+44 20 8123 2220
info@marketpublishers.com

Para IV Plus Database

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Abstracts

What does Para IV Plus contain?

A comprehensive legal understanding of each product as regards its litigation and also measures taken outside of courts (like settlements, Citizen Petitions etc.)

Identifying cases that are not litigated and claims of generics accepted by innovators – something that never comes to the public domain until the generic is launched

An attempt to anticipate (and not speculate) to find ‘what could be next’, including possible settlements, possible at risk launches, possible launches as per undisclosed settlement dates, based on available facts.

In other words, Para IV Plus is not merely a database but is a tool with in-depth insights for every product (and not just every litigation) such that an expert in the field can easily gauge opportunities for various parties.

The Advanced Search feature helps in company analysis & product analysis in different permutations & combinations. Eg list of products belonging to Pfizer, with sales more than $500m where Teva is the FTF along with date of generic launch by Teva as well as other generics thereafter.

How accurate is the information?

The information that we derive is strictly from (1) court filings and judgments (2) official filings and announcements of the companies involved (3) our own

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communications with the companies involved (4) USFDA's actions and announcements (5) patent documents and (6) at times, from relevant third parties like marketing and manufacturing partner for a drug (if other than the innovator) etc.

Some of the preliminary inferences that we derive (like possible 180-day exclusivity holder, likely forfeiture of exclusivity etc.) are based on our understanding of the Hatch Waxman Act.

Simply put, since our information is sourced only from official and company announcements / publications, the facts we mention are 100% accurate with some amount of delay as we update every fortnight. However, some of the inferences we derive are our best guesses – that may change later with additional new information.

How does it help a Company?

This tool is a solvent for many common issues arising to a API company. The prime question it answers is "what product to manufacture". The tool helps guage generic entry of a particular brand and competition there after. Thus the manufacturer can get a view of what API will have maximum buyers and when. It also gives list of potential API buyers

To a pharma company desirous of banking on the Para IV litigations, this tool will help them strategize their entry.

To a pharma company already involved in Para IVs, this tool can help (a) identify those Para IV opportunities where there is still potential even after 180-day exclusivity is already awarded to another company and (b) identify opportunities thrown up on ongoing Para IV litigations due to some sudden change in circumstances.

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