Chapter-7

Impact of changing Indian IPR regime on
Access to medicine from the Medicos' perspective
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With the objective of studying the perception of medical fraternity on the implication of TRIPs agreement on pharma business particularly drug prices, in post-2005 scenario when the product patent regime is enforce. Since pharma industry is the only industry wherein the decision making is done by the influencer i.e. doctors and not the consumer, it becomes imperative to on the feed back of medicos as they are the drivers of market through prescription.

7.1 SAMPLE SIZE AND SAMPLE DISTRIBUTION

For the purpose of the study, the sample size is one hundred. Medicos from across India has been contacted and a questionnaire(Annexure-II) containing a set of questions was being filed by them. The sample distribution is as follows:

Super specialty doctors (cardio thorasic, obstiatrician...etc.) -- 20

Specialty Doctors -- 30
(Cardiology, Diabetlogy, MD medicine, orthopedic...etc.)

General Physician -- 50
7.2 PRIMARY DATA ANALYSIS

Following is question wise detailed analysis of the data collected through primary means.

7.2.1 This question was directed to check the current awareness level on the enforcement of intellectual property rights protection and its strategic importance in medical fraternity.

Graph -7.1 – Awareness level in medical field about IPR

The above graphical representation of the results depicts that the overall awareness level in the Medical field is low as 64% of doctors surveyed perceived that the medical fraternity is not taken as much interest although they are concerned about the adverse implications of the IPR enforcement.
7.2.2 This question was directed to measure the level of interest taken by doctors in understanding of changing intellectual property regime specially when it has significant implication on drug prices.

Graph -7.2- Interest in understanding the implication of IPR on Drug prices

The results show that 95% of the doctors were interested in knowing and understanding of changing intellectual property regime especially when it has significant implication on drug prices. This reveals that they are very much concerned about the adverse implication of the changing scenario on drug prices.

7.2.3 This question measure the importance of the price factor while prescribing medicine

Remarkably, a unanimous answer from all the doctors surveyed which is affirmatively endorses the importance of drug prices even while prescribing the medicine. All the doctors (100%) surveyed has acknowledged that they
indeed are very much concerned and consider the price factor while treating any patient.

7.2.4 This question measures the direct impact new Intellectual Property Rights regime which recognizes product patent in India.

Graph – 7.3 Direct impact of new IPR regime on drug prices

Majority of medical fraternity (88%) perceived that there would be a direct impact of product patent regime on drug prices. However, a small fragment of doctors surveyed (11%) also of the belief that it would encourage innovation by Indian pharma industry and therefore more and more new molecules would be developed by and introduced by Indian companies which would result in very low or no impact on the drug prices.

7.2.5 The objective of posing this question is to evaluate whether Intellectual Property(IP) protection is now considered as one of the strategic element post-2005 by majority of companies in Indian Pharma Industry. For
example while promoting a drug to the doctor, they highlight that this exclusively protected by our own IP or invented by them.

This results highlights that 68% of the companies has already started recognizing intellectual property as an important strategic element which is depicted in their promotion strategy to the doctors. On the other side there are still a healthy number of companies 32% not giving the due importance to intellectual property.

7.2.6 This question is subdivided into ten questions. These questions are directed towards accessing the overall perspective of Medico for the changing environment of the Pharma Industry, post-2005. Medicos were ask to tick one of the options out of which expressively depict their provenance towards each statement provided in each sub questions.

7.2.6.1 Intellectual property Management is one of the important component for an Indian Pharmaceutical industry
The results states that 57% of the medical fraternity strongly agrees with this and 37% are not very strong but in agreement with this. They perceived that all the pharmaceutical companies should develop a strong portfolio of intellectual property so that more and more molecule can enter into the market which gives a choice to doctors to choose the best for the patients.

7.2.6.2 The awareness level of Intellectual property regime in the medical fraternity needs to increase in order to benefit from future IP regime

All the doctors surveyed affirmatively endorsed the fact that there is a need for the Indian Pharmaceutical Industry to increase the level of awareness so
that benefits of product patent regime can be maximized and would become more innovation driven rather than manufacturing copycat drugs. The result shows that 44% strongly endorse the fact and 51% are agreeing to this perspective.

7.2.6.3 **Indian Pharmaceutical companies should increase the investment in research and development to increase the Intellectual Property particularly in bringing new molecules in the therapeutic area where medical needs are unmet**

Here also, all the medicos surveyed affirmatively endorsed the fact that there is a need to cater the unmet medical needs for critical diseases such as Parkinson's, Alzheimer's, HIV/AIDS etc. Indian companies should build IP which helps in introducing new molecules which cure such vital diseases. The result shows that 84% strongly endorse the fact and 16% are agreeing to this perspective.
7.2.6.4 Indian government should strongly consider public health concern while implementing the Trade Related Intellectual Property (TRIPs) standards in India.

The graph depicts that all the doctors surveyed unanimously feel that Indian government should strongly consider public health concern while implementing the Trade Related Intellectual Property (TRIPs) standards in India. The result shows that 52% strongly endorse the fact and 48% are agreeing to this perspective.

7.2.6.5 Compulsory licensing is must to bring control the drug price hick in the product patent regime.
“Compulsory licensing is essentially a tool to control the adverse use of the monopoly by the innovator company which may result in substantially increase in the prices” feels majority of doctors. The result reveals that 57% strongly agrees with the perception while 38% are in agreement with this. A very small segment of doctors i.e. 5% decided to remain neutral as they did not understand the concept of compulsory licensing.

