

TRIPS, PHARMACEUTICAL PATENTS AND HEALTH CARE FOR THE POOR IN INDIA

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I Introduction

INDIA HAS for long been a pioneer in the developing world in attempting to adapt pharmaceutical patent law to take account of the domestic health needs, emphasising more on the need of the common man, thus to be in line with its development. In India, large part of the population is living below the poverty line, and the expenses towards healthcare are out of pocket which clearly indicates that there is a significant health crisis with inadequacy with respect to healthcare and the accessibility, affordability and availability of the medicines in

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India. Section 3(d) is an exclusive provision under the Indian patent law. It achieves a great balance between the Agreements on Trade Related Aspects of International Trade (TRIPS) mandate and protects access to medicine for the poor. This has made India a leader in pharma industry. The situation has undoubtedly experienced a change after the TRIPS regime. The pharmaceutical patenting in India is of special relevance to the current issues of public health since the Indian market and the pharmaceutical firms are important suppliers of the low-priced pharmaceutical products in the form of generic drugs. The issue of access to medicines has assumed global dimensions since a millennium because of India being a part of the Doha Declaration on the TRIPS Agreement and Public Health, 2001. With its established and increasingly export oriented pharmaceutical industry being complimented by civil society awareness. India has been at the centre of the global access to medicines campaign. The Indian industry gave the campaign an economic backbone by showing that an alternative pharmaceutical industry was possible. The recent patent law decisions including that of the Supreme Court in the *Novartis* case,¹ indicates that India continues to put a premium on public health in relation to pharmaceutical patent law decisions. Thus we see that the pharmaceutical patents restrict the generic competition and thus increase prices, and are thought to be a significant barrier to access of medicines in developing countries

II Availability, affordability and accessibility: Concerns of the developing countries

In 1994, India signed up TRIPS as negotiated in the Uruguay round of the General Agreement on Tariffs and Trade (GATT) treaty. As a result, India was required to introduce patents on products by January 2005.² This had affected the developing and third world countries in two ways:

- a) By directly undercutting the supply of affordable medicines and;
- b) Indirectly by removing the generic competition on which India had been for long surviving by supplying copies of the patented medicines cheaply throughout the world's poor regions.

¹*Novartis AG v. Union of India* (2013) 6 SCC 1: (2013) SCC (Civ) 227: (2013) SCC OnLine SC271 decided on April 1, 2013. A division bench of Aftab Alam and Ranjana P. Desai, JJ.

²Peter Singer and Doris Schroeder, "Ethical Reasons for Intellectual Property Rights Reform: A Report (D1.3) for Innova-P2", available at: http://healthimpactfund.org/wp-content/uploads/2012/11/DP7_Singer_and_Schroeder.pdf (last visited on April 1, 2015).

India for long had been thriving on the generic pharmaceuticals industry that supplied copies of patented medicines cheaply throughout the world's poor regions. Until the mid-1990s, research and development in the Indian pharmaceutical industry focused on four aspects³ of research and development for the development of new processes for manufacturing drugs (i) new drug delivery systems (NDDS);⁴ (ii) research and development for generic products for the regulated market;⁵ (iii) non-infringing processes; and (iv) new drug development research (NDDR).⁶ With regard to the generic industry the generic manufacturers cannot enter the market unless they develop and come up with non-infringing because the patent holder may hold patents for manufacturing processes even after the product patent has expired.⁷ Availability and affordability of preventive and curative pharmaceutical products are the two major problems encountered by the developing countries.⁸

It must also kept in mind that grant of patent protection is not the only problem endangering the health of the people in the third world or developing countries. The life threatening diseases which the people of the developing and third world countries suffer are much less investigated. The international research community have referred to these diseases as the 'neglected diseases'.⁹

The problems related to affordability, accessibility and availability arose because:

- a) The innovators were to be granted patent protection this indirectly led to monopoly pricing powers being given to the innovators for considerable lengths of time and the common man is unable to afford medicines that are still under patent protection.

³Atsuko Kamiike and Takahiro Sato, "The TRIPs Agreement and the Pharmaceutical Industry: The Indian Experience" *Comparative Studies on Eurasian Culture and Society* 78-79 (2012).

⁴ This is considered to be the most vigorous area in which most of the top Indian pharmaceutical companies have been involved and are investing in research and development like Ranbaxy for Ciprofloxacin.

⁵ Indian companies have also increased the development of non-infringing processes for filing drug master files (DMFs) and abbreviated new drug applications (ANDAs).

⁶ NDDR is not only time consuming, but huge costs are involved in discovering a molecule and eventually launching the product into the market. And the rate of failure is relatively high.

⁷*Supra* note 3 at 85.

⁸ T G Agitha, "Global Governance for facilitating Access to medicines: Role of World Health organisation" 18 *Journal of Intellectual Property Rights* 589 (Nov. 2013).

⁹*Supra*. note 2 at 8. The Pre-TRIPs regime did not provide the pharmaceutical industry with incentives to look into the neglected diseases, the diseases developing mostly in developing and third world countries as a result not even the affluent could have their health looked into. Thus a dire need was felt for improvement.

- b) The medicines were priced way beyond the affordability power of the common man in the developing and the third world countries most of whom are poor, this has affected the accessibility of medicines.
- c) The drugs that are needed to cure the disease which the poor are suffering from are never developed thus affecting the availability of medicines.

In the pre-TRIPS era no medicines had been stimulated for the use in the less-developed countries. If we look at the brighter side there were a lot of points to the benefit of the developing countries for signing the TRIPS agreement they were:

- a) The signing of the TRIPS agreement had the potential of awakening the interest of the pharmaceutical companies in developing those medicines for the type 3 diseases (those diseases that occur exclusively or overwhelmingly in poor countries) that would help to cater the interest of the minority.
- b) After the term of the patent protection is over the medicines would be able to reach out to the people of the relevant developing or third world countries which as of now is the major concern as the drugs are not being developed for the poor.

