India – Natco Pharma obtains compulsory license to manufacture Bayer's patented 'Naxavar' anti-cancer drug

In an eagerly awaited decision, India's Controller of Patents has granted a license to generics pharmaceutical manufacturer, Natco Pharma Ltd (Natco) to manufacture Bayer's patented anticancer drug 'Naxavar'. Although it may well be appealed, the decision is likely to result in a surge of applications for compulsory licenses in respect of expensive, potentially life-saving patented drugs.

Background

In response to patent infringement proceedings brought by Bayer, Natco applied to the Controller of Patents, under s.84 of the Indian *Patents Act,* for a compulsory license to manufacture the patented anti-cancer drug, Naxavar. For more details please see our earlier update in this regard as attached.

In essence, Natco argued that Bayer had not made the patented drug available to the public at a reasonably affordable price and, further, that it had failed to work the patent in India. It undertook to manufacture the drug for sale in India only.

Two controversial issues

Two important issues dealt with by the Controller were the interpretation of 'reasonably affordable price' and 'working' the patented invention.

'Reasonably affordable price'

This was hotly debated by both sides. Bayer argued that the price of its drug had to take account of overall R&D costs, which it demonstrated were rising every year. It argued that it was in the public interest to fund research into areas of unmet medical needs, and that this cost of such research was necessarily reflected in the price of patented drugs. Further, it raised a fundamental argument that has long been a cause of debate between generic and innovator companies: it is the prerogative of an innovator to decide what constitutes a 'reasonably affordable price'. Natco, on the other hand, relied on various studies to show that the price of Bayer's drug was clearly unaffordable for many potential users in India.

The Controller held that 'reasonably affordable price' must be construed predominantly with reference to the public and not the patentee and that, so construed, the price of Bayer's drug was not 'reasonably affordable'.

'Working' the patent in India

The interpretation of 'working the patent in India' has been controversial: does it mean manufacturing the patented product in India or commercially working the patent by way of importation of the patented product?

The Controller interpreted 'working' to mean local manufacture.

Our Comment

India is the second country in Asia, after Thailand, to grant a compulsory license in relation to a patented cancer drug. Clearly, the Controller's decision will be disappointing for research based pharmaceutical companies, and welcomed by generics manufacturers. It

is, however, likely that Bayer will appeal the decision, particularly in relation to the Controller's definition of 'working the patent'.

In the meantime, multinational pharmaceutical companies should consider taking the following steps to pre-empt compulsory license applications: (a) entering into licensing arrangements to ensure better distribution and (b) taking steps to introduce a differential pricing structure for the sale of patented drugs to different sections of the public.

Vatika Towers
10th Floor Block-B
Sector-54
Gurgaon-122002
National Capital Region (Haryana)
India

Tel. +91 124 4655999
Fax +91 124 4045047
Email info@indiaiprights.com