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Ever Greening of Patents and Accessibility of Life Saving Drug: The Socio Legal Issues

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ABSTRACT

In the invention of a new drug pharmaceutical companies have to spend billion dollars. Thousands of potential drugs screened, out of which only three – four reach of clinical trial and hardly one gets the approval for marketing. Pharmaceutical companies patent the drug and get the exclusive rights for marketing, research cost and their profits are realized from the patients who consume the patent drug. Internationally, drug patents and the exclusive marketing rights associated there with are awarded for a period of 20 years; during this time, no other drug company is allowed to manufacture or market the same drug. After the patent expires, other companies are permitted to manufacture and market the drug; their brands are known as generic versions. But the patentee company generally use to alter certain molecular changes and claim further patents right on the same medicine which should become a generic one, so that it could be accessed by the needy and poor, but they pled the argument that molecules are patented very early during the process of drug discovery, but unique clinical characteristics or benefits are not discovered until much later, when clinical trials are conducted, if at all. Therefore, it is unreasonable to ask that unique characteristics of a slightly altered molecule be described at the time of the application for the patent, itself.

Key Words : Product Patent, Process Patent, DOHA Declaration, Compulsory Licensing

INTRODUCTION

Constitution of India guarantees every person right to life and personal liberty. Socio economic rights enumerated in the constitution or interspersed between the chapter on fundamental rights and directive principles of state policy. The directive principles of state policy encompassed under the Indian constitution signify a finishing line for which the state should Endeavour to make efforts. Though the content of the enlisted directives have been made non justifiable in the courts of law. Indian courts have time and again read the directives under the umbrella of various fundamental rights to make the justifiable. In the early 1970s, the Indian Patent was passed under the Indra Gandhi Government to permit greater access of medicines at lower rates to the poor in the country. According to the Act, process patents but not product patents would be recognized. Expressed otherwise, India would award patents not to individual drugs but to the process whereby the drug was manufactured. This allowed Indian drug companies to manufacture the same drug using other processes (this is otherwise known as reverse engineering). As the Indian companies incurred little expenditure on research and development of new drugs, it became possible to make new drugs available to the country at affordable rates.

According to section 3(d) of Indian Patent the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employees at least one new reactant.

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Explanation:

For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixture of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

Thus is very evident that mere minor or major molecular changes in the original composition is like producing the old wine in anew bottle and should not be construed as a new invention and hence the question of repatenting the drug does not arise.

Issues of Evergreening:

Formally patents were not granted to pharmaceuticals, but the 2005 amendment of the Indian patent Act 1970 allowed the patent grant on pharmaceuticals. Productive patent on pharmaceuticals products have drawn many scholarly writing into the front. The ever greening process has caused some controversy in the pharmaceutical industry. In this context, ever greening may be used by manufacturers of a particular drug to restrict or prevent competition from manufacturers of general drug. In 2002, an extensive and lengthy inquiry by the US Federal Trade Commission, found that the Hatch-Waxman legislation which was instrumental in establishing the US generic pharmaceuticals industry had resulted in as many as 75% of new drug applications by generic drug manufacturers experiencing legal actions under patent laws by the original brand name patent owner. These were driving up US costs by keeping the cheaper generic versions off the market. The FTC recommended only one ever greening injunction against a potential generic market entrant be permitted per product, and an expedited process of resolving such claims.

Accessibility of Life Saving Drug:

India will respect product patents. However, the patents so respected will only be those issued in India. Product patents will be respected for a period of 20 years from the time of application and not from the time of grant of the patent. About 10,000 applications for patents were pending with the government in 2005: these date back to 1995 and are designated as mailbox applications. When the mailbox applications are cleared and patents awarded, newly-introduced generics in the Indian market may have to be withdrawn.

This, for example, is why Indian brands of Tadalafil have disappeared from the shelves. And, newer antipsychotic, antidepressant, antiepileptic and other drugs will be permitted to the marketed only by the patent holder. Costs to the patient will then inevitably rise. This scenario is feared but is by no means certain to occur as the international patents for almost all currently available drugs had been awarded before January 1, 1995, the cut-off date new drugs that emerge in the international arena will be available to the Indian patients only from the patent holder. Again, the cost is almost certain to be high.