Dependence of Indian economy on pharmaceutical industry

The Indian pharmaceutical industry has a strong generic base with almost 60,000 generic brands in 60 therapeutic categories in the market¹⁰ which was fostered by the then legal structure regarding patent. The evolution of the domestic pharmaceutical industry constitutes one of success stories of the Indian economy. From being an import dependent industry in the 1950s, the Indian pharmaceutical sector has today achieved global recognition as a low-cost producer of high-quality pharmaceutical products and its annual exports turnover is in excess of \$1.5 billion. This could be possible only because there was no product patent system for drugs and pharmaceuticals.¹¹

¹⁰ Nidhi Joshi, "Data Protection for Pharmaceutical Products under TRIPS: Data Exclusivity Legislation a Necessary Evil for India" 1 *Delhi law review* 104 (2005).

¹¹ *Ibid.*

The existence of process patents under the 1970 Indian Patents Act resulted in a robust growth of domestic pharmaceutical industry in India. At the same time, there was a steep decline in the business of foreign pharmaceutical companies in India.¹²

The Indian patents Act 1970, made it legally possible for the domestic pharmaceutical industries to reverse engineer those drugs that were patentable. The Indian scientists and businesses being well equipped with technological expertise started to reverse engineer the drugs and launched them in the domestic market as well as exported them to other countries.

Many countries feared that the patent protection in the pharmaceutical sector will limit the spread of knowledge and thus hampering the scientific innovations that were necessary in the public interest. The concerns of most of the developing countries were that once a product is patented the same product cannot be produced by an alternate method or process during the period of protection. However, if the process alone is protected (process patents), then an alternative process which is mostly 'invented' could be used to produce a similar product, since in pharmaceuticals, a product can be produced by more than one method.

Accordingly, the share of the domestic Indian market held by foreign drug manufacturers declined to less than 20 percent in 2005. As the multi-national corporations abandoned the Indian market, local firms rushed in to fill the void, and by 1990, India was self-sufficient in the production of formulations and nearly self-sufficient in the production of bulk drugs.¹³

Since there was no efficient patent protection between 1970 and 2005, many Indian drug producers copied expensive original preparations by foreign firms and produced these generics by means of alternative production procedures that proved to be more cost-efficient than the expensive development of original preparations as no funds were required for research, which contained the financial risks.¹⁴ The competitiveness of generics producers is based on cost-efficient production. At the same time, India's pharmaceutical companies gained know-how in the manufacture of generic drugs. Hence the name "pharmacy of the

¹² Pradeep S. Mehta, "TRIPS and Pharmaceuticals: Implications for India", *available at*: <http://sjep.revues.org/718> (last visited on April 1, 2015).

¹³ William Greene, *The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market*, <http://www.usitc.gov/publications/332/EC200705A.pdf>. (last visited on Mar. 31, 2015).

¹⁴ "India's Pharmaceutical Industry on Course of Globalisation", *available at*: https://www.dbresearch.com/PROD/CIB_INTERNET_EN-PROD/PROD000000000224095.pdf (last visited on April 1, 2015).

poor” which is frequently applied to India.¹⁵ The confidence and expertise in reverse engineering became counterproductive to an extent that it set in the belief that developing new drugs for domestic and global market apparently was beyond their reach, but new partnerships between academic and commercial organisations within and outside the country had started to emerge, the expenditure by the Indian companies on research and development has been abysmally low.¹⁶

The Indian patent term had been curtailed from 14 years to seven years from the date of filing or five years from the date of sealing of a patent whichever is shorter. The pharmaceutical process patents are automatically deemed to be endorsed a license right for three years from the date of sealing a pharmaceutical patent.

The pharmaceutical industry has developed in such a way that innovation relies on the high price of pharmaceutical products. The striking feature of the continuing discussions about pharmaceutical product patents is the divergence between the strength of the claims made by both sides and the weakness of the empirical foundations for those claims.¹⁷

The Indian pharmaceutical industry has shown a steady growth during the last three decades and has emerged as one of the leading global players in generics.¹⁸ India today is one of the major drug-producing countries in the world, being the fourth-largest producer by volume and the thirteenth largest by value, with about a 20-22 percent share in global generic production.¹⁹

III Impact of TRIPS on pharmaceutical patent and health care

Impact of TRIPS on pharmaceutical inventions

¹⁵*Ibid.*

¹⁶Sanjeev Chandran, Archana Roy and Lokesh Jain, “Implications of New Patent Regime on Indian Pharmaceutical Industry: Challenges and Opportunities” 10 *Journal of Intellectual Property rights* 269-280, 2005.

¹⁷Sudipta Sarkar, “Product Patent for the Indian Pharmaceutical Sector under the TRIPS regime” *available at*: <http://www.legalserviceindia.com/articles/ppch.htm> (last visited on April 1, 2015).

¹⁸ There was a major improvement in the ability of the Indian Pharmaceutical Companies to manufacture the generic drugs during the mid-1970's to 1990's.

¹⁹ *Supra* note 3 at 78.

The TRIPS appears to give member states some leeway with regards to ensuring that the protection of intellectual property rights (IPRs) does not impede public health interests.²⁰ Patent protection is the cornerstone of a healthy and dynamic research environment of any country; product patents protect the newly developed products from exploitation without permission of the patent holder, whereas process patents protect the method of production of a product.²¹ India's accession to world trade organisation (WTO) and its obligation to implement the TRIPS Agreement has resulted in drastic change in Indian pharmaceutical industry.²²

TRIPS initiatives, challenges and concerns of the developing countries

The objective of the TRIPS Agreement is to implement the international minimum standards for the protection of intellectual property, the agreement does not set down a single and universal IPR system that the members have to follow, they are free to adopt a regime that is stricter than the one required by TRIPS Agreement (article 1).²³ The WTO acknowledges the need for the members to meet the objectives regarding development and public health, though the members can legislate in respect of principles such as the promotion of public health and public interest in sectors of vital importance to their socio-economic and technological development.²⁴ TRIPS Agreement intends to implement an adequate protection of IPR that fits with the public health priorities of developing countries and dissemination of innovation in the world.²⁵

Thus it is observed that the developing countries are unable to make use of these flexibilities even when they have incorporated them in their national legislations because of the pressure from the industrialised countries. Thus the current global patent law regime does not favour the developing countries in securing the right to health to their citizens in general and to poor in particular.

²⁰Emmanuel KolawoleOke, "Incorporating a Right to Health Perspective into the Resolution of Patent Law Disputes" *available at*: <http://www.hhrjournal.org/2013/12/06/incorporating-a-right-to-health-perspective-into-the-resolution-of-patent-law-disputes/html> (last visited on April 1, 2015).

