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**Impact of Drug price control, Patent rebuke and Generic drugs availability of
Pharmaceutical Companies**

With Special focus to

Developing Countries like India and to its public health

By

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ABSTRACT:

In today's scenario, where we are faced with numerous threats to life, the biggest question to life itself is its longevity. Drug/Medicine helps us to sustain our lives and we consistently strive to survive in an ever increasing demand for such drugs.

India has significantly widened its control over drug prices, a decision that will make medicines more affordable for people but hurt the profit margins of pharmaceutical companies. Glaxo, Wyeth and Novartis among the multinationals, and Alembic, Unichem and JB Chem among the mid-sized Indian companies are expected to bear the brunt of the new regime as they all have a higher exposure to the domestic market.

The World Health Organisation (WHO) estimates two-thirds of India's 1.2 billion people have no medical insurance versus 15% in China and about half in Africa. According to industry estimates, about 70% of health-care spending in India comes from an individual's own resources, and more than half of this is spent on buying medicines.

The study of this paper focuses on issues with drug price control restricting its scope to patent rebuke and generic drugs availability of Pharmaceutical companies in developing nations like India and to its citizen and the pros and cons of the same.

Scope of Study of the Research:

1. Affordability of drug pricing in developing countries like India for the needy consumers/patients.
2. Availability and accessibility of generic drugs to needy consumers/patients in India.
3. Pharmaceutical Companies' ethical concern for Patients' life.
4. An area of concern- Medical Insurance in India.

KEYWORDS: Longevity, profit margins, multinationals, Glaxo, Wyeth, Novartis, Alembic, Unichem and JB Chem, mid-sized, regime, domestic market, WHO, generic, medical insurance, DPCO, NPPA, NELM, market-based pricing method, Cipla, Cadila, Ipca, Glenmark, Sun Pharma,

Lupin, MNCs, Ranbaxy, Pfizer, R&D, niche segments, leukemia, WTO, Doha Agreement, TRIPS, IMS, druggists, impunity, intellectual property, HIV, Aids, FDA, differential pricing, evergreening.

INTRODUCTION:

Drug-price control has been a topic of debate in India. The Indian Supreme Court ruled recently that the Swiss drug maker Novartis AG (NYSE:NVS), saying Glivec, a drug the company makes to treat a rare form of leukemia, wasn't different enough from similar drugs on the market to permit a patent in India. India has some of the most stringent rules regarding drug patents in an effort to keep down the cost of medicine in the national marketplace. The ruling has global implications for generics because of India's top position as an exporter of these drugs to impoverished countries.

The authorities argue that price controls are necessary to ensure that expensive drugs are available at affordable rates to the poor, especially since most people in the country have no medical insurance. But according to pharmaceutical companies, intense competition in India already keeps prices low. According to India's new Drug Price Control Order (DPCO) as many as 348 medicines including cancer drug fluorouracil and lamivudine-zidovudine used in the treatment of HIV will now come under a new price-control rule and reduction by up to 80%. Previously India controlled the prices of 74 drugs. The 2013 DPCO authorises the National Pharmaceutical Pricing Authority (NPPA) to regulate the prices of products included on India's 2011 National List of Essential Medicines (NLEM). As a result, the ceiling prices of NLEM products will be set at the simple average of all brands with a market share of at least 1%, replacing the current cost-plus basis, and this should see many prices of drugs including cancer treatments and anti-infectives decline by as much as 80%.

Prices of 652 formulations under 27 therapeutic areas like anti-allergic (cetirizine), cardiac (aten), gastro-intestinal medicines (omeprazole), pain-killers (paracetamol) and anti-diabetic drugs (insulin) are expected to come down. Others in the list include anti-fungal, anti-tuberculosis, anti-leprosy, anti-hypertensives and cancer drugs. The policy uses a market-based pricing method: 'the simple

average method' for determining the ceiling price of all the molecules (drugs) under a particular therapeutic area with over 1% market share. The price to the consumer will be determined by adding 16% margin (to the retailer) as well as the local taxes to the average price (ceiling price).

Among large caps, Cipla and Cadila will see a 4-6% impact on their sales revenue. Among mid caps, Ipca may be impacted 2.5% and Unichem 5.3%, while Glenmark, Sun Pharma and Lupin will see lower impact (1-2%). Among MNCs, Glaxo's sales may fall 8%, Ranbaxy's 7%, Pfizer's 6% and Wyeth's 11%. In terms of operating profit or Ebitda, impact on Glaxo is expected to be in double digits.