Patenting Issue of Life Saving Drug Before the Apex Court:

Serious concerns expressed by multinational companies over the Supreme Court's judgment in the Novartis case, India today said its laws are WTO compliant and no country could allow "ever greening " of patents. There has been a lot of debate about a judgment given by the Supreme Court. I suppose it is not an issue of law because section 3(d) is embedded in the Indian.

It a major blow to Swiss Pharma Giant Novartis, the Supreme Court earlier this month had rejected its plea for a patent on cancer drug Glivee. The verdict was hailed by the Government of India and the NGO as it would pave the way for domestic firms to provide affordable drugs to Lakh of cancer patients in the country. While rejecting the plea for Novartis, the Apex Court said there was no new invention and no new substance used in the drug prescribed for treating blood, skin and other types of cancer.

Earlier, the Comptroller General of Patent and Design had denied patent to Glivacon several grounds including its alleged failure to meet stipulations under sections 3(d) and 3(b) of the Indian Patent Law.

Section 3(d) restricts patents for already known drugs unless the new claims are superior in terms of efficacy while section 3(b) bars patents for products that are against public interest and do not demonstrate enhanced efficacy over existing products.

Ever-greening of patent right is a strategy allegedly adopted by the innovators having patent rights over products to renew them by bringing in some minor changes such as adding new mixtures or formulations. It is done when their patent is about to expire.

The Apex court dealt a blow to western drug makers on April 1 when it threw out Novartis' bid to win patent

protection for cancer drug Glivec and set a benchmark for intellectual property cases in a country cases in a country where many patented drugs are unaffordable for most of the population of 1.2 billion.

Speaking during a visit to the World Intellectual Property Organization in Geneva, a commerce and industry minister Anand Sharma said the court decision was "absolutely justified" under the intellectual property rules of the World Trade Organization, known as the TRIPS.

Patents and Evergreening:

Ever greening refers to variety of legal and business strategies by which technology producers with patents over products that are about to expire retain royalties from them, by either taking out new patents (for example over associated delivery systems, or new pharmaceutical mixtures), or by buying out of frustrating competitors, for longer periods of time than would normally be permissible under the law. Ever greening is not a formal concept of patent law; it is best understood as a social idea used to refer to the myriad ways in which pharmaceutical patent owners use the law and related regulatory processes to extend their high rent-earning intellectual property rights, otherwise known as privileges, particularly over highly profitable (either in total sales volume or price per unit) "blockbuster" drugs. Thus, while the courts are in instrument frequently used by pharmaceutical brand name manufacturers to prolong their patent royalties, ever greening is rarely mentioned explicitly by judges in patent protection cases. The term usually refers to threats made to competitors about a brand-name manufacturer's tactical use of pharmaceutical patents (including over uses, delivery systems and even packaging), not to extension of any particular patent over an active product ingredient.

Ever greening of patents refers to developing or increasing the life of the patent or the patent term beyond 2 decades to reap the benefits for much longer period of time. Drug patent ever greening is the single most important strategy that multinational pharmaceutical companies have been using since 1983 in the US (and since 1993 in Canada) to retain profits from "blockbuster" (high sales volume) drugs for as long as pos

When the original patent over the active component of a brand name drug is about to expire, these drug companies often claim large numbers of complex and highly speculative patents.

Laws in the US and Canada require manufacturers to notify the original brand name patent holders of their intension to market copies at the expiry of the original patent. The original patent holders can then threaten these potential generic competitors with breaching their now "ever greened" patents and seek a court order preventing their marketing approval.

The ultimate consequence could be the generic equivalents of the drug will be prohibited from entering the market so the price of the drug of Innovator Company will be higher even after the patent expiry in absence of competition from generic drug makers.