²¹ National working group on patent laws and public interest legal support and research centre, Report of the Fourth Peoples' Commission on Review of Legislations Amending Patents Act 1970, *available at*: <http://www.who.int/intellectualproperty/documents/Report4thCommission.pdf> (last visited on April 1, 2015).

²²*Ibid.*

²³ Samira Guennif and N Lalitha, "TRIPS Plus Agreements and issues in Access to medicines in Developing Countries" 12 *Journal of Intellectual Property Rights* 471 (Sep. 2007).

²⁴*Ibid.*

²⁵*Id.* at 472.

The TRIPS Agreement has left some room for countries to take public interest measure including measures to protect the public health, the flexibility provides the government with opportunities to tune the protection granted to meet social goals, the concerns of the developing world with regard to pharmaceutical patent has been clarified and enhanced by the 2001 DOHA declaration on TRIPS and public health and the 2003 design enabling countries who cannot manufacture medicines themselves to import pharmaceutical made under compulsory licence.²⁶ The main DOHA ministerial declaration, WTO member governments stressed that it is important to implement and interpret the TRIPS Agreement in a way that it supports the public health by promoting both access to existing medicines as well as the creation of new medicines. Thus adopted a separate declaration on TRIPS and public health. TRIPS flexibilities were used to gain access to the low-priced generic drugs. They agreed that the TRIPS agreement does not and should not prevent members from taking measures to protect public health.²⁷

Apart from compulsory licenses, the TRIPS Agreement also offers certain flexibilities that countries can use to address public health challenges in their countries. Such flexibilities include the freedom to exclude new forms of known drugs from patent protection, freedom to adopt the principle of international exhaustion of patent rights to facilitate the parallel importation of drugs (article 6), regulatory review exemption for producers of generic drugs, research exception, and delinking the grant of marketing approval for generic drugs from the patent status of branded drugs.²⁸ The use of flexibilities was further reinforced and reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health of 2001.

IV Right to health and pharmaceutical patents

Human Right to health v. Patent Right

Henry Sigerist ²⁹has rightly observed that health is one of the goods of life to which man has a right; wherever this concept prevails the logical consequence is to make all the measures for

²⁶ Elizabeth Verkey, *Law of patents* 565 (Eastern Book Company, Lucknow, 2nd edn., 2012).

²⁷ *Ibid.*

²⁸ "India's Pharmaceutical Industry on Course of Globalisation", available at: https://www.dbresearch.com/PROD/CIB_INTERNET_EN-PROD/PROD000000000224095.pdf (visited on April 1, 2015).

²⁹ Ravi Duggal, "Operationalising Right to Health care in India" available at: <http://www.cehat.org/rthc/rthpaper.htm> (last visited on Aug. 31, 2015).

the protection and restoration of health to all, free of charge; medicine, like education is then no longer a trade it becomes a public function of the state.

According to the Black's Law Dictionary, health means, "freedom from pain and sickness, the most perfect state of animal life and the natural agreement and concordant disposition of the parts of the living body".³⁰ Health is defined as an ideal condition and an important social and political good and also is the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.³¹ According to World Health Organisation Report (2000) Health care is defined as the prevention, treatment and management of illness and the preservation of health through the services offered by the medical, nursing and allied health professions, so healthcare embraces all the goods and services designed to promote health, including "preventive, curative and palliative interventions, whether directed to individuals or to populations.

Human rights are claims held by the individuals against the state in virtue of their humanity. At root if we see that human rights are those rights that people deserve to have realised irrespective of the legal regime they reside under.

Access to health care focuses mainly on the availability of medical care as part of a person's individual right, the various international conventions like Universal Declaration Of Human Rights, 1948,³² International Covenant on Civil and Political Rights, 1966,³³ International Covenant³⁴ on Economic, Social and Cultural Rights, 1966,³⁵ Convention on the Elimination of all forms of Discrimination Against Women, 1979,³⁶ and Convention on the Right of the Child, 1989,³⁷ recognise access to health care at the international level. Article 27(2)³⁸ of the

³⁰Mallika Ramachandran, "The Right to Health and the Indian Constitution" 1 *Delhi Law Review* 1 (2004).

³¹G.R.Lekshmi, "Access to Health Care: Problems and Prospects", *Cochin University Law Review* 271 (2007).

³² Article 25 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 necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control, United Declaration of Human Rights, 1948.

³³ International Covenant on Civil Political Rights, 1966.

³⁴The states parties to the present covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The steps to be taken by the States parties ... to achieve the full realization of this right shall include those necessary for: (a) The provision for the reduction of the still birth rate and of infant mortality and for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical services and medical attention in the event of sickness.

³⁵ Art. 7, 11 and 12, International Covenant on Economic Social and Cultural Rights, 1966

³⁶ Art. 10, 12 and 14, Convention on elimination of discrimination Against Women.

³⁷ Art. 24, Convention on the Right of the Child.

Universal Declaration of Human Rights (UDHR) and article 15(1) (c)³⁹ of the International Covenant on Economic Social Cultural Rights (ICESCR) try to equate IPRs with other types of human rights, this has led some authors to conclude that they provide a human rights basis for patent rights and other forms of IPRs.⁴⁰

Right to health is a human right intrinsic to the inclusive growth of human personality. Health is central to development, the role of health in the post-2015 has taken up much debate as to how the health issues can be addressed more effectively. The new agenda as taken up by the UN system Task Team on the Post-2015 UN development agenda⁴¹ is to challenge how to make health as an inclusive right globally thus framing an overarching health goal that appeals to the public and is actually measurable.

The above mentioned covenants impose obligations on the state/countries to respect, protect and fulfil the right as well as the access to health thereby making it obligatory on the part of the state along with the state actors to refrain from direct violations of right to health thereby protecting this human right.⁴² The cost incurred towards improvement in healthcare is a serious challenge in view of limited supply of resources and humungous demand for healthcare.

