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Patent Effect on Pharma Products in India After its Implementation

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ABSTRACT

This paper studies the Product Patent effect in INDIAN Pharma market after its implementation in 2005. No new research based product are coming as generic, because of product patent . Multinationals are coming with only patented products and their dominance too. Restriction of growth of Indian Pharma Houses may be there. The study aims to investigate, taking data of 30 top Indian Pharma houses along with some multinationals who are now dominant in India ,from 125 chemists , that their generic brands share is taking away by Multinationals with their new researched base patented products.

KEYWORDS Patent, Product Patent,Indian pharma Houses, Multinationals, Generics ,TRIPS,R&D

INTRODUCTION

India's pharmaceutical sector is currently undergoing unprecedented change. Much of this is due to the country's introduction, on January 1, 2005, of a system of product patents; before that, only patents for processes were permitted to be issued, a fact that has been instrumental in the domestic industry's huge success as a worldwide exporter of high quality generic drugs .

The new patent regime has also led to the return of the pharmaceutical multinationals ,many of which had left India during the 1970s. Now they are back, and looking at India not only for its traditional strengths in contract manufacturing but also as a highly attractive location for research and development (R&D), particularly in the conduct of clinical trials and other services.This way these Multinationals are bringing new patented products may or may not be with better efficacy but must be on very higher side so far price is concerned, if compare with the same type of generic brands of Indian Pharma houses . The multinationals are trying to uproot Indian Pharma Houses as was dominant before 1970,when Product patent was there in India.

REVIEW OF LITERATURES

There was no product patent effect in Indian Pharma Industry before 1970.The absence of product patent protection for pharmaceuticals and agrochemicals led many multinationals to limit their portfolios to patent expired products or a few selected patented products.This resulted in an erosion of their market share because local manufacturers introduced the most advanced medicines through reverse engineering.Foreign firms were required to pay royalties for international drugs, while Indian companies could access the newest molecules from all over the world and reformulate them for sale in the domestic market. Thus, this resulted in the systematic weakening of patent rights for pharmaceutical products in India and led to the exodus of several international research-based pharmaceutical firms.

PRESENT POSITION

India currently represents just U.S. $6 billion of the $550 billion global pharmaceutical industry but its share is increasing at 10 percent a year, compared to 7 percent annual growth for the world market overall. Also, while the Indian sector represents just 8 percent of the global industry total by volume, putting it in fourth place worldwide, it accounts for 13 percent by value, and its drug exports have been growing 30 percent annually.

PRESENT POSITION AND POSTION EARLIER 1970

There are five main differences between the regime being ushered in by TRIPS in January 2005 and the regime in 1970 after product patent abolished in INDIA.

System as per Indian Patent Act 1970	System after January 2005 as per TRIPS
1. Process Patenting only recognized. 2. Patent given only for 5 to 7 years. 3. Compulsory licensing (which helps in making drugs available to society) is available. 4. When a company alleges another company is copying it, is the complainant's burden to prove the fact of copying. 5.Plant and Microorganisms can not be patented.	1. Process as well as product patenting recognized 2. Patent given for up to 20 years. 3. Compulsory licensing only in emergency situations (In Doha meeting of WTO it was decided to allow compulsory licensing for AIDS, Tuberculosis and Malaria) 4. Reversal of burden of proof will be there. When a complainant lodges a complainant the company against which complaint is lodged should stop production and prove that it has not been copying. 5. Plant varieties and Microorganisms in which genetic modification work is done can be patented. All over the world this clause is being used for "Biopiracy" India's neem, wheat, were patented and Indian Government could get the patents cancelled only after a big fight in the WTO dispute settlement body.

RESEARCH METHODOLOGY

Objectives:

- To study how Multinationals are coming with only patented products with their dominance vis a vis restriction of growth of Indian Pharma Houses .
- To study how Indian Pharma houses loose their generic brands share, which is taking away by Multinationals with their new researched base patented products.

