EXPRESS Pharma

Insight

Legal due diligence: Key to successful M&As in pharma industry

Mergers and acquistions may be the fastest way to grow, but they need to be preceded by a thorough due diligence exercise, cautions ***Dr Milind Antani*** *– Head Pharma & Life Science Practice,* ***Nishchal Joshipura*** *– Head M&A Practice and Vedant Shukla – Associate, Nishith Desai Associates*

The theory of natural selection, even though not meant for the corporate world, is squarely applicable to contemporary corporates. Evolve or perish seems to be the mantra for doing business in the present times. As a result of the constant evolution, corporates tend to adopt various strategies to expand and innovate and one such strategy is to pursue 'Merger and Acquisitions'.

M&A has been the most preferred strategy used by corporates to expand into both domestic and foreign markets due to various benefits attached to it such as creating synergies and economies of scale, expanding operations, cutting costs, enhanced market power and reach. However, before growing inorganically, it is essential for an acquiring company, to get all possible information about the target company so as to make a reasoned and informed decision.

The basic yet most effective tool to accumulate information about the target company is to conduct a proper and thorough legal due diligence on the target company. Legal due diligence is simply an investigation into the target company, which is undertaken by the counsels of the acquirer company, for ascertaining the level of compliance and adherence of the target company with the legal and regulatory requirements prescribed by law and followed by the industry.

In the pharmaceutical industry, a proper due diligence becomes all the more important due to the risk that this sector entails with regard to litigations and heavy dependence on the licenses and approvals which are required to operate the business.

Elements of due diligence

In order to extract information from target company, a thorough review of all the documents related to the target company is imperative. However, while capturing the data for the due diligence process, it is essential to keep some basic objectives in mind such as ascertaining:

- accuracy of the past data
- knowledge about the target's existing key personnel, suppliers and customers
- whether the target has good title to its assets, free from any encumbrances
- whether those assets are worth the value that target attributes to them; and
- whether there are any existing liabilities (known, unknown and contingent) ongoing or past, contracts that may manifest themselves in the future to disrupt the operation or financial performance of the target.

Apart from the general objectives listed above, emphasis shall be given to the following topics, while conducting a due diligence on a pharma company:

- **Corporate Structure and Compliances**: It is important to ascertain the corporate structure of the target company and also to ascertain whether there are any shares which carry any differential voting and dividend rights and if yes, what shall be its implications on the current acquisition. This is of significance as most Indian pharma companies are family owned. Apart from the above, it is also important to undertake a thorough review of the corporate compliances of the pharma company as non-compliance may attract stringent penalties and also imprisonment in certain cases.
- **Approvals and Consents**: Since pharma industry is a highly regulated industry a special emphasis should be on the review of the approvals and consents obtained by the pharma company and the status of the same. It is important to record separately and analyse the consents and approvals which are on

the verge of expiry and what is the importance of such approvals in the scheme of the business of the pharma company. With the growing concerns over environmental pollution, it is important to check whether the pharma company has obtained all applicable environmental clearances and whether any of those clearances are due for approval in near future. Typically, a pharma company is required to obtain a number of approvals and consents including, but not limited to, approvals from Drug Controller General (India) (DCGI) regarding import, manufacture, sale and distribution and conducting clinical trials, Good Manufacturing Practices (GMP) certification, approvals from Indian Council of Medical Research (ICMR) and Department of Biotechnology. Another set of licenses and approvals that are pertinent to pharma industry and bear significance are licenses obtained in relation to the manufacturing facilities including license under Factories Act, 1948, registration from industrial departments, Pollution Control Board, Boilers Act, Explosive Department's license and all the licenses related to environmental matters including disposal of biomedical wastes, etc.