Therefore it is not just about improvement in average health but also about the health and economic welfare of the socially and economically marginal groups in the society and an attempt must be made to achieve an equitable distribution of the financial burden of ill health and morbidity.⁴³ The realisation of the right to health recognises that “health is the most important worldwide social goal the realisation of which requires the action of many other social and economic sectors in addition to the health sector”. Thus, the states have a duty to provide both material resources and the societal and economic conditions necessary to ensure that the right to health is affective as a legal right.⁴⁴

³⁸ Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

³⁹ Right of everyone to “benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”

⁴⁰ Joseph Millum, “Are Pharmaceutical Patents Protected By Human Rights?” *25 Journal of Medical Ethics* 34 (2008).

⁴¹ Health in the post-2015 UN development agenda, http://www.un.org/millenniumgoals/pdf/Think%20Pieces/8_health.pdf (last visited on August 31st, 2015).

⁴² G.R.Lekshmi, “Access to Health Care: Problems and Prospects”, *Cochin University Law Review* 271 (2007).

⁴³ *Id.* at 470.

⁴⁴ *Ibid.*

Right to health encompasses a spectrum of rights. The continuous development of modern science and technology helps in catering to the health needs of individuals thus we can say that the development of new technology is an integral part of right to health both at the national and international level.⁴⁵

Right to health is recognised as a fundamental right not only in India but also in many other third world countries. Even the TRIPS Agreement recognises that the member countries may exclude from patentability certain inventions, exploitation of which is necessary to protect public order and morality including human, animal or plant life or health and to avoid serious prejudice to environment⁴⁶ therefore the right to health care and also access to health care at affordable prices have become universally recognised human rights. In a country like India which has a variety of socio economic settings, national health programs have to be designed with enough flexibility to permit the state public health administration to craft their own programs according to their needs.

Recognition of right to health under the Indian constitution

Right to health has not been recognised directly by the constitution of India but the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion and political belief, economic or social condition. Right to health is an integral component of right to life enshrined under the Indian Constitution.⁴⁷ The constitution of India under article 14 and 21 have an indirect bearing on the health care thus directing the state the measures to improve the conditions of health care of the people of India. Apart from the fundamental rights, the constitution provides for certain directive principles or be followed by the state which have an indirect bearing on the access to healthcare that include articles 39, 41, 42, 43 and 51A. In addition article 51 of the constitution of India provides India's commitment to abide by an implement the treaty obligations that have a direct impact on the health condition.

In order to realise the above goals the government of India has launched various policies for poor in the urban as well as the rural areas, for example National Rural Health Mission,⁴⁸

⁴⁵G.B. Reddy, "Impact of TRIPS Agreement on Patent Regime in India with Special Reference to Health Care-strategies for the New Millennium 5 *Apex code expressions Journal* 11 (2003).

⁴⁶ Art. 27(2) TRIPS Agreement, 1995.

⁴⁷*State of Punjab v. Mohinder Singh Chawla*, (1997), 2 SCC 83.

⁴⁸Available at: <http://nrhm.gov.in/nhm/about-nhm.html> (last visited on Aug. 31, 2015).

National Urban health Mission⁴⁹ which is a reproductive and child health care programme to implement institutional deliveries so that skilled deliveries is available so that women and new born can be saved from pregnancy related deaths, and the most important initiative taken by the government under this scheme is free drugs to the pregnant mothers and new born children, Universal health coverage model,⁵⁰ Polio Drop Scheme, Mission Indradhanush is focussed on immunization drive through the ‘catch-up’ campaign where the aim will be to cover all the children who have been left out or missed out for immunization.⁵¹

The developed countries as well as the developing countries have their respective problems with respect to healthcare. The consciousness relating to health is high among the people and also the demand for the quality of health care thus in a way the health care expenditure is also high. So the government has not been successful in providing universal access. On the contrary the developing countries have less access to health both in terms of health determinants and factors providing access to healthcare. The majority of the population in these countries is below poverty line or is uneducated or not conscious of advantages and disadvantages of sanitation and cleanliness.

In India, the access to healthcare faces various challenges and for this reason there are constitutional provisions and a plethora of judicial decisions supporting access to healthcare. Though the judiciary has pronounced a number of decisions of a number of aspects of access, legislative implementations is what is lacking. A lot needs to be done in the administrative field and the constitutional framework along with the statutory, administrative and judicial role in this regard needs to be examined.⁵²

Judicial approach to right to health: India

In the case of *Peoples Union for Democratic Rights v. Union of India*⁵³ it was held that the state is under a constitutional obligation to see that there is no violation of the fundamental right of any person. The government is, therefore, bound to ensure observance of various social welfare measures in compliance with directive principles of state policy.

⁴⁹Available at: http://www.health.mp.gov.in/nuhm/Implementation_Framework_NUHM.pdf (last visited on Aug. 31, 2015).

⁵⁰Rakesh Sarwal, “Reforming Central Government Health Scheme into a ‘Universal Health Coverage’ model”, 28 (1) *National Medical Journal of India*, (2015).

⁵¹Available at: <http://indiatoday.intoday.in/education/story/union-government-launched-health-mission-mission-indradhanush/1/408944.html> (last visited on Aug. 31, 2015).

⁵²*Ibid.*

⁵³ AIR 1982 SC 1473.

In *Consumer Education and Research Centre v. Union of India*⁵⁴ the Supreme Court ruled that the right to health and medical care to protect health and vigour while in service or post retirement is a fundamental right of the worker under article 21. In the instant case the court also held that the health insurance while in service or after retirement, is a fundamental right and even private industries are enjoined to provide health insurance to the workman.⁵⁵

In *Bandua Mukti Morcha v. Union of India*⁵⁶ Bhagwati J in this case held that:⁵⁷

It may not be possible to compel the state through the judicial process to make a provision by statutory enactment or executive fiat for ensuring these basic essentials which go to make up a life of human dignity but where legislation is enacted by the state providing these basic requirements to the workmen and thus investing their right to live with basic human dignity, the state can certainly be obligated to ensure observance of such legislation; for inaction on the part of the state would amount to denial to the amount to live with human dignity enshrined in article 21, more so in the context of article 256⁵⁸ which provides that the executive cannot remain inert when the administration does not provide adequate measure to provide access to health.

Scope for implementing right to health under Indian Patent Act articles 7, 8, 30, 31.

The single most significant contribution of the TRIPS Agreement to Indian patent law was the re-introduction of the product patent regime.⁵⁹ Article 7 of the TRIPs Agreement lays down the “objectives” that is: “The protection and enforcement of intellectual property rights should contribute to promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological

⁵⁴ AIR 1995 SC 922.

