Ms. Gargi Nadkarni

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Title: Demystifying the 505(b)(2) Pathway – A Business Perspective

Abstract : The number of drug approvals in the US through the 505(b)(2) pathway has shown significant double digit growth in the past two years. 505(b)(2) drug products are developed to achieve either (or both) of two primary purposes: 1. To realize earlier entry into the market by designing around patents and 2. To cater to an unmet need in a therapy area – be it patient compliance or enhanced pharmaceutical or clinical performance of drug products. Repurposing older marketed drug products using novel drug delivery technologies or platforms may provide additional marketing/data exclusivity and patent protection, thereby offering an effective tool for product life cycle management. However, it is important to appreciate that not all approved products achieve commercial success. Multiple factors determine commercial viability such as market situation, label claims, entry of competing products, etc. Hence, it is imperative for formulators to holistically look at commercial and regulatory requirements before delving into product development. This session aims to create awareness amongst researchers into commercial, patent and regulatory aspects of 505(b)(2) product development with examples of successful and unsuccessful products.

Ms. Gargi Nadkarni

Professional Biography

Gargi Nadkarni has over 10 years of experience in IP Litigation & Business Development. Her role currently includes identifying robust generic products for regulated markets & 505(b)(2) opportunities. She started her career as an IP professional, where she worked hand-in-hand with R&D & outside counsel to develop effective IP strategy for generic products. Over the years, her repertoire has evolved into a rich amalgam of technical, legal, commercial & regulatory aspects of product selection and development. She has extensive experience in patent litigation, settlement negotiations & the entire gamut of Hatch Waxman activities & is an expert in shaping IP strategy. She has worked across geographies & cultures, & independently handled IP activities for business functions such as In-licensing & New Product Identification. Gargi is a qualified lawyer & has completed her post-graduation in Pharmaceutical Sciences with specialization in Drug Delivery Technology from prestigious institutes. She has received numerous scholarships & accolades throughout her educational journey. Her master's dissertation was selected for oral presentation at the prestigious Controlled Release Society's annual conference in Copenhagen & was the only paper authored by a master's student globally – a testimony to her exceptional academic record. She is a focused and logical person, who finds business strategy, and the myriad challenges it offers, to be intellectually invigorating.