CHAPTER-VII
CONCLUSIONS AND SUGGESTIONS

After having gone through various steps of the study especially the hypothesis it is arrived at a conclusion that, TRIPs was a hidden agenda of the WTO, as initially they convinced the member countries that WTO came into existence to address trade barriers that existed between countries as to currency differences, tax issues, and most importantly to address geographical and regional imbalances that exists can be resolved by mutual exchange of goods and services. TRIPs Agreement protects the technically developed countries and their trade interests. TRIPs Agreement on IPR especially with regard to Patents Act does not take into consideration of the poor nations concerns with regard to the fixing of prices of patented medicines. There is no proper method followed for fixing the prices.

TRIPs Agreement puts no obligation on the patent holder to disclose the fact that what actually the expenditure has been made on conduct of research and development. Usually the research in the fields of medicines and drugs are conducted by the companies through the experts who are paid consideration and the inventions are purely owned by the companies. The TRIPs Agreement does not make any obligations on the companies as to whether they have claimed any deductions under the Income Tax Act, or a declaration on the part of the company that they have written off the expenditure on R and D in their profit and loss account, whereby they have decreased the profits of the company thereby saving the taxes. The intangible assets are either self developed or innovated through regular research and development in both the cases the cost so incurred on patents as an asset is shown in the company’s balance sheet against which amortization is claimed by the companies thereby getting the benefit. There is no obligation on the companies to disclose as to what is the exact amount of investments and expenditure has been done by the company on Research and Development for developing the medicines.

The TRIPs Agreement does not take into consideration the social cost benefit with regard to the selling and pricing of the medicines. The companies should be made obligated to provide free medicines to the poor community especially in poorer countries. The TRIPs Agreement imposes stringent conditions
to invoke the flexibilities which act as a constraint in effective implementation of the available flexibilities within the framework of TRIPs Agreement.

TRIPs Agreement is silent as to the formation of health impact fund nor does not impose corporate social responsibility for the contribution of a particular sum of money towards the supply of patented medicines to the poor as was done under Consumers Act wherein Consumer Welfare fund is framed for the education of consumers and other such things.

7.1. TRIPs AND IPR PROTECTION IS MOTIVATED BY PROFIT, NOT HEALTH

As Smith (1994) points out, ‘There is a direct conflict between the pursuit of health and the pursuit of wealth.’ This is substantiated by the fact that many of the innovations are made to market the drugs but not according to the requirement of patients need as highlighted by Prof B.M. Hegde’s.

The lack of infrastructure in developing countries makes it difficult for essential drugs to reach those who need them, which can increase the time it takes for technology to ‘diffuse’ to the poor, even after patents have expired. For example, oral re-hydration therapy, a simple and cheap salt-and-sugar solution, has been mass distributed since the 1980s and has greatly reduced child deaths from diarrhoea, ‘but even though it only costs 10 cents a sachet, it is still unavailable for 38% of diarrhoea cases in Third World countries.’ Another example, Penicilllin, discovered in 1928 and first marketed in 1943, is unavailable to 2 billion people.

TRIPs Agreement does not address the issue of flexibilities within the TRIPs Agreement as there are number of hurdles as to utilization of the compulsory licenses.

For example payment to patent holder compensation is usually high.

a) The eligible importing Member(s) has made a notification to the Council for TRIPs, that:

(i) Specifies the names and expected quantities of the product(s) needed;

(ii) Confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no

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manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) Confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPs Agreement and the provisions of this Decision;

(b) The compulsory license issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the license and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPs;

(ii) Products produced under the license shall be clearly identified as being produced under the system set out in this Decision through specific labeling or marking. Suppliers should distinguish such products through special packaging and/or special coloring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) Before shipment begins, the licensee shall post on a website the following information the quantities being supplied to each destination as referred to in indent (i) above; and - the distinguishing features of the product(s) referred to in indent (ii) above;

(c) The exporting Member shall notify the Council for TRIPs of the grant of the license, including the conditions attached to it.

The information provided shall include the name and address of the licensee, the product(s) for which the license has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the license. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

Despite the flexibilities provided by TRIPs, Doha Declaration on TRIPs and Public Health, as well as the August 30 Decision, there are new barriers for developing countries to use the flexibilities provided by TRIPs, as discussed below.
1) There have been inadequate or no changes to national laws. For some reason developing countries were waiting for the Amendment of the TRIPs Agreement in March 2005 to see how other developing countries would do in their countries.

2) Data exclusivity: Article 39.3 of TRIPs requires protection of marketing approval data under certain conditions. Further, Article 39.3 requires countries to protect against “unfair commercial use” of marketing approval data. It needs to be noted that the US and the EC protection of data for registration of pharmaceuticals go beyond the TRIPs requirement.

3) Bilateral and regional trade agreements: challenges include the requirement of developing countries to strengthen IP rights beyond minimum requirements of TRIPs Agreement or TRIPs –plus situations. In that case, countries might not be able to use flexibilities provided by TRIPs and the Doha Declaration as well as the August 30 Decision. Some TRIPs-plus provisions in the bilateral and regional trade agreement are:
   a) Patent-DRA (Drug Regulatory Authority) ‘linkage’ requirement
   b) No marketing approval without consent of patent holder
   c) 5 years data exclusivity
   d) Compensation for unreasonable delays in patent grant in the form of extension of patent duration beyond 20 years.
   e) Restrictions on right to determine grounds for compulsory licensing.

Before 1970, India’s patent laws, like many others, were derived from its colonial days resulting into some of the world’s highest drug prices. However, by 1970, India, along with other developing countries had adopted “process patenting regime”. The Act of 1970 by granting “process patents” on drugs in combination with extensive use of fertilizers and pesticides not only led to low drug prices but also extended life expectancy and ended regular famines. In order to appreciate the gravity of the amendment and its repercussions on the international drug industry it is imperative to understand the difference between “product patents” and “process patents”. Process patenting implies the patenting of the method of manufacturing a

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product. Under the Indian Patents Act of 1970, process patenting was provided for. Besides from the fact that India has surplus flow of relatively cheap labor, it also has a long tradition of manufacturing drugs of various types. This resulted into several new techniques of making drugs cheaply. After the product has been manufactured with the patented process, it would then be known as patented product in patented in a country adhering to process patenting, such as India. Any other manufacturer cannot produce a product by the patented process, although the manufacturer can produce it by another process. Thus, patenting a product assumes a slightly different complexion from the patenting of a process.

