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Impact of World Trade Organization on the Indian Pharmaceutical Industry: An Assessment From Manufacturer's Perspective

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Abstract

World Trade Organization (WTO) is now relevant for signatories. India being one of the initial signatories need to ensure that product patent concerning pharmaceutical industry is considered seriously. Even though it was clear that Indian companies are not investing in the Research and Development (R&D) activities, it was pertinent to understand the magnitude of the same from the managers themselves. This study was conducted through a questionnaire, which was circulated among the 400 registrants of the Indian Drug Manufacturers Association (IDMA). However, there were only 231 responses. Inferential statistics, descriptive calculations, Klomogrov- Simrnov test, discriminant function analysis were used for the analysis. Considering the importance attached to the variables, the study revealed very important findings which were provided in the article as suggestions. Now all the major Indian companies have started realizing the importance of new product development and R&D.

Keywords: *India; intellectual property; management, pharmaceutical industry, TRIPS*

1. Introduction

The first patenting system was introduced in India way back in 1856 in line with the British Patent Law of 1852. Several amendments and legislation's provided for further patent acts. The most important one was the Indian Patents & Designs Act of 1911, which established for the first time in India a system of patent and design protection under the management of Controller of Patents and Designs. Indian Drug Industry grew to its current position of 18th most developed pharmaceutical market in the World during the last 30 years on account of the Indian Patent Act 1970 which did not recognise the product patents. Indian pharmaceutical industry grew significantly after independence. This act was passed with an idea to reduce the cost of medicines in India. Even prior to the Indian Act, Mexico, Turkey, Israel and even Italy and to a lesser extent Spain, Portugal, Canada and China had considerably diluted the patent systems for pharmaceutical products. Even though over 20 countries in the developing and developed sectors had poor patent protection, none of them exploited the opportunity to the level that Italy and India did. This resulted in a proliferation of pharmaceutical companies in India. Consequently, Drug Price Control Order and the World Trade Organisation (WTO) has become a key element of discussion in the pharmaceutical sector.

2. Literature review

Harvey (1999) in his thought-provoking article on patent regime quoted that India's joining the WTO in 1995 has definitely sent positive signal to the world pharmaceutical industry. It is hard to predict the shape of the

new patent regime in India since the full implementation of the new patent law will only be in 2005. International companies are closely watching the developments in this regard and it will take sometime for them to consider establishing basic research facilities in India. Bhadury (1997) opined that after the introduction of the patent regime, only two drugs out of more than 250 in the WHO list of essential drugs are covered by patents with an approximate sales value of Rs.7 Crores against India's total turnover of Rs.9, 000 Crores. Globally only 15-20 patented drugs enter the market every year and only a few of them are a commercial success. At the same time, each year, patents expire for earlier drugs. On an average, there will be not more than 15-20 patented drugs in any market. There is a myth that Intellectual Property rights will drive Indian companies out of business. This is far from truth.

None of the drugs presently in the Indian market or any that have been patented prior to January 1,1995 anywhere in the world can be patented in India. About 90 percent of existing drugs would have been off patent in the existing patent regime. The average time from a new chemical entity's discovery to market introduction is 12 years. It is, therefore, unlikely that these drugs would reach the market in the TRIPS transition period. Japanese and Italian experience confirms that local companies flourish after IPR implementation. In fact, the strong product patent protection will offer massive opportunities for R&D for Indian companies in diseases relating to topical or developing countries.

Gupta (1997) asked industry people to look at WTO as an opportunity – an opportunity to leverage the strengths of India's R&D manpower and pursue international market development through the creation of new chemical entities, using basic research as the fundamental tool. Mukherjee (1999) felt that the bigger pharma companies have realised the implications of the new bill. Companies such as Ranbaxy, Torrent are big spenders. Ranbaxy is already in a strategic alliance with Cipla to market cardiovascular and anti-infective products. This co-marketing alliance with Glaxo will allow both companies to leverage their considerable marketing abilities in a product area where both have dominant strengths. Indian pharma marketers need innovations. They know that it will take long for them to make their own molecules. They could, of course, survive serving as distribution arms for MNCs. According to experts, drugs that are prescribed for 90 percent of the market are under no threat from the Patents Bill, but it is the other 10 percent for ailments such as AIDS, cancer and tuberculosis which require the services of the new drugs. On the other hand small drug companies have their own role to play- as low-cost bulk drug manufacturers.