⁵⁵ Art. 21, read with art. 39(e), 41,43, 48-A

⁵⁶ (1984) 3 SCC 161; AIR 1984 SC 802. Decided on Dec. 16, 1983 by three judge bench P.N. Bhagwati, R.S.Pathak and Amarendra Nath Sen JJ.

⁵⁷ *Id.* at 183-184.

⁵⁸ Constitution of India art. 256 reads:

obligation of states and the Union- the executive power of every state shall be so exercised as to ensure compliance with the laws made by the parliament and any existing laws which apply in that state, and the executive power of the Union shall extend to the giving of such directions to a state as may appear to the government of India to be necessary for that purpose.

⁵⁹Gopakumar G. Nair, “Impact of TRIPS on Indian Pharmaceutical Industry” 13 *Journal of Intellectual Property Rights* 432 (2008).

knowledge and in a manner conducive to social and economic welfare, and to balance of the rights and obligations.”

Thus this article in simple words provides two phrases “to the mutual advantage” and “the balance of rights and obligations” which circumscribes the manner in which the objectives would be realised. The substantive goals of promoting innovation; transfer and dissemination of technology, and furthering the social and economic welfare have been explicitly recognised.⁶⁰ Article 8 states the “principles” “Members may in formulating or amending their national laws and regulations adopt measures necessary to protect public health and nutrition and to promote the public interest (health) in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this agreement.”⁶¹

Appropriate measure may be needed to prevent the abuse of intellectual rights by the right holders or resort to practices which unreasonably restrain or adversely affect the international transfer of technology.⁶² Article 30 of the TRIPS Agreement permits the member countries to “provide limited exceptions to the exclusive rights that have been conferred by patents” subject to the condition that it does not “unreasonable conflict with the normal exploitation of the patent and do not unreasonably conflict the rights of the patent holder (owner), keeping in mind the legitimate interests of the third parties. But the TRIPS in no way defines these terms of ‘legitimate interests’, ‘unreasonably conflict’, ‘limited exceptions’.⁶³ Article 31 of the TRIPS Agreement dealing with compulsory license, this article does not place any restriction on the grounds for granting compulsory license.⁶⁴

V The national pharmaceutical pricing policy 2012

Access to essential drugs has become a major concern in today’s date. The national pharmaceutical policy was approved by the cabinet and notified in the year 2012, subsequently new drugs price control order was notified in May 2013. This will result in several drugs to come within the ambit of the price control under the national list of essential

⁶⁰“Report of the Fourth Peoples’ Commission on Review of Legislations Amending Patents Act 1970”, available at: <http://www.who.int/intellectualproperty/documents/Report4thCommission.pdf> (visited on April, 02 2015).

⁶¹*Ibid.*

⁶²*Ibid.*

⁶³Sudip Chaudhary, “TRIPS Agreement and Amendment of the Patents Act in India” 10 *Economic and Political Weekly* 3356 (2002).

⁶⁴*Ibid.*

medicines. The provision on exclusion of patented drugs in this policy for a period of five years might have been designed to keep the opportunity for innovation for pharmaceutical companies but will have a deterrent effect on the right to health which is a constitutionally guaranteed right.⁶⁵ In the case of *All India Drug Action Network v. Union of India*,⁶⁶ the Indian Supreme Court opined that the Government of India must make every effort to provide access to the life saving drugs to its citizens.⁶⁷

The Indian patent Act has been revised three times in 1999, 2002 and 2005 to implement the provisions of TRIPS including the product patent regimes for chemicals, pharmaceuticals, and food products.⁶⁸ These three articles of the TRIPs provide policy guidelines as well as flexibilities to the member states. The Indian Patent Act has incorporated these flexibilities and guidelines in the form of section 83, 84, 91, 92 and 92A providing general and special provisions for issue of compulsory license on patents.

The DOHA declaration in para 5(b) confirms the rights of countries to issue compulsory licenses: “each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such license is granted”. Paragraph 6⁶⁹ of the DOHA declaration addresses the WTO members lacking or with insufficient manufacturing capacities in pharmaceuticals can make effective use of a compulsory license. For interpretation and application of the compulsory licences for the public interest, the DOHA declaration on the TRIPS Agreement and public health provided some clarification. The declaration declared:

- i) The agreement does not and should not prevent members from taking measures to protect public health;

⁶⁵Dipika Jain, “Is the National Pharmaceutical Policy, 2012 Really Cheering The Pharma?”, available at: <http://www.ijlt.in/archive/volume9/Dipika%20Jain.pdf> (last visited on April 2, 2015).

⁶⁶(2011) 14 SCC 479. A division bench comprising of G.S.Singhvi and S.J.Mukhopadhyaya JJ decided the case on Oct. 11, 2011.

⁶⁷*Ibid.*

⁶⁸Neena Bedi, PMS Bedi *et.al.*, “Patenting and R & D in Indian pharmaceutical industry” 18 *Journal of Intellectual Property Rights* 105 (2013).

⁶⁹ The WTO members with insufficient or no manufacturing capacities in the pharmaceutical factors could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the council for TRIPS to find an expeditious solution to this problem and to report to the general council before the end of 2002.

- ii) The agreement can and should be interpreted and implemented in the manner supportive of the WTO member's right to protect public health and, in particular, to promote access to medicines from all.⁷⁰

However B.P. Jeevan Reddy J feels that the TRIPS Agreement favours only the MNCs and that the Indian government has not done enough to counter that onslaught.⁷¹ He also cites the case of wide differences between the prices of medicines produced in India by Indian companies and those produced by foreign MNCs and warned that the exclusive marketing rights permitted by the 1999 amendment Act and the product patenting permitted from 2005 would be detrimental to the common man.

The Supreme Court of India has explained that the object of patent law is to encourage scientific research, new technology and industrial progress. The grant of exclusive privilege to own use or sell the method or the product patented for a limited period stimulates new inventions of commercial utility.

However, the product patenting of drugs and pharmaceuticals was bound to contribute to increase in the prices of life saving drugs, thus once the lifesaving drugs became dearer and inaccessible the worst sufferers were going to be the people living in the third world countries who were not in a position to spend huge amount on health care. On a clear analysis of the TRIPS obligations to be discharged by the third world countries, more particularly developing countries like India, it becomes clear that a conflict arises between the health and welfare of the society and the economic rights of the individual patent holders in the case of product patenting of drugs.

