



API Process Patents in India: Key Patent Infringement Disputes and Court Decisions

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An active pharmaceutical ingredient (API) is the substance responsible for a medicine's therapeutic effect. Developing one can involve years of chemical research, experimentation and process optimisation. For pharmaceutical manufacturers, however, the commercial challenge does not end with discovering a molecule. It also raises a critical legal question: when does manufacturing an API cross the line into patent infringement?

The answer depends on what the patent actually protects. A patent may cover a new chemical compound, a particular form of that compound, or a manufacturing process. These distinctions matter when competing manufacturers produce the same API using different methods, or when a generic manufacturer seeks to enter the market before a patent expires.

Indian courts have addressed these questions through disputes involving pharmaceutical compounds, manufacturing methods and the scope of patent claims.

When a Manufacturing Process Defines a Product

The dispute in [*Kudos Pharmaceuticals Ltd. & Ors. v. BDR Pharmaceuticals International Pvt. Ltd.*](#) concerned Olaparib, an anticancer pharmaceutical compound, and Indian Patent No. 228720. Kudos sought to restrain BDR from manufacturing and selling products allegedly infringing the patent, which was due to expire in March 2024.

The case raised questions about patent enforcement, the relationship between earlier and later patent claims, and the practical limits of interim relief when a patent is close to expiry. With the patent nearing the end of its term, the Delhi High Court considered the dispute under significant time pressure.

The proceedings later took a different turn. On 17 July 2026, the Court recorded a settlement between the parties and disposed of the suit in accordance with its terms. It did not determine infringement on the merits in that order.

The dispute illustrates a commercial reality of pharmaceutical patent litigation: the timing of enforcement can matter almost as much as the scope of the patent itself. For API manufacturers, a patent dispute can affect market entry, manufacturing plans and potential liability even when the patent has only a short period remaining.



When a Different Chemical Form Raises a Patent Dispute

A second question arises when a manufacturer produces a different form of a known pharmaceutical compound.

In [*Natco Pharma Ltd. v. Novartis AG*](#), decided by the Delhi High Court on 24 April 2024, the dispute concerned eltrombopag olamine, a salt form of eltrombopag. Novartis asserted patent rights over the compound, while Natco challenged the patent's validity, including on grounds relating to prior claiming, novelty and Section 3(d) of the Patents Act, 1970.

The litigation examined the relationship between an earlier patent covering eltrombopag and the later patent asserted over its olamine salt. The appeal concerned whether Natco had raised a credible challenge to the later patent's validity and whether the interim injunction against Natco should stand.

The dispute illustrates why API patent analysis cannot stop at identifying the chemical name. The claims, the disclosure in earlier patents and the statutory requirements for patentability can all influence the outcome. A different salt form does not automatically establish either a valid new invention or infringement.

When API Manufacturing Meets the Regulatory Exception

Patent infringement questions also arise when a manufacturer produces a patented API before the patent expires.

In [*Teva API India Pvt. Ltd. v. Merck Sharp & Dohme Corp.*](#), decided by the Delhi High Court on 30 May 2016, Merck alleged infringement of its patent covering sitagliptin. Teva acknowledged manufacturing the relevant product but argued that its activities were undertaken for research and development and regulatory submissions.

The dispute brought Section 107A of the Patents Act into focus. This provision excludes certain acts from infringement when they are undertaken solely for uses reasonably related to developing and submitting information required under applicable regulatory laws.

The exception is not a blanket permission to manufacture and sell a patented API before expiry. Its application depends on the purpose and nature of the acts in question. The case demonstrates why the distinction between regulatory preparation and commercial exploitation matters.



What these Disputes Mean for API Manufacturers

These decisions reveal three distinct dimensions of pharmaceutical patent litigation: the scope of the claims, the patentability of the compound and the purpose for which a patented invention is used.

For API manufacturers, the existence of a patent is not the end of the analysis. Nor does using a different manufacturing process automatically avoid infringement. The relevant questions concern what the patent claims, whether those claims withstand a validity challenge, and whether the conduct falls within the rights conferred by the Patents Act or a recognised statutory exception.

In this field, the difference between a protected invention and a permissible alternative often lies in technical detail. Courts must interpret that detail against the language of the patent and the statutory framework.

For pharmaceutical businesses, that makes patent analysis more than a filing exercise. It is central to decisions about process development, generic entry, regulatory planning and the commercial risks of manufacturing an API.



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