- **Intellectual Property (IP)**: In pharma industry, competitive differentiation is created by the pharma company by constant innovation and by obtaining adequate IP registrations with regard to the innovation. Thus it becomes all the more important that while conducting due diligence on a pharma company, a special emphasis is given to the diligence with regard to the IP owned by the pharma company. There are various aspects of IP of a pharma company that must be reviewed, such as the coverage of the IP that the company has. For eg. what kind of the products are protected by IP and within how many years does the patent expire, territorial protection that IP has (eg. what are the key territories for the supply of the product and whether the product is properly protected in those territories?) Also the ownership of the IP and confidentiality in case of know-how must also be properly reviewed. It is also important to find out if the pharma company is using any IP that is licensed by a third party and any issues related thereto as well as the status of any IP developed in-house, since ownership of IP has a significant impact of the future cash flows of the company.
- **Assets**: While conducting a due diligence on the assets of a pharma company, the documents must be analysed so as to ascertain whether the pharma company has a valid title over the assets and the assets are free from any encumbrance and lien. It is also important to check whether there are any risks, liabilities, or commitments that may reduce the value or use of those assets and whether there are any other existing or potential liabilities that may adversely affect the business. The pharma company is also required to obtain various certifications for the premises like Schedule M compliance and US Food & Drug Administration (US FDA) approval. It would also be necessary to know the status of these approvals while doing due diligence of the pharma company.
- **Litigations and Penalties**: In a pharma company, litigations generally entail huge amount of monetary consideration and consequently heavy risk and thus it becomes important to study very closely the litigations by and against the pharma company, the risks involved and the estimated damages / costs involved in such litigation. Also, it must be closely studied whether there are any sanctions or penalties levied / pending against the pharma company by any governmental authority anywhere in world for any breach or non compliance of any of the regulations and what is or shall be the quantum of sanctions involved? It would be worth assessing if the Indian pharma company is involved in litigation or penalties by respective FDA of the country as well as any patent related litigation in India or in any other country.
- **Material Contracts**: Contracts form an integral part of any business and especially in pharma sector such contracts might be the most valuable asset of a company. Thus it is pertinent to capture the important contracts such as technology agreements, supply agreements, distribution agreements, property transfer related agreements, IP transfer agreements and collaboration agreements especially with reference to liabilities, term, scope i.e. exclusive or non-exclusive, payments, territory and duration etc.
- **Listed companies**: In case the pharma company is a listed company, a thorough review should be done as to whether the pharma company is in compliance with the various regulations promulgated by Securities and Exchange Board of India (SEBI) such as Takeover code, Insider Trading regulations, etc. In addition to the above, adherence to the Listing Agreement and other circulars by the relevant stock exchanges must also be verified.
- **Exchange control compliances**: If the pharma company has transactions involving foreign investments, overseas borrowings or has a subsidiary outside India, then it is important to check whether the pharma company has adhered to all the applicable compliances provided under relevant regulations promulgated under Foreign Exchange Management Act, 1999. However, if the acquirer is a foreign entity and has an existing joint venture or technology collaboration agreement then it becomes important to check if the acquirer has adhered to Press Note 18 of 1998 and Press Note 1 and 2 of 2005.
- **Product Portfolio and Drug pipeline**: It is essential to know the list of the products being imported, manufactured, distributed or under development of the pharma company and applicability of Drug Price

Control Order (DPCO). However, from a futuristic perspective, it would be important to review the business plan of the pharma company so as to understand about the kind of the products that the pharma company is in process of development and also to understand about the capital expenditure which the pharma company may incur for development of such products. To understand the portfolio of product in pipeline and their status would be very crucial as may change valuation of the pharma company.

Due diligence analysis:

The most important stage, after capturing the information is to translate the information into a report highlighting the pertinent issues which may have a bearing on the transaction. The reports should highlight:

- The issues which are sensitive enough to be deal breakers
- The appropriate structure for the transaction-asset purchase or share acquisition
- Existence of change of control and non-assignability issues and its effect on the transaction
- Taking care of any non-compliances or violations etc by corrective action and
- Whether any adjustment in the valuation is required.

Key to successful M&A

Due diligence is a lengthy and tedious process, but at the same time is crucial from acquirer's perspective.

The number and magnitude of recent M&A transactions (Daiichi-Ranbaxy, Abbott-Piramal, etc) indicate that the size and magnitude of M&As in pharma space is set to increase. Due diligence is a key component in any M&A transaction and thus it is important that the due-diligence not only focuses on highlighting issues that might pose potential risks, but also resolves the issues in a constructive manner. Thorough due diligence is key to a successful M&A transaction.

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