VI Compulsory licensing under TRIPS, India, USA, Europe, Canada

The WTO countries may provide for different forms of compulsory licenses in respect of patents that are explicitly authorised by the TRIPS Agreement.⁷² Compulsory licenses as set out in the TRIPS Agreement are intended to strike a balance between public interests and the legitimate interests of the owners of the patents. The TRIPS Agreement also provides several restrictions for the use of the compulsory licenses and can be granted on a case-by-case basis,

⁷⁰“TRIPS and Public Health”, available at: http://www.wto.org/english/tratop_e/ta_docs_e/modules9_e.pdf (last visited on April 30, 2015).

⁷¹Available at: <https://www.scribd.com/doc/99001894/3/chapter-no-IV> (last visited on Feb. 23, 2016).

⁷² Art. 31 TRIPS Agreement.

various grounds for compulsory licenses: emergency and extreme urgency; anti-competitive practices; public non-commercial use and dependent patents.

Compulsory licensing will enhance the public interest while still maintaining the incentive to develop new inventions, it is important to keep in mind that compulsory licensing be allowed only where it is necessary to promote public interest, not significantly reducing the incentive to develop a new drug.⁷³

One should not forget that patents represent an interventionist instrument, ultimately for the sake of community welfare. Thus intervention to restrict some of the effects of patent may be required, when the community welfare is no longer served. Michael Kern. Compulsory licensing means that the government allows someone else to produce the patented product or process without the consent of the patent owner. This is one of the essential pillars of the patent system. Compulsory license for patented invention is part of the Paris convention and the TRIPS Agreement.

Compulsory licensing in India

a) India

The Indian patent act provide that an application for the grant of compulsory license can be made only after three years from the date of the grant of patent unless exceptional circumstance like national emergency or extreme emergency can be used to justify the grant of a license on an earlier date. Three broad grounds for the grant of compulsory licenses have been spelt out thus; i) reasonable requirements of the public with respect to the patented invention have not been satisfied ii) the patented invention is not available to the public at a reasonably affordable price; iii) the patented invention is not worked in the territory of India. The patents act sets out the circumstances under which “reasonable requirements of the public” would not have been met.⁷⁴ Such circumstances would arise if the patent holder refuses to grant a license on reasonable terms, and which, in turn, affects:⁷⁵

⁷³Surabhi Shekhawat, “Compulsory Licensing of Pharmaceutical Patents, 5 *Madras Law Journal* 36 (2014).

⁷⁴Ricardo Melendez-ortiz and Pedro Roffe (eds.) *Intellectual Property and Sustainable Development Agendas in A Changing World* 106 Edward Elgar Publishing Ltd., Massachusetts, (2009).

⁷⁵ Indian Patents Act 1970, s. 89 reads: The powers of the controller upon an application made under s. 84 shall be exercised with a view to securing the following general purpose, that is to say:

a. That patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable;

- i) Development of new trade or industry in the country;
- ii) Establishment or development of commercial activity within India; and
- iii) The major impact of this provision can be felt in the pharmaceutical sector where India could well emerge as a major supplier of the generic pharmaceutical to those developing countries which do not have sufficient domestic manufacturing facilities (development of the export market for the patented article) The purpose of granting compulsory licences in India is to see that the patented inventions are worked on a commercial scale in the territory of India and that the interest of any person working or developing an invention is not prejudiced.

The presence of a strong and effective patent system may bring numerous benefits such as dissemination of information and providing an incentive to invest in the development of new products and process which will eventually fall into the public domain.⁷⁶

Compulsory licensing in USA, Europe and Canada

a) USA

In *eBay Inc. v. Merc Exchange L.L.C.*, 547 U.S. 388 (2006), the decision of the Supreme Court was that before an injunction is granted for the enforcement of a patent, the question of whether a compulsory licence on the patent will be a more equitable remedy had to be considered. Subsequent to this case, there have been several cases where the company that was infringing the Patent asked the court to grant a compulsory license to an injunction to enforce the patent. As a remedy for infringement, the court ordered royalty which is effectively an often referred to as a compulsory licence. “These are not licence granted by the government but they are granted by the judge and have been the biggest area of compulsory licence in United States (US) since 2006. This decision in the case of eBay places the US closer to legal traditions in Europe and Japan where the governments and courts have the authority to issue compulsory licence in a wide range of cases including those involving uses of dependent patents, refusal to license, and to more generally to protect public interest. Thus we see in the eBay decision given by the US Supreme Court that WTO members can make non voluntary authorisations to use patents, so long as the court provides

b. That the interest of any person for the time being working or developing an invention in the territory of in India under the protection of a patent is not unfairly prejudiced.

⁷⁶P. Narayanan, *Intellectual Property Law*, 21 (Eastern Book Agency, Kolkata 3rd edn., 2001).

for “adequate compensations” it can affectively issue compulsory licences when dealing with remedies to infringement.⁷⁷

b) Europe

In 2000, ROCHE asked the German Government to grant a compulsory license on a patent protecting the blood screening HIV probe owned by CHIRON. On May 22, 2001 a licensing agreement was reached between ROCHE and CHIRON. In return for its license, ROCHE agreed to end its attempts to obtain a compulsory license.

i) In Italy the competition commission forced Merck twice and GSK once to license their products to generic drug manufacturers so that they can manufacture and export the products.

ii) In France was amongst several European countries which were outraged by the high prices of breast cancer diagnostic test, because of the myriad Gene patents. In 2004 France amended its patent law to allow the broader use of Ex-official licenses, and in particular, to authorise the government to issue ex-official licenses to patents on certain diagnostic technologies. The new act provides that in the interest of public health and demand and in the absence of a voluntary agreement with the patent holder, the minister responsible for industrial property may by order of the minister responsible for public health, request ex-official licenses.

iii) In Belgium modified its patent law in 2005, creating a new compulsory cross-license for bio-technology inventions, and also a new compulsory license for public health purposes.⁷⁸

c) Canada

The first compulsory licence issued under the Doha declaration was the license allowing the Canadian company, APOTEX to use nine patented inventions for manufacturing and exporting the HIV drug, DRIAVIR to Rwanda. Though APOTEX had sought a voluntary

⁷⁷ Indian Patents Act 1970, s. 89 reads: The powers of the controller upon an application made under s. 84 shall be exercised with a view to securing the following general purpose, that is to say:

- a. That patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable;
- b. That the interest of any person for the time being working or developing an invention in the territory of India under the protection of a patent is not unfairly prejudiced.

