Case Study 3

Case Study 3: Use of little known strategy allows for earlier approval and never-ending protection against generic competition

Challenge: A company with strong philanthropic motives was blocked from bringing a low cost solution to community health by patent "picket fence" activities.

Background: Like generic drugs, a 505(b)(2) must certify to a Reference Listed Drug's (RLD) patent(s). In this case, the Listed Drug had a patent that would have prevented timely approval of Camargo's client's product. Unlike a generic, a 505(b)(2) does not have to have a Listed Drug. This strategy is not well-known. In addition to this, the FDA's own presentations generally talk about a 505(b)(2) being a change to an approved product. Very few consultants know how to gain approval without reference to an approved product. In fact, the client's licensee's (a major pharmaceutical company) regulatory VP said it was not possible.

Solution: Camargo was able to locate sufficient information from the literature that was not identified with the branded drug. It is not obvious, but the FDA will allow an argument to rely on information that is not product-specific so long as it is well-structured.

Outcome: The client was able to get the product approved much earlier than the licensee forecasted. This accelerated the milestone payments to the client and also allowed earlier entry into the market so that the client could start reaping royalty income sooner. A further benefit was that Camargo was able to gain approval of this product without it being declared an RLD. This means that our client's product will never have a generic competitor, since all generics require an RLD.