IJNRD.ORG ISSN : 2456-4184
INTERNATIONAL JOURNAL OF NOVEL RESEARCH AND DEVELOPMENT (IJNRD) | IJNRD.ORG
An International Open Access, Peer-reviewed, Refereed Journal

Challenges and Solution To Pharmaceutical Industry With Reference to Patent Laws

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1. *Over view Law Patent Law for Pharmaceutical Industry*

While India signed the TRIPS Agreement, it led to lot of changes in the country's patent regime. The two important provisions of Patents Act, 1970, were amended which was helping the generic companies for huge amount of benefit. While Product patents were introduced for pharmaceutical innovations, patent protection was provided for 20 years.

The Government of India while incorporating the TRIPS Agreement by amending two provisions in the Patents Act, which reduce the impact on the generic companies. The first change was done in Section 3(d) which does not allow patents by way of minor modifications in the existing product. The primary objective of this provision was to eradicate the chances or probability of ever greening of patents. Hence we understand that Section 3(d) ensures that public domain allows the generic companies to continue operating in the industry.

The second amendment in Indian Patents Act is the chances or probability for the grant of compulsory licensing for the patent in India or preventing the chances of exploitation by charging exorbitant prices using patent law as tool. Prominently both these flexibilities have successfully curtailed by the highest court of the India. Some of the result of the above mentioned amendment is mentioned below:

- While analyzing the performance of the Indian pharmaceutical industry in the post-TRIPS patent era it clearly evident that the leading generic companies of the industry have mixed performance. While there has been drastic growth in previous decade, against this during the current decade, there has been slump and or marginal growth rates.
- During the current decade the pharmaceutical industry have shown considerable focus on research and development while comparing with previous decades. This shift in focus indicates industry shift towards increase in its patenting activity for the benefit of their inventions
- Moreover last 20 years, Indian pharmaceutical industry is competing with global players where in pharmaceutical products are exported to many countries at very affordable prices.
- It is clear that the patent law's sole purpose is to protect the interest of both the inventors and general public/consumers.
- Pharmaceutical industry provides a decent health care while comparing with previous years. By this they are contribution to the welfare of society aligning with principle of natural justice.

2. *Problems faced by pharmaceutical industry on one side and the public healthcare on the other side:*

- From the perspective of public healthcare it is being generally understood that pharmaceutical industries are exploiting the common public in terms of their pricing and supply of medical facility
- With regard to pharmaceutical industry they are too worried about the competition prevailing amongst their co-players within the same industry.
- Similarly pharmaceutical industries based out of India are facing stiff competition from the multinational giants.
- Indian based pharmaceutical industry face competition in world export market as there are many global players who have pricing advantages in the bulk drug segment.
- TRIPS in its Article 7 stress the need for striving at balancing the needs of pharmaceutical industries and common public.

- This battle is lost. However, we can see during the course of time some of possible solutions which would enable to overcome the problems faced.

3. Solutions during current status of affairs:

- TRIPS provide a solution by the existing Article 30 in the form of Compulsory licensing, Generic Competition alternative etc. Though article 30 is available in spite of this article implementation is key solution to this issue.
- Hence the compulsory licensing should be implemented in such a way that it should not be too restrictive with respect to regulation of drugs and at the same time it should not be too lenient towards abuse of this article 30.

4. Outcome of the above solutions:

- In spite of the above solution pricing remained a main challenge which led to a conclusion that solution was not a complete one and the objective is totally defeated.
- If the statute enforce price restriction then availability of the products becomes a challenge. Instead it creates a parallel market wherein affordable public purchase at a prohibited cost which is completely out of the system wherein the quality controls is not monitored.

- Some products with competitive edge, generic/bio-similar drugs, are not immediately available due to patent right granted to the pharmaceutical organisations due to pricing restrictions laws implemented by various regulators and governmental organizations. Hence instead of price restrictions, pricing balancing could make a meaningful sense for the both pharmaceutical industry and public at large.