One form of ever greening occurs when the original manufacturer "stockpiles" patent protection by obtaining separate 20 years patents on multiple attributes of a single product. These patents can cover everything from aspects of the manufacturing process to tablet color, or even a chemical produced by the body when the drug is ingested and metabolized by the patient

A Scope in Ever Greening of Patents:

By the early 1950, because of the spread of manufacturing activities, the indigenous sector dominated the pharmaceutical industry in India, which accounted for about 62 percent of the market in 1952. However, with the rise and growth of multinational corporations (MNCS) worldwide in the post-second world war period, as well as, the therapeutic revolution afterwards that changed this scenario. Article 27 of the TRIPS Agreement harmonizes the subject matter of patent in a broad manner. However, the exclusion permitted under the TRIPS Agreement has created wide variance in the Indian Patent Act, 1970 ('the Act'). Complying verbatim with Article 27, section 2(1)(i) of the Act provides that 'invention means a new product or process involving inventive step and capable of industrial applications'. Section 3 of the article explicitly excludes certain categories of inventions from the scope of patentability. Critical categories include-plants, animals, parts of plants and/or animals, seeds, essentially biological processes, mathematical or business methods of treatment, diagnostic, therapeutic and surgical methods. Section 2(1)(i) and section 3 are inextricably linked with each other; any addition in the latter would result in the constriction of the former.

While section 3 per se poses a direct conflict with the general mandate of Article 27 of the TRIPS Agreement, some of these restrictions can in fact stay

on, provided they come under the general exceptions under the TRIPS, as provided in the Art. 27(2) and (3). One needs to closely watch the dialectics of Section 2(1)(i) and Section (3) of the Art in view of the substantive provisions contained in Art. 27(1) and the exceptions to patentability provided under Article 27(2) and (3) of the TRIPS Agreement.

In a triumphant victory for patients fighting for access to medicines, a division bench of the Supreme Court of India comprising Hon'ble Justice Aftab Alam and Hon'ble Justice Ranjana Desai dismissed Swiss MNC Novartis' appeal[1] for a patent to Novartis for its anti-cancer medicine, imatinib mesylate (Gleevec). The case is especially pertinent because it involved the interpretation of Section 3(d) of the Patents Act, 1970, a public health safeguard introduced by Parliament in 2005 to prevent ever greening. Putting an end to the controversy over the provision, the Supreme Court has recognized the impact of patents on access to medicines and called for a strict interpretation of section 3(d).[2]

Rejoicing at the decision, Mr. Y.K. Sapru of Cancer Patients Aid Association (CPAA), which had opposed Novartis' patent application, said, "WE are very happy that the Apex court has recognized the right of patients to access affordable medicines over profits for big pharmaceutical companies through patents. Our access to affordable treatment will not be possible if the medicines are patented. It is a huge victory for human rights".

The government of India seems to be adopting a balanced approach in addressing this issue. In the proposed patent (Amendment) Bill, 2003, it is proposed to substitute the words "new use of known substance" in section 3(d) of the Act. The interpretative scope of this is yet to be seen. It could eventually lead to the acceptability of 'Swiss-type' new use claims.

The patentability of diagnostic methods under section 3(i) of the Act poses another important question with respect to the possible distinction between 'in vitro' and 'in vivo' methods of diagnostics. The Patent Amendment Bill, 2003 has not introduced any distinction between 'in vitro' and 'in vivo' methods of diagnosis. While 'in vitro' methods of diagnosis would involve tests on samples taken from the body and performed outside the body, (like taking blood samples and testing for diagnosis of disease like malaria), the 'in vivo' methods of diagnosis would include performing the methods on the human body (like CT scanning of the body). Section 3(i) of the Act provides that any process for the diagnostic or other treatment of human beings or any process for a similar treatment of animals is not patentable. In view of this, 'in vitro' diagnostic methods may be considered as a patentable subject matter. The above being the position, the exact nature and scope of patentable inventions in the field of pharmaceutical arts will become clear only when the amended law is put to use, and possibly reviewed by the Courts of Law. Hopefully the textual law will acquire more clarity in the days to come when the Judges opine what it means and contains.

Under the Agreement on the Trade Related Aspects of Intellectual Property (TRIPS) to which Jamaica subscribes by virtue of its membership of the World Trade Organization (WTO), patents which grant an exclusive right to exploit an invention are available for products or processes, provided that they are new, non-obvious and are capable of industrial use.

