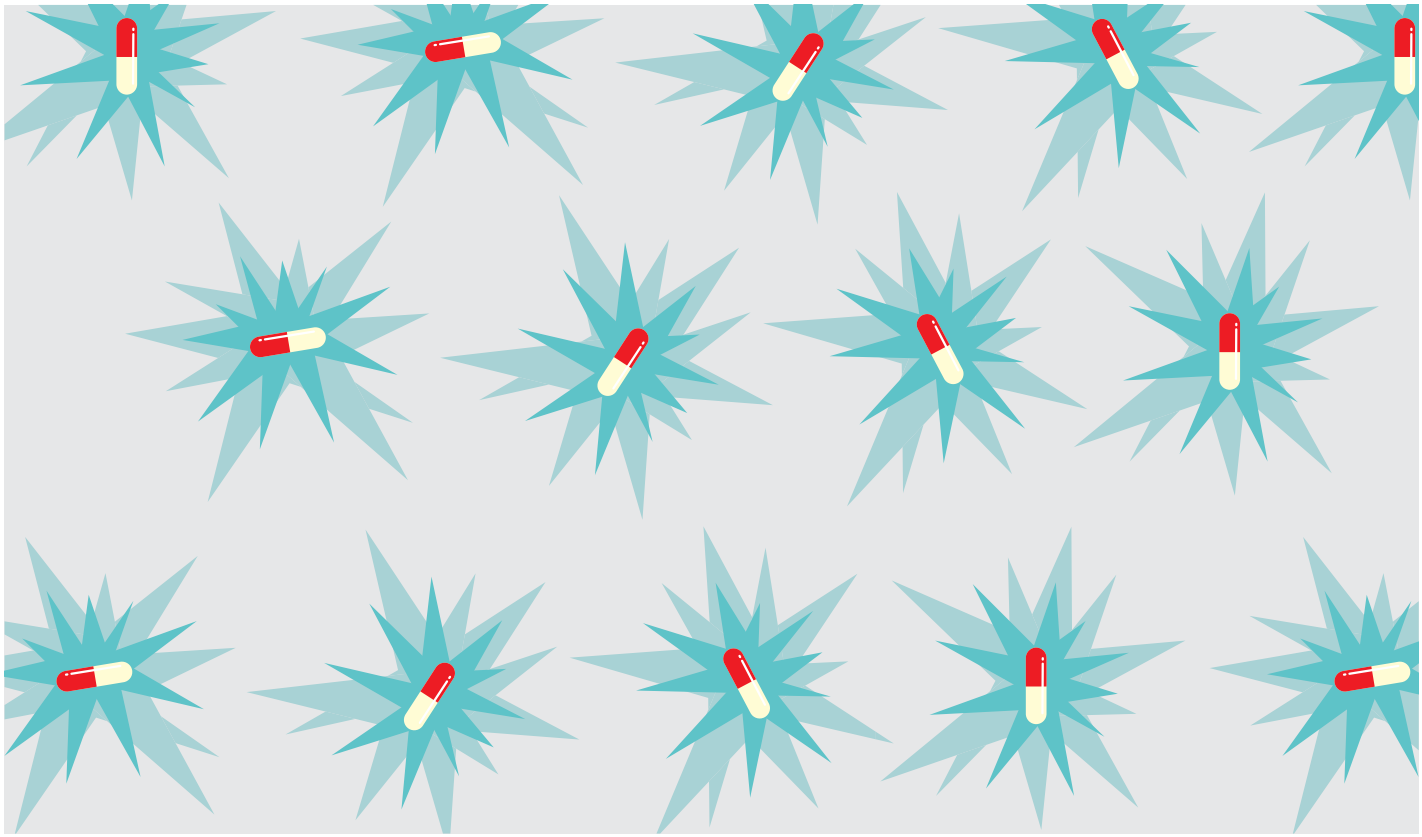
GLIVEC

THE *GLIVEC* CASE: GETTING BEYOND EFFICACY

The Indian Supreme Court has failed to provide the clarity which is craved by practitioners in its latest pronouncement on the controversial Section 3(d), says Jitesh Kumar.

The judgment of the Indian Supreme Court concerning Novartis' anti-cancer drug Glivec has dominated all recent discussions on Section 3(d) of the Indian Patents Act. Despite being a landmark reference for issues pertaining to Section 3(d), it is often forgotten that there is much more to Section 3(d) beyond the "enhanced efficacy" requirement, which the judgment did not address.

While cogent in many aspects, the ruling has evaluated issues primarily in the context of specific facts and circumstances of the case, leaving us with dicta rather than binding precedence.



