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Single Brand Retail – Relaxation of Local Sourcing Condition

India Grants its First Compulsory License

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Single Brand Retail – Relaxation of Local Sourcing Condition

The Government of India ("GoI") is actively considering relaxation of the 30% local sourcing requirement presently applicable to single brand retail trading ventures wherein foreign equity participation exceeds 51%.

The requirement of sourcing 30% of the value of products from small industries, village and cottage industries, artisans and craftsman was prescribed by the GoI in January this year while allowing foreign investment beyond 51% in single brand retail trading ventures in India. The condition has proved to be a major impediment for brand owners wishing to invest in India owing to concerns over availability and seriousness of small suppliers, quality control and protection of intellectual property rights.

GoI is considering whether to relax the sourcing requirement for all single brand retailers, or to provide for GoI to relax the condition on a case to case basis, if the foreign investor establishes technical or practical impossibility of sourcing whole or part of its products from small suppliers.

The relaxation would make life easier for the investors. The policy would, however, require additional clarifications, inter alia, on some of the other issues highlighted in our newsletter of January 11, 2012.

Indian Grants its First Compulsory License

The Controller General of Patents Designs and Trademarks ("Patent Office") on March 12, 2012 granted its first ever compulsory license to the Hyderabad based Natco Pharma Limited ("NATCO") for a cancer drug sold under the brand name "Nexavar" owned by a German based company Bayer Corporation ("Bayer") and which until now was more or less inaccessible to the common man.

The Patent Office believes that NATCO's application qualified for the grant of a compulsory license under Section 84 of the Patents Act, 1970 ("PA 70") on three main grounds, viz.:

- Bayer was able to supply the drug only to about 2% of the India's patient population thereby unable to fulfill the reasonable requirements of the public within the meaning of Section 90 of the PA 70;
- the price of the drug was not affordable [monthly cost of the drug per patient being INR 2,84,428 (US$ 5689)]; and
- the drug was imported and not manufactured in India.

With a compulsory license, NATCO will be able to manufacture, sell and distribute the drug indigenously, thereby making it affordable to the common man. NATCO has announced that its drug will be sold at the rate of INR 8,880 (US$ 178) for a month's dose.

The Patent Office has also attached certain conditions to the compulsory li-

cense, such as, maintenance of account of sales; payment of royalty to Bayer at 6% of the net sales on a quarterly basis; and supply of the drug for free to at least 600 needy and deserving patients per year.

Although a revolutionary step, the compulsory licensing invited mixed reactions from the industry. While the Indian Drug Manufacturers Association applauded the Patent Office's decision, the Organisation of Pharmaceutical Producers of India maintained that compulsory licenses should be given in exceptional cases only, such as, national health crisis, which was not the case here. Some believe that such compulsory licenses would highly discourage pharmaceutical companies from investing in Research and Development of innovative drugs in the proportions they invest as of date. Arguably, such compulsory licenses may lead to disturbance of international patent regime together with dilution of patentee's intellectual property rights in its drugs as it may start a ripple effect and encourage other pharmaceutical companies as well to seek compulsory licenses.

The decision has gained support from the social sector, which says that the decision reminds the patentees not to arbitrarily charge exorbitant amounts in the name of innovative drugs.