003)

Resources and the subsequent Plant Genetic Resources Treaty, which has an obvious impact on the pharmaceutical sector. [185]

According to Article 8(j) of the CBD, each party, subject to its national legislation, is required 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 their 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 utilization of such knowledge, innovations and practices." In other words, parties to the Convention are required to pass on the benefits of the Convention and to replicate benefit-sharing mechanisms at the local level.

4.4 The Intersection of CBD and TRIPS: A Tenuous Link

In view of above mentioned provisions of CBD, it is imperative to look at linkages between CBD and TRIPS, because of the reason that TRIPS sets up a framework in which the compliance has to be mandatory made. It is in this regard that Clause 19 of the Doha Declaration stipulates that the Council for TRIPS shall review "the relationship between the TRIPS Agreement and the UN Convention on Biodiversity; the protection of traditional knowledge and folklore; and other relevant new developments that member governments raise in the review of the TRIPS Agreement." It adds that the TRIPS Council's work on these

[185] While the International Undertaking on Plant Genetic Resources and the subsequent Plant Genetic Resources Treaty are confined to plants for food and agriculture, the CBD extends also to plants for medicinal and pharmaceutical purposes. Indeed, desire by providing countries of genetic resources to share in the profits made from pharmaceutical research was a substantial reason for the negotiation of Article 15. *See* Gregory Rose, as note 184 above

topics is to be guided by the TRIPS Agreement's objectives (Article 7) and principles (Article 8), and must take development fully into account".[186]

A careful perusal of the two instruments gives an indication of no conflict as such between them from legal perspective, in fact balance can be maintained between these two by placing reliance on Article 7 and 8(with premium on development). But, even than CBD and TRIPS entails different aspects and also certain provisions in each of the instruments which are at odds with each other, especially from practical working perspectives. The following gives an indication of the same.

A. Article 3 of CBD And Its Nexus With Trips

Article 3 of CBD stipulates that state has "sovereign right to exploit their own resources pursuant to their own environmental policies"[187], whereas TRIPS indicates the ownership with an individual inventor which in turn leads to privatization. National Sovereignty principle delineates the dominant feature under CBD which empowers the countries to examine and streamline the access to the biological material, done by foreign entities and also to establish the amount or % of benefit sharing. Complementarily of this principle under CBD with TRIPS, does not seem to exist as TRIPS does not restrict individual entities or firms to ask for a patent using particular genetic resources in other countries and therefore the State's Sovereignty as contemplated under Section 3 of CBD gets diluted . An argument can be advance that nothing stops the country of origin to legally challenge the same but in the light of paucity of financial resources or deficiency of resources to keep an eye over the patents sough in different jurisdictions based on TK

[186] <https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm>(visited 19 April 2016)
[187] Convention on Biological Diversity, Art 3.

B. ARTICLE 8 (J), 'DISCLOSURE OF ORIGIN' AND ITS NEXUS WITH TRIPS

The phrase, "with the prior consent of knowledge holders"[188] is closely connected to another phrase, i.e. Disclosure of origin, which is the subject matter of deliberation under this heading.

Amendment in TRIPS with a view to harmonize it with the provisions of CBD, has been suggested by many erudite scholars so as to make it mandatory for the applicant of patents to disclose the geographical origin of genetic resources which have been used by them and also to furnish a certificate which shows the adherence to the domestic framework of ABS. The proposed amendment seems to be an apt suggestion, especially in the light of the restricted domain of Article 29.[189]. There are instances where patent protection was granted to even TKGR inventions[190]. A careful perusal of the letters of Article 29 of TRIPS indicate that prospect of making it mandatory for the patent applicant to comply with the disclosure requirement, is more than the requirements of Article 29 of TRIPS .

It is quite palpable that in the cases of inventions primarily based on genetic or biological resources and / or associated TK, the source of origin carries immense importance for determining whether the applicant has really "invented" what he claims to have invented in the patent application, or he has just made

---

[188] Article 15.5 of CBD stipulates that "the access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that party.

[189] Article 29 requires that the disclosure of the invention must be in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art (and contains two optional requirements upon patent applicants). Its objective is different from the disclosure requirement for genetic resources. Indication of the origin is, in general, not necessary for a person skilled in the art, unless the source is unique in which case the disclosure of that material's source is essential to put the invention into practice. But in many cases the origin will not be essential.

[190] *See* WIPO document WIPO/GRKTF/IC/ of April 2003, Information on National Experiences with the Intellectual Property Protection of Traditional Knowledge where there are examples of patents granted on TKGR based inventions in Russia and Vietnam.

use of the material that he got from the TK or genetic resources in the country of origin. This becomes even more important in the cases where TK used during the course of invention exists in undocumented and is in the oral form, or is documented in a vernacular language. Disclosure of origin enables the patent examiner to assess the novelty and inventive step of the claimed invention.

Principle of equity also dictates that a person is not to reap benefits by exploiting IPRs on material taken from the country origin without following the ABS provisions, which in turn requires the compliance with disclosure of origin requirement. The rationale for placing the burden of discloser on the patent applicant is that it is he who has the information about all the details and in fact doing the research based on those genetic resources. He also possesses the information about the compliance with the legal regime of the country of origin in context of Prior informed consent (PIC) and fair and equitable benefit sharing. Therefore, mandating such disclosure is a "reasonable procedure" and a legitimate expectation.

C. ARTICLE 15 OF THE CBD (ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING) AND ITS NEXUS WITH TRIPS

Article 15, CBD focuses on the distribution of an amount or % of benefits to the indigenous communities for allowing the other entities to access their biological or genetic resources. To ensure the effectiveness of this provision, rejection of patent application in cases where the applicant fails to furnish the evidence of benefit sharing, carries immense importance. However, Article 27 of TRIPS entails no such criterion. Therefore the efforts from any member nation making it mandatory to show the evidence of benefit sharing at the time of filing application, may be seen as something that falls outside the purview of Article 29 TRIPS.

Article 15.4 of CBD provides, "the access to genetic resources shall be subject to Prior Informed Consent of the Contracting Party providing such resources, unless otherwise determined by that Party"[191]. Therefore the consent of local communities or State acting on their behalf needs to be obtained which means that if consent is given, it has to be based on 'Mutually agreed terms', which in turn facilitates the equitable and fair benefit sharing. TRIPS does not have any provision on the basis of which applicants can be compelled to obtain PIC and secondly, Patent office of the country where the applicant has filed an application is under no obligation to scrutinize that whether the sough claim under application is based on the TK of country of origin. The only option that remains is that challenge from the side of country of origin, which does not seem to be pragmatic solution due to various factors shown above in this thesis.

Article 15.7 of CBD indicates that 'benefit sharing' is to be done on national level under which the pharmaceutical company gives a % or an amount of benefits to the state, and then the state gives the same to the local communities. TRIPS does not have any provision, making it mandatory for the company to share the benefits either with the local community or state. It is also worth mentioning that if a company gets a patent in a country other than the country of origin of genetic resources, country of origin cannot do much[192] in this regard.

[191] Convention on Biological Diversity, Art 15.4

[192] When a pragmatic analysis of the coherence between IPR and CBD is conducted, the palpable outcomes that emerges is that IPR framework as highlighted in TRIPS does not contemplate about any safeguards to be placed having the potent of ensuring ABS under CBD being implemented in a proper way. In fact by the virtue of reverse engineering, patents are granted which directly affects the developing countries to optimally utilize their own resources which is in contravention to Article 3 of CBD

D. ARTICLE 16 OF THE CBD (ACCESS TO AND TRANSFER OF TECHNOLOGY) AND IT NEXUS WITH TRIPS AGREEMENT.

CBD indicates a system in which the country of origin(which is most developing nations as they are rich in biodiversity), get well acquainted with technological know- how, so that it can be used for the capacity building in a longer run, however, TRIPS focuses on individual rights regime to a considerable extent.

TRIPS entails certain provisions for technology dissemination.[193] In particular, by the virtue of Article 8, member nations can adopt measures [194]which can prevent the use of IPRs in an abusive manner and also promote Technological transfer. But the absence of clarification on the point as to what constitutes "unreasonable practices" and "appropriateness of measures"[195], increases the complexity which makes it susceptible to diverse interpretations. Also, Article 8 is confined to restrictions of anti-competitive nature. However, prior researches demonstrate that if developing countries are able to enforce this article, TT is possible to an extent. [196]

Most notable provisions relating to TT are under Article 16[197] [198] [199]. Many scholars see Article 27[200] of TRIPS as a provision having the potent to act as an

---

[193] TRIPS entail provisions with emphasis on prevention of IPRs from attaining such position that acts as an impediment in disseminating technology.

[194] Art. 8(2) provides that "appropriate measures... may be needed to prevent ... the resort to practices which ... adversely affect the international transfer of technology"

[195] *See* Art. 8(2) TRIPS

[196] "Refusal to deal to a competitor on commercial terms, thus adversely affecting the international transfer of technology, is an abuse under Article 8.2 which Members may address in their legislation" (Hutchison, 2006).

[197] Art. 16(1), CBD provides that each contracting party undertakes "to provide and/or facilitate access for and transfer to other contracting parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources.

[198] Art. 16(2) provide that such transfer of technology to developing countries shall be provided on fair and favourable terms and in the case of technology subject to patents or other IPRs, the transfer shall be provided on terms which recognise and are consistent with adequate and effective protection of IPR

obstacle in the implementation of above mentioned CBD provisions.[201]TRIPS provides minimum Standards with in relation to Patent Law as clearly stipulated in Article 27[202] of TRIPS.

Article 16.2 and 16.3 of CBD indicates that access to technology is to "be facilitated under fair and most- favorable terms, including on concessional and preferential terms where mutually agreed"[203]. Nuno Pires de Carvalho is of the opinion that "fair and most- favorable terms" means that "transfer will be on the terms that prevails in international market without discrimination."[204]

In the light of the above mentioned factors it can be stated that provisions of Article CBD dealing with "access to and transfer of technology to the developing countries under fair and most favourable terms"[205] may remain unachievable owing to the fetters placed by TRIPS. Therefore, due to inconsistency between

---

[199] Art. 16(5) further provides that "the contracting parties, recognising that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives".

[200] Art. 27 relates to the patentability of products and/or processes and in basic terms states that all inventions shall be patentable provided they are new, involve an inventive step and are capable of industrial application

[201] It is primarily because of the fact that Patent Law is based on western legal concepts with slight variation form nation to nation, but the major premise remains hinged to the economic aspect to a large extent. Complying with exclusives rights granted under TRIPS may make it an arduous task for the states to obtain TT.

