



## **Designing around patents in the pharmaceutical product development, case studies**

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Not surprisingly innovator pharmaceutical companies have mounted a number of patents for each drug product to protect their intellectual property and block Generic Competition. At the same time Generic drug companies increasingly use aggressive tactics to design around those patents and enter the market as early as Possible. This legal war between Innovator & Generic companies has been created a huge scientific effort on both sides.

Innovators companies are becoming smarter for filing new patents in different aspects of their blockbuster drugs seeking delay of generic drug approvals and Generic companies use innovative and novel scientific methods to circumvent those patents and develop generic countertypes of branded drugs.

In this lecture three real cases of how Generic companies challenge innovator companies patents will be discussed. These cases are coming from real projects implemented in two major US Generic firms SANDOZ and WATSON during 2004 to 2008

Each case reveals how Generic companies use the latest pharmaceutical sciences principles to find ways not infringing Innovator Patents.

In the first case the story of an acid labile product in the form of enteric coated tablet will be discussed in which the Tablet core must be protected from enteric polymer using an intermediate layer. However the use of intermediate layer is patented.

In Second case formulation of a PH independent extended release tablet will be discussed in which the active ingredient has PH dependent Solubility. Problem here is that the innovator company has patented using ingredients which impart PH independent dissolution rate to the extended release tablet.

The third case an interesting discussion will be made about taste masking of an extremely bitter drug and preparation of orally Disintegrating Tablet which the brand product had not been launched yet & the brand formulation had to be deduced from several patents surrounding this product.