7.2.6.6 Public health will suffer if the TRIPs standards will not be customize in such a way that drug prices are controlled

The medical fraternity surveyed are in agreement with the view that Govt. should not carried way by the international pressure from the developed countries like USA to implement the minimum standard as desired by the TRIPs agreement. Rather, it should be customize in such a way public interest should be safely guarded. Particularly, the adverse impact should not be on the drug price which reduces the access to medicine for life saving diseases wherein poor section of the society is getting the direct affect. The result depicts that 47% strongly agrees with the perception while 37% are in agreement with this whereas 16% could not comment on this.
Interestingly, the result reveals that majority of doctors either choose not to comment of this or they feel it may not have negative impact on the Indian Pharmaceutical Industry. This shows the strong confidence of the medical fraternity on the capability of Indian Pharmaceutical companies in inventing new chemical entities which provides substitutes to the innovative drugs launched by others. The number depicts that 59% feels that it is not the right time to comment and they choose to remain neutral while 30% are in agreement that product patent regime may create monopolistic environment whereas 11% have decline except that it would result in monopolistic situation when product patents are enforce and no other company is allowed to market a patented drug other than innovator or license.
In the post-2005 scenario, government's role is important to protect the domestic industry

Every one has shown complete agreement towards to the perception that government's role is extremely critical in negotiating with WTO for TRIPs compliance as well as encouraging innovation culture by providing various incentive for investment in R&D through addition or modification in policies governing this instruments. In summary, medical fraternity feels that government should actively involved in protecting the domestic industry. The result as depicted in the graph states 71% are strongly in agreement whereas as 29% are in agreement with this.
Small scale industry has contributed a lot in providing low cost drugs to the patients as expressed by most of the doctors because they sell the copy cat drugs at as reasonably low price mostly through general practitioners. But after the product patent regime in place this small scale would not be able to sell the patented drugs and they also can not invest in R & D because it requires substantial amount of investment. Therefore, 59% (24% strongly agreed whereas 35% agreed) of doctors surveyed, supported the perception that small scale industry may adversely affect in the post-2005 scenario. However, 41% choose to remain neutral as according to then the impact may be seen after 10-15 years after the product patent regime implemented.
7.2.7 The objective of this question was to evaluate the perceived role of government institution in determining the fate of Indian Pharmaceutical Industry.

Surprisingly, a common answer from all the doctors surveyed which is affirmatively endorses the importance of role of government institutions in collaborating with Indian companies for innovating new molecules through vigorous research and development. All the doctors (100%) surveyed has acknowledged that public private partnership would give fruitful results and would work in favor of Indian Pharmaceutical Industry.

7.2.8 This question is an open ended question to understand their beliefs about their perception on the impact of product patent regime on the public health concern in general.

All the doctors surveyed had expressed their feeling and a general perception about the implication on both the pharmaceutical industry as well as public health concern. A general inference can be drawn out of the analysis of the answers provided by the medicos surveyed in briefly summarized in following points:

- The impact could be adverse on the patients if drug prices are not controlled by the government in the long
o A positive impact would be introduction of more and more new molecular entities which can open new avenues in the treatment of vital diseases.

o The product patent regime would help Indian pharmaceutical industry in becoming globally competitive as they are forced to invest in research and development particularly in the basic research.

o Public private partnership would be greatly appreciated in the future scenario both in terms of basic research and clinical trial.

o The role of the government would be extremely important in not only implementing the minimum standard set by TRIPs but also introducing policies that would encourage more and more investment in research and development which is a need of the hour in the current scenario.
7.3 KEY FINDINGS

Following is the gist of perceived implications of the impact of product patent regime on the Indian Pharmaceutical industry as well as access to medicine from the medical professionals derived from the study done of medicos:

❖ Awareness level is low on the enforcement of intellectual property rights protection and its strategic importance in medical fraternity it needs to be increase as medical field play an important role in deciding the fate of Indian Pharmaceutical Industry.

❖ Medical fraternity is extremely concerned about the implication of product patent scenario on drug prices as it is not only one of the most important factor considered while prescribing any drug but it also affects the access to medicine in the poor section of the society.

❖ The medical fraternity surveyed are in agreement with the view that Govt. should not carried way by the international pressure from the developed countries like USA to implement the minimum standard as desired by the TRIPs agreement. Rather, it should be customize in such a way public interest should be safely guarded. Particularly, the adverse impact should not be on the
drug price which reduces the access to medicine for life saving diseases wherein poor section of the society is getting the direct affect.

- Small scale industries may adversely affect in the post-2005 scenario and therefore Govt. should take adequate measure to minimize the possible adverse impact on small scale industries.

- Indian pharmaceutical industry has started recognizing intellectual property rights as important strategic element. However, it needs to be increase the recognition which would results in improvement of global competence of Indian Pharmaceutical industry.

- The Government must play an important role in not only implementing the minimum standard set by TRIPs but also introducing policies that would encourage more and more investment in research and development which is a need of the hour in the current scenario.

- The implementation of product patent regime would lead to increase in drug prices in the long run.
The government should use the flexibilities provided in the TRIPs provision such as compulsory licensing, data protection, patentability criteria...etc. to protect the interest of domestic pharma industry.

In summary, the findings of this chapter suggest that the medical fraternity is deeply concerned about the foreseeable negative impact of the new IPR regime on the drug prices. In particularly Medical fraternity is perceives downside of the implication of product patent scenario on drug prices for the poor section of the society as it is not only one of the most important factor considered while prescribing any drug but it also affects the access to medicine. As mentioned above there have also provided the suggestive measure for the government and the industry which would be mitigate the adverse impact.

This chapter elaborates the overall finding of the study and correlates the same with the predefined objective and hypothesis. Based on the conclusion from hypothesis testing recommendations have been made and lastly likely area of future researches has been suggested.