[202] This article provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an incentive step and are capable of industrial application. However, nations can choose to exclude certain inventions, such as those that harm the public, types of medical treatments, and certain plants from patentability

[203]Nuno Pires de Carvalho, *"The TRIPS Regime of Patent and Test Data"*,(Kluwer Law International, 2014)p. 346

[204]*Ibid*

[205] See Art. 16.2 of CBD

these two instruments, Article 31 of TRIPS needs to be reviewed with top most priority[206]

Article 66.2[207] of TRIPS is also a relevant provision in this regard,[208] which has been internationally acknowledged, but the same has attracted criticism also. C. Correa remarks that this article provides no guidance regarding the assessment of nature and also the magnitude of incentives that are to be given to enterprises and institutions of developed nations in course of fostering TT to the developing nations.[209]

Also, Article 66 is confined only to Least developing nations which reduces the effectiveness of this article to a great extent because there are researches in abundance showing the rich biodiversity in developing nations.
In my opinion, Text of Article 66.2 does not make it mandatory on the part of the Government to pressurize the firms to perform the functions of charitable institutions.

Analyzed from Corporate Governance perspective, it is quite legitimate to expect these firms with humungous resources at their end to act as just institutions. But the aspect of charity cannot be imposed under the domain of Article 66.2.The

---

206Christophe Bellmann, Ricardo Melendez-Ortiz, *"Trading in Knowledge: "Development Perspectives on TRIPS, Trade and Sustainability"* (Routledge, 2013), p. 88

[207] Article 66.2 stipulates —Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

[208] It imposes obligations on developed countries to incentivize enterprises and institutions so as to facilitate TT to LDCs.

[209] Correa, C. (2005). *"Can the TRIPS Agreement foster technology transfer to developing countries?"* In Maskus K. and J. Reichman (eds.) *"International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime"*, (Cambridge: Cambridge University Press), pp. 227-256.

need of the hour is to explode the myth of conventional wisdom, which states that "firm's sole purpose is profit maximization". There is a requirement of a more balanced approach putting premium on the combination of ethics and interest, in particular "order ethics approach". This approach contemplates of implementing ethical norms through the means of interests.[210]

4.5 Traditional Knowledge Protection through Indian Platform: Analysis of the Indian Patent System

India Patent entails a clear provision stipulating that "an invention falling under the ambit of traditional knowledge is outside the purview of patentability, similarly, an invention based on aggregation or duplication of known properties of traditionally known component or components is also excluded from patent protection."[211] Section 3(p), deals with the exclusion of patentable subject matter, which seems to be very broad in nature because of the fact that traditional knowledge has not been defined in the Act or in other Legislations, having the force of Law in India. Therefore, the amplitude of the same will have to be decided by the authorities examining the claims along with the number of years required to make it a traditional knowledge. The authorities have also to decide that whether any claim based on the traditional knowledge in any form has to be completely barred or if ingenuity has been shown in the claim which has produced final results which are in effect different from that of the medication based on traditional knowledge. [212]

In order to accomplish the same Indian Legal framework has devised certain provisions in Indian Patent Act stipulating certain parameters and also several databases have been created. To clear the parameters established under the

[210] This approach is based on the notion that firms cannot be expected to make sacrifices, but they van invest in human capital and social order as a prerequisite of long run benefit.
[211] Section 3 (p), Patents Act 1970.
[212] *See* Christoph Antons, as note 206 above

Patent Act, claims are to be examined from traditional knowledge databases, which also entails Traditional Knowledge Digital Library. "Inventions which typically come under the scanner for ineligibility are extracts and alkaloids and active ingredients that are naturally present in plants, combinations of plants with known therapeutic effects, combination products of known active ingredients and discoveries of optimum or workable ranges of traditionally known ingredients through routine experimentation."[213]

Though TKDL has been a great source in dealing with bio-piracy issues but sometimes regarding certain aspects entire information is not uploaded on TKDL. Sometimes even after the availability of numerous documents, they are not readily available on browsing. Therefore, it becomes complex to ensure that whether the ongoing research undertaken by an individual or a firm falls under the domain of Traditional Knowledge. When the required documents are easily accessible with accuracy, it helps to take an informed decision regarding the investment on the ongoing research with or without up gradation, so as to not to be hit by these provisions. Therefore, to avoid the prospects of stagnancy in technological growth, it holds utmost importance that requisite steps are taken to ensure accessibly with accuracy.

However, the crucial role played by the TKDL cannot be negated and deserves due acknowledgement for its imperative role. [214]

---

[213] *See* Debashish Banerjee & Pankaj Musyuni, "*Biotechnological inventions in India: law, practice and challenges*", Available at:< http://www.iam-media.com/intelligence/IAM-Yearbook/2016/Country-by-country/Biotechnological-inventions-in-India-law-practice-and-challenges>(visited 20 April 2016)

[214] It is important to mention here that access to all documents of TKDL has been provided to selective Patent Offices across the world, such as Indian Patent Office, European Patent Office, United States Patent and Trademark Office, Japanese Patent Office, Australian Patent Office etc. by way of access agreements. This enables the Patent Offices to conduct holistic search

Further, section 25(j) and section 64(p), provides for the opposition or revocation of the patent based on the ground "*that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention.*"[215]

Also, under sections 25(k) and 64 (q) ,opposition and revocation are based on the ground "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."[216] An invention primarily based on TK may be revoked or opposed under the Indian Patents Act on the ground of invention being anticipatory in nature.[217]

This exclusion is one of the numerous provisions introduced to the new Act as an endeavor to prevent the claim of proprietary rights on India's genetic resources and traditional knowledge and thereby paving the way for its misappropriation [218] For example, disclosure requirements under the Act mandates specification of the origin of source and geography related to biological material involved in the invention on which patent is sought. [219]. The most obvious difference that exists between Section 3(p) and Section 25 and 64

---

and prevent misuse of Indian Traditional Knowledge as well. It is noteworthy to mention here that during prosecution, some of the International Jurisdictions, such as Australia, Europe etc. frequently cite documents obtained from TKDL for raising objections against patentability of Patent Applications. This reaffirms the fact that TKDL has become an integral part of the search conducted during prosecution of a Patent Application. *See* Sindhu Vijayakrishnan, Lakshmi Rajagopal & Meenakshi Chotla, "*Protection of Traditional Knowledge*", Available at:<http://www.pharmabioworld.com/features_sindhu_vijayakrishnan.html>(visited 20 April 2016)

[215] See Section 64(1)(p), The Patents Act, 1970

[216] On the 2002 amendments, *See* S. K. Verma, "*Plant Genetic Resources, Biological Inventions and Intellectual Property Rights: The Case of India*", (Intellectual Property And Biological Resources 2004), pp. 147-148

[217] Sections 25(1) (k) and 64 (1) (q), Patents Act 1970

[218] *See* N.S. Gopalakrishnan, "*TRIPS and Protection of Traditional Knowledge of Genetic Resources: New Challenges to the Patents System*", (European Intellectual Property Review 2005), pp. 11, 17

[219] See The Patents Act, No. 39 of 1970, § 10(4)(ii)(D) (Universal 2005) (amended 2005)

is that the former bars those inventions which are in effect represent traditional knowledge while the later sections relate to the inventions capable of being anticipated by the traditional knowledge. Hence these two parts can be reconciled to create a better and effective framework for the protection of TK. Section 3(p) bars the invention lacking any transformative or creative use of the traditional knowledge while Section 25 and 64 seems to go beyond this and have modified or refined the non- obviousness requirement by mandating that now the rules of anticipation entails the traditional knowledge which was earlier neglected.[220]

A patent application can be opposed on the ground that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention.[221]Prior Knowledge in Local or Indigenous Community: The provision concerning mandatory disclosure of the source of biological materials in an Indian patent application was only recently adopted[222]. If the invention claimed in a patent application relates to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere, the patent application can be opposed[223]

Also, Section 10(4)(ii)(D) of Indian Patents Act makes it mandatory to disclose the origin of source and geographical origin relating to biological material found mentioned in the patent specification, but not adequately described under it or made available to the public. There is also a supplementary requirement in the form of a declaration in the patent application form stating that "the invention as disclosed in the specification uses biological material from India and the

[220] Debashish Banerjee & Pankaj Musyuni, as note 213 above
[221] *See* Section 25(1)(j) The Patents Act, 1970
[222] This ground of opposition was inserted by The Patents (Amendment) Act, 2005
[223] *See* Section 25(1)(k), The Patents Act, 1970

necessary permission from the competent authority shall be submitted before the grant of patent". Section 10(4)(ii)(D) was introduced in the year 2005 with a view to complement the Biological Diversity Act 2002, which puts premium over protecting sovereign rights over genetic resources and in particular requires prior approval from an independent NBA, before seeking for a patent for an inventions based on biological material from India. However, practice was time-consuming and also very slow to ensure compliance with the 2005 amendment and also the NBA approval requirement was a mere theoretical provision for a considerable time. This loophole has been identified and efforts to rectify the same was made by introducing the guidelines[224] which reaffirmed the compliance with NBA approval in cases of processing the patent applications related with biological material from India. In itself, obtaining NBA approval poses a serious challenge as this is a cumbersome and lengthy process.

As regards the consequences of non-disclosure, India's position over the same is unique and remarkably distinct from many other jurisdictions. For example, the EC supports the inclusion of "disclosure of origin" as a part of the patent application itself but the consequences of non-disclosure are to be dealt outside the patent system. This raises a pertinent concern regarding the dilution of the very nature of the provision itself as it leaves the consequences to dealt outside the purview of patent system. Also in some countries, for example one amongst them is Norway, where the patent is not invalidated due to the non-disclosure but only penal sanctions are imposed on the same which is quite

[224] "It is important to appreciate that the traditional patentability criteria of novelty, inventive step and utility can be used to prevent patents on traditional knowledge/medicine *See* Guidelines for Processing Patent Applications Relating to Traditional Knowledge and Biological Material, Indian Patent Office, Available at: <http://www.ipindia.nic.in/iponew/TK_Guidelines_18December2012.pdf>(visited 24 April 2016).

different from Indian system as in India nondisclosure results in invalidating the patent.

It is now a cardinal principle of the patent law in most of jurisdictions that warrants inadequate disclosure as an offence, which invites revocation or opposition of a patent. Under the present Indian Patents Act, 1970, failure to disclose or wrongful disclosure invites revocation of the patent. The Indian Patents Act, as amended in 2002, provides in Section 25 provides numerous grounds for revocation of patents owing to non-disclosure, which have been mentioned above.

