First compulsory licence in India serves as wake up call to global pharmaceutical firms

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In the first judgement of its kind, the Indian Patent Office has granted a compulsory licence to generic drug manufacturer Natco Pharma Limited to manufacture and sell Bayer Corporation's patented cancer treatment Nexavar. The judgement could have ramifications for how global pharmaceutical firms do business in India and other countries.

Bayer's drug Nexavar contains a patented bi-aryl urea which inhibits enzyme targets in the MAP kinase pathway. Since protein kinases are often overactive in cancerous tissue, the inhibitor was found to be useful in the treatment of advanced stage liver and kidney cancer. A patent was granted in a number of countries with the grant in India coming in early 2008. Although the drug does not cure the cancers outright, it does extend the life of a patient with kidney cancer by an average of four to five years, and with liver cancer by an average of six to eight months.

As discussed in our July 2010 Patent Prose Article, *Compulsory Licensing in a Nutshell*, every major patent system in the world has provisions for the government or court to intervene and grant a competitor the right to use or manufacture a patented invention if certain conditions are met. However, use of these provisions by governments to grant compulsory licences has been rare. In these rare instances, the governments have generally relied on a provision in the WTO's TRIPS Agreement which allows the grant of compulsory licences in cases of "extreme urgency" or "national emergency".

Indian patent law also allows for a compulsory licence to be granted by the Patent Office if certain other criteria are met. Firstly, a reasonable request for a voluntary licence must have been refused by the patentee. Natco Pharma had previously asked Bayer to grant them a licence to sell the drug, but Bayer had refused; therefore, this criterion was met. In addition, further criteria stipulate that a compulsory licence may be granted if the patentee has not:

(a) satisfied the reasonable requirements of the public with respect to the patented invention; or

(b) made the invention available to the public at a reasonably affordable price; or

(c) worked the invention in the territory of India.

Only one of criteria (a) to (c) needs to be met for a compulsory licence to be granted.

The Commissioner of the Indian Patent Office found that the first criterion had been met as Bayer had only made their drug available to about 2% of patients with kidney/liver cancer at the appropriate stage for treatment. In their defence, Bayer argued that the alleged infringement of their patent rights by another generic drug manufacturer had limited their sales. The Commissioner did not accept this argument, based mainly on the fact that Bayer is currently suing the other generic manufacturer for alleged patent infringement in an attempt to stop such sales of the drug. Therefore the reasonable requirements of the Indian public had not been met.

The second criterion requires the patentee to make the invention available to the public at a *reasonably affordable price*. There was debate about how this price should be calculated. Natco Pharma argued that a government worker would have to work for three and a half years to be able to purchase a month's course of the medicine at the standard dose (approximately $NZ6,600), and that this was not reasonably affordable. Bayer argued that the price of the drug is justified as it not only encompasses the considerable research and development costs to bring Nexavar to market, but must also fund a drug pipeline that includes many failed drug targets that do not make it to market. Bayer pointed out that since 2007, they have brought only two new molecular entities and one new combination product to the market; this for a cumulative research and development spend of 8 billion Euros.

The subjective nature of such a debate makes it hard to draw any firm conclusions on how a reasonably affordable price should be calculated. Bayer pointed out that if the equation is purely one in which the cost of production by a generic manufacturer is compared to the patentee's price, the generic will always win out. The Commissioner considered that despite Bayer's arguments, the primary reason that the drug was only used by 2% of the eligible patients was due to it not being reasonably affordable to them therefore the second criterion was also met.

The third criterion requires that the invention be worked in India by at least three years from the date of grant. This is a general requirement for any patented invention in India and a statement must be filed with the Patent Office each year stating how the invention has been worked. Critically, the Commissioner interpreted the term "work" to mean more than simply importing the invention and also requires manufacturing of the invention in India. Despite having manufacturing facilities for drugs in India, Bayer had not manufactured Nexavar, therefore, the Commissioner adjudged the third criterion for grant of a compulsory licence to be satisfied.

The judgement as it relates to the "working" requirement is likely to be a serious bone of contention for many patentees. It means that a competitor may potentially be granted a compulsory licence solely due to the fact that

the patentee does not manufacture their invention in India. This has ramifications for a huge number of international patent owners and raises serious questions about how far the Indian Patent Office can go in stipulating how a patentee conducts their business. In addition, it brings home the importance of a patentee actually commercialising a patented invention in India rather than relying on the patent to block competitors.

Having decided that a compulsory licence was to be granted, the Commissioner also decided the terms of the licence. A 6% royalty margin on Natco's sales of the drug is to be paid to Bayer. Additional terms include a) that the price of one month's treatment should not exceed 8,880 rupees (NZD$210), b) Bayer will provide no legal, regulatory, medical, technical, manufacturing, sales, marketing or any other support of any kind to Natco, and c) that Natco shall provide the patented drug to at least 600 needy and deserving patients per year free of charge.

Bayer have appealed the judgement. Therefore, it is unclear whether this could be the start of many such licences or if the judgement will be overturned. In the wake of the judgement no doubt other pharmaceutical companies in similar positions will be carefully reviewing their business and pricing strategies. In addition, they would be wise to treat any request for a licence from a local generic manufacturer as a sign that further action may be in the offing.

The judgement and its subsequent appeal will be carefully watched by other countries that are a base for thriving generics manufacturing businesses, such as Brazil and China. The outcome may pave the way for these countries to follow suit when faced with similar circumstances. While the immediate impact of the judgement on Bayer is likely to be small, the potential for future judgements in the same vein relating to different products and markets will set alarm bells ringing throughout the global pharmaceutical industry.

If you have any queries regarding intellectual property related matters (including patents, trademarks, copyright or licensing), please contact: *tim.stirrup@baldwins.com or katherine.hebditch@baldwins.com*

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