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Novartis v. UOI - What you Need to Know

In *Novartis A. G. v. UOI & Others*, the Supreme Court rejected a patent claiming the beta crystal modification of imatinib mesylate for failure to overcome the prohibition under Section 3(d) of the Patents Act, 1970. The case was keenly watched for its interpretation of Section 3(d), which prohibits the patenting of *new forms of* known substances, unless there is a significant enhancement of *known efficacy.*

Important Findings

The most awaited aspect of the decision was the interpretation of the term **'efficacy'**. In this respect, the Supreme Court ruled:

> "...the test of efficacy would depend upon the function, utility or the purpose of the product under consideration....in the case of a medicine that claims to cure a disease, the test of efficacy can only be 'therapeutic efficacy'....With regard to the genesis of section 3(d), and more particularly the circumstances in which section 3(d) was amended to make it even more constrictive than before, we have no doubt that the 'therapeutic efficacy' of a medicine must be judged strictly and narrowly."

Novartis had proved that the claimed new form had better physic-chemical properties (beneficial flow properties, better thermodynamic stability and lower hygroscopicity). The Supreme Court held:

> "...[these properties] may be otherwise beneficial but these properties cannot even be taken into account for the purpose of the test of section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy."

Novartis had also relied upon increased **'bioavailability'** to overcome Section 3(d). In responding to this argument, the Supreme Court held:

> "...just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data. In this case, there is absolutely nothing on this score apart from the adroit submissions of the counsel. No material has been offered to indicate that the beta crystalline form of Imatinib Mesylate will produce an enhanced or superior efficacy (therapeutic) on molecular basis than what could be achieved with Imatinib free base *in vivo* animal model."

Notable Flexibilites

The Court did not rule that increase in bioavailability will never be sufficient to overcome Section 3(d).

The Court leaves the door open to overcome Section 3(d) by showing reduced toxicity.

The judgment is fact specific and cannot be read in a manner that undoes the legislative change of granting product patents in all areas of technology. The Court held that:

> "We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances."

Purpose behind Section 3(d) is specific and narrow. The Court in this regard observed:

> "The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds..."

Section 3(d) is only limited to the pharmaceutical industry and its implications cannot be extended to other areas. The Court held:

> "We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially to deal with chemical substances, and more particularly pharmaceutical products."

Note:
A more detailed appraisal of the decision will follow shortly.

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