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Generic



Patent

Legal battles

Patents vs generics: Who will rule?

India being a progressing economy, product innovations attract very few investments from the industry players. Increasing costs of drug development are a mammoth hindrance for countries like India. Being a leader in reverse engineering innovator drugs, India has made a definitive mark for itself in the global healthcare market.

With niche markets such as biologics, biopharmaceuticals and contract research gaining momentum, and their patents expiring in the next few years, pharma players are taking keen interest in the generics segment. Moving up the value chain would require Indian pharma companies to upgrade their profiles in the international market. USA and Europe is also dispensing a good number of generic drugs to the patients. However, there seems to be an urgent need in the west to shift focus back to research.

Between 1995 and 2013, the Intellectual Property Rights (IPR)/patent river has been flowing turbulently enough. The 'doomsday omens and prophecies' by pharma pundits have been proved wrong till now. Early grant of product patents, post-2005 did result in extensive, often frivolous infringement suits, injunctions, counter claims and revocations. Other than the section 3(d) litigations, majority of suits and writ petitions were relating to patent-regulatory linkages. Despite early settlement by the Delhi High Court and the Supreme Court, the legal battle continues to be dragging on in various courts, owing to adjournments. 'Patent is valid, but not infringed' judgements are under appeal by both sides. Frivolous

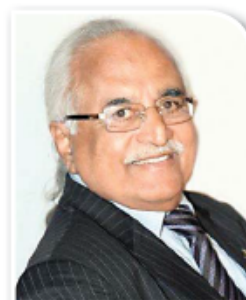
litigations on incremental innovations, between Indian pharma companies are mostly driven by 'market-share' ego-trips are also increasing.

To predict the pharma scenario in India in 2020 with specific reference to patented molecules and dosage forms vis-à-vis generics is no tall order. Dr Gopakumar G Nair, CEO, Gopakumar Nair Associates, opines, "Generics are here to stay and will continue to be in the pink of health in 2020 too. By 2020, the early challenges to patented molecules viz, New Chemical Entity (NCE) will substantially diminish. However, licensing of patented molecules to Indian domestic companies (often more than one) will increase substantially, thereby extending the early reach of advanced 'life saving' and 'quality of life' medications to a wider cross-section of the needy community.

It is predicted that the pharma patent litigations will come down in days to come by 2020. There will be 3 types of pharma patent litigations raging in India - NGO-driven, greed-driven and ego-driven. NGO and generics driven litigations will continue to be related to lack of affordable access, non-working, government use and compulsory licenses. The greed-driven litigations will continue to be driven by evergreening intentions despite section 3(d), especially since

the new drug pipeline is drying out. Litigations against Indian born NCEs and dosage forms are unlikely in 2020 or thereafter, because issues like Form 27, non-working, not manufactured in the country, unreasonable price etc, are unlikely to come to play in such patents."

"If the current trend is to be extrapolated, the third category of ego-driven patent litigations is expected to increase by 2020. These litigations will follow the path of 'mother of all ego-driven pharma patent litigations' ie, the 'Gleevec' patent battle. Ego-driven litigations in pharma patents are most likely to be played between Indian generic companies than between MNCs and Indian companies. MNC patent wars are mostly in the second category of greed-driven litigations. The segment-wise leadership issues, market share disputes, infringement of incremental innovations, disputes on confidentiality violations (due to migration of resources and IP stakeholders) are likely to be drivers for such pharma litigations in 2020," Nair reiterates. **MR**



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Dr Gopakumar G Nair
CEO, Gopakumar Nair Associates

Key takeaway points

- » Pharma industry shifting focus towards generics
- » Confidentiality violations
- » New drug pipeline is drying out
- » Frivolous litigations on incremental innovations