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For a "Pretty Picture" in Indian pharma industry

Dr. Gopakumar G. Nair

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The latest decision of the Court of Justice of the European Union (equivalent to the Supreme Court) is a welcome relief for all generic exporters. The in-transit seizures had generated shock-waves among the generic industry and had led to serious reactions from the Indian and other African and Latin American governments, as well as Pharmexcil, IDMA and IPA. The Indo-EU bilateral negotiations as well as India-Brazil complaint at the Dispute Settlement Body of the WTO had softened the EU attitude on in-transit seizures. However, the ACTA (Anti Counterfeit Trade Agreement) and provisions therein using the language "at least copyright and trademarks" was still an irritant. This recent judgement from CJEU, has laid to rest this long-standing dispute.

On the domestic front, India has completed 15 years of TRIPs transition, though the transition-related product patent litigations are in full swing. The harmonization of Intellectual Property Laws has led to "reverse engineering" effect, for skills of which India has been acknowledged as a pioneer. The US courts, European courts as well as the PCT WIPO offices have commenced recognizing the need for "enhanced efficacy", which incidentally is a technology, borrowed by Indian lawmakers from the European regulatory definitions. In a recent example, for a product such as "Fesoterodine", which is an ester of "Tolterodine", CDIR (Center for Drug Information and Research) has cautioned as follows.

"Festerodine is a "me-too" drug (of Tolterodine) and should not be recommended or prescribed for at least seven years, until November 2015, because of the limited safety data available at the time of a new drug approval." (This warning originates from "Timing of new black box warnings and withdrawals for prescription medications in JAMA 2002").

Evidently, the me-too concept and need for enhanced efficacy is catching up globally, thanks to Indian Patent Act.

The statute of "Patents" originated with a positive intent of protecting innovation to reward the inventions. However, over the last 20 years, there have been overzealous, organized, orchestrated, mischievous initiatives to throttle the use of patented knowledge even after the ever-increasing period of patent protection. This has led to plethora of disputes and litigations. Even the US has moved closer to Indian and other nations, in introducing an IPAB (Intellectual Property Appellate Board) style appeal board in the latest amendments in 2011 to the 35 USC (US Patent Act). Post-WTO/TRIPs, there have been concerted efforts to convert India also into a "Patent-Litigating" state (like the US) rather prematurely. Unlike in the US, this over-enthusiasm for patent litigation is likely to attract the wrath of the masses, over and above the

NGOs and the civil society.

Dr. Yusuf Hamied of Cipla had received enormous global accolades for his strong anti-evergreening actions and responses. So far so good, though India had not been forthcoming in such appreciation, domestically. The era of post-TRIPs pioneers like Keayla are almost coming to an end.

The silver lining could be that, the frivolous patenting and frivolous litigation era of the TRIPs-transition may also be coming to an end. This could lead to some serious innovation phase in India. It must be admitted that Indian Pharma cannot ride on its laurels of being a global generic leader being the third largest in volume and 13th largest in value. This statistics indicates that there is substantial scope for value-addition/value - creation, value - generation and value-extraction by moving from routine standard generics to innovative generics in the first phase, innovative biosimilars thereafter and NCE/NME molecules in the long run, 10 to 20 years from now.

“Innovation, Innovation and Innovation” is the mantra for the Indian pharma industry. A “Pretty Picture” need to be directed, with “improved quality of life” and “healthy living for all” as heroes and heroines, eliminating not only the villains of mortality and morbidity for the billion-plus population of India, but also extending the pharma innovation thrust and benefits to the global community. Let us hope that a “Pretty Picture” emerges for the Indian Pharma, with innovation as the theme for a happy and healthy future.

The author is CEO & Principal Patent Attorney, Gopakumar Nair Associates