Also in the US law, when a patent application is identifies as one in which material information has not been disclosed or false material information has been submitted, with an intention to mislead others, the patent cannot be enforced any more. This is known as 'doctrine of inequitable conduct'. Therefore, "the consequences for non-disclosure have thus been dealt with within the patent system, and should continue to be done so, despite suggestions to the contrary."[225]

> "*Information on origin of a biological resource and knowledge pertaining to the resource used for a patentable invention are material to determining the novelty and innovation involved in the appetent claim, and hence should be treated as "material information". This would be an inevitable outcome of recognizing the centrality of such disclosure in assessing "novelty" and "inventiveness", elements necessary to grant a patent.*

[225] *See "Reconciling TRIPs and CBD through disclosure requirement-II"*, Available at: http://worldtradereview.com/news.asp?pType=N&iType=A&ilD=114&siD=14&nlD=22846 (visited24April 2016)

Consequences for non-disclosure would, therefore, have to be built into the patent system, since any departure from this should strike at the very root and logic of the patent system. Wrongful or inadequate disclosure can defeat the entire objective of the patent system."[226]

There is one more important section, i.e. section 3(b), which stipulates that "an invention the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment." will be non-patentable. This Section has not been cited much with regards to the protection of Traditional Knowledge, but researcher is of the view that keeping in the mind the unique nature of the Traditional Knowledge that wide domain of the same that needs to be protected, It is very much possible to take recourse to this section at least for justifying an exclusion of the patent from ethical and justice perspective. This section uses the terms

(A)Prejudicial to human life and prejudicial to environment- As it has already been pointed out that the traditional communities' share a symbiotic bond with the surrounding environment of which they are a part of and hence any imposition of alien nature might affect their lives affected due to bio-piracy. By Saying this, I do not suggest that owing to the special claims of indigenous/ local communities, the pharmaceutical companies or any researcher should be completely prohibited from carrying out the research, rather the focus must be on the point to ensure that the research is undertaken by complying with the needs of the following:

---

[226] *Ibid*

(a)Prior informed Consent

(b)Access and benefit sharing

(c)Mutually agreed terms

In the light of the combination of all these attributes, the local communities can work for the capacity building which makes the win-win situation for both the parties, i.e. Local communities and patent applicant.

4.6 Case studies from India on Traditional Medicine and Patentability: Analyzing the Success Story of TKDL & Section 3(p) of Indian Patent Act

The provisions mentioned above provide India with legislative force for averting attempts to obtain patents based on the exploitation of genetic resources and associated traditional knowledge from India. The well known instances of patents obtained over inventions based on Indian genetic resources such as seeds of neem tree, basmati rice and turmeric spice are considered as infamous instances of bio piracy, therefore Government of India made sincere efforts to avoid any alike embarrassment in the future.

In *Natural Remedies Private Limited v. India Herbs Research and Supply Co*,[227] the Karnataka High Court revoked a patent for 'Zigbir', a herbal composition of four medicinal plants used to cure liver ailments on the ground that it was obvious. Similarly, Patent Application No. 1576/DEL/2006/ by the Central Council for Research in Unani Medicine was refused by the Controller of Patents in December 2012 on the ground that the said invention, consisting of a

[227] *Natural Remedies Private Limited v. India Herbs Research and Supply Co,* MANU/KA/2739/2011.

combination of herbal extracts, was traditional knowledge and obvious to those working in the field.

"After conclusion of the access agreement with the European Patent Office, citation of TKDL references as prior art have led to significant strides towards achieving the goal of preventing misappropriation of Indian Traditional Knowledge."[228] Following are the important instances which delineates the success story of Indian Patent framework and the imperative role of TKDL in realizing the same

CASE STUDY 1

Avesthagen Ltd., a company based out of Bangalore, filed for a European Patent, bearing No. EP2152284, dated June, 29, 2007, for a "synergistic ayurvedic/functional food bioactive composition"[229]. EPO gave an adverse research report, as a part of the formulation was primarily based on TKDL references. Avesthagen Ltd. Filed no reply to the EPO, as a result of which it was construed as a deemed abandonment on January, 6, 2012.

However during 2012, as a matter of surprise Indian Patent Office, did not have access to the TKDL and only European Patent Office and the U.S. Patent Office could access the TKDL. At no cost. India was therefore in an absurd situation, which brought International opprobrium to the Indian Government and hurt the sentiments of Indian citizens as well. Finally after sincere endeavours from the side of many, like Mr. Prashant Reddy(A Law Graduate from National Law

[228] *See* "*TKDL Outcomes Against Bio-piracy*", Available at: <http://www.tkdl.res.in/tkdl/langdefault/common/outcome.asp?GL=Eng>(visited 27 April 2016)
[229] *See* European Patent Register, Available at: <https://register.epo.org/application?number=EP07805634&lng=en&tab=doclist>(visited 28 April 2016)

School of India University, Bangalore) who wrote on this discrepancy which in turn resulted into deluge of discussions on this point and ultimately system did get the much needed improvements and Government scraped patent for "jamun-based diabetes drug".[230]

CASE STUDY -2

Mars Incorporated / US, filed a patent application with publication no. 20100061944 entitled "Oral hygiene composition comprising myrtle", the Examiner rejected the claims based on the TKDL evidences.

The present invention relates to myrtle for use in oral health applications, an oral composition comprising myrtle, and the use of myrtle or the composition, in the improvement or maintenance of oral health in an animal, preferably through the reduction or control of dental plaque and/or alteration of the bacterial content of dental plaque, in the oral cavity of the animal. The invention also includes myrtle for use in the prevention or treatment of gingivitis in an animal. The invention also provides a method for improving or maintaining oral health in an animal.[231]

The following claims were rejected

- "Claims 3-5, 7-10 and 19 were rejected under U.S.C. 103(a) as being unpatentable over ***Mc Genity etal.***(US 6, 652, 892) in view of ***Dard –e-Dandaan***(1909) in further view of ***Murad(1911).***Dard-eDandaan

[230] *See*<http://timesofindia.indiatimes.com/india/Govt-scraps-patent-for-jamun-based-diabetes-drug/articleshow/16975263.cms>(visited 29 April 2016)
[231] *See* WIPO PATENTSCOPE, Available at: <https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2008065382>(visitd 30April 2016)

discloses an oral composition for treating gingivitis and toothaches. The compositions include ***Myrtus Communis (Common Myrtle)***"[232].

"It would have been obvious to one of ordinary skill in the art to have used the animal food of Mc Genity etal comprising myrtle to treat gingivitis motivated by the desire to use a food with components disclosed by the art that are used to treat gingivitis as disclosed by Dard-e dandaan and to treat a condition that vauses bad breath."[233]

- "Claims 3-5, 7-10 and 19 were rejected under U.S.C. 103(a) as being unpatentable over ***Rossel***(WO 2006/029893, already of record) in view of Murad(1911) as evidenced by Dard-e-dandaan(1909)."[234]

"It would have been obvious to one of ordinary skill in the art to have used powdered leaf[235] in the compositions of rossel motivated by the desire to use an active part of the plant that comprises actives for treating Gingivitis and also strengthens the teeth."[236]

CASE STUDY-3

Taichung Veterans General Hospital / Taiwan, filed a patent application with publication no. 20130095171 entitled "Herbal composition and method for

[232] *See* United States Patent & Trademark Office, Available at: <http://www.tkdl.res.in/tkdl/outcomes/US20100061944.pdf>(visited 30 April 2016), p.4
[233] *Ibid*
[234] *See* United States Patent & Trademark Office, as note 62 above, p. 5
[235] Murad discloses oral compositions comprising Myrtus Communis(myrtle) leaf in powdered form. Available at:< http://www.tkdl.res.in/tkdl/outcomes/US20100061944.pdf>>(visited 30 April 2016), p.5
[236] *Ibid*, p.6

treatment of airway inflammation using the same", the Examiner rejected 7-18 claims based on the TKDL evidences.[237]

"Claims 7-18 were rejected under pre-AIA U.S.C.103(a) as being unpatentable over ***Abu Bakar Mohammad***(Kitaab- al- Haawi- fil- Tbb, Vol xx1, part, pgs 4-7, 1968), ***Mohmaad Azam Khan***(Muheet-eAzam, Vol1, pgs 8-11, 1896), ***Agathiyar***(Agasthiyar 2000 Vol iii, pgs 12- 17, 1963), *Liang etal*(US Pregnant Pub 2002/0031559), and ***Chae et al***(KR 2009084159 A)."[238]

"Abu Bakar Mohammad teachesMentha Piperita is used for treatment of bronchial asthama through oral administration. [239]

"Mohmaad Azam Khan teaches Prunus Dulcius is used for treatment of dry cough and bronchial asthama through oral administration."[240]

"Agathiyar teaches the use of Nelumbo Nucifra for treatment of rhintis through oral administration."[241]

CASE STUDY- 4

Santalis Pharmaceuticals Inc., US, filed a patent application with publication no. 20130005830 entitled "Sandalwood oil and its uses", the Examiner decided to reject the claims 1-4 and 6-8 on 18-Oct-13. Applicant amended the claims on 21-Jan-14. Examiner again rejected the claims 1-4 and 6-8 on 22-Apr-14 & then on 29-May-15.

---

[237] <http://www.tkdl.res.in/tkdl/LangGerman/Common/Abouttkdl.asp?GL=Ger>(visited 30 April 2016)
[238] *See* United States Patent & Trademark Office, Available at: <http://www.tkdl.res.in/tkdl/outcomes/US20130095171.pdf>(visited 30 April 2016) p.3
[239] *Ibid*
[240] *Ibid*
[241] *Ibid*

In this matter, claims 1-4 and 6-8 were rejected[242] on the grounds of traditional knowledge available in the form of ***Azam***, ***Va gasina***, ***Thiruvalluvar gnana vettian***, ***Haque***.

CASE STUDY -5

M/S Jensen; Ned L, US, filed a patent application with publication no. 20140106002entitled "Homeopathic composition and method for the treatment of Skin Irritations and other Skin diseases", Examiner decided to reject the claims 1-19 on 06.01.2015 based on "***De Rijk***(US 200902146298)"243and ***LeCompte***(US 20040052757)244 in view of De Rijk(US 200902146298).

From India's traditional knowledge, claims 1-19 were rejected as being unpatentable over "***Basavaraja***".[245]

Traditional knowledge prima facie is not patentable as it is already known by the mankind. Now, "an invention that is in effect traditional knowledge or which is an aggregation or duplication of known properties of traditionally known properties of traditionally known component or components is not an invention."[246]In other words, any invention that falls short of adding a new and non-obvious element to a substance that is already known through traditional knowledge or is a close derivative of traditional knowledge, would not amount to a 'new invention' and hence is outside the purview of grant of patents.