Medicines and their method of production are commonly protected by patents. These patents remunerate a researcher's innovation stimulating further research and development of medicines from which we all benefit. Patents also encourage investment in the development of new medicines as investors are assured of their returns via the monopoly at a patent brings. Ernst & Young's 2007 Global Biotechnology Report indicates that capital raised by the world's biotechnology companies grew by 42% in 2006.

Production of the generic drugs in India, the world's biggest provider of cheap medicines, was ensured on Monday in a ruling by the Indian Supreme Court.

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.

Specially, the decision allows Indian makers of generic drugs to continue making copycat versions of the drug Gleevec, which is made by Novartis.[3] It is spelled

1. BMJ 2013; 346: f2218, http://www.bmj.com/content/346/bmj.f2218?tab=citation.

2. Patents Act, 1970.

Glivec in Europe and elsewhere. The drug provides such effective treatment for some forms of leukemia that the Food and Drug Administration approved the medicine in the United States in 2001 in record time. The ruling will also 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 version costs about $2,500 a year.

The ruling comes at a challenging time for the pharmaceutical industry, which is increasingly looking to emerging markets to compensate for lackluster drug sales in the Unites 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.

Gleevec is widely recognized as one of the most important medical discoveries in decades. In a televised interview, Ranjit Shahani, vice chairman of the Indian subsidiary of Novartis, said that companies like Novartis would invest less money in research in India as a result of the ruling. "We hope that the ecosystem for intellectual property in the country improves India exports about $10 billion worth of generic medicine every year. India and China together produce more than 80 percent of the active ingredients of all drugs used in the US.

"It really is in our view another example of what I would characterize as a deteriorating innovation environment in India," said Chip Davis, the executive vice president of advocacy at the Pharmaceutical Research and Manufacturers of America, the industry trade group. "The Indian government and the Indian courts have come down on the side that doesn't recognize the value of innovation and the value of strong intellectual property, which we believe is essential."

Both the WTO and R&D companies acknowledge that patents should not prevent the needy from obtaining affordable medicines. TRIPS incorporate measures such as public health exceptions and compulsory licenses which allow WTO members to either not issue patents or to override them if exigent circumstances arise. In addition, many R&D firms have special pricing arrangements enabling developing countries to acquire patented drugs on more favorable terms. For instance, Merck's HIV/AIDS Pricing Policy varies the price of its medicines between countries based on the economic climate and prevalence of HIV.

According to the TRIPS agreement, the term of protection for patent is 20 years or 2 decades counted from the filing date. As a patent prosecution and management strategy, 'Ever greening' enables patent term extension by developing a portfolio of patents around a basic invention. The child patents may be directed at any one of the various ancillary inventive aspect explained in the earlier section.

Adding new claims to a basic patent disclosure is permissible in certain jurisdiction. This is achieved by the effective use of patent prosecution routes including continuation patent application, divisional patent application, continuation-in-part patent application and application for patent of addition. It is also possible to build on chains of priority from a basic patent disclosure to preserve novelty. The limitations or restrictions in the criteria of patentability and the exclusions of certain subject matters from the scope of patentability can impose serious limitations on patent prosecution strategies aimed at 'Ever greening'.

A number of fundamental issues come in sharp interplay when structuring patent prosecution aimed at 'Ever greening'. Unless the later applications disclose independent inventions (or inventive aspects), though linked to the invention disclosed in the basic application, the allowance of the later application(s) can lead to double patenting. On the other hand, inclusion of multiple inventive aspects (consequently multiple independent claims) in a single application can lead to 'unity of invention' issues. In India, the Patents (Amendments) Act, 2002 brought in an amendment to Section (10)(5) introducing 'single inventive concept'. However, the Indian patent offices are yet to start allowing multiple independent claims. Consequently, dividing out applications is considered a normal patent prosecution step. As the effective date of filing of a divisional application is the same as the date of filing of the basic application, this may not contribute to patent term extension or 'Ever greening'.

In the absence of multiple prosecution avenues, where the applicant has the scope of working around various prosecution routes, the Indian Patents Act is rather rigid as to the time lines for priority, patent term and patentable subject matters. Hence, 'Ever greening' may not acquire dimensions in India.

