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Navigating the Indian legal maze: Challenges

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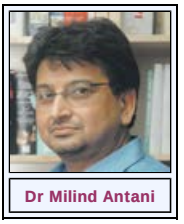
Dr Milind Antani

Around 30 years ago when eminent author Robert Schuler penned down one of his excellent works 'Tough Times Never Last but Tough People Do', he would not have thought that this will hold so true for the pharmaceutical industry in present day India.

2013 has been a particularly tough year for the Indian pharma industry. This is in sync with the slowdown of Indian economy and the record depreciation of its currency.

To add to the woes, the pharma sector was adversely affected by unpredictable and often sweeping changes in the Indian legal and regulatory regime. The legal woes were accentuated as Indian courts put emphasis on 'public interest', placed premium on therapeutic efficacy like never before, and expressed concern on clinical trial subjects. It has also been a year when various malpractices committed by Indian pharma companies were reported and led to serious consequences.

These developments have placed some pharma companies in a tight spot with their stocks taking a heavy beating at the stock markets and adversely affecting their growth prospects in both India and overseas markets. In this backdrop, it is imperative to understand the legal developments as well as why and how pharma companies can adopt various risk mitigation strategies to ensure adequate adherence to the laws.


Anay Shukla

This year, Indian pharma companies received an unprecedented number of import alerts from United States Food and Drug Administration (US FDA). An 'import alert' is an announcement by the US FDA when it determines that there is considerable possibility of a drug produced at a certain facility being adulterated, misbranded or unapproved. A drug produced at a facility that has been issued an import alert is detained by the FDA or denied admission within the territory of the US. Naturally, import alerts result in significant loss of revenue as well as reputation to a company. As per the official data available at this time, 19 facilities located in India received import alerts in 2013.

The principal reasons for a spurt in these alerts are as follows. First, US FDA has increased the number of inspectors assigned to India who conduct unannounced inspections, a practice which was not followed earlier. Second, there are reports of possible non-compliance by Indian companies. An analysis of import alerts issued to Indian facilities indicates that most defaults were due to absence of data integrity and vendor due-diligence. The reason for this was possible lack of awareness. It is extremely important that each individual in the production chain is made aware of legal risks of non-compliance. Due-diligence of vendor must not be compromised since it will expose the history of non- compliances and lead to potential recall of products as per the applicable law.

Also, this year, India's product patent regime has faced intense criticism from media as well as the industry bodies for its failure to protect pharma patents. Principally, the criticism is on three grounds 1) denial to award patent for improvement or modification; 2) possibility of grant of compulsory license, and; 3) option to apply for revocation of existing patents.

Section 3(d) of the Patents Act, 1970 covers the subject of patentability of improvements or modifications of a

known substance. It holds, amongst other things, that a new form of a known substance that does not result in enhancement of the known efficacy will not be considered as an invention hence is not patentable. In the Novartis case, the Supreme Court of India found Novartis' molecule to be a 'new form of known substance that did not result in enhancement of known efficacy'. In arriving at this conclusion, the Court chose to interpret efficacy as 'therapeutic efficacy'. The critics of the case observe that the Court has defined 'efficacy' too narrowly, and thus weakened intellectual property protection afforded in India to innovator drugs.

Though the merits of the judgement will continue to be debated, the industry must learn from the Supreme Court ruling and take effective measures to ensure that it is not caught on the wrong foot. All innovating companies must ensure that their patent application contains data that indicates 'therapeutic efficiency' in their innovation. This can help negate a possible challenge under Section 3(d) in future. The catch here is that, the data to indicate 'therapeutic efficiency is not usually available at the time of making a patent application. So, the validity of patent claim may boil down to the proper drafting of a patent application.

Next, let us examine the controversy surrounding compulsory licensing. As per the World Trade Organization (WTO), compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. In the context of pharma patents, it means that compulsory licensing is a license granted to an applicant to manufacture and sell a drug over which there is a patent in existence. Compulsory licensing arrangements are usually coupled with revenue sharing.

Till date, India has granted only one compulsory license to Natco pharma for Bayer's cancer drug 'Nexavar'. In contrast, it is reported that fifteen countries, including developed and developing countries, have issued more than 35 compulsory licenses. The licensing authority took strong note of the fact that Nexavar was not domestically produced and records showed that its import into India had not been consistent. Thus, the exorbitant price of the drug coupled with absence of access to the drug contributed to the Government's decision.

