Supplementary Protection Certificates are Detrimental to Medicine Affordability

The cost for development of a single drug is estimated between $350 million and $5.5 billion depending upon the product range of the company.[1] According to the Tufts Center for the Study of Drug Development, the cost of developing a prescription drug is $2.6 billion, a 145% increase from the estimate of 2003. Moreover, $312 million is spent on postapproval development studies to test new indications, formulations, and dosage strengths that lead to the development of a new drug, from research and development (R&D) to marketing approval, which is approximately $2.9 billion.[2] The profit owing to patent with more demands of health-care system has huge effect of the cost of drug development.[3] The cost-effective new medicine is the challenge of the pharma industry.

By adopting Trade-Related Aspects of Intellectual Property Rights (TRIPS) by the World Trade Organization (WTO) in 1995, the pharmaceutical companies could protect their intellectual property rights (IPR) through patents. Under this, the innovating companies were granted exclusive manufacturing rights for 20 years for each new medicine, generating revenues that often exceeded initial investment costs, thus providing an incentive for pharmaceutical companies to continue to invest in R&D.[4] However, the increased competition from generic manufacturers who produced medicine similar to the branded medicine, after the patent expired, brought profits of innovator companies under pressure.[4]

Hence, the medicine manufacturers after their patent termination developed "ever-greening" strategies to compete with the generic manufacturers. These included marketing of slightly modified "follow-on drugs," for example, by combining formulations or producing slow-release forms, so that they can extend the patent. They were successful in maintaining market share in Geneva, offsetting competition by generics. However, the ever-greening strategies for follow-on drugs were found to substantially increase overall health-care costs.[4]

To maximize the patent term, the companies to seek patent protection for new formulations/new methods of use/potential combination products, even before launching the original product.[5] Since the pharmaceutical companies continued to build the hype that they were not given a fair opportunity to recover their R&D investments, prolonged market exclusivity through supplementary protection certificates (SPCs) was introduced. Multiple SPCs could be issued for the same product. The SPCs for the same product could be granted to multiple companies if each company held a patent on the product. The issuance of multiple SPCs for the same product was used by a single company to expand its monopoly.[6] Such strategies were developed before patent expiration and before the imminent market entry of generic competitors.[5]

The decision of the Indian Supreme Court regarding the Novartis patent of Gleevec in India was a landmark on patenting where monopolistic pricing of innovation was hindered and led to the amendment of the Indian patent law in 2005. This showcased the profit gaining by modification of known drugs and its influence in pricing. Thus, the new patent law which India adopted contains a grandfather clause that allows generic copies of drugs launched before 2005, which includes Gleevec, to continue to be sold, albeit with payment of a reasonable royalty to Novartis.[7] The Court made the nuanced distinction between the rent-seeking practice of ever-greening and the beneficial practice of incremental innovation and clarified that Indian patent law forbids only the former.[8] International organizations such as WHO supported the decision against ever-greening of pharmaceutical patents. Thus, there is a huge price difference between patented Gleevec of Novartis and the generic versions of Cipla and other generic companies.[9] This strict patent requirement would actually enhance innovation as the pharmaceutical companies would have to invest more in R&D to come up with new cures rather than repackage known compounds.[10]

However, SPCs instead of being productive in stimulating innovation opened up incentives for companies to go for prolonging monopolies through "ever-greening" strategies, including the filing of multiple patents and pursuit of prolonged patent terms for the same medicine. The SPCs disproportionately empowered the commercial interests by enabling the companies to charge unaffordable prices since these expanded and extended their existing monopoly rights, leading to higher medicine prices by preventing generic competition for a longer period and prolonging the monopolies of originator pharmaceutical companies. This was against the public interest and affected the medicine affordability. Hence, recently, 33 civil society organizations have called on the European Commission (EC) to abolish the SPC mechanism.[11]

India introduced product patents for pharmaceuticals in 1995 by signing the TRIPS agreement and as a part of its TRIPS and WTO commitments amended its Patent Act in three phases in 1999, 2002, and 2005. With the 2005 Patent Act, India introduced new patentability standards which were further restricted by the inclusion of a unique provision Section 3(d).[12] Patentability standards of India restrict the inclusion

of a unique provision in which new forms of already known substances were not granted a patent unless they are proved to have enhanced known efficacy of that already known substance which has curb on unethical practices of ever-greening. Thus, India has effective provision for checking the unethical practices of extending the patent term.[13] The compulsory license to a domestic generic drug-maker has been introduced by the Indian Patent Office, in which government authorizes a party other than the patent owner to produce the patented product or process, without the patent owner's consent. This has paved the way for Indian generic manufacturers being granted licenses on patent-protected medicines if the right-holders fail to supply the products at affordable prices and in sufficient quantities. With the ruling, Indian generic drug manufacturer Natco Pharma Ltd started manufacturing and selling in India, the Bayer's patented drug "Sorafenib tosylate."[14,15]

The USA Patent Term Restoration Act (Hatch-Waxman Act) provides provision to reward a generic manufacturer who first challenges the innovator's patent with a successful challenge, and the applicant is rewarded with a 180-day exclusivity period, which provides generic manufacturer an opportunity to exclusively market its products, allowing the generic manufacturers launch generic versions of the branded drug, and to challenge bogus and stall undue monopolies enjoyed through bogus patents.[12] Moreover, for a new procedure, Abbreviated New Drug Application can be filed by the generic drug manufacturer to the US Food and Drug Administration (FDA) for marketing authorizations for the generic versions.[12] The ever-greening practice leads to multiple divisional patents from single patent application to compound, pharmaceutical composition, and method of treatment with 20 years of patent term from filing date. Moreover, in US, 30-month provision stay is also followed with Hatch-Waxman patent linkage with the drug gets published in FDA's Orange Book/Approved Drug Products with therapeutic equivalence evaluations; thus, the generic manufacturer can refer to originator's 30-month stay of generic approval to resolve the dispute. This provision aims at protecting the interests of innovator firms; still, companies have misused this provision. The US Federal Trade Commission analyzed that approximately 72% of innovators exploited the provision.[16] In European Union (EU), patent is an exclusive right granted to the patentee and the patentee has the right to exploit the patent for monopoly, so this does not necessarily count as the abuse of dominant position. The EU patent laws are still lenient, and there are not much laws concerning ever-greening; however, ever-greening in the EU is considered as the abuse of dominant position and is counted under the scope of Article 102 from the Treaty on the Functioning of the EU.[12]

The SPC is in conflict with the mechanisms designed to accelerate the generic and biosimilar medicines. Mechanisms to oppose the granting of SPCs should be bolstered, and the EC should stop encouraging SPCs, such as patent term extension, through free trade agreements.[6] All SPCs should be suspended forthwith to improve affordability and resultant access to the medicines. May the awakening of civil society organizations succeed in their endeavor.

Vijay Thawani

Department of Pharmacology, People's College of Medical Sciences and Research Centre, Bhopal, Madhya Pradesh, India

Address for correspondence: Dr. Vijay Thawani, Department of Pharmacology, People's College of Medical Sciences and Research Centre, Bhopal - 462 037, Madhya Pradesh, India.
E-mail: vijaythawani@rediffmail.com

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