The impact on overall profits will depend on three key factors: 1) coverage of the National List of Essential Medicines or NLEM on total product portfolios; 2) price premium these drugs carry; and 3) revenue diversification out of India. A molecule-wise analysis based on the list of drugs enclosed in NLEM has indicated that the overall impact on the industry would be to the tune of about Rs 2,000-2,500 crore.

While the overall price cuts of the molecules are expected to be 18-20%, the multinational companies (MNCs) would take a higher cut. "The MNC prices of molecules are at higher levels. On an average-price formula, they would end up cutting the prices most. The net negative impact of the order would be more on MNCs than Indian companies.

The new regime would encourage Indian pharma players, specifically small and medium-size players, to actively invest more in R&D and also help expand the market in many ways. It is also going to help smaller players achieve some price parity in certain niche segments.

The notification also states that manufacturers of non-essential medicines will be allowed to increase their prices by 10% a year, while new products which are discovered and developed in India could seek exemption from price controls for five years.

Issues:

- The prime focus of this research is to ascertain that drug price control is inevitable in developing countries to its needy patients as they suffer from major threat to life due to Cancer, Aids and other life threatening diseases.
- The other area of concern is the drug patent in developing countries to its needy patients. As the Indian Supreme Court has given its verdict of rebuking drug patents on some of the biggest names in the pharmaceutical sector, it has only helped maintain a low cost factor and of course less burden on of expenditure involved by such patients to buy them.
- Generic drugs availability to the needy patients helps save the patients' or his/her family's pockets and ensures recovery as much as the branded drug would promise.

REVIEW OF LITERATURE:

From the 1980s, during the negotiations leading up to the formation of the WTO, public health advocates and domestic drug producers mobilised public opinion against looming pharmaceutical patents.

When India became fully TRIPS-compliant in 2005, with the introduction of pharmaceutical product patents, the legislation incorporated in full the “flexibilities” available under TRIPS, as confirmed in the 2001 Doha Agreement.

These flexibilities include the right of national governments to define patentability in domestic legislation, limits on data protection, pre and post-grant opposition to patents, and provisions for the issuing of compulsory licensing.



The debate over global drug pricing is one of the most contentious issues between developed countries and the developing world. While poorer nations maintain they have a moral obligation to make cheaper, generic drugs available to their populations by limiting patents in some cases the brand name pharmaceutical companies contend the profits they reap are essential to their ability to develop and manufacture innovative medicines. Specifically, the decision allows Indian makers of generic drugs to continue making copycat versions of the drug Gleevec, which is made by Novartis.

The drug provides such effective treatment for some forms of leukaemia that the Food and Drug Administration approved the medicine in the United States in 2001 in record time. The ruling made by the Supreme Court of India will help India maintain its role as the world's most important provider of inexpensive medicines, which is critical in the global fight against deadly diseases. Gleevec, for example, can cost as much as \$70,000 a year, while Indian generic versions cost about \$2,500 a year.

It is a challenging time for the pharmaceutical industry, which is increasingly looking to emerging markets to compensate for lackluster drug sales in the United States and Europe. At the same time, it is facing other challenges to its patent protections in countries like Argentina, the Philippines, Thailand and Brazil.

It is believed by Ranjit Shahani, Vice Chairman and Managing Director of the Indian unit of Novartis AG, that the immediate impact on sales and margin "will be quite significant." He also said that companies like Novartis would invest less money in research in India as a result of the ruling. It is also hoped by these pharmaceutical firms that the ecosystem for intellectual property in the country would improve. They feel strongly that the original innovation should be

recognized in patents to encourage investment in medical innovation, especially for unmet medical needs.

India's Supreme Court ruled that the patent that Novartis sought for Gleevec did not represent a true invention. In 1993, Novartis patented a version of Gleevec that it later abandoned in development, but the Indian judges ruled that the early and later versions were not different enough for the later one to merit a separate patent. The other side of the story is that fairly liberal rules on patents spur innovation, a growing number of countries are questioning why they should pay high prices for new drugs. Argentina and the Philippines have passed laws similar to the one enacted in India, placing strict limits on patents. And Brazil and Thailand have been issuing compulsory licenses for AIDS drugs for years under multilateral agreements that allow such actions on public health grounds. On the other hand, GlaxoSmithKline believes that the company has always undertaken a low-price, high-volume strategy in India and its flexible pricing approach means that the products are carefully priced in order to make it more affordable and accessible to people in India. Sales in emerging markets like Brazil and China are expected to account for 30 percent of global pharmaceutical spending by 2016, up from 20 percent in 2011, according to IMS Health.



