



## IMPACT OF TRIPS COMPLIANCE IN THE PHARMA AND PUBLIC HEALTH INDUSTRY IN INDIA WITH RESPECT TO INDIAN PATENT LAW

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### INTRODUCTION

India is known to be the hub of the pharmaceuticals products of the generic medicine statistically 50% of the global demand and 40% of the generic demand in USA and about 25 % of the medicine in UK are provided by India , India is 3<sup>rd</sup> in pharmaceuticals production and 14<sup>th</sup> by value the market valuation of the current pharmaceuticals industry is around 42 billion \$ and is expected to be 120 billion \$ by next 3yrs but the situation could have much more better had we not been the signatory to the TRIPS. The TRIPS compliance had in a way restricted our growth potential for that we have to look at the insight of the development that have happened in the past India never had the strong pharmaceutical sector. During the course of the paper we will see how the new TRIPS regime has changed the fate of flourishing pharmaceuticals companies dealing with generic version of patented drugs. Giant pharmaceuticals MNCs have railroaded the growth of generic manufacturer of drugs India has never have been of the view that we should grant product patent in chemical and agrochemical sector but instead it is the process which is to be patented which has helped the generic manufactures to produce the drugs with same chemical properties at a cheaper price which has forced the MNCs to reduce the drug price which has otherwise been very expensive and

they have done so as an act of compulsion rather than compassion.

### History of Pharmaceutical and public Health industry

The Britisher left India in the late 40s with a weak health infrastructure and the mortality rate was very high in the 1950s 90% of the total drug industry was controlled by the foreign MNC's. Drugs were manufactured outside India and were then exported to India at high cost this came to knowledge of public when a committee of USA sonnet published their report that India is the nation with highest drug price this led the government to constitute a 5 yr. plan to crave India development path followed by the avenger committee which was constituted to give its recommendation on the patent law in India the committee did exhaustive study in the patent system of USA and UK and Germany on their recommendation they said that Germany weekend their patent law which has helped the chemical industry to grow and also emphasized that there should be a compulsory licensing and process patenting of drugs and based on it the patent act and rules of 1970 came into force in 1972.

### Salient features of patent act 1970

- Section 2(j) define invention
- Section 3 defines things what are not patentable which includes
  - 1) frivolous invention
  - 2) invention which are contrary to morality and public health
  - 3) Mere discoveries
  - 4) Admixtures
  - 5) Trivial rearrangement etc.
  - 6) Invention relating to atomic energy
    - Restriction of product patent in the field of chemical food and drugs



- Term was 14yrs, in case of chemical food and drugs it was 7yrs from filling and 5 yrs. from sealing
- This act involve provision for compulsory licensing and royalties
- While framing the act the interest of domestic industry was also kept in mind and if patent is contrary to the domestic working of patent and for import monopolies the same should not be granted

### International Developments

Prior to the existence of WTO, GATT was responsible to govern the trade affair and they had very specific policy to promote the trade by restricting or eliminating the protectionist policies the very first time the question of inclusion of the intellectual property rights in the trade agenda come in the mid of the Uruguay round in the mid 80's prior to this the situation of the IPR was governed by the Paris agreement in beginning India along with other developing countries like Brazil Thailand and Argentina were reluctant to join the but ultimately in the late 90's they agreed to be the member of the TRIPS which covered the protection of pharma product as well the only compelling reason why they agreed to be the part of TRIPS was they believed to be member to it would help Free flow of trade, investment and technical know how It is believed that complying with TRIPS agreement of 1995 and ratifying its provision in the Indian patent law will have adverse impact in the pharma and public health industry in India. India is one of the largest manufacturers of generic version of life saving drugs which are available at a cheaper price than the patented drugs. The new patent regime will give control to large foreign multinational corporations to fix the prices at their will. As enshrined in the part 3

