First Compulsory License Granted in India on Buyer's Patent

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The first ever grant of compulsory license in India took place in the case of Nacto Pharma Ltd Vs Buyer Corporation as Controller of Patents; Mumbai decided the application on March 12, 2012 and allowed the same for patented medicine 'Sorafenib' which is sold under the brand name of Nexavar and used for the treatment of Renal Cell Carcinoma- RCC (Kidney Cancer) and Hepato Cellular Carcinoma (Liver Cancer).

The patent was applied in India by 'Buyer' after PCT phase was over on 05th July' 2001 and was granted on 03rd March' 2008. Natco's application was made to the Controller of Patents on 29th July' 2011, for the compulsory license under Sec.84 of Patents Act, 1970. Natco contended various grounds including, non-fulfillment of reasonable requirement of public; unreasonable and unaffordable price and non- working of invention in India.

Natco claimed to sell the drug for 88,000 Rs as compared to the Buyer's price of same 280,428 Rs. Also, question of availability of drug in market was substantiated against the Buyer (Patentee) as drugs were never exported in the sufficiency to meet the requirement.

Buyer contented that another generic pharmaceutical company Cipla is selling infringing product of the same medicine Nexavar and for which they've filed an infringement Suit. The market share of Cipla's infringing drug is much higher as the cost of infringing drug is lesser (30,000Rs) and the total market need is hence satisfied if the sell by Cipla is accumulated. Tribunal opined that the sales of infringing goods cannot be taken into account as its liability of Patentee to make the product available for people and not of infringer.

Also; taking into account various statistics made available by both the side about the number of patients and pricing methods and norms applied in various cases; the tribunal concluded that the during the last four years the sales of drugs by patentee at the price of 280,000 (for a therapy of one month) constitute a fraction of requirement of public and was not available to the public at reasonable affordable price.

On the issue of non-working of invention in India; applicant alleged that patentee did not worked the product in India as it was being to imported from the outside; whereas patentee

has been working the patent in other countries since 2006. On the other hand patentee argued that even minimal working would satisfy the requirement set by sec. 84(1)(c), which was rejected by the Tribunal by saying, minimal working is no working at all and a invention must be worked out to its fullest extent and possibilities to escape from the rigor of Sec. 84(1) (c).

Further, the Tribunal decided to its satisfaction to grant the Compulsory License to Natco Pharma on the following terms:

> The price of the drug covered by the patent and sold by the licensee shall not exceed Rs. 8880 for a pack of 120 tablets, required for one month's treatment. Licensee has to give account of sales every quarterly and has to pay 6% royalty to the patentee. Patentee will not be restraint to compete with licensee in any manner and he could enjoy his residual rights. Licensee does not have rights to represent itself in relation to said patent and he cannot outsource the product from elsewhere. The license conferred is non-exclusive; non-assignable and to be worked out within the territory of India and does not cover right to export or import. Only licensee will have product liability for its manufacturing. And also; licensee has to distribute drug, free of cost to 600 needy and deserving patients per year.

Reading the terms of judgment it really seems bit philanthropic but this very case can give rise to opening of flood gates for similar applications and that could be very detrimental to the development of pharmaceutical industry. Also, the Buyer lost the battle because it was inherently on the fault and was not much concerned about his duties as a patentee. It has been shown by them in the case also were they kept changing stances and their initial aggregation want to be proved as failed defense. An appeal against the decision would be foreseen but certainly this decision is remarkable in many ways.