---

[242] *See* United States Patent & Trademark Office, Available at: <http://www.tkdl.res.in/tkdl/outcomes/20130005830.pdf>(visited 30 April 2016), pp. 1, 3-5, 7-8
[243] *See* United States Patent & Trademark Office, Available at: <http://www.tkdl.res.in/tkdl/outcomes/20140106002.pdf>(visited 30 April 2016), p.9
[244] *Ibid*, p.12
[245] De Rijk(US 200902146298), p.14
[246] *See* Section 3(p) of Indian Patent Act, 1970

Since prima facie, parameters of patentability, i.e., novelty and non-obviousness do not get fulfilled in the case of a traditional knowledge, it is non- patentable. But it cannot be stretched to such an extent that any invention whatsoever based on traditional knowledge will be kept outside the purview of grant of patent.

It is in the public domain that turmeric has healing properties and hence the essential attribute of Turmeric as a healing agent is under the domain of traditional knowledge and hence an invention which is traditional knowledge in effect, cannot be patented.[247] But if the patent is sought on a product that is novel and is made by process which is novel in nature, even if the end product entails similar chemical compositions and properties as that of turmeric, it might get patent protection, provided it adds something new to the already existing pool of knowledge and can be used for or over something, which is capable of producing noteworthy results.

4.7 Journey from Defensive protection to Positive protection approach and the need of a Sui Generis Model

It is important to mention that India follows the system of defensive approach to protect traditional knowledge which puts premium on ensuring that the traditional knowledge is not used/exploited without obtaining the consent of the holders of the traditional knowledge. The main focus of this approach is on dealing with the problem of bio piracy and the associated knowledge. A strong defensive protection[248] approach exists in India which has been widely acknowledged as

---

[247] See *Badische Anillin & Soda Fabrik vs Cochrane et al,* 111 U.S. 293 (1884)

[248] Defensive protection aims to stop people outside the community from acquiring intellectual property rights over traditional knowledge. Defensive protection aims to safeguard illegitimate Intellectual Property rights taken out by others over TK subject matter. It does not seek to assert those rights that are primarily claimed under the positive protection approach, but it merely aims at preventing third parties from claiming other IP rights in TK subject matter. Defensive

well. Numerous initiatives for TK documentation exists in several forms in India, most notable among them are: "People's Bio-diversity Register"[249], "the Honey Bee Network"[250], Traditional Knowledge Digital Library (TKDL)[251], by the virtue of which Government of India deals with biopiracy issues and also protect the interest of the TK holders.[252]

But it has not given positive protection and hence there is immense scope for working in the area of positive protection. In particular, it s required to identify more ways for mapping the traditional knowledge in a better manner along with the modern healing systems with view to a make a significant contribution to the public health initiatives. The present defensive approach system needs to be made even more robust by doing sincere endeavours in positive protection approach .Although Indian government has contemplated over legislation in this context but no outcome in the form of a concrete policy has been seen as of now.

On international level even after the absence of draft treaty, endeavours made in this regard seem to be gaining momentum, Article 31 of the UN Declaration on the Rights of Indigenous Peoples stipulates that "indigenous people have the

---

measures have, so far, mainly focused on the patent system of IP: This type of protection should not be mistaken as an alternative or substitute for the positive protection. Its impact is limited to preventing other parties from acquiring rights over TK. *See* Vera Shrivastav, "*Protection of Traditional Knowledge within the existing framework of Intellectual Property Rights: Defensive and Positive approach*", p.15 Available at:< http://dx.doi.org/10.2139/ssrn.2463017>(visited 1 May 2016)

[249] The Biodiversity Act, 2002, recognizes these registers as a valid way to establish prior art.

[250] Network run by SRISTI (Society for Research and Initiatives for Sustainable Technologies & Institutions, Ahmedabad), which has the world's largest database on grass root innovations.

[251] TKDL is a collaborative project between Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology, and the Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH).

[252] National Innovation Foundation (NIF), Gujarat Grassroots Innovations Augmentation Network (GIAN).

right to maintain, control, protect and develop their Intellectual Property over their cultural heritage, traditional knowledge and traditional cultural expressions."[253]

An "Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC)" came up under the aegis of WIPO in the year 2000, which contemplates about the feasible protection that can be extended to commercially valuable TK, genetic resources and traditional folklore.[254] As a result of the IGC active participation has come from the side of various stakeholders which entails indigenous people and/or indigenous community as well.[255]In 2009, a renewed mandate towards the creation of an international instrument (or instruments) for the "effective protection of GR (genetic resources), TK (traditional knowledge) and TCEs (traditional cultural expression)" through text-based negotiation was given by the WIPO General Assembly.[256] The mandate as such does not stipulate about the legal character pertaining to the international instrument, but it does put premium on the aspect of affording effective protection.

---

[253] UN General Assembly, United Nations Declaration on the Rights of Indigenous Peoples, Resolution, Adopted by the General Assembly, October 2, 2007, A/RES/61/295, Available at: <http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf>(visited 2 May 2016).

[254] *See* David Vivas-Eugui, Anamika, *"Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee (IGC")*, (ICTSD Programme on Innovation, Technology and Intellectual Property 2012), Available at: <http://www.ictsd.org/downloads/2012/02/bridging-the-gap-on-intellectual-property-andgenetic-resources-in-wipos-intergovernmental-committee-igc.pdf>(visited 3 May 2016).

[255] *Ibid*

[256] WIPO General Assembly, Agenda Item 28: Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, 38th Session, September 22 to October 1, 2009, Available at: <http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_15/wipo_grtkf_ic_15_ref_decision_28.pdf> (visited May 3 2016)

Draft articles on the protection of TK, genetic resources and traditional folklore have been prepared by the IGC. These Draft Articles have contributed to a considerable extent due to the rigorous deliberations made under Various meetings which are held with a view to finalize the text of treaty and also discuss issues pertaining to definition of traditional knowledge, identifying beneficiaries, amplitude of protection, sanctions and remedies, disclosure requirements, exceptions and limitations and also as the term of protection.

All this needs to be done form the side of India also so as to ensure more clarity and to prevent the chances of abuse of discretion that might be alleged in certain cases due to lack of clear guidelines in the present Indian System.

NEED OF SUI GENERIS MODEL

> "*Traditional knowledge is not the mere sum of its separate components: it is the consistent and coherent combination of those elements in an indivisible piece of knowledge and culture.*" [257]

According to pajé, the merit of the healing resides in the combination of the extract with the religious rituals, and not in the potion individually. The unique aspect about it is that the healing properties are because of the combination of the extract and religious rituals, which is not possible if the two elements are taken in is isolation. IP regimes as such do not seem to have taken TK as a combinations of the above mentioned aspects.. Hence, it is the need of the hour to devise a system that deals with the holistic nature of traditional knowledge and adopts a comprehensive approach towards it.

---

[257] *See* Charles R. McManis, as note 173 above, p.259

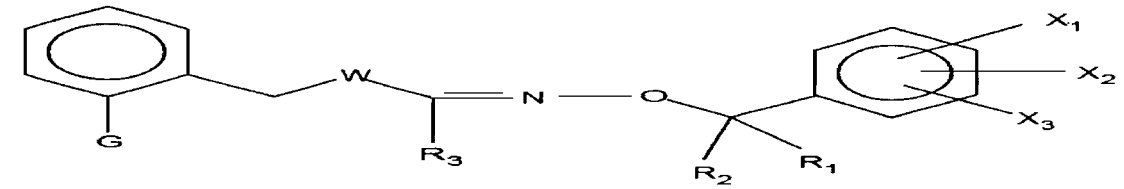
Patent Protection as deliberated in this research work seems to be an effective tool for protecting the TK to an extent, but that's not all encompassing in nature which in turn requires extended interpretations of the provisions and also the need of viewing the provisions in totality. Even if this approach is adopted, it takes time for the settlement of issues and in assessing the strength of the arguments given, which might jeopardize the interest of the concerned parties.

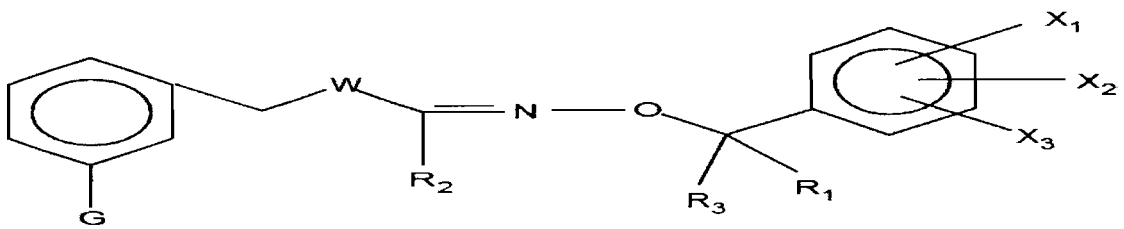
THE ABOVE MENTIONED EXAMPLES FURTHER BOLSTERS THE STRENGTH OF THE ARGUMENT THAT PUTS PREMIUM ON THE NEED OF HAVING A SUI GENERIS SYSTEM WHICH IS HOLISTIC IN NATURE AND ADOPTS A COMPREHENSIVE OUTLOOK TOWARDS TK PROTECTION

CH 5. SECTION 3(D) IMPLICATIONS AND PRICING POLICY: ASSESSING THE GROUND REALITY

Much hype has been created by the western world, especially U.S. regarding the patent framework of India. I enquired into the very basics of the explanation to Section 3(d) and tried to related the Novartis case with the same and found out that any minor innovation or tweaking of molecules in the form of polymorphs is nothing but the practice of ever-greening and Patents are not be granted for the same as a matter of obligation by any of the countries that follow TRIPS.

Section 3(d) precisely provides that a genuine invention can be patented in India, but mere tinkering with the molecule and making minimal changes that can be anticipated by anybody who understands the subject, cannot be granted patent protection. Reliance on Section 3(d) was placed at all the steps to show that Imatinib cannot be patented in India because this is an old molecule which is not a genuine innovation. The following molecular composition related with minor tweaking of the polymorphs illustrates my argument with great clarity.