3. Supra note 73.

Drug Patents and Ever Greening:

The problem associated to the patenting of minor incremental development has special implications in the case of pharmaceuticals necessary tom protect public health. Patents are on the pharmaceuticals products or process may be used to block generic completion by Evergreening the patents granted. Evergreening means the granting of patent on the products which is not novel, but a simple change on an existing known product. This practice is often adopted by the pharmaceuticals companies to extend their monopoly even, when the patent has expired and block the completion. This practice prejudices the accessibility and the affordability of the drugs.

India has had lax patent laws compared with the countries. They allow Indian companies to produce generic versions of drugs that are under patent elsewhere. The competition between manufacturers drives down the price of the drug. Cipla, an Indian drug company, is one of the largest suppliers of low cost generic anti-retroviral drugs in the world. In 2001, Cipla made its cocktail of anti-retroviral drugs available to MSF for $350 (€218; €271) per patient per year, and $600 per patient per year to governments in developing countries. At the time that they announced this, the lowest market price for the drugs anywhere in the world was $10,500. Copal are also a large producer of many cancer treatments.

For many years, India did not recognize drug patents at all.[4] However, in 1994, India singed up to the TRIPS agreement (Trade Related Aspects of International Property Rights), an international law that gives drug companies a 20 year patent on the production of drugs. TRIPS required India to introduce patents on medicines in 2005.

In contrast to other countries in the TRIPS agreement, India also introduced laws that prohibited an industry tactic called "ever greening". Ever greening is where a company extends its patent on a drug by repatenting slightly modified versions of the drug. For example, they might release the original drug in its salt form, even if this does not bring a therapeutic improvement.

India – alongside Brazil, Thailand and South Africa – is one of the few countries with laws against ever greening. The Indian Patent Act, as amended by the Patents (Amendment) Act 2005, states that drugs cannot be patented if they result from "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance". This has allowed the continued production of cheap generic versions of drugs by Indian companies.

For the 170,000 HIV/AIDS patients in developing countries treated by MSF every year, 80% are with anti-retroviral treatment sourced from India, with South Africa and Brazil making up most of the other 20%. It is why India is called "the pharmacy of the developing world" by MSF.

After the Supreme Court's decision in the Novartis case, the government said on Friday that it couldn't permit ever-greening of patents. "There has been a lot of debate about a judgment given by the Supreme Court. I suppose it's not an issue of law because section 3(d)[5] is embedded in the Indian Patent Acts which are TRIPS (Trade Related Aspects of Intellectual Property Rights) compliant. I suppose everybody agrees that ever-greening should not be permitted, "Saurabh Chandra, Secretary, Department of Industrial Policy and Promotion (DIPP) said.

Chandra, who was speaking at an event on Intellectual Property Rights (IPR) organized by industry body, FICCI, said that India's laws were WTO complaint. Earlier in April, the country's apex court had rejected Swiss pharma major Novartis' plea for a patent on cancer medicine, Glove which is used to treat blood, skin and other kinds of cancer.

While the verdict was welcomed by the Indian government and NGOs as a means of cheaper cancer drugs benefitting thousands of cancer patients, multinational companies had expressed their concern at the order.

Ever-greening of patents gives the inventors a chance to retain monopoly over its product even after the patent term has expired. The innovators usually bring in small changes and then claim patent rights for 20 years. In the Novartis case, the Supreme Court ruled that there had been no new innovations, in the form of new substance used in the drug.

The DIPP secretary batted for India's stance on issuance of Compulsory License on the anti-cancer drug, Nexavar.

"India has issued one compulsory license. The order

4. P. Narayan, Patent Law 6 (2006).

5. Patents Act, 1970.

of Comptroller General of Patent has been upheld by the Intellectual Appellate Board (IPAB). We have a system in place where orders of the Comptroller General of Patent was first scrutinized by IPAB and after that any aggrieved party can go to the Supreme Court. I must compliment the patent office for both these judgments which have been sustained," Chandra said adding that India had acceded to the Madrid Protocol which permits Indian companies to register trademarks in 89 countries through a single application. In a major blow to Swiss pharma giant Novartis, the Supreme Court earlier this month had rejected its plea for a patent on cancer drug Glove. The verdict was hailed by the government and the NGOs as it would pave the way for the domestic firms to provide affordable drugs to Lakh of cancer patients in the country.