The Act of 1970 stated that with regard to medicine or drug and certain classes of chemicals no patent is granted for the substance itself even if new, but a process of manufacturing the substance is patentable. Therefore, with respect to food, medicine or drugs, patents were granted only for the process of manufacture of the substance but not for the substance itself. Such restrictions on the grant of product patents do not exist in virtually any other country. All Western countries grant “product patents” on new inventions - i.e. the patent is granted for the substance itself. However, since 1970, India has granted “process patents,” which allow another inventor to patent the same product as long as it was created by a “novel process”. In pharmaceutical industry, it could mean that a tiny tweak in the synthesis of a molecule yields a new patent. Several companies can produce the same drug, creating competition that drives down prices and puts multinational corporations that spend millions of dollars in research and development at a serious disadvantage.

The old patent system allowed Indian pharmaceutical companies to copy drugs patented abroad by merely changing their manufacturing process. This served two purposes: one, it kept cost of drugs inexpensive in India; two, it also allowed a local pharmaceutical company to thrive which otherwise would have faced multi-million dollars lawsuit for patent infringement. By copying drugs other companies spent millions of dollars to develop, Indian pharmaceuticals companies could sell them at as little as one-tenth their original prices.

7.2. THE AMENDMENT TO THE PATENTS ACT

The 2005 amendments were made mainly due to international pressure, as the WTO demanded that India observe international drug patents. In 1995, the WTO’s TRIPs Agreement was reached in Marrakesh, Morocco, where India, along
with many other countries, agreed to grant 20-year patents on pharmaceutical products from January 1, 2005.

In March 2005 onwards the concept of the reverse engineering was stopped as Indian manufacturers are restricted due to the reason of Product Patents. The new law, amending India’s 1970 Patent Act, affects everything from electronics to software to medicines, and has been expected for years as a condition for India to join the WTO. Previously, companies could copy drugs discovered or invented by other companies by tweaking the processes used to make them. As an executive of a leading Indian company puts it: “The winner used to be the guy who could copy faster, now that has completely changed so that companies that don’t innovate will die, especially in the pharmaceutical industry”\(^5\) the new patent system recognizes registered original drugs as products no matter how they are produced, thus making it illegal to copy drugs still under patent. The 2005 amendments have done away with the practice of “evergreening” of pharmaceutical patents, where patent owners allegedly try to extend patent life through grant of new patents by minor “innovations” or improvements on formulations, dosage forms or minor chemical variations of an earlier patented product. The new law under section 3(d) also makes it clear that any invention that enhances the known efficacy of the substance or results in a new product or employs at least one new reactant is patentable and that only the mere discovery of a new form or of any new property or new use of a known substance or process is excluded. It may not be too difficult to prove that the improved dosage form is more efficacious or that one new reactant is involved in the known process to make the product.

These amendments to India’s patent law have sparked worries that Indian companies will face tough global competition, and that the cost of medicines would jump in poor countries now supplied by Indian generic drugs. Many international aid organizations use inexpensive Indian generic drugs to save money as they save lives. Though the new patent law provides for flexibilities, subject to stringent conditions the international organizations worry that the need to pay royalties or get licenses may constrict supplies of new drugs. All generic drugs could have been removed

\(^5\) Shrikumar Suryanarayan, President for Research and Development at Biocon Ltd., Bangalore, India. See Wall Street Journal, dated April 11th, 2005 at A20.
from the market. However, all the generic drugs already approved in India can still be sold, though sellers must pay licensing fees\(^6\).

Due to LPG India opens its markets and its companies venture abroad, companies are seeking to ensure that they profit from their own innovations. The list of top applicants in shows the importance of patents in global competition. Among the top applicants are Sony Corp, Procter and Gamble Co. and Daimler Chrysler AG - all with more than 300 applications each last year. From the Indian side, the top applicants include Dr. Reddy’s Laboratories Ltd. and Ranbaxy Laboratories Ltd. - both have more than doubled their research-and-development spending to about 10% of revenue\(^7\). India’s generic drug companies, which until now made money copying best-selling foreign drugs, has now increased spending on research with an eye to launch low-cost drugs for the global market. As Dr. Swati Piramal, Director for Strategic Alliances and Communications of Nicholas Piramal says: “If an Indian company makes a drug whose development costs are under $50 million, compared with a billion-dollar-plus development costs in the West, we will be able to change the paradigm of drug discovery.”\(^8\)

Three international legal texts now define the WTO legal framework for the protection of intellectual property rights in the context of countries’ right to take measures to protect public health, including the promotion of access to medicines. The TRIPs Agreement sets out the minimum prescribed standards for the protection of intellectual property rights, within which the means for exercising national discretion and flexibility in its implementation are specified. The Doha Declaration subsequently re-affirmed and clarified a number of these flexibilities, but also provided a general rule or principle for the overall interpretation and implementation of the other TRIPs provisions.

Paragraph 4 of the Declaration, not only confirms the right, but also the obligation of WTO Members to interpret and implement the TRIPs Agreement in a manner supportive of measures to protect public health and, to promote access to medicines for all. Finally, the 30 August Decision sets out a system by which the

\(^6\) There are also provisions allowing companies that make generics to copy drugs in the future. However, there are relatively tough criteria for such copying, and activists predict that prices for newly invented drugs will be much higher, because drug-makers will have the same 20-year patent monopolies as they have in the Western countries. See http://www.doctorswithoutborders.org/.