- The proof TRIP's implementation and with existing IP laws Novartis claim was rejected by the Indian court system. Indian generic companies can sell Glivec at a price one-10 per cent of the available price at that point of time.

- Correspondingly the TRIPS provisions to protect the health of ordinary people, has not been very successful in India verses developed countries. Hence regulators should play a balance role between pharmaceutical industry and health care consumers.

5. Critical Review:

- There are disagreements between countries with regard protection of IP rights since they do not have same patent law system.
- Implementation of TRIPS agreement is not uniformly followed by all the participating countries, since each country have their own way of interpreting TRIPS agreement. Further the monitoring and guiding authorities pertaining to TRIPS agreement are not strict and stringent. Hence compliance becomes difficulty towards uniformity.

- Post TRIPS regime the pricing of drugs has gone up drastically which prevents the reach of the poor. This situation pertains to certain drugs and not on all the drugs. However irrespective and drugs and situation affordability should not be compromised.

- Post TRIPS the situation is favorable to developed countries than the developing and underdeveloped countries. The main reasons are availability and affordability.

- TRIPS agreement without intent has encouraged monopoly pricing which at time appears to be exploitory in nature. The outcome of this situation is such that products are available only to elite class and poor could not afford these drugs, especially with regards to generic drugs.

- Few state has provided tax benefits, subsidies and relief favoring the poor in order to acquire these drugs. But at time these benefits are exploited by the rich too. Further these schemes are not supported by many states. Hence the effect is very marginal.

6. Future course of action – Solutions

- The regulators should play a role of promotion rather play a role of restriction which would be fair to both the side of the parties' namely pharmaceutical industry and healthcare consumers.

- Utmost importance should be provided to life saving drugs which are crucial for life and well being of society and public at large.
- The Utmost priority of the regulators should be health care for all and specifically to the poor and down trodden. Patent regulations in line with supply of medicines at affordable price to poor should not be compromised on the other hand.
- The response of the governments should be able rapidly, especially during communal disease especially during a situation similar to COVID 19.
- Liberalization in import policy is needed to critical drugs until it is being manufactured locally at out affordable price. Exemption from custom duty and other type of taxes should be considered to life save drugs medicines.
- Compulsory licensing procedure should be very simple with least complications such at pharmaceutical industry would be willing to follow at ease.
- Article 8 of the TRIPS agreement prevents the abuse of IP rights which exploits the society and common public. The international regulators will have to decide whether these proposed solutions will be materialized and provide a long-term solution.

7. Legislative solutions:

- Considering various aspects of various legal instruments and legislations regarding health, compulsory licensing plays a vital role in the patent system as the compulsory license acts as an important medium while balances both, the interest of various patent laws and public health stakeholders.
- Health for all can be achieved only with major support from legislators. Hence the legislators should have a proactive approach towards this goal without the compromising on the pharmaceutical industry
- Legislators should legislate with keen interest on the research and development needed for drugs innovation and also encourage mass production of drugs. Special incentives can be provided for Research and development which would encourage pharmaceutical industry towards innovation keep society need in mind.
- Government should invest in Open source drug discovery (OSDD) since pharmaceutical Industry would not find attractive to invest. Drugs under OSDD comes need not be patented since it is government money that has been invested into the research.
- Indian Patent Office grants the patent protection to the inventor and allows manufacturing of the medicines. The Drug Controller General of India (DCGI) provides marketing approvals. There is no "patent linkage" between these two Indian national regulatory authorities. Hence, a pharmaceutical manufacturer who releases new drug product in Indian market does with risk and unaware of any possible conflict in patents. As an example, recently Bristol-Myers Squibb Company prohibiting the Drug Comptroller General of India (DCGI) from granting marketing approval for a generic version of Sprycel and secured an ex-parte injunction.
- Currently the legislators are working on linking these two departments which are undergoing major roadblocks.

8. Conclusion:-

Legislators, international organisations and pharmaceutical industry has to work in tandem to resolve this issue. By resolving this issue medical care can be provided to all for a better welfare society.

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