of the Indian constitution which is the directive principle of state policy it is indicated that ideally every state should work so as to achieve the concept of welfare state which is a utopian concept but even then they should work towards it. Article 47 of Indian constitution states that state can make law nutrition standard of living and public health. Prior to 1995 the governing convention on patent law was the Paris convention but the TRIPS agreement in 1995 puts obligation on the signatory members to change their patent system and make it a subject of international trade prior to 1995 India was a country was not granting patent to product patents for drugs as it was prohibited by the 1970 patent act and in the absence of product patent the pharma industry in India flourished which help for the betterment of health infrastructure mortality rate came down. By 1996 out of top 10 pharma companies by sales in India 6 were Indian companies and 4 were subsidiaries of foreign companies, One of their major success was providing anti-retroviral (ARV DRUGS) used for curing AIDS at a cheaper price costs were reduced from 12000\$/13000\$ annually per person to 140\$ non presence of product patent help them bring fixed dose combination reduce consumption of pill by 6 in day to just 1. The 1970 act made Indian companies like Cipla and Reddy laboratories a global brand making them global suppliers of ARV in countries like Africa and whole Sub Saharan region which was badly affected by AIDS. Country like India having a population of over 1.02 billion in the year 2000 with a poverty rate of 40 % access to cheap and affordable medicine should be the major concern introduction of product patent led to hike in drug prices prior to 1995 only 30% of



total population has access to affordable medication.<sup>1</sup>

In the year 1999 the patent act was amended for the first time after the enactment of the 1970 act. A mere introduction of Exclusive Marketing Rights (EMR) to pharma product patent without including a clause of exclusion will forgo scrutiny of large area of patentability interest of foreign companies are safeguarded at the cost of public interest just to pacify public interest compulsory licensing provision was given under the act for production and manufacturer without giving them right to sell or distribute has no sense and led to serious lacuna.<sup>2</sup>

Then came the 2<sup>nd</sup> amendment in 2002 after the Doha declaration legislators passed patent bills of 2002 which have following noticeable points:<sup>3</sup>

It defines invention to have (New, Inventive Step and Industrial Application).

- Patent duration was extended to 20yrs.
- Non-disclosure or wrong disclosure was made a ground for revocation.
- The sec. 3 of the act was changed with positive assertion.
- Patent grant should not impede public health protection.
- Central government reserve right to take any action with respect to public health.
- The availability of patented product to general product is made at a reasonable rate.

The loopholes of the 1999 amendment were looked upon and an attempt was made to correct them.

The WTO while making the TRIPS agreement made certain provision whereby every developing countries which includes India will get 5yrs time to mould their IP laws as in consonance with TRIPS and an extra 5yrs was granted to countries who does not give product patent with condition stipulated the can disallow the grant of patent for 10 yrs. But have to provide EMRS provided other WTO country has granted patent after 1995 and corporation have to seek for marketing approval.

India to its advantage use full window of 10 yrs. and the final amendment came in the year 2005, the 3<sup>rd</sup> and final amendment with following key features

- The amendment opens the gate for the product patent in the field of food, Drugs and Pharmaceuticals.
- The existing sec.5 (1) of the 1970 act was omitted which talks for process patent in these fields.
- Definition of food was omitted.
- Invention was added in the definition of patent.
- More clarity was brought with reference to inventive step and its standard was raised.
- New definition for pharmaceutical substance was given.
- Second medical use of known substance was made patentable.
- Sec.92A mandates compulsory licensing in generic medicines to

<sup>1</sup> Carlos M. Perera, "The National Public Health Policy Framed as per Direction of WTO", 47(9) Journal of World Trade, 1998, p.34.

<sup>2</sup> Abhijit Dey et.al, "Landscape of Pharmaceutical Marketing in India", Jan 1997.

<sup>3</sup> Patent Act and Access to Medicines, <http://www.listskabissa.org>.



countries in need of it on the ground of having shortage of medicine or no production of medicine to address public health if that country has notified such importation of medicines from India in their legislation.

- An attempt to regulate drugs pricing if application is made under section 5(2) to the enterprises in the business of making such medicine can charge only a reasonable royalty however to remove ambiguity with regard to reasonability royalty rates fixed to 4% or 5% of the net sales from the companies who were doing business in the same field prior to grant of patent and also infringement proceedings against such corporations were barred.
- Procedure for opposition of patent was strengthened and made a two-stage process:
  - (a) Pre grant opposition
  - (b) Post grant opposition
- Pre grant as the name suggest opposition before the grant of patent for these 11 grounds were laid down under section 25 another way was Post grant opposition in which any interested party can make application for revocation of patent after it is granted.<sup>4</sup>

### **Impact of TRIPS obligation on public health**

Access to medicine is a basic human right that have a higher significance than a International trade agreement and under Indian constitution state is under obligation to reduce the cost and make availability of life

saving drugs at a cheaper price a balance is to made between the interest of large public and rewarding the inventor if there is no access to life saving drugs at a cheaper price than there is no point rewarding the inventor

### **In the case of Vincent Panikur langar V/S UOI**

The SC has settled that public health to be the matter of top priority.