\(^7\) See Wall Street Journal, dated April 11th, 2005 at A20

\(^8\) The New York Times, March 24, 2005, Section C , Page 6 , Column 5
export limitation under compulsory licensing in TRIPs Agreements is waived so as to allow production and export under compulsory license, subject to notification and other requirements to prevent diversion of the products to unintended markets. Since these texts are not self-executing, it is important that specific legal provisions be enacted in domestic laws to enable countries to make full use of the flexibilities. A widespread lack of clarity about the options available, coupled with the lack of local legal and technical expertise to incorporate and implement TRIPs flexibilities in national law and policy, are the obvious and major problems. These countries’ experience in implementing TRIPs and its flexibilities is limited and requires effective cooperation between different government agencies and departments, including trade, health and industry that may have not had to coordinate before in developing common policy. In this regard, apart from addressing these specific problems, it is suggested that there is a need for guidance in implementing a good policy on intellectual property protection in the context of public health. Although it is clearly stated that countries are enabled to take public health measures, it seems less clear what would constitute such measures. The effects of the intellectual property-related policies of developed countries and recent FTAs need to be fully examined and understood. In this context further guidance will be required to facilitate the incorporation of TRIPs flexibilities into FTAs. Clarity can be achieved by defining those public health objectives or principles, which such measures are intended to meet. Policy makers in developing and developed countries need to construe pro-public health and pro-access norms and principles to guide their implementation of the collective legal framework provided by the TRIPs Agreement, the Doha Declaration and the 30 August Decision. The rapid and effective response to public health needs;

i) sustainability of supply of quality medicines at affordable prices;

ii) competition, through the facilitation of a multiplicity of potential suppliers, both from developed and developing countries;

iii) the provision for a wide range of pharmaceuticals to meet an array of health needs, as well as the need to ensure equality of opportunities for countries in need, irrespective of their level of technological capacity, including countries with insufficient or lack of manufacturing capacity and, irrespective of their membership of the WTO.
7.3 TRIPs FLEXIBILITIES INCORPORATED IN INDIA’s PATENT LAW IS NOT SUFFICIENT TO MEET THE REQUIREMENTS OF ITS PEOPLE IN ACCESS TO MEDICINES.

1) Exemptions from Grant of Patents in Certain Cases

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 agreement, however does not define these terms. This provides a flexibility which India has used to some extent. The Patents Amendment Act of 2005 has provided the important qualification that salts, esters, polymorphs, particle size, combinations and other derivatives of known substances cannot be patented “unless they differ significantly in properties with regards to efficacy” (explanation to section 3(d)). In other words secondary patents are not permitted unless these are therapeutically significant.

2) Compulsory Licensing and Government Use

Article 31 of TRIPs, the Doha Declaration and the 30 August 2003 WTO/decision allow for the issue of compulsory licenses in various circumstances. India’s patent law contains detailed provisions regarding compulsory licenses including those that generic companies can apply for, government use licenses, those issued in cases of national emergency, extreme urgency and public non-commercial use and compulsory licenses for exports.

3) Exceptions to Exclusive Rights in Certain Cases

Article 30 of TRIPs permits member countries to “provide limited exceptions to exclusive rights conferred by a patent...” The following three are the most significant and common exceptions:

a) Early working Also known as the Bolar exception — under section 107A(a) of India’s Patents Act, 1970 use of a patent for development and submission of information for regulatory approval will not be considered an infringement of the patent. Thus generic companies need not wait till the actual expiry of the patents to develop generic products and hence can introduce generics immediately after the expiry of patents.

b) Parallel imports Under section 107A (b), “importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the product shall not be considered as an infringement of patent
rights.” Thus, if need be, India can shop around the world and import patented drugs from the cheapest source.

c) **Research and experimental use** Under section 47, patented products/processes may be made or used by any person for the “purpose merely of experiment or research including the imparting of instructions to pupils”.

d) **Opposition and revocation proceedings** Section 25 provides for pre-grant and post-grant opposition proceedings before the Indian Patent Office. Section 64 also allows for revocation petitions to be filed at any time; revocation may also be applied for as a counter-claim during the course of an infringement suit.

e) **Limits on data protection** India’s Drugs and Cosmetics Act, 1940, which regulates the marketing approval of new drugs, as well as the amended Patents Act, 1970 do not contain any provisions relating to data exclusivity. Thus test and clinical data relating to safety and efficacy of drugs submitted by the patent holder can be used by generic companies and the drug regulator for introducing and approving generic products.

**7.4. NO LINKS BETWEEN PATENT STATUS AND MARKETING APPROVALS**

This is not required under TRIPs and India has kept the two issues separate drug approval procedure does not require consideration of patent status.

Despite these challenges, some countries have actually implemented the flexibilities provided by TRIPs to ensure access to drugs at the national Level. For example, in October 2003 Malaysia issued a Government Use authorization for importing drugs from India, to be used by the government for HIV/AIDS treatment. Mozambique issued Compulsory Licensing in March 2004 and Zambia in September 2004.

The Implementation Agreement fails to satisfactorily resolve several issues, including:

(i) the scope of diseases and product coverage;

(ii) countries that would be eligible to use the system;

(iii) ensuring adequate remuneration; and

(iv) Safeguarding the system against diversion of drugs into other markets.

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7.5. LACK OF CLARITY IN THE NEW LAW FOR UTILIZATION OF FLEXIBILITIES

The 2005 amendments to the patent law have many ambiguities that need to be addressed. To illustrate a few: under the new law, a maker of generics can apply to copy a patented drug, but only after it has been marketed for three years. The generic’s maker however must pay a “reasonable” royalty. The new law does not define what can be considered to be “reasonable”. This can result into unwarranted complications and needless litigation. Further, the amendments have sparked fears that with the new law, prices on patented breakthrough drugs would most likely raise to nearly the level in the United States, while prices on more commonly used drugs would most likely rise only moderately. The Indian government has said it would step in if price rises were excessive but has not said how that would be determined. In fact, the new law bars the government from overriding any patent for at least three years - a provision not required under the TRIPs Agreement. Further, the new law states that the Controller of Patents has a series of wide-ranging discretionary powers to determine all kind of criteria like “reasonable affordability,” “reasonable pricing,” and “reasonable royalty.” As Subbaraman Ramkrishna, senior director for corporate affairs at Pfizer India Ltd. noted, the word “reasonable” appears 42 times in the bill, giving the impression that royalty rates would be imposed subjectively what amount of royalty is fair is not clear. as it does not take into the consideration all the factors of cost of production and the basis for pricing is arbitrarily made in the shelter of research and development of the patented product and along with it provides the Indian companies to take the advantage of tax benefits on the amount spent on R and D as an encouragement in the scientific field which in turn is deemed that the companies pass on the benefit to the general public but patents comes as an obstacle for the access of the innovated products at least cost this is where social cost benefit is ignored. With the removal of Section 5 of the law, it is not clear if chemical processes continue to be defined to include biochemical, biotechnical and microbiological processes.

