PHARMACEUTICAL PATENTS AND SECTION 3(D): THE ONGOING STRUGGLE OVER ENHANCED THERAPEUTIC EFFICACY IN INDIA

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The pharmaceutical industry and the Indian Patent Office have long been locked in a contentious battle over patent grants, with Section 3(d) of the Indian Patents Act, 1970, emerging as a central point of contention. Modified to align with India's commitments under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Section 3(d) mandates that a new form of a known substance is not patentable unless it demonstrates "enhanced efficacy." The lack of a precise definition for the term "enhanced efficacy" in the Act has fueled ongoing disputes, creating a challenging landscape for pharmaceutical innovators seeking patent protection in India.

However, in the landmark case of Novartis AG v. Union of India (2013), the Supreme Court of India clarified that, for pharmaceutical inventions, "enhanced efficacy" must equate to "enhanced therapeutic efficacy'. This landmark ruling has significantly shaped patent strategies, pushing pharmaceutical companies to explore creative approaches, such as patenting intermediates used in the synthesis of Active Pharmaceutical Ingredients (APIs), to navigate the rigorous requirements of Section 3(d).

The Zeria Pharmaceutical Precedent – A test of Intermediates Under Section 3(d)

The recent decision in Zeria Pharmaceutical Co. Ltd. v. Controller of Patents (Delhi High Court) exemplifies the judiciary's commitment to enforcing Section 3(d). The case involved Patent Application No. 3630/DELNP/2011, filed on May 13, 2011, as a divisional application stemming from the parent Application No. 1090/DELNP/2007. Zeria Pharmaceutical sought patent protection for an intermediate compound, used in the synthesis of a known pharmaceutical compound.

Submissions by Zeria Pharmaceutical

In its submissions, Zeria argued that the claimed intermediate compound, represented a novel and inventive step over the prior art. It emphasized that the compound featured a methoxycarbonyl group, distinguishing it from the ethoxycarbonyl group disclosed in the prior art. Zeria further contended that this structural modification warranted patentability, asserting that the intermediate's role in the synthesis process constituted a significant technical advancement. However, it acknowledged that, as an intermediate, the compound's direct

therapeutic efficacy could not be assessed, and no comparative data was provided by the Zeria to demonstrate how the intermediate contributed to the enhanced therapeutic efficacy of the final API.

Key Observations of the Court

1. Structural Similarity to Prior Art: The court found that the claimed compound and the prior art compound were derivatives of each other under Section 3(d). This minimal structural variation did not suffice to establish novelty or inventiveness in the absence of evidence of therapeutic enhancement.

2. Absence of Therapeutic Efficacy Evidence: The court noted that Zeria's submissions were devoid of comparative data demonstrating that the claimed intermediate enhanced the therapeutic efficacy of the final API. Zeria's admission that therapeutic efficacy could not be directly evaluated for an intermediate further undermined its case.

Court's Ruling

The Delhi High Court upheld the Controller of Patents' rejection of the patent application, reinforcing that incremental innovations in the pharmaceutical sector must substantiate enhanced therapeutic efficacy to satisfy provisions of Section 3(d). The court categorically rejected the notion that intermediates could serve as a workaround to bypass Section 3(d) without clear evidence of their contribution to the therapeutic efficacy of the final product. This ruling shows that the Indian Patent framework prioritizes genuine therapeutic advancements over marginal chemical modifications.

Implications for the Pharmaceutical Industry

The Zeria Pharmaceutical decision sends a clear message to the global pharmaceutical industry: India's patent regime demands rigorous evidence of therapeutic benefit, even for intermediates. This precedent highlights the challenges of securing patents for incremental innovations in a market critical for both innovation and affordable healthcare. Pharmaceutical companies must now invest in comprehensive data to demonstrate how their inventions, whether final active pharmaceutical ingredients or intermediates, deliver meaningful therapeutic improvements. The ruling also reaffirms India's commitment to balancing Intellectual Property protection with public health imperatives.

Conclusion

The Zeria Pharmaceutical case epitomizes the ongoing struggle between the pharmaceutical industry and Indian patent law, in the context of Section 3(d). By upholding a high threshold for patentability, India continues to challenge innovators to prioritize therapeutic advancements. This decision not only clarifies the application of Section 3(d) to intermediates but also reinforces India's role as a gatekeeper in the global pharmaceutical patent landscape, expecting pharmaceutical companies to meet exacting evidentiary standards to secure protection. However, it also posses a threat to all the incremental inventions that are underway for the intermediate products or processes.