PTI news (1999) analysed the findings of the NCAER study on pharmaceuticals predicted the changes in the market in the post-WTO era, where there would be a radical reduction in copied products in the market. Companies should adopt a co-marketing approach to protect the market from such products. It also suggested that the Government should take measures to curb the price of essential drugs. A national agency for drug distribution and retailing of drugs through fair price shops is needed to decrease costs involving middlemen.

3. Methodology

Even though it was clear through secondary sources that Indian companies are not investing in the Research and Development activities, it was pertinent to understand the magnitude of the same from the managers themselves. With these topics in mind, the researcher identified the following variables as crucial in the discussion on the impact of WTO on the Indian pharmaceutical industry.

1. Concerns of WTO impact on the industry
2. Drug prices in the post WTO era
3. Impact on Small Scale Manufacturers
4. Forecasts pertaining to WTO
5. Type of research undertaken and DPCO and R&D

The study was conducted through a questionnaire, which was circulated among the 400 registrants of the Indian Drug Manufacturers Association (IDMA). However, there were only 231 responses. These responses were tabulated and fed into the SPSS package for the analysis purpose. Inferential statistics, descriptive

calculations, Klomogrov- Simrnov test, Discriminant function analysis were used for the analysis. Based on the secondary data and on the basis of the variables under study, there were about 15 hypotheses made. A frequency distribution study was undertaken to identify the number of respondents who had an idea about the extent of impact WTO would create on the Indian Pharmaceutical industry. Table1 summarizes the concerns as received from the respondents.

Table 1 : Distribution of respondents on the concerns of WTO impact

	Fully Disagree	Disagree	Neither agree nor disagree	Agree	Fully agree	Mean	Standard Deviation
There is a discernible change towards WTO	—	—	—	109 (47.2%)	122 (52.8%)	4.53	0.5
Exclusive marketing rights will only help the MNC's	—	—	—	96 (41.6%)	135 (58.4%)	4.58	0.494
Indian companies are capable of being a major supply point for bulk drugs and formulations to world markets still under patents	—	—	—	95 (41.1%)	136 (58.9%)	4.59	0.493
The major bulk drug manufacturers have much to gain by not having a strong patent system	—	—	—	123 (53.2%)	108 (46.8%)	4.47	0.5
Specific endemic disease focus on R&D in India	—	—	1 (0.04%)	92 (39.8%)	138 (59.7%)	4.59	0.501
Need for further dialogue with WTO on compulsory licensing system	—	—	—	122 (52.8%)	109 (47.2%)	4.47	0.5
IPR to be defined in broader context of our national assets and interests	—	—	—	164 (71.0%)	67 (29%)	4.29	0.455

Table 2 : Inter-correlation Matrix between various factors influencing WTO accord

Factors influencing WTO accord	Changes towards WTO	EMR	Supply point	Marketing products without license	Specific R& D Capability	Further dialogue with WTO	IPR for National assets and interests	Total
Changes towards WTO	1.0000	-0.1108	-0.1203	0.8336	-0.1276*	0.8240**	0.5659**	0.5777**
EMR		1.0000	0.9733**	0.0508	0.9476**	0.0404	0.5003**	0.6833**
Supply point			1.0000	0.0426	0.9738**	0.0322	0.5148**	0.6861**
Marketing products without license				1.0000	0.0512	0.9913**	0.6439**	0.7290**
Specific R&D Capability					1.0000	0.0582	0.5202**	0.6876**
Further dialogue With WTO						1.0000	0.6571**	0.7267**
IPR for National assets and interests							1.0000	0.8818**
Total								1.0000

** - p < .01 , * - p < .05

It is clear that the industry has taken a decision to live with the WTO accord. This means that there is a widespread interests and understanding of the WTO accord among the decision makers in the industry.

They are also of the unanimous opinion on the agreement being lop sided on favouring the Multinational corporations with the exclusive marketing rights as their weapon. 58.9% of the respondents are still in favour of the Indian companies being a major supply point for bulk drugs and formulations to the world market which are still under patents, where product patents have either not been filed by the innovating company or are not valid.

India's R&D capabilities are considered to grow upto expectations as 59.7% strongly agree that it can be utilised to discover and develop new drugs including those which are specifically needed for some of the endemic diseases of the developing nations. The researcher was told informally that there is a possible reverse brain drain of Indian scientists to bolster this effort. Even though compulsory licensing system was accepted by all the respondents, 52.8% felt that there is a need for equitable system and hence there is a need for further dialogue with the WTO. An overwhelming 71% were of the opinion that the interest of the country should be taken into account and hence there is a need for a broader definition of intellectual property rights in this context. With a view to know the relationship between the various factors influencing the WTO accord, intercorrelation matrix between them has been worked out and presented in Table 2.