DATA INTERPRETATION/ ANALYSIS

Drug pricing is a major issue in India. The Indian government believes that the prices of lifesaving drugs shouldn't be set by market forces. In a country where very few people have health insurance, 70% of Indians pay for healthcare expenses out of their own pockets. 85% of people believe that generic drugs should be made available across the country. Another insight is that people think and feel that life should not be considered cheap and so the price of these life saving drugs for cancer or AIDS should be made available as cost effective as possible. On the other hand, Chemists and Druggists are of the opinion that the demand for such drugs are aplenty, however, it is highly priced and these pharmaceutical firms need to be optimistic to put life first before the price of these drugs. It should be a win-win situation but not at the expense of a valuable life.

The Glivec situation is not unique. India has granted compulsory licenses to other cancer drugs, including Bayer's Nexavar, Roche's Tarceva, and Pfizer's Sutent. These licenses allow India generic drug manufacturers to make these drugs with impunity.

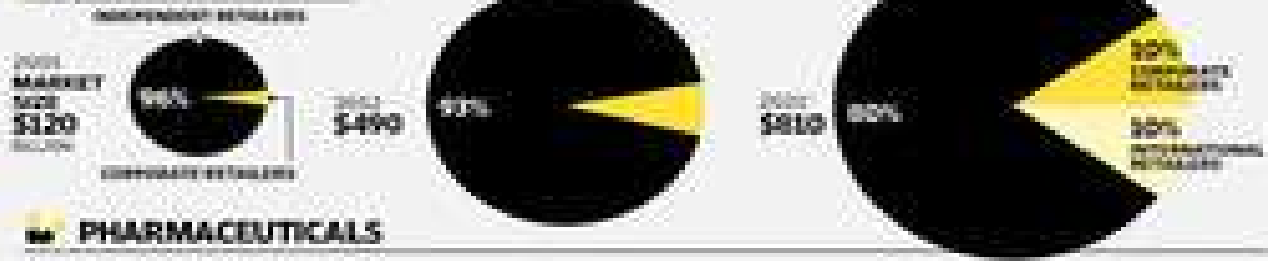
Indian Supreme Court refused to prevent an Indian generic manufacturer, Glenmark Pharmaceuticals, from manufacturing and selling Merck's diabetes drug, Januvia, in India. Merck will likely appeal this decision. While it is an important drug, Januvia does not carry an expensive price tag. In fact, when it was launched in India, Merck charged \$0.86/tablet, one-fifth the US cost. Nevertheless, despite recognizing the need to make Januvia affordable in India, Merck's intellectual property for this drug will be ignored in this country for the foreseeable future.

Drugs that have some form of innovation that can be attributed to Indian researchers can be IMMUNE from price controls for five years. Three types of innovation can qualify for this benefit:

- 1) drugs that arise from indigenous R&D;
- 2) improvements by an Indian company on a process for making an existing drug;
- 3) development of a new drug delivery system by Indian R&D.

Hard to Crack | A look at India's retail and drug markets

RETAIL



PHARMACEUTICALS

DEMAND FOR DRUGS

SALES BY SELECT COUNTRIES IN BILLIONS



Source: Technipaq study, Pharmaceuticals, pharmaceuticals

REVENUE OF INDIA'S FIVE BIGGEST DRUG MAKERS

FOR THE 12 MONTHS ENDING JULY 2020 IN BILLIONS



Source: Statista (company financials) | The Wall Street Journal



RESULTS & FINDINGS:



The countries such as Indonesia and Brazil for several years have been licensing local pharmaceutical companies to make cheap generic versions of medicines, usually drugs for HIV, the deadly virus that causes AIDS.

