

### Patent | Case Law Update

## Delhi High Court Restores Syngenta's Polymorph Application Clarifying Section 3(d) for Agrochemical Patents

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In *Syngenta Participations AG v. The Controller of Patents & Designs*, the Delhi High Court ("Court") passed an order on 4<sup>th</sup> May 2026, restoring Syngenta's patent application refused by the Assistant Controller of Patents and Designs.

Syngenta Participations AG (Appellant) had filed a patent application No. 201617031900 ("application") for a specific monohydrate crystalline polymorph of a fungicidal compound. The Controller of Patents had rejected the application on the grounds of lack of inventive step (Section 2(1)(ja)) and non-patentability under Section 3(d) of the Patents Act, 1970 ("Act"), vide order dated July 21, 2023 ("Controller's order").

### Controller's Reasoning for Refusing the Application

- The Controller had held that the prior art documents D1–D4, cited during the examination proceedings already disclosed the anhydrous form of the compound and its preparation process. The applicant's only distinguishing claim was the monohydrate form. The Controller maintained that no credible comparative data was provided to show any surprising or unexpected advantage, such as reduced phytotoxicity. The Controller considered the X-ray diffraction data merely as characterization, not a technical advancement, stating that the claimed composition contained only common excipients and carriers without inventive merit.
- The Controller held that the claimed monohydrate polymorph was simply a new form of a known

substance (the anhydrous form) and therefore subject to Section 3(d) of the Patents Act. Since the applicant failed to demonstrate any enhanced efficacy of the monohydrate form over the anhydrous form, the data provided was deemed insufficient. Applying the pharmaceutical standard of "therapeutic efficacy," the Controller concluded that improved stability or physical properties alone did not meet the threshold, and thus the invention lacked patentability under Section 3(d).

### Appellant's Arguments:

Challenging the Controller's order in the Appeal before the Court, the Appellant argued the following:

- Controller erred in rejecting thermal stability data provided in the specification and the Expert's affidavit.
- Thermal stability is not an inherent property, as polymorphic forms are unpredictable in nature.
- The comparative data showing reduced phytotoxicity was not properly considered, and the law on inventive step does not limit recognition of inventive merit to only one specific type of evidence.
- The Controller wrongly applied Section 3(d) by treating the monohydrate crystalline polymorph of Compound I as a new form of a known substance without considering the enhanced efficacy data showing reduced phytotoxicity compared to the anhydrous form. Thermal stability data also qualifies as evidence of efficacy, and since the invention relates to agrochemicals, the strict test

of “therapeutic efficacy” under Section 3(d)—as clarified in *Novartis v. Union of India*, cannot be applied to agrochemical inventions. The appellant relied on the *Novozymes* case, arguing that the thermal stability of the crystalline polymorph reduces phytotoxicity. The appellant emphasized that different polymorphs could exhibit advantageous physical, chemical, and biological properties, which may significantly improve production methods, formulations, and the overall efficacy of agrochemical agents like fungicides.

### Court's Analysis

Agreeing with Syngenta, the Court held:

- Polymorphism in active ingredients is crucial since different forms, though chemically identical, can show varied properties. These differences—such as hydrogen bonding—affect solubility and stability. Under changing temperature, pressure, and humidity conditions, polymorphs may exhibit different energy states, making their control vital for efficacy and stability.
- The Controller's reliance on “common general knowledge” without citing any source was improper. Referring to the *AGFA NV* judgment, the Court stressed that sources must be specified. Therefore, the Controller's claim that thermal stability is inherent to polymorphs could not be accepted, as no supporting sources were cited and the cited documents contradicted such a blanket assertion.
- The Court observed that the monohydrate crystalline polymorph of Compound I was not previously known, and the patent specification clearly demonstrated its superior thermal stability compared to the anhydrous form. This enhanced stability constitutes a technical advance over prior art (D1–D4), directly supporting its suitability for SC formulations by reducing phytotoxicity. Given the unpredictability of polymorph development and the absence of any disclosure in the prior art regarding the existence or stability of this monohydrate form, the Controller's reasoning failed to adequately address inventive step, rendering the objection untenable. The Court referred to *F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd.* and *Agriboard International LLC v. Deputy Controller of Patents and Designs*.
- Referring to Section 3(d), the Court observed that the 2005 amendment introduced a stricter standard to prevent “evergreening” of patents while still allowing genuine incremental innovations. The Supreme Court in *Novartis AG* emphasized that the amendment was primarily aimed at pharmaceuticals, with some reference to agrochemicals, and clarified that “efficacy” must be understood in terms of therapeutic effectiveness in the pharmaceutical context. Thus, the amendment set a second tier of qualification to balance public health concerns with encouragement of true innovation.
- The Court observed that para 157 clarifies that “efficacy” depends on the product's purpose—therapeutic efficacy for medicines, and functional or utility-based efficacy for other products. Without such enhancement, patents are barred under Section 3(d).
- The Court referred to the *Novozymes* judgment and reiterated that the Supreme Court's definition of “efficacy” in *Novartis AG* was specific to pharmaceuticals, but for other products like biochemical substances, efficacy is not confined to therapeutic effect. The Court observed that increased thermostability, enabling enzymes to withstand higher temperatures and remain active during pelletization, amounts to enhanced efficacy. The Court further held that Section 3(d) does not restrict efficacy enhancement only to variants with inherently higher enzymatic activity, but includes functional improvements such as thermostability, depending on the product's purpose.
- The Court emphasized that the subject patent's assertion of thermodynamic stability in the monohydrate crystalline polymorph of formula-1 is crucial for agrochemical use. The stability at high temperatures prevents crystal formation and clogging in spray equipment, ensuring effective delivery in India's hot agricultural regions. This

functional improvement directly enhances the efficacy of the compound under Section 3(d), as stability in such polymorphs is unpredictable and requires significant research. Thus, the claimed thermodynamic stability itself constitutes an enhancement in efficacy.

**Court's Ruling:**

- The Court set aside the Controller's refusal order, finding the reasoning on inventive step and efficacy insufficient.
- The matter was remanded to the Patent Office for fresh consideration, with a clear direction that,

for agrochemicals, enhanced thermodynamic stability at high temperatures constitutes enhanced efficacy under Section 3(d).

**Significance:**

This judgment emphasizes that, for agrochemicals, efficacy under Section 3(d) may include important practical attributes such as thermal stability that directly influence field performance. It provides valuable guidance for patent applicants and examiners in assessing inventive step and efficacy for new forms of known agrochemical substances.