Analysis of the table shows how far the various factors influencing the WTO accord are related to one another. The total score to the each and every factor is highly significant ($p < .01$ level). The discernible change towards WTO is highly related to the other factors like, strong R&D capabilities for specific diseases, need for further dialogue with WTO and the IPR for specific national assets and interests. It clear that companies have started to realise the need for developing country specific R&D capabilities which can be patented like, drugs for endemic diseases of the developing nations. Hence it is highly correlated to the quest for further dialogue with the WTO on the broader context of the national assets and interests. The other factors like exclusive marketing rights (hereafter called, EMR), as being major supply points for other companies and producing patented products without license are not correlated with changes towards WTO. This is because of the strong undercurrent on the need to concentrate on the R&D.

EMR is highly correlated with the other factors like being supply points, using R&D capabilities to discover new drugs for endemic diseases and IPR to be used for broader national assets and interests. This shows that EMR is going to help the MNCs is vouched by the fact that they may use the country as the supply points due to lower costs in the country and hence it will force the Indian companies to concentrate on R&D. The factors such as marketing patented products without license and IPR to be defined in broader context of national assets and interests. It is hence clear that, the MNC's certainly will not market drugs without licenses and may not be interested in the IPR to be defined on the national interest and assets which will be only detrimental to them and so they are not related to the EMR favouring MNCs.

Indian companies' capability of being major supply point for bulk drugs and formulations to the world market is highly correlated with other factors as using R&D capabilities to discover new drugs for endemic diseases and IPR to be used for broader national assets and interests. It is hence possible that using the R&D capabilities to find country specific drugs could help in marketing products which are possibly not patented by the innovating company. Under this context it is mandatory that the national assets and interests are to be protected through the IPR and hence there is a high correlation between these factors. The other factors are not related to major supply point. The factor 'marketing patented drugs without licenses' is highly correlated to the factors like need for further dialogue with WTO and the IPR for specific national assets and interests. This confirms the fact that the companies which have poor patent system would like the Indian government to have further dialogue for the relaxation in the patent regime. This factor is not related with the other objectives that are weighed by the respondents such as change towards WTO, EMR for MNCs, being major supply point and R&D capabilities for country specificity.

'R&D capabilities to develop specific drugs for endemic diseases' is highly correlated to the factors like changes towards WTO, EMRs, being supply points and the IPR to be defined on a broader context of the national assets and interests. Hence companies can obtain EMR, can be a supply point and also can exploit the national assets and interests for the benefit of the R&D based companies. However, this factor is not related

to marketing without licenses and need for further dialogue. Those factors which are related emphasise the need for R&D concentration from companies. The factor 'Need for further dialogue with WTO' is highly correlated to the factors like discernible change towards WTO, marketing products without license and IPR to be defined in a broader context of national assets and interests. The need for further dialogue with WTO is gaining momentum for protecting the national assets and interests. All other factors are not related.

The last factor 'IPR to be defined on a broader context of the national assets and interests' is highly correlated to all other factors. Hence it is clear that the government has to move towards the WTO for protecting the national interests and assets. The case of neem and basmati being patented by other country personnel and companies has forced a consensus on the part of the respondents to consider the dialogue to be more important. It is clear from the foregoing analysis that composite score for each and every factor is highly significant ($p < .01$ level) and the relationship of each and every factor with other factors is found to be more logical and meaningful.

With a view to know the relationship between the various factors influencing the SSI's due to the WTO accord, inter-correlation matrix between them has been worked out and presented in Table 3.