The scope of Section 3(d)

To begin with, the Supreme Court has not thrown much light on the scope of Section 3(d). Careful analysis will show that the court's position is that Section 3(d) sets up a second tier of qualifying standards for chemical substances and/or pharmaceutical products in order to check any attempt at repetitive patenting or extension of the patent term (ie, evergreening), but at the same time leaves the door open for true and genuine inventions.

A seemingly clear assertion which is in agreement with the legislative intent behind its enactment, it should imply that Section 3(d) may not be applicable to genuine inventions which do not entail any attempt at evergreening or repetitive patenting. However, the assertion may not be of any practical significance because the court has not laid down any guidelines/parameters in this regard. The Indian Patent Office continues to raise objections under Section 3(d) against the majority of pharmaceutical applications, at times even in the case of applications for new chemical entities and new synergistic compositions of two or more known active substances.

Efficacy as "therapeutic efficacy"

Another inadequate explanation in the judgment is with regard to the interpretation of efficacy as "therapeutic efficacy". Will this interpretation stand the test of time? Many stakeholders have already shuddered at the court's interpretation,

> "THE DEBATES ON SECTION 3(D) IN DIFFERENT FORUMS HAVE OFTEN IGNORED THE TECHNICAL ASPECTS OF SECTION 3(D) AND THE POSSIBILITY OF MISINTERPRETATION OF THE VARIOUS TERMS OF THE PROVISION."

which is narrow and unscientifically limiting. Many, like me, believe that the jurisprudence will evolve to a better explanation, if only because science and technology develop and stabilise along several different pathways, which prohibits the possibility of a general rule, especially for a term as important as "efficacy".

In fact, a deliberate reading of the judgment shows that the Supreme Court has left open the question of how to interpret "therapeutic efficacy" and has only affirmed that physicochemical properties must be excluded from its domain. The exclusion itself may have to be reconsidered in future, as in certain circumstances it may become necessary to take physicochemical properties into consideration. As a simple case in point, take for instance a situation where the already known compound is toxic, so that generating *in vivo* therapeutic data may not be practically possible on account of moral and ethical issues.

What is a "new form"?

Another important aspect left out in the *Glivec* case is with regard to the scope of the term "new form" and the extent of its application in real situations. The "new form" claimed in the *Glivec* case was a new crystalline polymorph and the Supreme Court did not have the opportunity to analyse aspects related to other forms mentioned in the explanation part of Section 3(d) such as esters, ethers, complexes and combinations. The only dictum made by the apex court with regard to these forms is the generalisation that each of the different forms mentioned in the explanation part has some properties inherent to that form.

The court generalised it as: "While dealing with the explanation it must also be kept in mind that each of the different forms mentioned in the explanation have some properties inherent to that form, eg, solubility to a salt and hygroscopicity to a polymorph. These forms, unless they differ significantly in property with regard to efficacy, are expressly excluded ... (continued)."

This generalisation, which may be difficult to apply to forms such as complexes and

combinations, indicates a lack of sufficient consideration to the scientific nuances associated with Section 3(d). In fact, the debates on Section 3(d) in different forums have often ignored the technical aspects of Section 3(d) and the possibility of misinterpretation of the various terms of the provision. The consequence is that raising objections under Section 3(d) by misapplying the terms has become widespread during the examination/opposition proceedings of applications for pharmaceutical inventions at the Indian Patent Office. For instance, it may be improper to construe the term 'combinations' to extend it to combinations/compositions of two or more different active ingredients (which at times may belong to completely different classes).

The outcome is that it has caused, *inter alia*, an impediment to the grant of patent for several applications including, for instance, Pfizer's patent application covering its drug, Caduet. The misapplication of the term 'derivatives' has played a part in the refusal of grant of patent for applications such as Astra Zeneca's application covering its anti-cancer drug, Iressa. The Supreme Court judgment does not provide any insights to the interpretation of these technical terms which is going to be central to many applications pending before the Indian Patent Office.

Conclusion

Apart from the above, there are other aspects related to Section 3(d) which need resolution and the observations/affirmations of the Supreme Court are inadequate to provide any insights as to the paths which may be taken for their resolution. It is apparent that the judgment of the Supreme Court will act as a limited precedent because, instead of the legal clarifications that almost everyone was hoping for, the court followed a very facts-specific approach which arguably does not give this case the legal teeth it deserves.

So, as the debate on Section 3(d) saunters on and many more patent cases enter into contentious battles for a resolution of these issues, I am reminded of words of Robert Frost: "But I have promises to keep, And miles to go before I sleep, And miles to go before I sleep." ■

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