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10 India being questioned as to implementation of the Patents Act is concerned with the use of CL and innovations claiming patents on new use of known substances by the WTO recently
11 For details see Lorando Joshi Trial Lawyers blog. www.LorandoJoshi.com
13 Section 5 of The Patent Act, 1970 states, inter alia, "In the cases of inventions - (a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or (b) relating to substances prepared or produced by chemical processes ..., no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.
The amendments made to the patent law by India have been ostensibly to comply with its WTO obligations on intellectual property, the amended law represents a compromise between opposing interests. This compromise has resulted in a complicated and confused law with potential negative consequences that could have been avoided. The new law at times seems to exceed the requirements of the Agreement on TRIPs, or has provisions unique to India, and at other times, appears to be in conflict with the TRIPs Agreement. It is also believed that India, ironically, has swung from one extreme to another, moving from 1970 law that was clearly anti-patent to a law that is pro-patent applicant but not necessarily pro-innovation.

At a time when there is increasing skepticism around the world over the patent-system as it has evolved so far, particularly in the U.S., as to the implementation of sec 3(d) as Indian Patents Law does not provide patents easily as to the patenting of new use of known substances it remains to be seen whether the hybrid Indian patent-system stands the true test of time.

In a nut shell we can say that the new Patent Act aims to curb ‘me-too’ product patent applications by requiring one or more inventive steps and excluding derivatives such as salts, esters, ethers, polymorphs and similar forms and combinations of known substances, unless their properties differ significantly in the context of efficacy. This is likely to decrease the likelihood of ever greening or giving patents to incrementally modified medicines. However, the inexactness of some of the language leaves scope for interpretation of giving patents to new drugs and therefore expensive and time-consuming litigation is likely to ensue.

There are no adequate provisions supporting human rights concerns as prices are fixed arbitrarily high without disclosing the cost of expenditure for the development of the drug and benefits taken under the Income Tax Act in relation to that patented product eg cost of the asset, amortization in the profits and loss account, taking advantage of the benefits of certain provisions under the income tax act encouraging in house Research and Development 100 to 150% deduction is given under the Indian Income tax act. This saves the companies tax and increases Profit after tax.
“The works of founders of states, law givers, tyrant destroyers and heroes
cover but narrow spaces, and endure but for a little time, while the work of
the inventor though of less pomp is felt everywhere and lasts forever.”

– Francis Bacon

Access to essential drugs, from this perspective, becomes a critical part of
the fundamental human right to health. While WHO accepts that “patent protection
stimulates development of needed new drugs,” it argues that “countries must ensure
a balance between the interests of the patent holders and the needs of society.”

Patent law, which aims to reward innovation by providing a limited
monopoly to the patent holder, provides intellectual property-intensive industries,
such as the pharmaceutical industry, with one means of attaining profitability. But
the fruits of medical innovation raise questions that go beyond profitability. As the
WHO points out, medicines are “not simply just another commodity,” but rather a
public good “generic competition should begin promptly upon patent expiration”
and that “preferential pricing is necessary for lower-income countries and should be
actively pursued,” WHO also argues that because the research and development
priorities of the pharmaceutical industry do not necessarily respond to the needs of
the bulk of the world’s population, there should be public involvement to “ensure
development of new drugs for certain priority health problems.” access to these
drugs depends on their affordability in the market and, for the vast majority of
patients in the developing world, on whether the state is able to make the drug
available through the public health system. In this latter case, states have mostly
relied on the availability of generic substitutes or used their relative market power
to bargain for sustainable public sector prices. Despite the state’s formal status as
sovereign power, many developing countries, particularly in Africa, in the era of
structural adjustment and neoliberal fiscal constraints, have lost the capacity to keep
their public hospital dispensaries well stocked the same is in case of India. The
implementation of national essential drugs programs that rely to a large extent on
the model lists produced by WHO had provided one mechanism for governments to
manage the supply, use and cost of pharmaceuticals. Narrow scope for defining the
invention to facilitate ease of imitation, and relatively permissive use of compulsory
licensing to dilute the monopoly power of the patent Holder, (Compulsory licenses
allow third parties to exploit the technology protected by the patent. Patent holders

14 Francis Bacon, quoted in Mainly on Patents at page 1, edited by Felix Liebesny, Butterworths.
are compensated, albeit only partially, for the dilution of their exclusive rights through the payment of royalties.

Industrial countries, in contrast, provided “strong protection,” with a patent term of about 20 years and limited possibilities for imitation or dilution of monopoly power.

7.6. THE DRACULA EFFECT OF THE PRODUCT PATENT REGIME

The immediate problems of access to affordable medicines faced by the poorest countries in the world have, to some extent, been addressed by the recent agreement. But the controversies and tensions over affordable medicines are far from over. Ostensibly, these have related to access in the poorest countries. The real battleground, however, is going to be the larger markets both in developing countries and in the industrial countries themselves15.

In the larger developing countries with indigenous pharmaceutical sectors—such as Brazil, India, South Africa, and Thailand—the key issue is whether the TRIPs agreement affords them enough flexibility to dilute the monopoly power, conferred by TRIPs on pharmaceutical companies, through the use of compulsory licensing. In a series of skirmishes between developing country governments on the one hand and foreign companies and their governments on the other, the limits of what the TRIPs agreement permits have been tested. Brazil, South Africa, and Thailand have all authorized the production of patented drugs by their own firms to reduce the prices of AIDS drugs and help address their own public health challenges.

The consequences in industrial countries could be profound too. The TRIPs debate has highlighted the large wedge between the cost of supplying drugs by generic producers in developing countries and the prices charged in industrial countries. Increasing public awareness of this discrepancy—what might be called the Dracula effect because of the perceived price gouging in industrial countries—has led consumer and civil society groups in industrial countries to question whether patent protection is too restrictive and whether the resulting prices are excessively high. In their defense, major pharmaceutical producers argue that, in

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15 As quoted in Health and Development Why investing in Health is critical for achieving Economic Development. A compilation of Articles from finance and development. Edited by Jeremy Clift Published by International Monetary fund, 2004 p24 Available at http://www.imf.org
contrast to the generic manufacturers, they spend a significant portion of their revenues on research for new drugs. Against the background of runaway health costs in the United States and the consequent fiscal pressures, drug prices in industrial countries have also become an important public policy issue, leading to calls in the United States for imports from Canada, where prices are lower. In a number of industrial countries such as Australia, Canada, and New Zealand, public health systems use reference pricing to provide drugs at the lowest available prices. *Comparison shopping* for Stavudine + lamivudine + nevirapine.