UN bodies have reiterated if there is conflict between the IPR regime on one hand and international human right law on the other hand human rights shall always prevail. As per the report of by the commission on UK IPR we can't have the same approach for the developing and developed countries with regards to the ipr policy the same was supported by the report published by the world bank which states that the complete implementation of the TRIPS will lead to a loss of 20 billion \$ which includes the public health sector. India has stop producing the generic version of the new patented drugs which would lead to high price of the drugs for example Hepatitis C affects a total of 170 million people and the patented drugs cost around 3 lakh US\$ for an annual treatment which is not possible for a poor country with the introduction of the new patent regime a large number of people will be left untreated which is a clear violation of Article 21 and the constitutional mandate which constitution puts

This new regime has completely stop the scope of reverse engineering which was the bread and butter for the Indian generic industry. The Extension of the pharma drug from a period of 5yrs by 1970 act to 20yrs by the new amended patent act is perceived as a

<sup>4</sup> Ibid. pp. 111-118.



negative as it would allow the manufacturer to enjoy the monopoly for a larger period of time and will lead to an expensive price of drug price for e.g. penicillin a lifesaving drug was made first in the year 1941 and it took India more than 20 yrs. that is 1963 to made that drug but the situation changed with the implementation of the 1970 patent act but with full implementation of the TRIPS Indian will again be sent to the dark ages

### OPTIONS AVAILABLE TO INDIA POST TRIPS

- 1) **Compulsory licensing**
- 2) **Utilizing parallel trade**
- 3) **Enforcing price control**

**Compulsory licensing** is the authorization permitting the third party to make use or sell patented invention without the patent owner consent. TRIPS is however silent on the conditions when the patent owner can be compelled to compulsory licensing but makes a clear distinction whether the compulsory licensing is done to stop anticompetitive practices or otherwise one of the condition listed under article 17 of the TRIPS agreement is the prospective licensee has failed in the reasonable period of time in negotiating with the patent holder on reasonable commercial terms and condition. This condition can even be bypassed in case of national emergency extreme emergency or non-commercial public use. Provided adequate remuneration to patent holder is given these cases are to be dealt exclusively dealing in the subject matter of each case and no uniform approach can be adopted. This adequate remuneration is a vague and ambiguous term royalty can be claimed by the patent holder at a higher rate and the licensee is having no bargaining power but to work on the dictates of the large MNCs.

**Parallel Imports** Indian patent act have specific provision for parallel import that is section 107A (b) importation of the patented product by any person from a person who is duly authorized under the law to produce, sell or distribute the product shall not be considered as an infringement of the patent rights. The objective is the availability of the patented product at a cheaper price to the consumers with huge variations in the price of identical medicines in different countries this is seen a major policy measure to reduce the ill effect of post TRIPS era

**Price control** is one other measure by which the government across the globe regulates the price of medicines a report suggest that the medicine which are covered under the price control shows a price increase of 1% whereas that of non-covered sees a price hike of 7% but even this has it flaws the Drug price control in India mainly relies on the ORG MARG data to analyses the data which take into account only the retail price and major medicine for desires like cancer and HIV AIDS are left out as the authority which is responsible is institutional that are the hospitals and escapes the economic criteria of the order. We still follow the list of 1990 which does not include the important medicine these need to be re-examined one of the major issue is this policy does not cover the drugs which are manufactured outside which has allowed the subsidies to placed their medicine at relatively higher price.

### CONCLUSION

The compliance to TRIPS agreement in 1995 in my opinion is not in the favour of India's pharma and public health sector with regard to pharma sector this sector is a capital intensive sector and require a lot of capital for R&D which at time becomes difficult for



small entities restricting their business which was not there prior to TRIPS to safeguard the interest of public health we have only provision like compulsory licensing which left us with no bargaining power to negotiate with the MNC's as the rate are fixed at 4% or 5% that to after application made under sec. 81 which can only be filled 3yrs after the grant of patent to maintain the principle of natural justice the patentee reserve right to oppose such grant and manner is Suo motu by controller under sec.91A can only be invoked in case of national emergency or urgent emergency but if I was to compare TRIPS compliance with the interest of public health i will always chose public health.

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