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FDI in Pharma

Need to look beyond non-compete clause

The government should bring in clarity in identifying brownfield and greenfield investments

The Department of Industrial Policy and Promotion, Ministry of Commerce and Industry has recently announced that the existing foreign direct investment (FDI) policy in the pharma sector will remain unchanged, except with a condition that that the non-compete clause will be permitted only as an exception, with prior approval of the Foreign Investment Promotion Board (FIPB).

The decision will, hopefully, keep the spirits of the foreign investors intact while protecting the interest of domestic players. The decision to maintain the status quo on FDI caps will send a message to the international investor community that India has stable FDI policies; after all, a perception of an unstable policy environment will affect the decision of any investor in committing large funds.

Whether the protection provided to the domestic pharma manufacturing companies will be as effective as anticipated or not will be clear only after the implementation of the policy. However, it is important to understand the broad contours of the non-compete clause and its implications, especially for the pharma sector.

As the nomenclature suggests, a 'non-compete' clause in an investment agreement restricts either party in a JV or the acquired entity in an acquisition from engaging in a similar business for a mutually-agreed period which, as per market standards, could range between three to seven years, depending upon the profitability of the entity or other business requirements. As a thumb rule, any non-compete clause is narrowly drafted as it is designed to further a legitimate business justification, such as to ensure that the acquirer is able to put the assets purchased to their productive use.

There is no doubt that the non-compete clause provides reasonable protection to any investor against arbitrary competition from its own JV partner or from the promoter who has recently exited the business and has the know-how after selling it to the investor at a fair market value. However, it may not be so important for the pharma industry which is primarily driven by the ownership of patents and other intellectual property rights (IPRs).

In case of a brownfield investment, the Indian promoter/sellers will automatically extinguish their rights in any patent or other IPRs by selling their stake in the Indian drug manufacturing company or the drug business itself. The non-availability of the non-compete clause will only permit the Indian promoter to start a new venture for manufacturing generic drugs, which may not be in direct competition with the foreign investor. Hence, the absence of non-compete clause in the investment agreement will have minimal impact on the decision of the foreign investor for investing in India. For greenfield investments, especially in case of joint ventures, it may be important, but cannot be a guiding factor.

AKASH GUPT

The pharma non-compete clause may not be very important for the industry as it is primarily driven by the ownership of patents and other intellectual property rights

The way the Press Note has been worded, it appears that even in case of a greenfield investment, should there be a non-compete clause, the same may also attract a prior FIPB approval. This is specifically because the words "non-compete clause would not be allowed except in special circumstances with the approval of FIPB" are not linked only to brownfield investments. The government should clarify this, as a mandatory FIPB approval in the case of greenfield investments would be going back on the policy.

It was expected that while revisiting the position for the pharma sector, the government will also consider the existing outstanding issues in the policy which require clarity. First, the sector needs to be defined; does it comprise singularly drugs as defined under The Drugs and Cosmetics Act, 1940, or does it also cover all allied medical products, equipments and apparatus that are used in the medical industry? On one hand, this will bifurcate the foreign investment in appropriate verticals and help retrieve more logical data of FDI, while on the other, it will save the Indian companies engaged in allied medical products from going through the stringent approval process.

Second, the parameters for classifying investments as greenfield or brownfield need to be clarified. Usually, foreign investment related to the setting up of new assets/facilities is referred to as greenfield and the purchasing of existing facilities/assets or assuming ownership of or acquiring stake in an existing company is classified as brownfield investment. Accordingly, the foreign investment for setting up of new assets/facilities needs to always be treated as greenfield even if it requires additional funding for expansion or otherwise at a later date. Similarly, reorganisation of an existing investment within the group is neither brownfield nor greenfield. However, at present, FIPB approvals are being granted for the above situation classifying them as brownfield investment. Equally important is the determination of the point a project becomes brownfield, i.e., whether during the construction phase or post commencement of commercial production or after the commercial launch of product in the market.

On the implementation part, brownfield investment needs to be considered at the project level as against at the company level. This will be in line with the FDI policy for the construction sector wherein brownfield investment classification is made at the project level. This will reflect a more stable and analogous FDI policy across sectors.

Press Note 1 of 2014 also states that the government may incorporate appropriate conditions for FDI in brownfield cases at the time of granting approval. Currently, FIPB incorporates three standard conditions relating to the National Essential List of Medicines, R&D expense and technology transfer in all approval letters. It would be useful if the government can clarify on the guidelines/guiding factors which it will consider at the time of vetting applications. This will help avoid any confusion and bring transparency in the approval process.

We expect the government to look into these issues for furthering clarity and strengthening the investor belief, thereby creating a win-win situation.

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