But recently, India has overturned patents for several cancer drugs, including Bayer AG's Nexavar, AstraZeneca PLC's Iressa, Pfizer Inc.'s Sutent and Bristol-Myers Squibb Co's Sprycel. This indicates that there is a growing need for cost/price control of such drugs along with keeping in mind the public health and well being. Moreover, it has global implications too on R&D as well as to sustain India's top position as an exporter of these drugs to impoverished countries.

PATENT BENEFITS

THE NEWS Novartis applied for a patent for a modification of existing drug Glivec that fights a form of chronic blood cancer. Supreme Court denied the patent saying the modification cannot be considered an invention as it is not shown to have more efficacy than existing drug.

IMPLICATION Cost of Novartis drug about Rs 1 lakh per month. Generic drugs cost some Rs 10,000 per month. SC ruling saves money for 300,000 patients.

REACTION "India can continue to produce affordable, quality medicines without the threat of patents for minor modifications of known medicines," Dr. Yusuf K. Hamied, chairman of Cipla. Novartis says big drug firms will not invest in R&D in India.

Pfizer and Roche are fighting for similar patents on their Cancer and Hepatitis C drugs. Ruling is bad news for them.

Essential to know the 'why' and 'how' of the law to understand what it really is...?
SUPREME COURT OF INDIA

IMPLICATION Big boost to Indian generic drug suppliers as ruling sets a precedent against the practice of drug companies extending patents by introducing small modifications of old drugs. India exports \$10 billion worth generic drugs.

The other major areas of findings are:

- Importance to Consumer Driven Health Care.
- FDA Regulation & Medical Innovation.
- Along with rejecting patent applications, the Indian government has also granted (or has plans to grant) compulsory licenses for at least five drugs targeting leukemia, breast, kidney and liver cancers.
- The licenses allow local drug companies to produce generic versions of the medications despite patents held by their original makers and without the need for their permission.

- Indonesia, China and the Philippines have adopted similar measures that allow them to circumvent patents and give their populations access to lower priced drugs.

India has changed a lot in regards to its pharmaceuticals market. Between independence in 1947 and the 1970s it was highly dependent on imports of expensive medicines. But between 1970 and 2005 India abolished product patents on medicines. The Indian government also put in place industrial policy measures and public sector research institutions to collaborate with local producers. The result was a strong and vibrant Indian generic industry. The entry of generics lowers prices and widens access to medicines. And it is much more effective in achieving these outcomes than philanthropy or the model of tiered or differential pricing strategies preferred by multinational companies. The patenting of trivial modifications, known as ‘evergreening’, is *one of a host of* ‘life-cycle management’ a strategy through which drug manufacturers introduce modifications of drugs to extend the five-year patents on them techniques, employed in response to generics competition. They say that other “evergreening” patent applications could be rejected citing this judgment, helping to keep many life-saving drugs out of the patent regime and pushing down costs.

CONCLUSION:



Merck, has also faced patent issue already begun "tiered pricing". Its plan includes India-specific, responsible pricing for its diabetes drugs. As the generic drug industry in India continues to expand, so does the country's desire to participate in innovative drug discovery. Several of India's leading drug companies have launched discovery units that are focused not on copying Western innovations, but rather improving them, and inventing entirely new remedies for widespread diseases.

PwC estimates that India's domestic pharmaceutical industry will grow from \$11 billion in annual sales in 2009 to \$30 billion by 2020. Much of that growth will be driven by India's famed generic drug manufacturers, such as Dr. Reddy's Laboratories, Cipla and Aurobindo Pharma. This is a matter of self interest for Indian industry. The determining factor was India's generics industry made up of big companies run by rich families versus multinational companies. India frames this as 'our companies versus the rest of the world's companies.

The intellectual property ecosystem in India is not very encouraging. Healthcare activists have asked the government to make medicines cheaper in a country where many patented drugs are too costly for most people, 40 percent of whom earn less than \$1.25 a day, and where patented drugs account for under 10 percent of total drug sales. This appears to be the best outcome for patients in developing countries as fewer patents will be granted on existing medicines. The judgment ensures that the prices of lifesaving drugs would come down as many more companies would produce generic versions. Patents will continue to be granted by India, but definitely the abusive practice of getting many patents on one drug will be stopped. But some say ending research in India would backfire, or that operating in India is so cheap a pullout wouldn't make sense. Finally, I would only emphasize and rest this research on a moral question to be pondered upon by these pharmaceutical players: *"What is good, to allow people to die or to make the medicine available?"*

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