Business Standard

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Rising legal costs stump pharma companies

Industry has to spruce up its legal armament, while driving ethical business practices, say experts

During the past couple of years, the Rs 72,000- crore Indian pharmaceutical industry has been at the receiving end of a backlash from global and Indian regulators. Apart from damage control to its brand image, the legal expenditure of major Indian drug makers has seen a steep hike. According to data from company annual reports, the legal expenditure of the top 10 drug makers in India has gone up on an average anywhere from 30 to 300 per cent in the past three years.

In a double-whammy of sorts, this comes at a time the industry is experiencing a slowdown in growth, largely attributed to the new drug pricing policy and the regulatory interventions. Legal experts feel that the globe-trotting pharma industry's legal expenses are set to balloon further, if it does not set its house in order when it comes to meeting regulatory compliances and manage its Intellectual Property better. **(PHARMA: RISING LEGAL SPENDS)**

Trouble at home

"The IPR regimes are very litigious. The foreign MNCs employ a battery of in-house lawyers. To this extent, the Indian companies are inadequately staffed," says D G Shah, secretary-general, Indian Pharma Alliance. Industry players point out that most of the litigation costs relate to the United States market. "It has become almost impossible to launch a new generic without inviting a lawsuit in the US," says Shah. The regulatory challenges relate mainly to drug registration and approvals in India and abroad. Increased scrutiny and stringent norms by the US Food and Drug Administration and other regulators and non-compliance issues are forcing Indian companies to spend more on legal advice, says Milind Antani, head of pharma and life sciences practice at law firm Nishith Desai Associates. In-house legal teams have not proved adequate to take on the rising legal challenges.

Indian regulators recently changed norms over pricing regulations creating a furore among the drug makers. Top Indian drug makers, including Cipla, Cadila Healthcare, Glenmark, Ranbaxy and Dr. Reddy's Labs are under the scanner of the National Pharmaceutical Pricing Authority (NPPA) for allegedly selling anti-asthma drug Doxofylline without prior price approval. The Ministry of Chemicals and Fertilisers had issued a notification to implement the order demanding pharma companies to reduce prices of 348 medicines. Dealing with such regulatory activism at home has added to the industry's headache.

In the recent past, the Indian companies have shown strong aggression over challenging patents of global pharma majors. "Pre and post grant oppositions and following compulsory licences are becoming common in India, causing increased expenditure for court procedures," says Sujay Shetty, leader - pharma and life sciences, PwC India. In March last year, India had granted its first compulsory licence, by ordering Natco Pharma to sell Bayer's cancer drug, Nexavar, after Natco challenged Bayer's patent in India.

Natco's success has motivated many mid-sized Indian companies to take on global companies in court

while challenging their patents at India. Local drug maker BDR Pharmaceuticals had challenged Bristol-Myers Squibb's patented blood cancer drug Dasatinib for allowing a compulsory licence in India.

According to experts, Indian companies' eagerness to tap fast-growing generic drugs market in the US, also force these to spend on large fee for US attorneys. Seema Singh, head, legal & intellectual property management at Macleods Pharma, notes: "Many of Indian mid-sized companies are ready to challenge US patents through paragraph IV litigations, which adds to their legal expenditure." The cost of filing paragraph IV abbreviated new drugs applications (ANDAs) can range from $5,000-10,000 for attorney's plain opinion writing for one patent to $2 million till the time of litigation gets concluded. This is set to go up again as the US FDA has decided to charge $60,000-70,000 as filing fee for each ANDA submission from October onwards. Indian companies hold about 10 per cent share of the $30-billion US generic drug market.

The way forward

According to Sarabjit Kour Nangra, vice-president, research, pharma, at Angel Research, Indian companies need to spruce up their documentation capacity as these enter newer markets.

Pravin Anand, managing partner, Anand & Anand, feels if the pharma industry harbours dreams of being a global player, it must be seen to be ethical in its practices first. On ways to contain rising legal expenses, his advice to pharma companies is - "be strategic in your legal fights".

However, there is no alternative to keeping one's house in order when it comes to compliance-related issues for goods manufacturing, laboratory or clinical practices. The way forward for the domestic industry, feels Shah, is to start dialogue with key regulators, such as the US FDA, and work jointly towards capacity building and training.