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THE PATENT PRESSURES

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India-EU Trade and Investment Pact is going to be concluded some time in March this year and the prime minister is expected to visit Europe for signing the same. One of the key agenda to be discussed and decided there is the changes EU has been proposing on Indian Patent Act. EU with the intention of protecting interests of drug MNCs of its member countries seems to be pushing for incorporation of a suitable clause in the Indian patent law to introduce data exclusivity so as to extend the market exclusivity of a drug beyond its patent life. Currently, patents on drugs are granted in most countries for 20 years from the date of filing. Indian Patent Act was amended in 2005 allowing product patent after a gap of 40 years striking a balance between patent rights and the access to medicines. And India's stand has been that the amended patent law as it exists today is compliant with the WTO's Trade-Related Intellectual Property Rights (TRIPS) agreement and therefore there is no need for further easing of the patenting criteria until and unless India's capabilities on innovation are reinforced. India is a major producer and exporter of generic drugs to the global markets especially to the developing countries. Any restriction on the export of generic drugs from India with a possible introduction of data exclusivity clause can affect the availability of these cheap but quality drugs to a huge number of poor patients in the developing world.

Apart from the move on data exclusivity, what is worrying Indian pharma industry is the EU's efforts to influence the PMO to get the Section 3 (d) in India's Patents Act removed. This Section in the Act seeks to prevent patenting of incremental inventions that don't bring substantial improvement in efficacy of a drug. Despite having the section in the Act, MNCs have already filed 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, MNCs are trying to cover a broader spectrum of protection for commercially significant forms of the same compound. On an average, 25 frivolous patent applications are being filed by MNCs in patent offices every month from 2005 in the country. And the patent offices in the country have already granted patents to dozens of such products that do not merit patent protection at all. As the global pharmaceutical industry is turning less and less inventive and is struggling to find new molecules, it should be expected that MNCs will continue its efforts to re-jigger 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. Now even with the Section 3 (d), if such frivolous patents can be obtained by MNCs one can imagine what can be the scene after the removal of the Section from the Indian Patent Act. Therefore, India should not make any more changes to the Patent Act now when domestic pharmaceutical industry is already facing a serious of take over threat from MNCs.