INTELLECTUAL PROPERTY - INDIA

Supreme Court offers limited definition of 'efficacy' under Patents Act

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In its recent judgment in *Novartis AG v Union of India*(1) the Supreme Court finally interpreted the term 'efficacy' in the context of patentability. The court dismissed the appeal by Novartis against the Intellectual Property Appellate Board and rejected the patentability of the beta crystalline form of imatinib mesylate.

A number of counts of obfuscation have hampered the understanding and interpretation of Section 3 (d) of the Patents Act 1970, which was amended in compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights in 2005. The 2005 amendment also introduced certain terms that required further explanation. For instance, the term 'enhancement of the known efficacy' became moot in the case at hand because although the statute introduced the term, it did not provide an explanatory provision to aid in interpretation of the same.

The definition of 'efficacy' must therefore be understood in light of the intent of the legislation, in terms of both common understanding and scientific understanding (ie, 'efficacy' could also mean higher efficiency in manufacturing process, better response to a change in temperature or improved delivery mechanisms).

In 2009 the Madras High Court(2) applied a restrictive interpretation and held that the definition of 'efficacy' could mean therapeutic efficacy only. This interpretation omitted the bioavailability of differentiated forms of derived substances from the definition.(3) The court further held that even a 30% bioavailability increment could not be efficacious.

In turn, the Supreme Court conclusively rejected a broad definition of 'efficacy', reasoning that:

> "*what is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy*."(4)

Furthermore, the court did not restrict the definition of 'efficacy' to "how effective the new discovery made would be in healing a disease [or] having a good effect on the body". It appears that reduced toxicity (in the case of a drug) or increased effectiveness without an increase in toxicity (for a herbicide) would also be regarded as 'efficacious'.

The courts have therefore not completely eliminated from the definition any non-therapeutic properties of a known form that could be understood to increase efficacy, such as heat stability, humidity resistance, side effects, toxicity and dosage (in the form of quantity, frequency, form and manufacturing efficiency).

The Supreme Court verdict appears to have been thoroughly reasoned and the verdict covers all bases. However, as the court refused to rule on the exact scope of 'therapeutic efficacy', the case sets a limited precedent and leaves room for further discussion.

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Endnotes

(1) Civil Appeal 2706-2716/2013 (arising out of SLP(C) 20539-20549/2009)

(2) *Novartis AG v Natco Pharma* (2007) 4 MLJ 1153.

(3) 'Bioavailability' is defined as "the proportion of a drug which reaches its site of pharmacological activity when introduced into the body; more loosely, that proportion of any substance so introduced which enters the circulation". *Oxford English Dictionary Online*, Oxford University Press (second edition, 1989)

(4) Paragraph 180.
