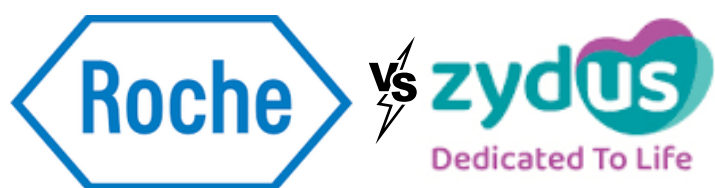


# DECODING ROCHE V. ZYDUS AND THE FUTURE OF PROCESS PATENT WARS

## Introduction- Section 104A Under Scrutiny

The Delhi High Court's recent decision in *F. Hoffmann-La Roche AG v. Zydus Lifesciences Ltd.* is more than just another patent dispute, it is a precedent-setting interpretation of *Section 104A of the Patents Act*, one that will resonate across India's pharmaceutical and biologics industries. Delivered on 23 July 2025, the judgment tackles a deceptively simple question: in process-patent cases, what exactly must a plaintiff prove before the burden of proof shifts to the defendant? The answer, as the Court put it, is hidden in one word—"identical."



## A Pre-Launch Showdown

The dispute began even before Zydus's product reached the market. Roche, the originator of Pertuzumab, a targeted therapy for HER2-positive breast cancer sold under the brand name Perjeta, believed Zydus was preparing to launch a biosimilar version.

Roche relied on two Indian patents:

- IN 268632 – covering the product itself,
- IN 464646 – covering the process of manufacturing Pertuzumab.

Instead of waiting for the biosimilar to be sold, Roche filed a quia timet (anticipatory) suit, arguing that it was entitled to protect its rights proactively. One key request was the creation of a confidentiality club i.e., a controlled arrangement where Zydus would disclose its manufacturing process under strict secrecy so that Roche's technical experts could compare it with their patented process.

But the procedural roadblock was Section 104A, which governs burden-shifting in process-patent infringement cases. Roche wanted the Court to direct Zydus to reveal its process. Zydus resisted, saying Roche had not crossed the statutory threshold for such disclosure.

## Section 104A Under Scrutiny

Section 104A was enacted to address the challenge patentees face in proving process-patent infringement. Since the details of a manufacturing method are usually known only to the manufacturer, the law allows courts to shift the burden of proof to the defendant, but only if the plaintiff first proves that the product made by the defendant is identical to the product obtained through the patented process.

This threshold is strict. It is not enough for the products to be broadly similar or even functionally equivalent. The law demands identity. Roche argued that in the case of biologics, this requirement should be applied with more flexibility, pointing to the 2016 Guidelines on Similar Biologics, which recognise a "high degree of similarity" standard in regulatory contexts.

## Judicial Line-Drawing: Similarity Isn't Enough

The Court agreed that Section 104A could be triggered even at the interlocutory stage, including for setting up a confidentiality club. However, it was equally clear that the word "identical" must retain its strict meaning—exact sameness. No exception would be carved out for biologics merely because of their complexity. Roche had not reverse-engineered Zydus's product or conducted analytical claim mapping to prove such sameness, so the statutory gate to burden-shifting remained closed.

Roche also attempted to rely on the Civil Procedure Code's general discovery provisions under Order XI, arguing that it did not need to establish a prima facie infringement case before obtaining disclosure. The Court disagreed, holding that Section 104A, as a specific provision designed for process-patent disputes, overrides the CPC's general discovery norms.

## Key Takeaways: Three Critical Points

The decision is significant for several reasons. First, it draws a bright line between "similar" and "identical" in the context of process-patent litigation. Plaintiffs cannot argue that functional equivalence or regulatory similarity is enough; they must produce empirical evidence of identity.

Second, it provides clear guidance for litigation strategy. Innovators seeking to invoke Section 104A must be prepared to invest in scientific testing i.e., reverse engineering, analytical profiling and detailed claim mapping, before even approaching the court. Without this preparation, the door to burden-shifting remains firmly closed.

Third, it strengthens defendants' ability to protect trade secrets. By holding that Section 104A's prerequisites are mandatory and cannot be sidestepped through general discovery provisions, the Court ensures that confidential processes are not exposed without strong cause. Hence, For the broader industry, the case is a reminder that in process-patent battles, proof of sameness is not a formality but it is the entire key to unlocking Section 104A.