

The long term consequences for smaller, generic manufacturers will also be considerable. Unable to copy patented drugs, many domestic firms will look for alternate strategies for survival. These might include searching for foreign strategic partners to provide both capital and R&D experience and ability. There may be a consolidation of the domestic industry through mergers and acquisitions.

In another attempt to spur R&D, the government has said that any drug discovered as a result of R&D based in India will be exempt from price controls

4. Governmental Affairs

a) Patent History

The Indian patent law is in the process of being amended. The current law, dating back to 1970 provides protection for most goods for a period of 14 years from the date of filing. However, food, chemicals and pharmaceutical substances are exempted from this provision. For products in these categories, India only recognizes process patents for a period of 7 years from filing or 5 years from the patent grant date.

The weak protection for pharmaceuticals has contributed to the growth of a large indigenous Indian pharmaceutical industry. Indian companies are given the opportunity to invent processes for new top selling drugs without the risk of patent infringement suits.

This may result in reduced production capacity since patent holding firms may be reluctant to invest in domestic production. It could also account for the fact that new drug introductions in India typically lag the rest of the world by 4-6 years.

b) Present / Future (India's International Obligations (TRIPS / GATT))

The Indian Pharmaceutical Industry is in a state of uncertainty. Recent international developments in the intellectual property arena have prompted the Indian government to introduce amendments the outdated 1970 patent law into the legislature. India, as a signatory to the Trade Related Aspects of Intellectual Property Rights (TRIPS) and General Agreement on Tariffs and Trade (GATT) agreements, must pass legislation which respects the provisions laid out in TRIPS. Among the clauses which will have profound effects on the pharmaceutical industry are the allowance of non-discriminating product patents and the prohibition of compulsory licensing (except under rare and extreme circumstances).

Upon the introduction of product patents, pharmaceutical companies in India will be prohibited from copying patented brand-name drugs for 20 years from the date of filing of the patent. Process patents will also be recognized for the 20 year period. Indian owned companies, especially the small units, would be negatively affected by this change. These are the units which produce and sell generic versions of new drugs.