Hypothesis:

- Multinational are coming with Patented Product but no dominance.(Ho)
- Indian Pharma Houses loosing their generic brand share. (H1)

Globalisation is a process which involves economic inter-dependence of countries world-wide removing all barriers for economic integration as if the whole world is a single village. Obviously, in this process, the rich nations with their superior financial power, control the scenario and the poor and the developing nations are forced to integrate surrendering their economic independence knowing fully well what they are forced to accept is really prejudicial to their own interest. In this process the world financial institutions like the World Bank, IMF and now the WTO advance the interest of the rich countries alone. The draconian policies of the World Bank and the IMF under the structural adjustment programme resulted in the net transfer of $178 billion between 1984 and 1990 from the poor countries to the commercial banks of rich nations. (UNDP Human Development Report, 1994). The Transnational Corporations (TNCs) of the rich nations are practically controlling the world finances. Today, the whole world is colonised by global finance and the TNCs supported by the neo-colonial structure including the World Bank, IMF and WTO are controlling the financial situation world-wide. The governments of third world countries are powerless against global finance and are unable to control its movement within their own national boundaries.

The situation of the world drug industry is no different. 'Operating at the behest of the Pharmaceutical Research and Manufacturers' Association (PhRMA) for a decade and a half, the U.S.Government has waged a ruthless crusade to force third world countries to adopt strait jacketing intellectual property rules at the expense of protecting public health', says the editorial comment in the June 1998 issue of *Multinational Monitor*, a journal published from Washington.

Sampling-

A study was done with 30 Indian Pharma Houses, 125 chemist regarding generic product information about these Indian houses vs newly coming patented brands by multinationals with their marketing style . 10 dispensing nursing home also taken into consideration. The study was done in KOLKATA and surroundings.

DATA ANALYSIS AND FINDINGS

Study clearly shows that when it is done with 30 Indian houses, their market share for generic brands are not only declining (H1) as compared to recently introduced patented products in India, but also their total share nationally and internationally is also decreasing and dominance of multinationals are increasing(H1) . The survey is made on 125 chemists and 10 dispensing nursing homes about these important 30 pharma houses in some specific segments like Emergency ,cardio segments, paed segments, Gyn segments, Onco Segments, Ortho segments.General segments.

Highest taken away shares in pharma segments of generic brands are in descending order is

Cancer drugs.2- Emergency drugs of any kind.3- Cardiac Drugs.4-Paed Drugs 5-Gyn, 6-Ortho,7-General.(H1)

During the survey we have taken the data of number of patients now purchasing the generic /patented brands vs earlier number of patients purchasing the generic brands , and we found that it is decreasing. This clearly shows that maximum poor patients are suffering because of their less purchasing abilities for the patented brands and generic brands sale is also decreasing again because of poor prescriptions.(H1).

Also we know that the Indian Pharma industry's exports were worth more than $3.75 billion in 2004-05 and they have been growing at a compound annual rate of 22.7 percent over the last few years, according to the government's draft National Pharmaceuticals Policy for 2006, published in January 2006. But after implementation of PATENT adverse effect has to come and already effected of the growth of INDIAN PHARMA HOUSES (H1).

The obligations imposed on India under the TRIPS Agreement are going to have a significant impact on India's successful bulk and formulation-oriented pharmaceutical industry. Indian companies will have to compete with the multinationals by focusing on drug development and thereby producing their own patented products. Alternatively, Indian companies could focus on producing patented drugs under license from foreign companies or concentrate on generating revenues from producing generic drugs. Currently, conflicting views exist within the Indian drug companies with regard to India's transition into the product patent regime.Some of the existing pharmaceutical companies believe that product patents will pave the way for innovation in India, while others hold the view that the high cost of R&D will stifle the growth of the Indian pharmaceutical industry(H1)

MAY BE SURVIVAL OF INDIAN HOUSES (LIMITATIONS)

The key to survival for Indian pharmaceutical companies would be the exponential growth of R&D expenditure. Indian companies need product patent protection to encourage research in developing inexpensive drugs that suit the Indian disease profile.

In addition, the advent of product patents is bound to be a boost for multinational companies that have previously been reluctant to invest in India in the absence of product patent protection, and it will increase competition in the domestic market.

CONCLUSION

The following facts are noteworthy to gauge the impact of

the introduction of pharmaceutical patents in India:

1) Consistent challenge by Multinational to Indian Houses.
2) Threat Indian houses to fight with multinationals.
3) Increasing penetration of more costly products on all fronts, especially after allowing entry of foreign players thus becoming more problematic for indian players.
4) For the 60% of the "poor" in India, who currently do not have access to pharmaceuticals, price rise and demand sensitivity due to patent introduction ,will suffer more.
5) India is governed by a government which relies more on populist politics for survival and this would ensure that the best interests of the population is not kept in mind under international pressures. All in all, INDIAN pharma industry may suffer.

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