While rejecting the plea of Novartis, the apex court said there was no new invention and no new substance used in the drug prescribed for treating blood, skin and other types of cancer.

Earlier, the Comptroller General of Patent and Design had detained patent to Glivec on several grounds including its alleged failure to meet stipulations under sections 3(d) and 3(b) of the Indian Patent Law. Section 3(d) restricts patents for already known drugs unless the new claims are superior in terms of efficacy while Section 3(b) bars patents for products that are against public interest and do not demonstrate enhanced efficacy over existing products.

Ever-greening of patent right is a strategy allegedly adopted by the innovators having patent rights over products to renew them by bringing in some minor changes such as adding new mixtures or formulations. It is done when their patent is about to expire.

Novartis vs. India: A Brief[6] :

Competition policy and IPR are complimentary to each other in fostering innovation. IPR policy seeks to provide incentive to innovate while competition policy regulates the market structure and price while competition policy regulates the market structure and price mechanism to keep up the level of competition. Article 8.2 and article 40.2 of TRIPS should be read in conjunction with section 3(5) of the competition Act, 2002 in particular and the objectives of competition law and policy in general. After 12 weeks of hearings in India's Supreme Court, Medicines Sans Frontiers (MSF) has learnt that final arguments into the Novartis vs. Union of India case challenging interpretation of Section 3d of India's patent law have today come to an end. During the hearings, which started on 11 September, the two judges presiding over the case heard arguments from Novartis as to why they deserved a patent on the mesylate salt of the blood and intestinal cancer drug imatinib. In recent weeks, the judges heard the counsel for the Indian government, and then representatives for the Cancer Patient Aid Association on arguments to defend India's stricter patentability criteria that discourages patenting of new forms of known medicines.

The judges have now retired to consider their verdict; there is no indication at this stage to suggest when the judges may hand down their findings.

"With this precedent-setting case nearing its end, we sincerely hope that the integrity and intension of India's patent law, and Section 3d in particular, is upheld. India's ability to continue production of affordable medicines for the developing world depends a great deal on the country's patentability standards and how they are interpreted by courts in India. We will now wait for the judge's verdict to be released".[7]

Background:

Section 3(d) led to Novartis being denied a patent for imatinib mesylate (marketed by Novartis as Glivec). Novartis is contesting the Indian patent office's and appellate body's decision to reject the company's application for a patent on the salt form of imatinib.

Conclusion:

A win for Novartis would set a dangerous precedent, severely weakening India's legal norms against 'ever greening', a common practice in the pharmaceutical industry. A single medicine can have several applications pending for separate patents, each relating to a different aspect of the same medicine. In this case Novartis is pushing for an interpretation of patentability standards that would inevitably lead to patents being granted far more widely in the country, blocking the competition among multiple producers which drives down prices and restricting access to affordable medicines for millions in India and across the developing world.

6. Supra note 73.

7. Leena Menghaney, Access Campaign Manager-India, Medecins sans Frontiers.

Ever-greening of patent right is a strategy allegedly adopted by the innovators having patent rights over products to renew them by bringing in some minor changes such as adding new mixtures or formulations. It is done when the patent is about to expire.

Patients in India have a vital interest in innovative therapeutics for diseases without effective treatments and our scientists and industry have the potential to be leaders in meeting these needs. Our country should not sacrifice its potential to be a pharmaceutical innovation powerhouse by limiting our local industry merely to supplying other nation's demand for low-cost generics.

India has the capability to create a sustainable pharmaceutical industry built on innovation alongside its existing generics industry. All it needs to unleash this potential is a fair and predictable patent system.

Truly speaking the ever greening of patent is nothing but awarding monopoly type of right to the patentee which keeps the drug often life saving, far away from the reach of poor and marginalized section of the society. Hence sleeping on the dead body of patients the Patentees should not be allowed to smile.

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