

Case Study 1

Case Study 1: A European generic API producer needs to offset declining revenues

Challenge: A European generic API producer experiences declining revenues as a result of the 'patent cliff'. Recognizes the need to challenge its business model to survive.

Background: Manufacturers of APIs are among the first to suffer from the generic cliff, since they are contacted 4-6 years in advance of a drug coming off patent so that an API's synthesis can be investigated and validated prior to drug product formulation. API producers are meeting this challenge in various ways: some are being acquired by pharma companies (so-called 'vertical integration') while others are investigating 505(b)(2) as a way to expand their portfolio of API's or increase the utilization of their existing API's

Solution: The generic API producer retained Camargo to examine the client's entire 90+ API portfolio for potential products. A "good" product was defined as a product for which (among 35+ criteria) an unmet medical need with a certain revenue threshold requiring a modest development cost existed. Camargo used its broad therapeutic expertise, its commercial evaluation, and development teams (CMC, clinical, regulatory) to reduce the list to 3 candidates for further development. Camargo's experience with more than 800 FDA meetings and 200+ NDA and ANDA approvals combines to make this service, Product Ideation, an important opportunity for drug development and market success.

Outcome: Client has 3 viable products to pursue, with a net revenue greater than the client's current revenues as a generic API producer. Will engage Camargo with the ongoing development program.