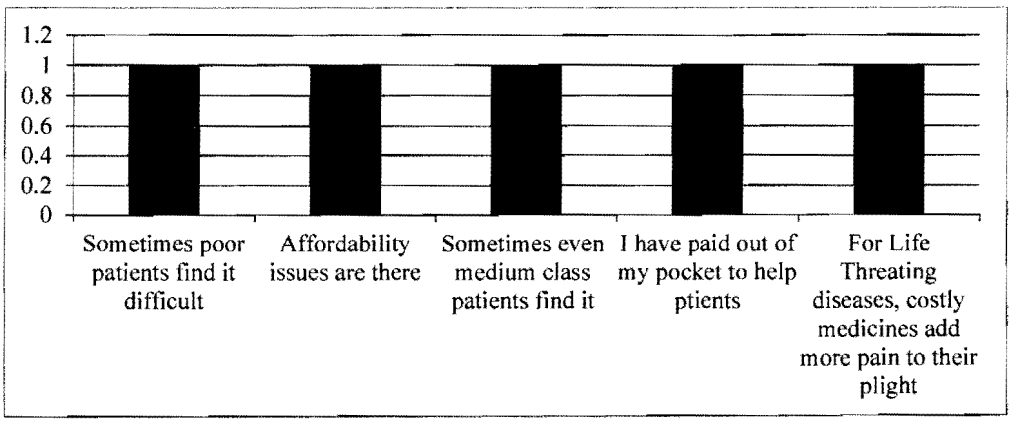




VARIATIONS AMONGST THE STRUCTURE OF POLYMORPHS R1, R2, R3 DOES NOT ENTITLE A PHARMACEUTICAL PRODUCER TO GET THE PATENT PROTECTION AS IT DOES NOT SATISFY THE BASIC NEEDS OF AN INVENTION.

With regards to the current pricing policy and the endeavours for ensuring the circulation of the generic drugs so as to make it affordable the general public, an empirical investigation has been done by interviewing Doctors , Chemists and Medical Representatives, so as to get apprised with the ground reality. As already mentioned in the chapters that this problem has to be seen in a holistic perspective and more importantly the solution cannot be based on isolated factors and it is very much devise a solution in totality. Current Pricing system entails many laudable provisions but still the problem of affordability exits. The following charts illustrate my argument and show the intensity of the problem.

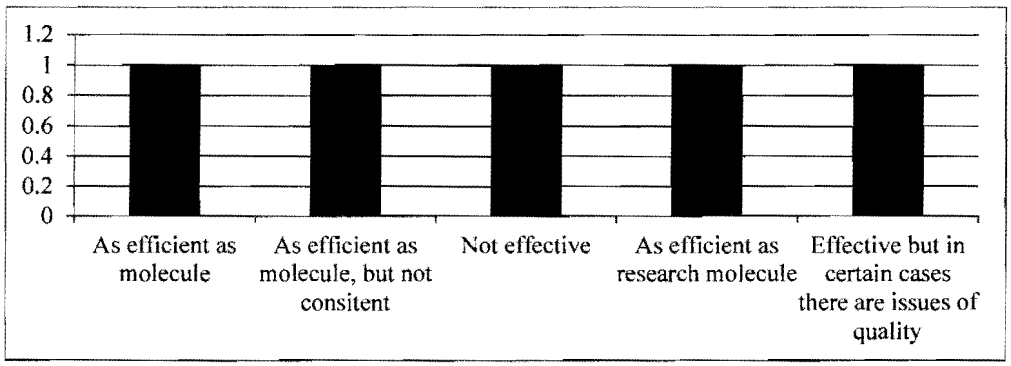
(A) Affordability Issues- 5 Doctors (Oncologists) have been interviewed for this research work. Following are the responses to the question on affordability issue, which has been summarized and presented in a diagram form as follows:



AFFORDABILITY: STILL STRUGGLING WITH IT

All the five doctors, who were interviewed, gave a unanimous answer and said that affordability is still an issue and it is worth mentioning that Dr. Uma (Kidwai Memorial Institute of Oncology, Bangalore) said that she sometimes pay out of her pocket to help the patients in buying the medicines. The above mentioned graphical representation shows in unequivocal terms that affordability is still a major issue.

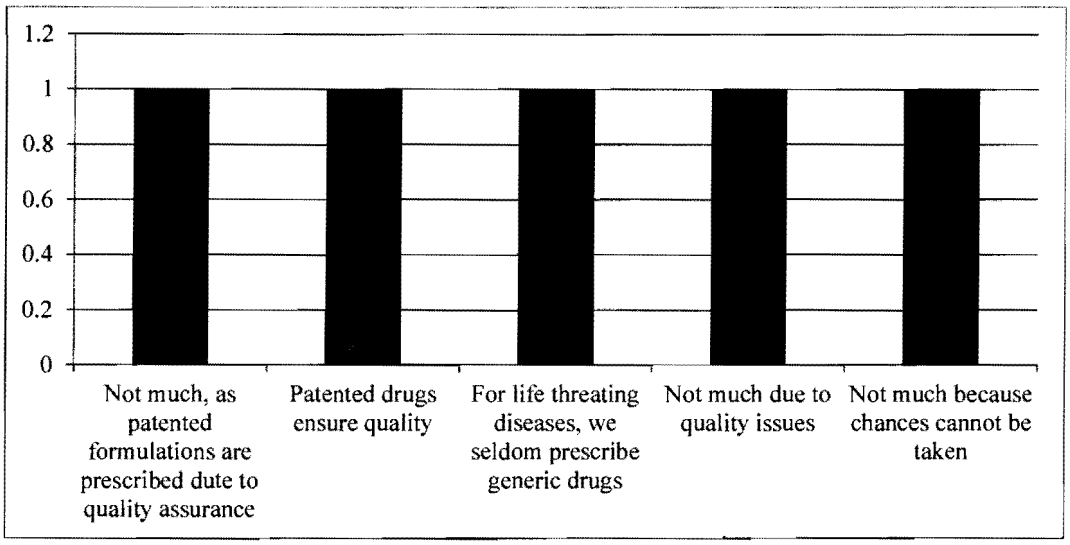
In order to find a solution for the problem related to the affordability, the fist solution that generally comes to the mind is of generic drugs. I asked series of questions regarding generic drugs to the 5 oncologists which are as following:



EFFECTIVENESS OF GENERIC DRUGS

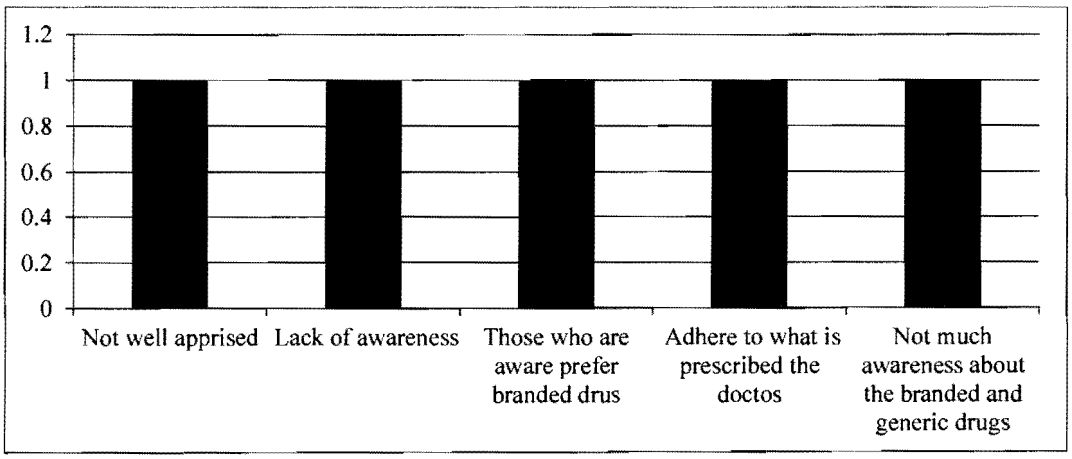
2/5 Doctors s clearly aid that generic drugs are as effective as research molecule and 2 others did not deny the credibility of the same but had reservations about the quality issues and only 1 doctor replied in negative about the effectiveness of generic drugs.

Next point of investigation was related to the prescription of generic drugs. The responses that I received from the doctors are depicted in the form of graphical representation as follows:



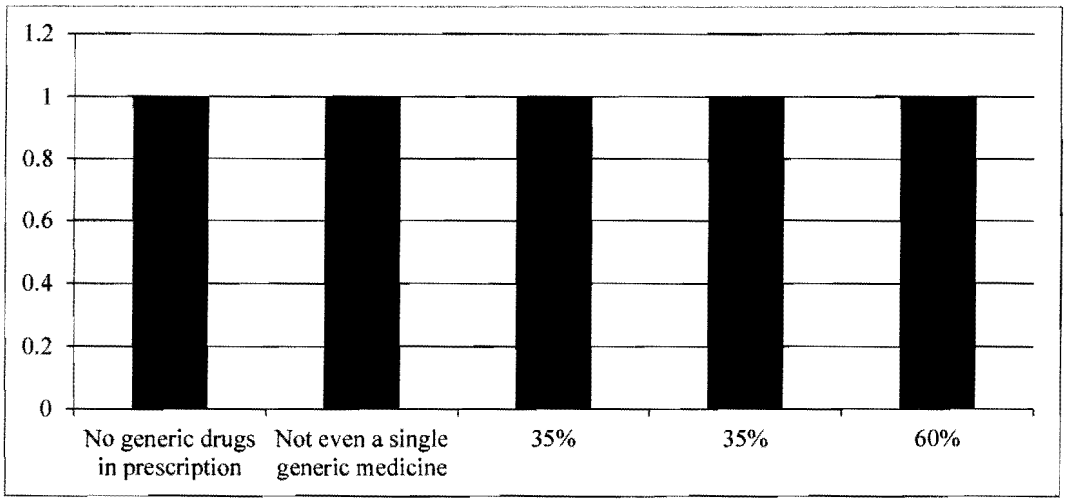
PRESCRIPTION RATIO OF GENERIC DRUGS

It reveals that generic drugs are prescribed by many doctors in the matters related to Cancer, because of the quality factor. Next area of investigation was about the Patient's perspective about the two kinds of drugs and on the basis of the responses given by the Doctors is the following:



