

## Case Study 5

### **Case Study 5: Mid-tier generic company facing declining revenues and weak business outlook due to the generic patent cliff.**

**Challenge:** Indian generic company tried to use its internal regulatory competencies to identify and develop drug candidates using the 505(b)(2) pathway with no success.

**Background:** Camargo had conducted an educational seminar with a potential client regarding the requirements and nuances of the 505(b)(2) regulatory pathway. The client had an internal regulatory team that had demonstrated its competency at generic drug development and regulatory approval via the 505(j) pathway. This internal team felt that they were able to save time and money by running the 505(b)(2) program without an experienced consultant, and, after over one year and millions of dollars wasted, engaged with Camargo to outsource the effort to experts.

**Solution:** Currently engaging with the Company to select top drug candidates for development through the 505(b)(2) pathway.

**Outcome:** The drug candidates are being selected and will be successful similar to other product ideation efforts.