**7.7. UNFINISHED AGENDA - NON COMMUNICABLE DISEASES AND INJURIES**

Three major such diseases viz., cancer cardiovascular diseases and renal conditions and neglect in regard to mental health conditions - have of late shown worrisome trends. Cures for cancer are still elusive in spite of palliatives and expensive and long drawn chemo - or radio -therapy which often inflict catastrophic costs, In the case of CVD and renal conditions known and tried procedures are available for relief. There is evidence of greater prevalence of cancer even among young adults due to the stress of modern living. In India cancer is a leading cause of death with about 1.5 to 2 million cases at anytime to which 7 lakh new cases are added every year with 3 lakh deaths. Over 15 lakh patients require facilities for diagnosis and treatment. Studies by WHO show that by 2026 with the expected increase in life expectancy, cancer burden in India will increase to about 14 lac cases. CVD cases and Diabetes cases are also increasing with an 8 to 11% prevalence of the latter due to fast life styles and lack of exercise. Moreover the doctors involved in irrational practices are in existence as doctors want to be enriched unjustly at the cost of the patients high cost of care is sometimes sought to be justified as necessary due to defensive medicine practiced in order to meet risks under the Consumer Protection Act. There is little evidence from decisions of Consumer Courts to justify such fears. While the line between mistaken diagnosis and negligent behaviour will always remain thin, case law has already begun to settle around the doctor's ability to apply reasonable skills and not the highest degree of skill. What has established is the right of the patient to question the

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treatment and procedures if there is failure to treat according to standard medical practice or if less than adequate care was taken.

7.8. THE RIGHT TO HEALTH IS NOT PROPERLY ADDRESSED IN INDIA

The right to life and health is a fundamental right guaranteed to every person living in India and is not negotiable. But in new patent regime, product patent protection for medicines and agrochemicals creates monopoly and eliminates competition in the pharmaceutical market. Drug companies often abuse the patent monopoly and fix exorbitant prices for the patented medicines. The introduction of product patent thus reduces accessibility and affordability of drugs. Health is one of the basic fundamental needs of all human beings. In legal terms fundamental human treaties recognize the right to the enjoyment of the highest attainable standards of physical and mental health. Health policies encompass a number of elements from prevention to cure and access to drugs. While all elements are important, the question of access to drug stands out in the context of the TRIPs Agreement.

Implementing a public health approach to patent policy requires not only appropriate legislation, but personnel -- in parliaments, patent offices, public health ministries, the private sector and the courts - equipped to handle patent legislation design and implementation. While all the issues are important for the design of a public-health sensitive patent law, priority should be given to those relating to the patentable subject matter and the treatment of the specific cases concerning pharmaceuticals. Public health goals can be significantly advanced through North-South co-operation, involving both the public and private sectors, through official assistance, licensing of technology, joint ventures and other modalities. The climate, scope and effectiveness of such co-operation, however, may be significantly enhanced if developed countries abandoned the use of unilateral actions for obtaining the protection of commercial interests of their patent holders in developing countries. International co-operation in this area should recognize the fundamental right of any person to have access to basic health care, and the corresponding obligation of governments to protect and promote public health. The “poor” in India are too poor to consume pharmaceuticals, even under the current regime. For the 70% or so of the population who currently does not have access to pharmaceuticals, the introduction of patent protection, and any price effects that may follow, there are a number of reasons for thinking that the low incomes of
India’s consumers and the lack of medical insurance will not ensure low prices, as is sometimes suggested. Historical and cross-country evidence also does not give confidence that this will be the case. And, perhaps most importantly, patent-owning firms may not be setting prices to maximize profits in the Indian market. They maximize global profits, and the politics of drug price regulation may dictate a limit to how low they will be willing to set prices in India.

Price control may also be ineffective in keeping down prices, since patent protection in combination with both the transfer-pricing of the patented medicines there exists a loophole a possible threat to not supply or give firms non-negligible power in bargaining with the government over the price of patented drugs. Whatever eventuates, the fact that the industry is very competitive today means that any monopoly profits obtained by patent owning firms once product patents become available can, with reasonable confidence, be attributed to the change in IPR Regime.

**7.9. FACTORS AFFECTING ACCESS TO MEDICINES IN INDIA**

The expenditure on health is the second most common cause for rural indebtedness.

1. Lack of health insurance facilities under government sectors undertakings.
2. The Health insurance premium is highly priced and in case no untoward incident occurs the policy lapses. There is no benefit of carry forward of the accumulated premiums hence it becomes a costly affair.
3. Expenditure on health is responsible for 3% shift from APL to BPL every year.
4. Over 23% of the sick don’t seek treatment because they are not having enough money to spend.
5. Expenditure on drug constitute about 50-80% of the health care cost.
6. Over 40% of hospitalized patients have to borrow money or sell their assets to get them treated. No banking company has a provision for lending money for health purpose.
7. A study by World Bank shows that as a result of single hospitalization 24% of people fall below poverty line in India.
8. Inefficient and iniquitous financing mechanisms
9. High and unaffordable drug prices
10. Procurement and distribution systems

11. Need for strengthening the regulation of medicines and vaccines

12. Insufficient Research and Development Focus

13. Irrational use of medicines.

14. Limited funds: funding is often insufficient to provide even the most basic healthcare services and products in developing countries. Hence, low prices of selected drugs may not necessarily mean that people have the capacity to purchase them.

15. Absence of a ‘social security umbrella’: Unlike in developed countries where the expenses on medicines are covered by insurance and social security measures, in developing countries e.g. India the percentage of people having access to support for purchasing drugs is quite small and expenses for drugs are borne by the people directly.

16. Self medications based on the recommendations of friends and pharmacists.

17. Not having faith on doctors due to the reason that doctors prescribe unnecessary tests making a lengthy and expensive diagnosis.

18. Doctor’s failure in correct diagnosis or not disclosing as to the actual disease a patient is suffering from in spite of heavy expenses and giving wrong medications.

19. Patients knowledge about the disease that they are suffering requires long term control of the disease since BP, diabetes, kidney disease, Asthama, Elephantisis, Cancers etc are controllable disease as they cannot be cured. The treatment is given so that the effect of the diseases on the human body spreads at a slower rate on the contrary no medication is given then the disease spreads at a faster rate shortening the life span for example people deem that disease remains with them as long as they are alive.

20. Patients not having awareness of the nature of the disease for example most of the diabetics are negligent to control blood sugar and face severe consequences at a later stage since diabetes is the mother of all diseases if ignored.