Table 3 :Intercorrelation matrix of influencers in small scale industries After WTO accord

Factors due to WTO	Stagnation	Job working	Lack of R&D and technology	Disorganized and Lack of finances	Producer of generic drugs	Total
Stagnation	1	0.0165	0.3374**	0.8094**	0.8094**	0.9203**
Job working		1	0.0000	0.3467**	-0.2070**	0.2794**
Lack of R&D and technology			1	0.0000	0.4296**	0.5294**
Disorganized and Lack of finances				1	0.5148**	0.8060**
Producer of generic drugs					1	0.8060**
Total						1

** - p <.01 * - p <.05

Analysis of the table shows how far the various influences in the small-scale industries after the WTO accord are related to one another. The total score to each and every influence is highly significant ($p < .01$ level). 'Stagnation' is highly related to all the other influences except job working. There is a possibility where by SSI's would reduce in number over the years due to the strong patent regime but at the same time there is scope for their survival in the off-patent and essential drugs category. The stagnation could come due to the lack of finances, R&D facilities, not amenable to technology and could end up being mere producer of such generic drugs. Inter-correlation matrix between these influences is highly correlated to one another. It is clear that since job working is not related, the companies would continue to be producer of generic drugs.

'Job working' is highly related to the influences like the lack of R&D, lack of finances, a disorganized structure and producing just generic drugs. By being a job working organization, SSIs are highly related to the paucity in funds which forbids them to acquire technology and hence they continue to produce the generic drugs only. 'Lack of R&D and technology' is highly related with stagnation and producer of generic drugs. It is very clear that this aspect of not concentrating on R&D would force them to divest their business over the years or with little funds, continue to produce the generic drugs only. This influence is not related to job working and being disorganised and lack of having finances. This is because, by being producers of generic drugs they would be able to generate funds and at the same time would continue on their own.

'Lack of finances and a disorganised structure' is highly correlated with all other influences except job working. This is due to the fact that even if they lack finances, the amount of working capital they are able to generate is sufficient to see them through. Hence there may not be any need for job working. This also goes with the claim that the consumption of drugs will rise. 'Producer of generic drugs' is highly correlated with all other influences. The SSI's have been involved in producing those drugs which are off- patent for a long time. Hence it was not surprising that considering their work related activities, being job workers, lacking in financ-

es and R&D and possibility of being stagnant were vouched after the WTO accord implementation. Hence, it is evident from the foregoing analysis that composite score for each and every influence is highly significant ($p < .01$ level) and the relationship of each and every influence is found to be more logical and meaningful.

4. Conclusion

The statistical analyses indicates clearly that WTO and intellectual property will have a long lasting effect on the Indian pharmaceutical industry and companies have to utilize their R&D to bolster their chances of succeeding in this highly competitive market. The study identifies that if the per cent of R&D investment is increased to at least 5%, the Indian industry should be able to discover and develop three new molecules per year for various disease conditions. Considering the huge population base and the tropical disease pattern in the country, exemptions available under TRIPS in the interest of public health should be used. It is important for the companies to concentrate on the R&D in basic research. The study has shown that only 2.2% of the companies are involved in basic research. In the case of Korea and Brazil, where product patent were adopted during 1997 have started getting multinational investments and the notable aspect is that the domestic industry has not been disturbed. Hence, India can take a cue from these examples and focus more on R&D.

It is advised that the R&D focus be in the areas of global medical and market needs such as cardiovascular diseases, central nervous system disorders, anti-viral, anti-inflammatory diseases, diabetes and cancer. It is found through the studies that companies like JB chemicals, Cadila Healthcare, Zydus cadila, Morepen Laboratories, Aurobindo etc., have started working in the area of Novel Drug Delivery Systems. Biotechnology is another area where companies have to focus their efforts in terms of R&D. MNC's will invest in basic research in India, including clinical research using either their own or contract research organisations especially in the area of biotechnology. A number of medium-scale companies in the turnover between 100-200 Cr. can also survive, as suppliers of bulk activities to large multinationals as most of these international companies will not be producing any bulk drug in India. The study reveals certain findings pertaining to R&D. 'Deconstructing the value chain' are going to be important in the industry as a growing group of companies in different turnover groups can come together. Each of them can take up separate parts of the R&D so that traditional, vertically integrated companies no longer need to own or perform the entire R&D activity to marketing.

In the next decade the respondents predict the following technological developments related to pharmaceutical industry. They are Genomics, combinatorial chemistry and high-throughput screening. Companies in the turnover group of above 200 Cr. can use these technologies to specifically study the disease patterns in the developing countries. Closer ties have to be forged between research institutions and the industry to bring down the cost of research especially in the area of fermentation and cell culture. Indian industry will become a major supplier of generics, drug intermediaries and fine chemicals in the world market constituting around 15% of the world production. It is estimated that generic penetration of the US market alone will rise to 60 per cent. This penetration will double the existing global market for generics and hence Indian companies in the turnover group belonging to 100-200 Cr. can exploit this opportunity.

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