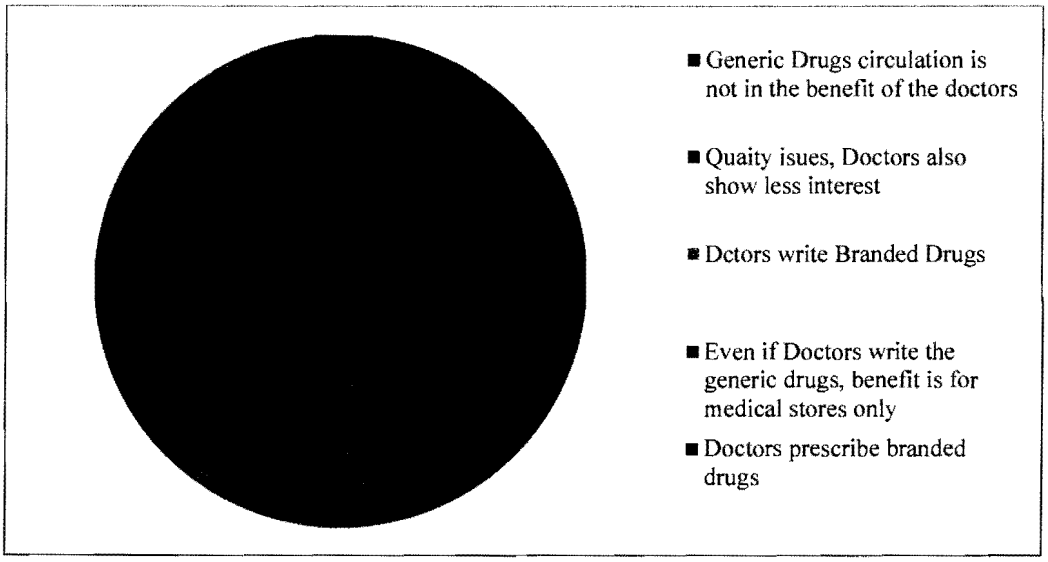
CONSUMER AWARENESS

On the basis of the responses I received, it can be stated that mostly patients are not aware and even if some of the patients know they prefer the brander drugs. In order to get apprised with the rate of circulation of generic drugs in the market, 5 Chemists were interviewed and the responses given by them are as following:



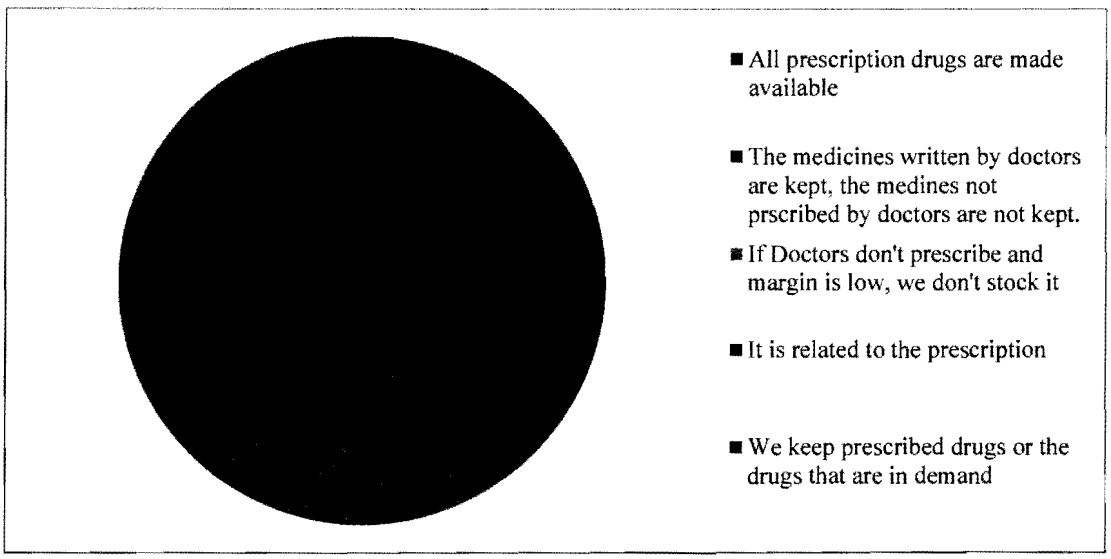
% OF GENERIC DRUGS IN A PRESCRIPTION

It is quite clear that even after sincere endeavours of the Government to ensure that cheaper drugs in the form of generic drugs are available in the market, the same is not happening to a considerable extent. In order to understand the reasons behind the same I took the interview of the Medical Representatives to get apprised with the fact that whether Gifts in several forms are given to Doctors by Pharmaceutical Companies through Medical Representatives.4/5 Medical Representatives said that gifts in several forms are given to the Doctors. I further investigated into the reasons for the low circulation of generic drugs and got the following responses:



REASONS FOR THE LOW CIRCULATION OF GENERIC DRUGS

As a result of it chemists also stock the prescribed drugs only, which is very clear from the following representation:



CRITERION FOR STOCKING THE MEDICINES

In the light of the highlighted responses, it is clear that the doctors have an important role to play in ensuring the circulation of generic drugs. Ethical standards are deteriorating and stern actions should be taken against the doctors who act unethically by prescribing expensive medicines even in the presence of cost effective alternatives. It is a clear violation of Right to Health and a blatant disregard of the human dignity.

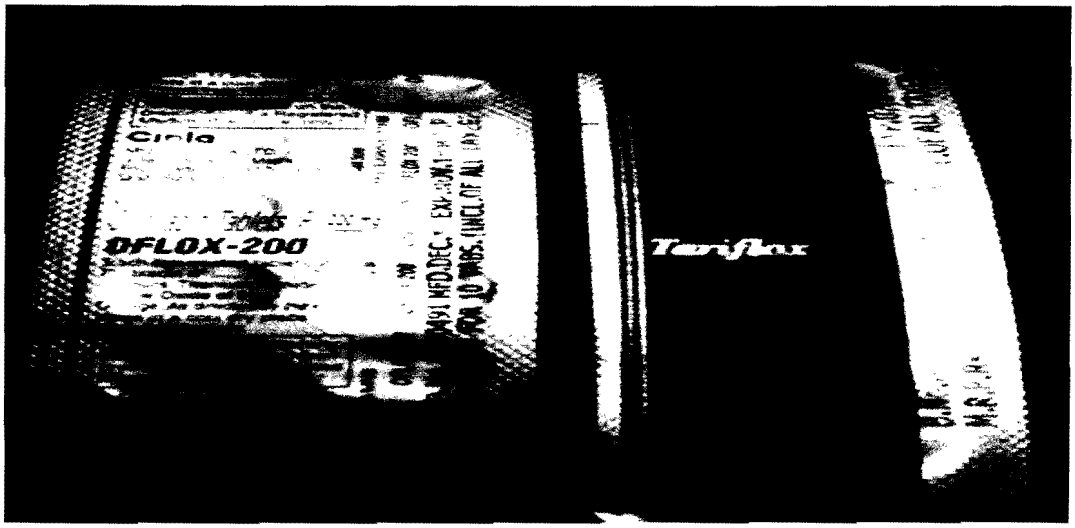
Apart from the need of ensuring ethical behavior from the side of doctors, there is one more important factor that needs to be addressed:

These two products (*Calmez –D3 & D-well aq*) belong to the same company, i.e. Sun Pharma. D-well aq is the ethical drug and Calmez –D3. The following shows the price of both the drugs having similar bio-similar effects and the use of similar active ingredients.

As clear from the picture that D-well aq has an MRP of Rs 150 while Calmez-D3 has an MRP of Rs 124. My investigation revealed some shocking facts that are as following:

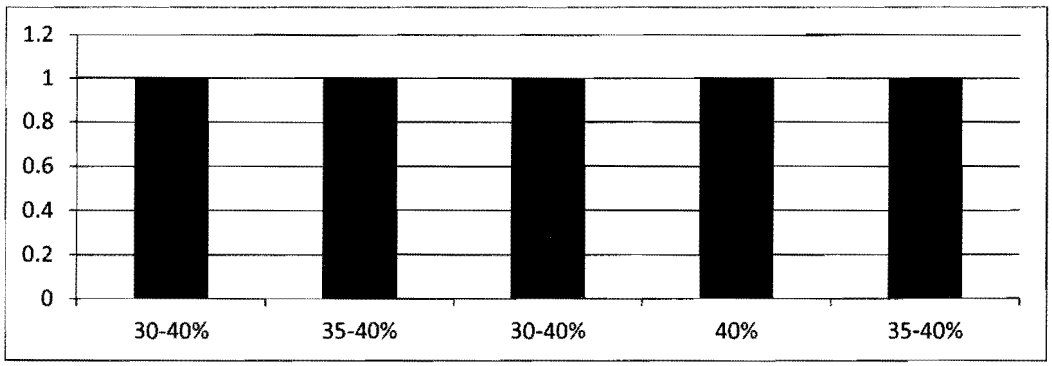
Ethical Drug is released from the manufacture to wholesaler at a discount of 20% of MRP, so D-well aq is given by manufacture at Rs 120, then it passes through distribution channels and reaches to the retailer. Interestingly for the generic drug, i.e. Calmez-D3, it is released at the rate of Rs 16 per strip, but the MRP is Rs 124, because of which the retailers are reaping enormous benefits.

In another case, the same thing is happening.



Oflox is the ethical drug and Tariflox is the Generic Drug. Both the products belong to Cipla. Oflox is released from the side of manufacturer at a discount of 20% on MRP. MRP of Oflox is Rs 56.69 and the MRP of Tariflox is Rs 56.77. Ethical and Generic Drugs are sold at almost same price. It is important to note that Tariflox is released from the side of manufacture at the rate of Rs 12 per strip.

It needs to be mentioned that patients are not also aware of the differences between Ethical and Generic drugs. Because of this lack of awareness the chemists are making huge profits by adversely affecting the interests of the patients. It should be mandatory that the word "*Generic*" is to be written on the generic drugs. Secondly there must be some regulations for printing the MRP on generic drugs. Thirdly Doctors must write the name of the molecule/salt required for medication so that the monopoly of certain drugs in the market can be checked.



% OF EXPENDITURE ON MEDICINES DURING TREATMENT (ONCOLOGY)

When it comes to affordability, the only thing that generally comes to the mind is about regulating the use and prices of medicines. I enquired about the % of expenditure on medicines during the treatment of Cancer. I got to know that it is around 40% at max. Rest of the expenditure is on Fees of Doctors, hospital charges, diagnostics. There are no regulations on these aspects which make it burdensome for the patients.

A HOLISTIC SOLUTION HAS TO BE DEVISED AND IMPLEMENTED HAVING THE POTENT TO PROTECT THE PATIENTS IN AN OVERALL MANNER.

CH. 6 CONCLUDING REMARKS

Section 3(d) and its judicial interpretation in India gives a clear signal that it is on the touchstone of socio-economic ethos of India, the interpretation of is made. monopolisation of Multinational Enterprises cannot be allowed to flourish on the basis of incremental developments made by them due to their capacity to invest in Research and department wing. Also, Public good and health[258] have to be maintained in India and 'Generic Medicines' available to public at large cannot be withdrawn unless Patent Claimer exhibits substantial amount of creativity because granting patent in life saving drugs entails huge costs and is infused with far reaching consequences.