21. Patients attitude not to go to a doctor because of Indian sentiment people won’t want to be called as a patient as in an Indian society if a person has a litigation
or a disease people say that something wrong has been committed by a person suffering from diseases and hence he is paying the price for his past karmas or he has been corrupt and has swallowed money of others and hence he is paying the price which is usually called as “Haram ke Paise Haram me”

22. “Pharmaceuticals, they are commodity. But they are not just a commodity. There is an ethical side to this because they’re a commodity that you may be forced to take to save your life. And that gives them altogether a deeper significance. But they big pharmaceutical companies have to realize that they’re not just pushing pills, they’re pushing life or death. And I believe that they don’t always remember that. Indeed I believe that they often forget it completely.”

23. Government policy supports the pharmaceutical industry, as strict patents favor the expansion of the industry and economic growth. Although business and governments are therefore dependent on scientists to design new drugs and technology, their common agenda allows them to exert political and economic control over science. Any social objective to deliver essential drugs to the poor is lost in this agenda. Scientific search for ‘truth’ therefore becomes a quest for profit, because of the vested interests of government and business.

24. Subsidizing research and development of essential drugs.

25. Companies taking the undue advantage of tax benefits for Research and Development encouraging them to unjustly enrich by fixing exorbitant prices for the medicines giving reasons for RandD.

26. Data submitted to the Joint Economic Committee of Congress by the National Bureau of Economic Research reveals that public research, not private, led to 15 of the 21 most essential drugs introduced between 1965 and 1992, and other studies in the 1990s suggest that only a minority of important drug discoveries in recent years (estimates range from 17% to 40%) were the result of commercial research. This shows that public funding is paramount to the production of essential drugs, and therefore to health in developing countries. The combined effect of shortening patents and increasing public funding in the

18 See http://www.legalserviceindia.com/articles/patents_geographical.htm
19 Ibid.
pharmaceutical industry would ensure that not only are more essential rugs produced, but that they also reach those who need them.

7.10 STRINGENT PRODUCT PATENT REGIME AND FAILURE TO ENACT A SEPARATE LAW RECOGNIZING ‘RIGHT TO HEALTH’

It has been rightly said that it is not patents but the inability of the member countries which is the cause behind the inaccessibility of costly patented medicines. As this can be clearly made out in the Indian scenarios where the government has clearly stated in the Health Policy of 2002, where it has expressed its inability to provide funds for the supply of costly medicines especially patented medicines. This clearly shows the helplessness of the government in allocating funds in its budget towards public health sector for the poor due to financial constraint a main area is neglected. As the Health of the people is the wealth of the nation. A wealthy nation is one which has healthy productive people who contribute to the development of the nation along with the individual’s growth. The sufferings of the individual in health terms hinder the growth of the nation. The true wealth of a society is measured by how it treats the helpless young, the slowing aged, and disabled and how society seeds in them a feeling of hope and encouragement. All the while, also strengthening the true contributors, of the longevity of any civilization and life span of its people helps its citizens become asset of the nation.

As poverty is still persistent in most rural areas and urban slums, reliance on private health providers is severely fraught with serious economic consequences, especially for low income households engaged in the informal economy. There is now a realization that the health situation in India is seriously entrenched in widespread poverty, malnutrition and enormous disparities in almost every sphere of human life. This is particularly true for rural areas where the per capita monthly consumption expenditure is alarmingly low. Disease prevalence is in many cases large among low income rural and urban households. There is an increasing role of the market in delivery of health and diagnostic services with a very high out-of-pocket expenditure for seekers of health care. Infrastructural bottlenecks are faced by health services provided by the central, state or local governments. These bottlenecks go beyond physical or financial resources and cover whole aspects of hospital administration including large-scale deployment of doctors to non-clinical services causing a considerable amount of dissatisfaction among users of public
services, thereby forcing a shift toward private medical services and the resultant out-of-pocket expenses. All these issues are in direct contradiction to the two most significant national policy documents – the National Population Policy, 2000 and the National Health Policy, 2002.

Despite its persistent efforts and inputs received from a number of specially constituted bodies, India is critically lagging in terms of its longstanding commitment towards building a healthy society based on certain norms of equity and efficiency. From the studies conducted in recent years a range of physical, financial and manpower-related anomalies suffered by public health facilities in India have been highlighted. However, how these anomalies have affected low income households, particularly in backward districts of states with a high poverty rate, remains almost completely a neglected subject. Much of the literature has also failed to examine the nature of households and the income level of those who are trapped within a poverty syndrome or experience catastrophe as a result of losses suffered due to expenditure on various health care services and components – especially drugs and medicines – in poverty-ridden rural and urban areas and sprawling slums.

Two broad reasons have been given by the responding households to secure loans–medical and non-medical; the latter combines all categories of loans including those for purely consumption purposes as also those required to finance productive needs of the families. With the exception of urban Dungar Pur (Rajasthan), we notice that loans for medical reasons are quite prevalent in most of the areas under study. More than a quarter of indebted households in urban areas have reportedly been driven to come under debt because of certain medical exigencies. The same in rural areas turns out to be little over 19 percent. Does it mean that public health care facilities in urban areas are insufficient or is it a reflection of easier loan accessibility for urban households Tribal and Muslim households are also ahead in loan borrowing in their respective categories. The role of private money lending appears to be especially large in rural areas where informal family sources appear to work less effectively - perhaps due to widespread poverty and cash flow constraints. A big majority of rural households had borrowed from private moneylenders. Interestingly, urban households are not very far behind either. Almost 52 percent of them had to borrow from local moneylenders despite a growing emphasis in public pronouncements to improve medical care as it has
generally been perceived; the presence of private money lenders in medical borrowings is considerably high. Also, it turns out to be the case in most of the areas and population groups in question. The results indicate a very urgent need for an institutional mechanism to finance the health care needs of low income households in the country.

India spends only 4.4% of its budget on health, which is far below the global median of 11.5%.\(^{20}\) As a consequence, India’s health-care infrastructure is sub-standard and inadequate, lacking doctors and hospital beds. There are six doctors and nine hospital beds per 10,000 people.\(^{21}\) Only 15% of the population has health insurance, making quality healthcare in private hospitals inaccessible for a vast majority of the population.