Each player in the pharma industry who may be affected by this decision should take some cues from the approach of the licensing authority. It should ensure availability of the patented drug in quantity in the Indian market that is sufficient to meet public requirement. Secondly, it should ensure that its patents are 'working on a commercial scale', that is, its patent drugs are utilised by the public in a commercially meaningful way. It is vital for the patent holders to file Form 27 to show working of patents. It is equally important to furnish adequate and correct information so as to avoid the risk of being penalised under the provisions of the Act. Further, all efforts must be made by the patent holder (either directly or through its licensees in India) to work the patent in India, else the patent may become susceptible to compulsory licensing. The expressions like 'public requirement', 'commercial scale' and 'reasonable price' are terms whose interpretation will depend upon facts and circumstance of each case and legal precedents decided by a court of law. Therefore, it is suggested that the industry should keep itself abreast of such legal developments.

Lastly in relation to product patents, let us examine the issue of patent revocation. The international media has taken strong note of the fact that in the past one year, India has denied or revoked nearly half-dozen patents. The Patents Act, 1970 allows opposition to a patent after it has been granted to a patentee within one year of the grant of the patent. This provision has been used by numerous generic companies and non-governmental organisation to oppose grant of patents. It is to be noted here that the post-grant opposition may be made only on a limited grounds specified under Section 25(2) of the Patents Act, 1970. Furthermore, the success of grant of opposition of patent only indicates that it did not deserve patent in the first place.

In addition to the patent law related developments, the industry witnessed quite a few regulatory changes this year. Two of them have had the most significant impact on the industry – the introduction of a new drug price control regime and notification of rules for compensation to be provided in case of clinical trial related death or injury. Let us examine each of the development separately in the following paragraphs.

The new drug price control regime regulates prices of essential medicines only. The price of the medicines is fixed based on the average of the market price of drugs belonging to the same category. This is major deviation from the earlier price control regime. The new regime affects 21 per cent of the industry, as opposed to the old

regime which affected 4.5 per cent of the industry. The new drug price control regime is captured under the Drug (Prices Control) Order, 2013 and the priced fixed by the Government is referred to as 'ceiling price'.

The implementation of this regime has posed unique questions before the industry. What happens when the drug is the only drug in its category? What happens if a competitor deliberately prices its drug below its cost price as a form of predatory pricing? The industry is also faced with certain practical difficulties. The 2013 order mandates that the new ceiling prices must be reflected on all drug containers and packages within 45 days of notification of the price. The easy solution to this problem would be if the players in the supply chain, which include the carrying and forwarding agent, the stockists, the distributors, the retailers etc. who are in possession of the drugs could stick a new price label to the drug. However, any form of alteration or modification to label is prohibited by The Drugs and Cosmetics Rules, 1945 as well as Central Excise Act, 1944. The government agency that is enforcing the 2013 order is unable to seek some sort of reprieve from the government agencies enforcing the 1945 Rules and the1944 Excise Act due to co-ordination issues. This possibly will lead to either product recall or challenge before a court of law. Recall is not feasible since it procedurally impossible to recall products in 45 days from the market. This leaves affected companies with no other option but to challenge the 2013 order in court of law.

We will also discuss the formal framework on compensation to be granted to clinical trial subjects for clinical trial related injuries or deaths. This was put in place by the Indian government in January this year by amending the Drugs and Cosmetics Rules, 1945. Under the present framework, the compensation is decided by the Drugs Controller General of India on the recommendation of an expert committee. The process for compensation has been made automatic which gets triggered as soon as an injury or death occurs. The new framework also imposes a strict liability on the sponsor of the trial to pay for compensation as well as pay for medical management of the subject for any injury that may arise in course of the clinical trial even if the fault lies with the investigator or the site. The compensation awarded by the DCGI may range between Rs 4 lakhs to Rs 72 lakhs. These changes have created concerns with 'claims-based' clinical trial insurance policies as technically the victim or his or her representative usually claims from the investigator. It is suggested that all existing insurance policies must be vetted to ensure adequacy of coverage. It appears that the new framework will not apply retroactively because the amendment does not expressly provide that it will apply retroactively as well, and there is some judicial precedent to adopt his view. Apart from the insurance policy, the language in the contract between various stakeholders will play significant role in deciding the liability of providing compensation.

Another regulation that is likely to impact pharma industry in India is around product promotion. Though the Code of Marketing Practice for Indian pharma industry by the Dept of pharmaceuticals is voluntary at the moment, it will have far reaching impact, as it is also linked to the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, once it becomes legally binding. It is important that the companies have their strong policies regarding product promotion to avoid prosecutions in future.

The last legal development worthy of analysis and discussion concerns both policy and law - foreign direct investment (FDI) in a pharma company. At present, FDI up to 100 per cent is allowed in a green field company without prior approval of Foreign Investment Promotion Board (FIPB) and up to 100 per cent is allowed in a brownfield company with approval of the FIPB for a company in pharma sector. Since FIPB has been granted the power to impose conditions when granting approval, it can add to the legal hurdles which a foreign investor has to cross. This can adversely affect in-bound investment in Indian pharma sector.

However, all is not lost for the India pharma sector. Those industry players which are efficient, innovative and manage to safely navigate the legal maze will come out winners.