As already mentioned, Section 3 (d) and its interpretation in Novartis Case has been a subject matter of debate all across the globe. Countries which wanted to follow the footsteps of India by restricting patent layering have shown their interest in establishing similar legal framework.[259] Argentina and Philippines are testimony to the same

Indian Patent regime has exhibited in unequivocal terms that endeavours to have conformity with western laws will not be at the cost utilitarian aspect of equality and social justice as enunciated in Preamble to the Constitution of India. India being party to myriad of human rights imperatives has clearly infused components of human rights in IP framework. Taking into consideration the aspirations of umpteen people heavily relying for their survival[260] on generic drugs manufactured in India, Novartis judgment seems to be a sincere

---

[258] Article 47 of Constitution of India, 1950

[259] *See* Rajarishi Banerjee, "The Success of, and Response to, India's Laws against Patent Layering", (Harvard International Law Journal, 2013), pp. 204-232

[260] James Love, "*The Production of Generic Drugs in India*", (British Medical Journal), Available at:< http://www.bmj.com/content/342/bmj.d1694> (visited 6 May 2016)

endeavour of Apex Court whereby 'human basic survival needs'[261] has been taken as a key component and any patent claim must satisfy high level of efficacy requirements on the basis of which the prospects of taking out a generic drug from the common stock, keeping in mind India's socio-economic ethos and also the dependability of several nations on India in this regard.

In the context of the pricing policy, it is noteworthy that for a India like India, a holistic scheme has to be devised in which there is an imperative need of overhaul of the entire system, ranging from the legislative front to making the implementation mechanism strong. Inequity is killing people on grand scale. It is true for India. There are large subsets of population in India where malnutrition exists in adults and children. Half of deaths of children in India is due to malnutrition. With reference to the communities in famine affected area, their Body mass index is below 18. All this warrants a sincere action from the side of Government which is much more than softening of prices.

India has a gap in terms of healthcare, especially in terms of buying capacity. It literally leaves the substantial section of our society with most of their saving washed off in affording the healthcare facilities. From the perspective of price ceiling of drugs, it is important to mention that varying prices between different states poses a matter of greater concern. The issues of corruption in bulk procurement and releasing the drugs with cheaper price is an area which warrants immediate attention. The price difference between ethical drugs and generic drugs is not helping the customers at the end, as the MRP on both the drugs is in a very close range which can be termed as a sheer ridicule of the entire system to promote healthcare. All this requires serious investigations from

[261] See Saby Ghoshray, "*3(D) View Of India's Patent Law: Social Justice Aspiration Meets Property Rights In Novartis V. Union Of India & Others*" vol. 13 (Journal Marshall Review of Intellectual Property Law 2014), pp. 719-760

the Government's and also the role of civil society is of paramount importance here as they can raise the awareness amongst the common masses which in turn will make system more robust.

With regards to the protection of Traditional knowledge, it needs to be adverted that the present defensive approach system needs to be made even stronger and that possible only if the positive protection approach is adopted by the Indian authorities. The following points shed the light on the same. It is worth mentioning that Indian Patent Act does not oblige a patent applicant for invention based on TK, to submit evidence of PIC.[262] PIC system under CBD serves as a check on misappropriation but it is not found mentioned under TRIPS. The absence of PIC in TRIPS acts as an obstacle in the process of implementing provisions of CBD at many instances. Also, it is important to note that while examining a patent application, absence traditional knowledge in documented form may not help the patent offices in identifying traditional knowledge. Therefore, TRIPS Agreement allows the patent authorities to grant patents even if the claimed invention involves genetic or biological material of country of origin or associated traditional knowledge, without adhering to the requirements of PIC and Benefit sharing, required under Article 15.7 of CBD.

Hence, it is important to note that absence of such a provision carries the potent to facilitate the grant of patent using such biological / genetic resource in other countries without obtaining the consent of the respective community or state government. Surprisingly, even in the Indian context, PIC is not a mandatory requirement which carries the same problems as mentioned above.

[262] See Jonathan Curci, "*The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property*",(Cambridge University Press, 2010), p. 142

BIBLIOGRAPHY

STATUTES AND INSTRUMENTS REFERRED

1. Patents Act, 1970
2. The Constitution of India
3. Convention on biological diversity 1992
4. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits

DICTIONARIES

1. Medical Dictionary
2. Oxford Dictionary

DATABASE

1. "*TKDL Outcomes Against Bio-piracy*", Available at: <http://www.tkdl.res.in/tkdl/langdefault/common/outcome.asp?GL=Eng> Available at:<http://www.ipindia.nic.in/iponew/TK_Guidelines_18December2012.pdf>
2. Credit Suisse, "*Global Wealth Report*" and "*Global Wealth Databook*", both available at: <https://responsibility.creditsuisse.com/app/article/index.cfm?fuseaction=OpenArticle&aoid=291405&coid=284071&lang=EN
3. Guidelines for Processing Patent Applications Relating to Traditional Knowledge and Biological Material, Indian Patent Office,
4. The Secretariat, *Traditional medicine*, A56/18, 2003, WHO, Available at : http://apps.who.int/gb/archive/pdf_files/WHA56/ea5618.pdf
5. UN General Assembly, United Nations Declaration on the Rights of Indigenous Peoples, Resolution, Adopted by the General Assembly, October 2, 2007, A/RES/61/295, Available at: <http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf>

CASE LAWS

1. Apotex v. Lundbeck Canada Inc., (2010) FCA 32.
2. *Badische Anillin & Soda Fabrik vs Cochrane et al,* 111 U.S. 293 (1884)
3. *Bombay Dyeing & Mfg. Co. Ltd. V. Bombay Environmental Action Group*, (2006) 3 S.C. 434
4. *Edye v Robertson*, 112 U.S. 580 (1884)
5. *Generics (UK) Limited and others v. H Lundbeck A/S*, (2009) UKHL 12.
6. H. Lundbeck A/S v. Alphapharm Pty. Ltd., (2009) FCAFC 70.
7. *Natural Remedies Private Limited v. India Herbs Research and Supply Co*, MANU/KA/2739/2011.
8. *Novartis AG v. Union of India and Ors*, (2013) 6 SCC 1
9. *Parmanand Katara v. Union of India,* AIR 1989 SC 2039
10. *State of Andhra Pradesh v. Mc. Dowell and Company.* (1996) 3 SCC 709,

ARTICLES

1. A D Damodaran, "*Indian Patent Law in the Post- TRIPS Decade: S&T Policy Appraisal*", vol.13, (JOURNAL OF INTELLECTUAL PROPERTY RIGHTS, 2008
2. A Gray, "*Between the Spice of Life and the Melting Pot: Biodiversity Conservation and its Impact on Indigenous Peoples*",(INTERNATIONAL WORKING GROUP FOR INDIGENOUS AFFAIRS IWGIA 1991), Doc. 70.
3. Aditya Kant, "*An attempt at Quantification of 'Efficacy' Factors under Section 3(d) of the Indian Patents Act*", vol.18, (JOURNAL OF INTELLECTUAL PROPERTY RIGHTS 2013)
4. Arvind Sahay & Saravana Jaikumar, "*Does Pharmaceutical Price Regulation Result in Greater Access to Essential Medicines? Study of the impact of drug price control order on sales volume of drugs in India*"?, (INDIAN INSTITUTE OF AHEMDABAD, 2016)
5. Ashok D.B. Vaidya & Thomas P.A. Devasagayam, "*Current Status of Herbal Drugs in India: An Overview*", vol. 41(1),(J CLIN BIOCHEM NUTR. 2007)

6. Branko Milanovic, "*The Haves and the Have-Nots: A Brief and Idiosyncratic History of Global Inequality*", (NEW YORK: BASIC BOOKS 2011).
7. Branko Milanovic: "*True World Income Distribution", 1988 and 1993: First Calculation Based on Household Surveys Alone*", (THE ECONOMIC JOURNAL 2002)
8. Branko Milanovic: "*Worlds Apart: Measuring International and Global Inequality*", (PRINCETON: PRINCETON UNIVERSITY PRESS 2005)
9. Calvin W.L. Ho, Klaus M. Leisinger, "*Intellectual Property and Access to Essential Medicines: A Tenuous Link?*",vol. 5(4), (ASIAN BIOETHICS REVIEW, 2013)
10. Chandra Nath Saha & Sanjib Bhattacharya, "*Intellectual property rights: An overview and implications in pharmaceutical industry*", vol. 2(2), (JOURNAL OF ADVANCED PHARMACEUTICAL TECHNOLOGY & RESEARCH 2011)
11. Charles R. McManis, "*Biodiversity and the Law Intellectual Property, Biotechnology and Traditional Knowledge*", (EARTHSCAN 2007)
12. Christoph Antons, "*Sui Generis Protection for Plant Varieties and Traditional Knowledge in Biodiversity and Agriculture: The International Framework and National Approaches in The Philippines and India*" (NLSIU BANGALORE - INDIAN JOURNAL OF LAW AND TECHNOLOGY 2010)
13. Correa, C. (2005). "*Can the TRIPS Agreement foster technology transfer to developing countries?*" In Maskus K. and J. Reichman (eds.) "*International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime*", (CAMBRIDGE: CAMBRIDGE UNIVERSITY PRESS),
14. Damanjeet Ghai, "*Patent Protection And Indian Pharmaceutical Industry*", Vol.3(2), (UNIVERSITY INSTITUTE OF PHARMACEUTICAL SCIENCES, CHANDIGARH 2010)
15. David Vivas-Eugui, Anamika, "*Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee (IGC")*, (ICTSD PROGRAMME ON INNOVATION, TECHNOLOGY AND INTELLECTUAL PROPERTY 2012),
16. Donald W. Light, "*Misleading Congress about Drug Development*", vol. 32(5) (JOURNAL OF HEALTH POLICY., POLICY & LAW 2007)
17. Ganapati Murdur, "*Indian Patients Go to Court Over Cancer Drug*", (BRITISH MEDICAL JOURNAL 2004)

18. Gregory Rose, "*International Law of Sustainable* Agriculture in *the 21st Century: Resources* for *Food and* Agriculture," vol.15 (GEORGETOWN INTERNATIONAL ENVIRONMENTAL LAW REVIEW 2003)

19. H. Unnikrishnan, "*Drug cos seek compulsory licensing*", (THE MINT 2008),

20. Hall, "*Patents and patents policy*" ,vol. 18 (4), (OXFORD REVIEW OF ECONOMIC POLICY 2007)

21. Iain M. Cockburn,"*Intellectual Property Rights And Pharmaceuticals: Challenges And Opportunities For Economic Research*", (THE ECONOMICS OF INTELLECTUAL PROPERTY), Available at:

22. India Pharma Summit 2014-15, "*Policy Landscape Reforms for Strengthening Indian Pharmaceutical Industry, "Focus on Critical Verticals to Foster Access to Pharmaceuticals, Enhancing Production and Technology Adoption in Pharmaceutical Enterprises & Medical Devices and Diagnostics*", Position Paper, (Ramada PLAZA PALM GROVE, MUMBAI, 23 MARCH 2015

23. J. Mestre-Ferrandiz, J. Sussex, and A. Towse, "*The R&D Cost of a New Medicine*", (OFFICE OF HEALTH ECONOMICS, LONDON, UK 2012)

24. James Love, "*The Production of Generic Drugs in India*", (BRITISH MEDICAL JOURNAL), Available at:< http://www.bmj.com/content/342/bmj.d1694>

25. Janice M. Mueller, "*The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*", (UNIVERSITY OF PITTSBURGH SCHOOL OF LAW, 2006

26. Jonathan Curci, "*The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property*", (CAMBRIDGE UNIVERSITY PRESS, 2010)

27. Jonathan J. Darrow, "*The Patentability of Enantiomers: Implications for the Pharmaceutical Industry*", vol.2, (STAN. TECH. L. REV 2007)

28. Joseph A DiMasi, Ronald W Hansen, Henry G Grabowski, "*The price of innovation: new estimates of drug development costs*", vol. 22(2) (JOURNAL OF HEALTH AND ECONOMICS 2003)

29. Lalitha, "*Doha Declaration and Public Health Issues*",vol.13, (JOURNAL OF INTELLECTUAL PROPERTY RIGHTS 2008)

30. Latha Jishnu, "*Patent issues delaying Ebola cure*", (DOWN TO EARTH), Available at:< http://www.downtoearth.org.in/content/patent-issues-delaying-ebola-cure>
31. Mahaveer Golechha, "*Healthcare Agenda for the Indian Government*", vol. 141(2), (INDIAN JOURNAL OF MEDICAL RESEARCH 2015)
32. Michael Blakeney, "*Intellectual Property Aspects of* Traditional *Agricultural* Knowledge",(IP In Biodiversity And Agriculture, Peter Drahos & Michael Blakeney eds., 2001)
33. Mueller, Janice M., "*Taking TRIPS to India - Novartis, Patent Law, and Access to Medicines*" (NEW ENGLAND JOURNAL OF MEDICINE 2007)
34. Murat Kartal, "*Intellectual Property Protection in the Natural Product Drug Discovery, Traditional Herbal Medicine and Herbal Medicine Products*",vol.21(2), (PHYTOTHERAPY RESEARCH 2007)
35. N.Lalitha, "*Trips And Pharmaceutical Industry:Issues And Prospects*" ,(GUJARAT INSTITUTE OF DEVELOPMENT RESEARCH, AHMEDABAD)
36. R D Hunshyal & S S Biradar, "*Intellectual Property Rights (Iprs) In Pharmaceutical Sector*", vol.19, (HEALTH ADMINISTRATOR JOURNAL 2005),
37. Rajarishi Banerjee, "The Success of, and Response to, India's Laws against Patent Layering", (HARVARD INTERNATIONAL LAW JOURNAL 2013)
38. S. K. Verma, "Plant *Genetic Resources, Biological Inventions and Intellectual Property Rights: The Case of India*", (INTELLECTUAL PROPERTY AND BIOLOGICAL RESOURCES 2004)
39. S. Narayan, "*Price Controls On Pharmaceutical Products In India*",(ISAS, 2009)
40. S.B. Puranik, Mamata Sangamesh & Mona Golshan S, "*Patent Laws In India And Its Impact On Pharmaceutical Industry*", v. 6(2)(INTERNATIONAL JOURNAL OF PHARMA AND BIO SCIENCES 2010)
41. Saby Ghoshray, "*3(D) View Of India's Patent Law: Social Justice Aspiration Meets Property Rights In Novartis V. Union Of India & Others*" vol. 13 (JOURNAL MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW 2014)
42. *See* Shamnad Basheer, "*Limiting The Scope of Pharmaceutical Patents And Micro-Organisms: A Trips Compatibility Review*" (INTELLECTUAL PROPERTY INSTITUTE , LONDON 2005)

43. Shamnad Basheer & Prashant Reddy, "*Ducking TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d)*", (National Law School of India Review 131-155, 2008)
44. Shamnad Bashir & Mrinalini Kochupillai, "*Exhausting Patent Rights in India: Parallel Imports and TRIPS Compliance*" vol. 13, (JOURNAL OF INTELLECTUAL PROPERTY RIGHTS 2008)
45. Sidonie Descheemaeker, "*India, Pharmacy of the Developing World IP, Trade and the Access To Medicine*", (JURA FALCONIS 2012-2013),
46. Sudip Chaudhuri, "*Intellectual Property Rights And Innovation: MNCs In Pharmaceutical Industry In India After Trips*", (INSTITUTE FOR STUDIES IN INDUSTRIAL DEVELOPMENT, NEW DELHI 2014)
47. Swaraj Paul Barooah, "*India's Pharmaceutical Innovation Policy: Developing Strategies for Developing Country Needs*", vol. 5(1) (TRADE, LAW AND DEVELOPMENT 2013)

MAGAZINES

1. "*Not Just Price Caps: Here's How The Govt Can Make Essential Drugs More Affordable*",(FIRSTPOST,2014),AvailableAt: : <Http://Www.Firstpost.Com/Printpage.Php?Idno=2010689&Sr_No=0>,
2. "*Price control problems: Get drug procurement right, boost domestic production*", (BUSINESS STANDARD, 2014), Available at: <http://www.business-standard.com/article/opinion/price-control-problems114102701332_1.html>
3. G Pramod Kumar, "*Healthcare: How govt can make essential drugs affordable*", (FIRSTPOST, 2014), Available at:< http://www.firstpost.com/india/healthcare-how-govt-can-make-essential-drugs-affordable-1621655.html>

NEWSPAPER REFERENCES

1. C.R.L. Narasimhan, "*Defending India's IPR*", (THE HINDU, 17 May 2015), Available at:<http://www.thehindu.com/opinion/columns/C R L Narasimhan/defending-indias-ipr/article7214559.ece>
2. Feroze Varun Gandhi, "*Drug Pricing: A Bitter Pill To Swallow*", Available At:<Http://Www.Thehindu.Com/Opinion/Columns/Drug-Pricing-A-Bitter-Pill-To-Swallow/Article8281282.Ece>
3. Nayanima Basu, "India Play's WTO Card Against US" , (BUSINESS STANDARD , 28 April, 2014), Available at:< http://www.business – stand ard.com/article/economy - policy/india – plays – wto – card - against – us - 114042800008_1.html>
4. Neelam M Kachhap, "*Breaking Ground on the way to success*",(FINANCIAL EXPRESS March 2015), Available at: <http://www.financialexpress.com/article/healthcare/cover-story-healthcare/breaking-ground-on-the-way-to-success/52795/>
5. Renita Tisha Pinto, "*Good News: Medicine Prices In India To Be 80% Cheaper*", Available at:< http://www.indiatimes.com/health/buzz/good-news-medicine-prices-in-india-to-be-80-cheaper-240120.html>
6. Shamnad Basheer and Swaraj Barooah , "*Patent Error*",(INDIAN EXPRESS 20 February, 2014), Available at: < http://indianexpress.com/article/opinion/columns/patent - error/99/>

BOOKS

1. Christophe Bellmann, Ricardo Melendez-Ortiz, "TRADING IN KNOWLEDGE: " DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY" (Routledge, 2013)
2. F.M. Scherer, "INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE", (Houghton Mifflin, 2d ed. 1980)

3. Jonathan Curci, "*The* PROTECTION OF BIODIVERSITY AND TRADITIONAL KNOWLEDGE IN INTERNATIONAL LAW OF INTELLECTUAL PROPERTY", (Cambridge University Press, 2010)
4. Nuno Pires de Carvalho, "THE TRIPS REGIME OF PATENT AND TEST DATA", (Kluwer Law International, 2014)
5. Ramesh Govindaraj, Gnanaraj Chellaraj, "THE INDIAN PHARMACEUTICAL SECTOR: ISSUES AND OPTIONS FOR HEALTH SECTOR REFORM", (World Bank Publications, 2002)
6. Rawls J. (1971) , "A THEORY OF JUSTICE", (Cambridge: Harvard University Press.)
7. Richard A. Posner, "THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW", (Belknap Press, 1st ed. 2003)

ONLINE ARTICLES

1. "*Market-Based" Price Controls In India?*",(PHARMACEUTICAL EXECUTIVE EDITORS, 2014),Available at: < http://www.pharmexec.com/market-based-price-controls-india-0>
2. "*Is Drug Price Control The Key Growth Barrier For Indian Pharma Industry?*",(PILMAN 2015),Available at:<http://www.tapanray.in/is-drug-price-control-the-key-growth-barrier-for-indian-pharma-industry/>
3. *"Is The New 'Market Based Pricing' Model Fundamentally Flawed?"*,(PILMAN 2014),Available at:< http://www.tapanray.in/is-the-new-market-based-pricing-model-fundamentally-flawed/>
4. Debashish Banerjee & Pankaj Musyuni, "*Biotechnological inventions in India: law, practice and challenges*", Available at:< http://www.iam-media.com/intelligence/IAM-Yearbook/2016/Country-by-country/Biotechnological-inventions-in-India-law-practice-and-challenges>
5. Shardul Nautiyal, "*State FDA finds atorvastatin being sold at higher prices after tweaking prescribed dosage*", (PHARMABIZ.COM 2014),Available at:< http://www.pharmabiz.com/NewsDetails.aspx?aid=81220&sid=1>
6. Varun Mishra, "*The Indian IPR Poilcy- Fitting Enough For The Pharma Industry?*", Available at:< http://stellarix.com/ip-news/the-indian-ipr-policy-fitting-enough-for-the-pharma-industry/>

7. Vera Shrivastav, "*Protection of Traditional Knowledge within the existing framework of Intellectual Property Rights: Defensive and Positive approach*". Available at:< http://dx.doi.org/10.2139/ssrn.2463017>

YOUTUBE REFERENCES

IT'S NOT A SOLUTION IF IT'S NOT AFFORDABLE: Dr. Devi Prasad Shetty at Tedxgateway, 2013, Available at:

< https://www.youtube.com/watch?v=C3CXhwJjnk4>