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Pharmaceutical industry-Opportunity to Grow by SLRao

The Indian pharmaceutical industry until the 1970s was dominated by multinational companies. Their profits were good while sales were small as compared to many other countries. So was the market.

Matters began to change in the 1970s. In 1972 our patent laws changedvto give recognition to patents for process and not for products. This meantthat our talented chemists could now explore ways to copy pharmaceutical products not introduced In India. The foreign companies called it 'theft' but it was not so under our laws. Ranbaxy, Cipla and later, Dr Reddy Labs and others pioneered this reverse engineering. Thus, for example, Ranbaxy introduced Diazepam (Valium and Librium of Roche and Burroughs Welcome) and doxycycline hydrochloride (Pfizer). Neither had been introduced into India though they were advanced in relation to existing products. The inventing companies were happy with their older products that were doing well (bromides and terramycin). Ranbaxy's copies made substantial profits. The company invested heavily in modern manufacturing and development facilities. So did other companies with profits from their copies of patented drugs, by developing new processes to make them. In time they also invested in research and discovery of new molecules. It was in their interest now to ask for product patents to protect their property in their discoveries.

Product patents were introduced in India by a new law in the 1980s. this was also in compliance with the TRIPS agreement in the GATT negotiations that led to the WTO, and which we had signed.

In 1963 India had introduced detailed drugs price control of all products, pack sizes and formulations. Each price was based on a standard production benchmark and efficient companies especially multinationals mad good profits even at controlled prices. Since economic liberalization in 1991 price control was relaxed, leading to higher prices, though much lower than in the uSA. The Indian pharmaceutical market also expanded rapidl, with rising incomes due

to economic growth. Government did not put much pressure on prices because, unlike for example in the USA, government pharma purchases were a fraction of household purchases. Household health care expenditures in India accounted for the dominant part of all such expenditures. The Western and especially American markets had government funded medical care and their Governments squeezed prices to reduce their liability.

At the same time, lblockbuster drug discoveries slowed down. Research was leading to new niche drugs with small markets and very high prices. India with its patent regime was able to make many drugs that had come off patents (patent life is 20 years) and sell them cheap as generics. India became the world's largest exporter of generics. This combination of declining new blockbuster drugs and generic competition from india and other countries made Western pharmaceutical companies try to extent the patent lives of their exsting large selling drugs. They did this by marginal changes to products and getting ew patents.

The Novartis judgment denies this life extension or "ever greening". It does not abolish patent protection, nor recognize patent violations. It is still not legal to copy a patented drug and market it without permission of the patent owner. But if the drug has not been introduced in India, it can be mae under a "compulsory license".

Indian manufacturers do find it advisable to collaborate with foreign ones because research is faster, clinical trials are better run, for getting permissions, and their distribution support is useful. Foreign companies are trying to buy successful Indian companies to access their research and development skills and markets. In the process they also get control over their production of generics. The Competition Commission of India must ensure that the consumer does not suffer as a result.

Pharmaceutical regulation in india has so far focused on manufacturing, clinical trials, and distribution. We must significantly improve our regulatory practices. There are between 20000 and 30000 pharmaceutical producers in India because of allowing small scale

sector to enter the sector. There is little inspection of hygiene and production practices. It is estimated that over 40% of drugs sold in India are fake. Hospitals, nursing homes and medical practitioners in India are also practically unregulated. This must change. Retailers in india sell any drug without prescription and face little retribution from regulators. Clinical trials are poorly monitored by regulators and cause untold damage respecially to poor patients.

Thus the pharmaceutical industry in india faces many serious issues that have to be tackled. The Novartis judgment will play a small role by permitting many products whose patents have expired to make generic equivalents. (However despite being the major exporter of generic drugs, very little of Indian sales are of generics).

The Novartis judgment neither removes patents, patentability of other rights of patent owners. Threats from foreign companies that the judgment will keep them out of India are empty threats. India is too large and rich a market and a research and production centre to be ignored.