⁷⁸ Available

at: http://www.eatg.org/news/166054/Knowledge_Ecology_International_statement_on_Thailand_Compulsory_licenses (last visited on 08 March, 2016).

licence with the patent holders it did not materialise, Hence on July 17, 2007, Rwanda notified the WTO council for TRIPS that it planned to import TRAVIR from Apotex and would not enforce any patents granted in that respect in Rwanda. Two months later Canada issued a compulsory license allowing Apotex to use nine patented inventions for manufacturing and exporting TRIAVIR to Rwanda.⁷⁹ On October 4, 2007, Canada notified the council for TRIPS of the compulsory license.⁸⁰ The compulsory license may be granted on diverse grounds to be determined by national laws of the country.

Judicial pronouncements on compulsory licensing in India

In the recent judgement of *Novartis v. Union of India*⁸¹ the supreme court of India through its judgement has had a major implication on the pharmaceutical patents. In this case, the Novartis, a Switzerland based pharmaceutical company engaged in manufacturing anti-cancer drug called 'Gleevec' and got it patented in many countries from 1994. Subsequent to this, the drug Gleevec was sold in India in the year 2002 after obtaining market approval although the patent application was filed in the year 1998. In the year 2006, many, domestic pharmaceutical industries like Ranbaxy, Cipla *etc.*, opposed this patent application and thus the patent was refused. Aggrieved by this order, the Novartis challenged section 3(d) on the grounds that this section was not compatible to TRIPS and is arbitrary, illogical, vague and offence article 14 of the constitution of India. This order had enabled the Indian companies to manufacture cheaper generic medicines that would be affordable to the third world countries for the treatment of blood cancer. On furtherance, the appellate board was of the opinion that under the TRIPS India has the right to protect public health and to promote access to medicines for all. The Novartis charged Rs1, 20,000 per month for the dosage; on the contrary, the generic version of this particular drug was available in India at an affordable price at Rs.10, 000 only. Article 27(2) which permit members to exclude certain inventions which is necessary to protect public order or morality and to protect human life. Many underlined factors were considered by the judges in the Novartis decision. The first factor was to uphold the intent of the legislature in introducing section 3(d) to prevent ever greening of patents which is a patenting strategy consisting of acquiring patents on minor, often trivial, modifications of existing pharmaceutical products or processes in order to indirectly extend

⁷⁹ Ashley Weber and Lisa Mills, "A one-time-only combination: Emergency medicine exports under Canada's access to medicines regime" 12 *Health Human Rights Journal* (2013).

⁸⁰ Holger P. Hestermeyer, "Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines" 11 *American Society of International Law* (2007).

⁸¹(2013) 6 SCC 1.

the period of patent protection over the previously patented compounds.⁸² Novartis was attempting to evergreen the patent by filing a patent application for the PETA crystalline form of Imatinib Mesylate. Thus meaning that the new version of the drug would have a later patent expiration date and Novartis could continue to sell the drug even after the original version was no longer protected. The Madras High Court⁸³ in its interpretation mentioned that sec 3(d) was introduced to prevent ever-greening so as to provide easy access to the citizens of this country for the life-saving drug and to discharge the constitutional obligation of providing good health care to its citizens. Section 3(d) was specifically introduced so as to grant patents for the truly meritorious inventions and not for those that are mere improvements of the existing drugs. The judges during the proceedings of this case felt that Novartis had already recouped its research and development cost for the Glivec drug within a very short span of time. Thus the judges were of the view that since Novartis had very well earned the price for its research in the particular drug, a further incremental innovation would have a serious impact on the Indian society. Thus the judges of the supreme court keeping in mind the interpretation of section 3(d) also intended to reduce the drug prices and make health care more affordable for the Indian patients. Thus we see through this judgement that the madras high court was right in defending the constitutionality of section 3(d) which were consistent with the earlier Supreme Court precedents.

In *Bayer Corporation v. Cipla Union of India*⁸⁴ this case is a major reported case that attempted to patent linkage practice of linking drug marketing approval to the patent status of the originators product and not allowing the grant of marketing approval to any third party prior to the expiration of the patent term unless consented by the patent owner. In this case, the petitioner Bayer was a corporation that got patent on its renal cancer drug ‘SorefenibTosylate which was being sold for Rs.2, 85,000 for one month dosage and file a petition to restrain grant of licence to Cipla to manufacture, sell and distribute its drug ‘Soranib’ the Delhi High Court in this case held that the system of patent linkage could not be read into the provisions of the Drugs Act and Patents Act system as such.

VII Criticism

⁸²Priyamvada Gupta, “Pharmaceutical Innovations in India: Balancing the Value of Incremental Innovations” 5 *Supreme Court Cases Journal* 23 (2014).

⁸³*Novartis AG v. Union of India* (2007) 4 MLJ 1153.

⁸⁴2009 (41) PTC 642 (Del); 2010 SCC Del 541.

There have been and there are still debates of disagreements between countries about the justification of the protection to be given or at least some IP rights are given to the holders of intellectual property, those who are in favour of economic growth are in favour of the protection of IP rights while those who are concerned with the health are opposed to those views.

In the case of *Bristol-Myers Squibb Co. v. Canada (Attorney General)*⁸⁵ in this case the court spoke in detail about the balance to be struck under the patent act in which the public gives an inventor the right to prevent anyone else from using his or her invention for a period of 20 years. The court further held that a balance needs to be struck because the Parliament is concerned not only between the inventors and potential users, but also of the protection of intellectual property on one hand and on the other hand the desire to reduce the health care costs and being fair to those whose ingenuity brought the drugs into existence in the first place.