### 7.11 ACCESS TO HEALTH SERVICES

The *National Rural Health Mission* was launched to improve availability and access to quality health care for the rural poor. While it is an ambitious central government programme, the benefits are not reaching the poorest of the poor. The announcement in the Budget 2012 to introduce a *National Urban Health Mission* is a positive step towards providing health care to the urban poor in the course of the Twelfth Five-Year Plan. The success of this mission would depend on adequate budgetary allocations, a clear plan of action incorporating a human rights approach, and a monitoring mechanism to ensure that targets are met.

Growing privatization of health care in India has resulted in gross disparities in service-distribution between rich and poor, and rural and urban areas. According to a 2011 Supreme Court order, private hospitals are supposed to provide free treatment and hospitalization to the poor. The right to the highest attainable standard of health remains unfulfilled for most of India’s population, as the health care system has collapsed in several parts of the country. For example, at least 83 children died in West Bengal between June and November 2011, due to lack of basic health care facilities in state run hospitals. Further, a total of 585 children died due to encephalitis in eastern Uttar Pradesh in 2011, according to official data as of November 2011 and 126 during the month of July, 2014 and around 750 deaths till Feb., 2015.

\(^{20}\) 69, 2008 statistics quoted in: WHO, World Health Statistics, 2011. India’s spending on health is lower than Bangladesh (7.4%) and Sri Lanka (7.9%).

Health care in India should be the core focus of the central and state governments in India. The disease profile is as follows: 80 million cardiac patients, 80 million afflicted with mental illness, 60 million diabetics, 50 million asthmatics, 50 million hepatitis B cases, and one in three Indians is a latent carrier of TB. The World Bank has said that India will have 35 million HIV cases by 2015 or approximately half of all the AIDS cases in the world. Given these facts, the patent regime in this country should be devised so that the utmost priority is granted to securing the people’s rights of access to affordable and quality healthcare, without monopoly.

7.12. SUGGESTIONS

7.11.1 Provide Medicines to the Poor for Free

This is a more sensible proposal than continued drug price control policy. Subsidizing consumers, should it be done, is a function of government, not the industry players. Of course, moral hazards problem should be minimized and controlled too. Put some cap; say “free up to xx amount” per year per patient. This will limit irrational drug use (people get drugs even for minor reason because they are heavily advertised and drugs are free anyway), limit fiscal bleeding of the government, and limit corruption in government procurement of drugs. The standard caution applies. That government procured medicines should be properly stored and monitored for temperature control, clean storage area, and adulterated and expired medicines should be disposed, not dispensed to poor patients.

Another alternative is for government not to procure medicines itself, but enter into an arrangement with some drugstores nearby for some discounts. Poor patients will get the medicines at those drugstores for free, say up to a certain amount, and then government will pay the drugstores later. The advantage of this arrangement is that government need not hire and train personnel for medicine storage, warehousing, monitoring and dispensing. Also set aside space for such drug storage.

7.11.2 Remove VAT on Medicines

Another sensible proposal is that Government is responsible for expensive medicines by at least 12 percent of the retail price of drugs. If this is removed, then that should be a significant “price discount” for the patients. This move will require
legislation. Hence, this should be one of the priorities legislative advocacies by various consumer groups and health NGOs.

Government is presumed to “promote good health and prevention of illness, through the attainment of optimal economic and social conditions, such that the people will need only the minimum amount of medicines.” But this has not been done effectively.

When people have stable jobs, they will have steady income source so they can eat better, live in cleaner environment, and have better education. This alone is a good preventive measure so that people will have better health. The end goal of public health policies should be to empower the patients to have more choices in finding medicines and healthcare that respond to their needs and budget, not to favor local companies and demonize foreign companies. Whether such medicines and healthcare are provided by local or foreign companies, it does not make much difference. People do not complain that there is no prestigious Philippine-made car or van. What is important for them is that they can choose from among the Japanese, Korean, American, European, Indian, Chinese, and other cars that are available in the country. Governments support for RandD of herbal medicines “Increase research on curative potential of herbal medicines strongly promotes the use of scientifically validated herbal medicine.”

This suggestion will further spread government resources for healthcare more thinly. Bulk procurement of essential medicines to be given away for free to the poor, giving the poor free hospitalization and diagnostic tests, etc. will already cost big amount of money. Also expanding the personnel and equipment of the Food and Drugs Administration (FDA) to monitor for registration and safety of more drugs, more skin whiteners and breast enhancers, more food and sauces, more drinks that are brought into the country will also cost a big amount of money. If the government spends further in drugs RandD, then advocacies and promotion of herbal and drugs, that’s spreading resources too thinly. Other departments (education, agriculture, agrarian reform, military, police, etc.) will also not allow that their budget will be slashed so that government can spend more on health.

Let the existing local pharma companies or new group of investors, develop and market those scientifically-validated herbal drugs. There will be buyers for those drugs and hence, there will be profit to be made. But what is lacking in the
perspectives shared by Delen, is that healthcare is both a right and a responsibility. In particular, healthcare is first and foremost, a personal and parental responsibility. People should not over-drink, over-smoke, over-eat, over-fight, and over-sit in sedentary lifestyle. People should not live in dirty places and should observe basic personal hygiene like washing hands carefully before eating.

Health inequity results not just because of income and social inequity, but also because of people’s unequal inputs in taking care of their body. A poor person who does not over-drink and over-smoke and observe personal hygiene in his daily life will have a better health outcome than a rich person who over-drinks, over-smokes, over-eats and over-sits. The former, even without a private health insurance, all other things being equal, will less likely develop lifestyle-related diseases like hypertension, high cholesterol and obesity.

For people living in dirty places like under the bridge or beside dirty and stagnant creeks, pulling them out from such places that are sure to generate various forms of diseases and move them to a cleaner environment, will probably be the “best medicine” that government can do.

Of course children of poor households who have been exposed to dirty places for several years will more likely have weaker lungs and other internal organs. This is where government can possibly put its limited resources – giving essential medicines for free to these patients.

Public policy on health or any other sector should be guided by empowering patients and the public to have more choices, more options. It is not advisable that politicians and health officials will come in anytime to coerce drug price control or coerce compulsory licensing (CL).

The damage to the country’s investment environment as a result of no-time table drug price control policy should be big by now. Many revolutionary drugs, new disease-killer drugs that are available in other countries around the world, may no longer be introduced and sold in the Philippines. The most adversely affected then will be the poor and some middle class. The rich, the politicians and government administrators who pushed the price confiscation policy, will have the

means and network to buy such drugs from abroad. But they are not the target beneficiaries of all those public policies.

