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MULTIPLE FILING OF PATENTS

Wednesday, April 21, 2010 08:00 IST
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Adoption of the new patent law in 2005 marked the beginning of a new era in the history of pharmaceutical industry in India. It was adopted as a part of India's obligation under TRIPS agreement and in the face of opposition from the Indian sector of the pharmaceutical industry. The concern of the Indian sector of the industry was on the fears that the powerful multinational drug companies could try to exploit the loopholes of the new patent law and dominate the Indian pharmaceutical scene once again by obtaining patents for all kinds of modifications of known molecules. As a safeguard against such a possibility, section 3(d) has been provided in the new Act. Yet, what is being witnessed today is the realization of the fears the domestic sector had five years ago. Companies, mostly MNCs, are filing applications for patenting different forms of the same drug, like salt, polymorph form, analogue form, crystalline form, solid dosage form and combinations with other drugs. By doing this, they are trying to cover a broader spectrum of protection for commercially significant forms of the same compound besides seeking extension of the term of patent protection. On an average, 25 frivolous patent applications are being filed in patent offices every month according to Indian Pharmaceutical Alliance. And the patent offices in the country have already granted patents to dozens of products that do not merit patent protection at all. A study conducted by IPA last year found that at least 86 cases of patents granted for pharmaceutical products were just minor variations of existing products. As the global pharmaceutical industry is turning less and less inventive and it is struggling to find new molecules, MNCs will continue to re-jigger the old drugs with the hope of getting new product patents. The cases of Glivec of Novartis and Caduet, a therapeutic combination of amlodipine and atorvastatin, of Pfizer are well known.

As per the figures available from the patent controllers office, after 2005 about 13,000 patents have been issued in both chemicals and pharmaceuticals. And nearly 70,000 patent applications are in the pipeline for examination and process. These figures are indeed quite astounding considering the fact that very few new molecules have been cleared by US FDA for marketing in recent years. Filing of multiple patent applications for various forms of the same drug is possible within the framework of the amended Patent Act. But, it is ethically incorrect to apply for multiple patents of the same molecule as it implies trying to get from one patent office what could not be obtained from another office. Multiple filing of patent applications also burden the patent offices which are seriously handicapped by manpower shortage and expertise. There are only four patent offices in India located at Delhi, Mumbai, Kolkata, Chennai with about 150 officers. There is no doubt that granting patent protection for pharmaceutical substances involving only incremental innovation is against the public interest as such research does not involve any huge expenditure or time line unlike in the case of a new molecule. The process of granting patents for pharmaceutical products, therefore, needs to be made extremely stringent and above suspicion.