Growers report (December 2006) Commissioned by the British Government has very well brought out the case for IP rights that state “Ideas are expensive to produce but cheap to Copy, the fixed costs of producing knowledge are high and research and development for drugs can cost billions of pounds, but at the same time the marginal cost of production is very low. If no protection is given then the others will free ride on the creator’s initial investment and sell the invention or creation at a much lower cost. If the innovator knows this then there will be no financial incentive to innovate in the first place.”⁸⁶

During the pre-TRIPS regime the patent protection granted was less stringent or probably none which was in a way better as the accessibility and availability of medicines was not a problem but now the coming of the TRIPS the post-TRIPS scenario the medicines being priced beyond the reach of the poor are working to their detriment and causing a serious loss to the poor as now they cannot obtain the new medicines that they could have in the pre-TRIPS era.

The current situation is preferable to the population of the affluent countries who gain access to additional medicines that would not have existed without the added market demand for

⁸⁵2005 SCC 26 (Canada).

⁸⁶Justice LTC Harms, *The Enforcement of Intellectual Property Rights: A case Book 25* (World Intellectual Property Organisation, 3rd edn., 2012).

patented medicines, now anticipated from less developed countries.⁸⁷With the TRIPS the less-developed, developing and third world countries are benefitting with respect to the availability problem that is those new medicines would not have existed and been worked on had the TRIPS agreement not come into existence. One of the advantages of the product patents is that the stronger patents will provide access to the latest inventions in drugs, which the developed world will not shy away from introducing in India.⁸⁸

On the other hand with regard to the accessibility problem they have become worse off because whilst they are able to afford high monopoly prices, they are no longer able to benefit from the low prices of generic medicines.⁸⁹ The poor people would not be able to afford new medicines but they may benefit from purchases made on their behalf by aid agencies and governments. The lack of access to life-saving drugs (medicines) take away the lives of the poor and the people of the developing, least developed or the third world countries are the ones who are affected.

The generic industry has helped to save the lives of millions of people that would not have been possible without the TRIPS. If viewed from the human rights perspective the human rights philosophers have endorsed the pre-TRIPS situation arguing that it is morally impermissible to cause severe harms, including deaths, to poor people now for the sake of protecting millions of poor people from similarly severe harms later on.⁹⁰

VIII Conclusion

The TRIPS Agreement by its flexible mechanisms such as compulsory licensing, parallel importation, and opposition of patent has tried to balance the access to medicines or treatment along with preserving the intellectual property rights. These instruments have stimulated and further acted as a hindrance to delay and deny the access to affordable medicines. Further we see that the pharmaceutical companies can increase their research in developing drugs for such diseases if they know that the incentive for this research they will get a patent protection and can demand high monopoly prices from the affluent patients, government agencies and NGOS's initially and after the term of patent protection is over in the long run large number

⁸⁷*Supra.* note 2 at 12.

⁸⁸S.B.Puranik, Mamata Sangamesh and Mona Golshan.S, "Patent Laws In India And Its Impact On Pharmaceutical Industry" 2 *International Journal of Pharma and Bio Sciences* 9, 2010.

⁸⁹*Supra.* note 2 at 12.

⁹⁰Prabhu Balasubramanian, "Pharmaceutical Patents: Life Savers or Profit Makers?" *The Bottle Prize Essays.*

of people will be able to benefit so taking into account both sides. The extension of strong intellectual property rights through TRIPS into less developed countries, burdens the poor disproportionately as they lose access to generic copies of drugs that are still under patent protection. On the other hand, this extension of intellectual property rights may benefit the poor of the future, given that additional incentives are being provided to address health needs in developing countries. From a utilitarian perspective one might therefore argue that the overall benefits outweighed the overall losses. Most importantly, though the three scenarios we have discussed so far (no IPRs, pre-TRIPS, TRIPS) are not the only alternatives. Pharmaceutical industry and trade negotiators alike should not forget the true goal of drug innovation: saving lives. Profit should always be a means to this end, not *vice-versa*. Only by keeping this principle in mind and achieving a better understanding of the modern world health situation can we hope to effectively ensure the safety and well-being of the world's population in the twenty-first century and beyond.

Thus we see that over-protection and under protection being both sides of the debate can be solved only when we take further insights of the legal debate. The “flexibilities” under TRIPS provide sufficient room for developing countries to secure their interest or not, the question will be answered by the times to come. Till then, a conclusion regarding the present state of Indian law as much as it has adjusted through these flexibilities reached by *Sarah R. Wasserman Rajec*⁹¹ seems to me most appropriate to cite at this point rather than reaching at my own.⁹²

The Indian tailoring measures discussed above were enacted through less complex legislation with more discretion left to the Indian Patent Office and courts. The law barring new forms and uses of known chemicals was meant to counteract criticism that pharmaceutical companies elsewhere have been able to gain protection for longer than their initial discoveries warrant through creative claiming of new forms and uses of chemicals. Thus, it can be seen as an efficiency-enhancing law, solving a discrete problem in line with the purposes of flexibility. It also meets the local needs, which, in the case of India, include both large patient need for lower-cost medicines and the needs of the local generic drug industry.

⁹¹ Sarah R. Wasserman Rajec, “Evaluating Flexibility in International Patent law” 65 *Hastings law Journal* 153 (Dec, 2013).

⁹²*Id.* at 205.

Thus it can be said that in an era where the health is assuming a transnational character, the importance of the international human rights cannot be understated. And all the countries should ensure an effective engagement at the international level. It should be understood that the right to health cannot by itself be understood as a traditional right which is enforceable against the state but a conscious effort should be made to formulate and acknowledge the right to health as a positive right at the global level.

Suggestions and amendment proposed

After analysing the status of India's pharmaceutical industry and the scope of the generic drugs in India as well as outside India and the various legal instruments and legislations regarding health, compulsory licensing has an important place in the patent system as the compulsory license acts as an important tool to balance out the interest of various IP and public health stakeholders. The government should step in to take pro-active measures to ensure accessible healthcare for all, insurance schemes where health coverage extends to the poorest of the poor, its only then can we translate mere good health on papers to practice. Further the government should invest in the form of research and development at the university level and come up with more economically priced drugs and that the government should encourage the public sector undertakings (PSU's) to undertake the necessary research. open source drug discovery (OSDD) network is an emerging platform to be able to garner resources for developing drugs that pharmaceutical companies would not find attractive to invest into. Whatever drugs OSDD comes up with wouldn't be patented because it is the government money that has been invested into the research.