7.11.3 Intellectual Property Rights

1. Creating an appropriate, TRIPs-compliant intellectual property (IP) regime, consistent with and enabling of the flexibilities reaffirmed in the Doha Declaration, appropriate to the level of development of its pharmaceutical sector.

2. Issue of compulsory licenses for increasing access to affordable medicines

3. Where people have to pay out of pocket, with generic policies, individuals can reduce costs by about 60% and this could make the difference between death or impoverishment and survival.

4. Ensure availability of free essential medicines by increasing public spending on drug procurement.

5. Strengthening national regulatory authorities and quality assurance mechanism for enhanced safety, quality and efficacy of medicines.

6. Supply of Quality Generic Drugs and strengthening ‘Jan Aushadi’ generic medicines’ stores at state level

7. Enforcing Rational Use of Medicines - Scaling up Rational Drug Use Initiatives, including use of essential drug lists, standard treatment guidelines, and containing antimicrobial resistance

8. Streamlining national and state procurement and supply chain management systems.

9. Reducing the Price differentials of medicines providing funding and technical support for NGOs who raise awareness of the issues surrounding the use of strict patents in the pharmaceutical industry. Promoting education in schools; collaborating with independent scientific organizations to provide information publicly, through the media.

10. Setting an example by increasing public funding in research and development; prioritizing investments in essential drug production; greater transparency; governments more accountable to the public than companies.

11. Campaigning for fairer drug policies at the international level.
12. Product patents on medicines defeats the interest of the consumers as prices are fixed arbitrarily and there comes an existence of monopolistic markets wherein competitors are excluded and consumers are left with no choice but to purchase the medicines offered to them in violation of consumer’s right to have choice.

13. Most persons with disabilities are denied health insurance, and many of them have been denied medical treatment in hospitals citing reasons such as inaccessibility, inadequate human resources or suitable equipment, and inability to communicate.

14. Promoting generic drugs in select categories, along with better quality control

15. Mandatory price negotiations for patented drugs.

16. Monitoring of prices of all drugs outside price control.

17. Giving the Competition Commission of India the authority to grant compulsory license for patented drugs.

18. No data exclusivity should be granted as it is not in the best interest of the country.

19. Checking collusive practices, particularly of the pharmacists and monitoring trade margins.

20. Checking anti-competitive practices like tied-selling at local level and empowering consumer forums to deal with such cases.

21. Regulation, accreditation and rating of hospitals and diagnostic centres with appropriate mechanism at state and central levels

22. Monitoring and checking anti-competitive practices arising from availability of health insurance

23. Finding alternatives to the proposed government sponsored health insurance cover, like replication of Rajasthan model of Medicare Relief Societies or National Illness Assistance Fund

24. Providing adequate incentives for R&D, including in herbal medicines creating awareness involving all stakeholders, namely, central and state governments and NGOs and prescription audit.


26. Passing of the separate law on Right to health and free access to life saving patented medicines
27. The Government of India should ensure the disclosure policy on expenditure incurred on Research and Development on bringing out the medicines so that the criteria to fix a proper price. This avoids unjust enrichment at the cost of patients as it becomes a binding on the companies to reduce their margin.

28. Competition, through the facilitation of a multiplicity of potential suppliers, both from developed and developing countries.

29. The provision for a wide range of pharmaceuticals to meet an array of health needs, as well as the need to ensure equality of opportunities for countries in need, irrespective of their level of technological capacity, including countries with insufficient or lack of manufacturing capacity and, irrespective of their membership of the WTO.

30. Despite the flexibilities provided by TRIPs, Doha Declaration on TRIPs and Public Health, as well as the August 30 Decision, there are new barriers for developing countries to use the flexibilities provided by TRIPs, is to be addressed in the interest of health of the people.

31. Promoting generic drugs in select categories, along with better quality control

32. Mandatory price negotiations for patented drugs

33. Monitoring of prices of all drugs outside price control

34. Passing of the separate law on Right to health and free access to life saving patented medicines as is done in case of Right to Education and Right to food (Food Security Bill).

35. In Income Tax Act a provision under Section 80 D on health care insurance and deductions for physical disability of the assesses or any of his family members a deduction to the extent of Rupees fifty thousand and permanent disability under section 80 U which includes mainly non-communicable diseases are provided with a deduction to the extent of Rupees one lakh or Rupees forty thousand as the case may be or actual amount spent whichever is less under Section 80DDB and for senior citizens it is Rupees sixty thousand the criteria framed for rich class persons who are assesses the same scale should be taken as a social security scheme to the poor for providing health care who are below poverty line for accessing drugs and medicines at free/reasonable costs.
36. Creating Health care fund as has been done in case of Investors Awareness Fund and Consumer’s Welfare Fund so that the needy people can have access to medicines specially the patented drugs.

37. Providing health insurance at least premium making it compulsory to have a health insurance policy as has been done in case of motor vehicles.

Finally it is concluded that the Indian patent regime without the product patent was a welfare legislation both rewarding the patent holder and ensuring the access to medicines especially the lifesaving drugs. India, a major producer of affordable generic medicines, has faced an increasing barrage of intense criticism for its progressive patent law and policies, not only from multinational pharmaceutical companies but also from the developed countries. The adoption of product patent regime has taken away the advantage from Indian firms, as they would not have the option to adopt the reverse engineering to produce the same product. India being a country densely populated with least amenities and moreover with people having less earning are forced to live in unhygienic conditions inviting the diseases especially the communicable diseases example H1N1 has created a mess as reports say that more than 850 people have died due to lack of awareness and improper medication at rural areas. The accessibility to the generic medicines and patented medicines for non-communicable diseases have posed severe questions to both the government and general public because of the reason that we are lagging behind in meeting the needs of the general public. Product patent protection in India is emerging to be a very decisive factor in determining access to medicines, both in India and other third countries especially in Africa. As the governments of many of the developing countries have failed to make appropriations in their budget towards health sectors as was required to do so in the light of strict patent regime. This is the cause of concern as the right to life includes right to health but the right to health is given as a charity but not as right, the constitutional validity to Article 21, for not properly being implemented comes into question. The government should frame public health policies to protect its citizens to create real wealth of the nation. So to ensure accessibility and affordability to life saving medicines an effective health policy is the need of the hour.