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How to leverage and protect IPR for biosimilars

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Although new biologic-based drugs are becoming increasingly important in addressing a variety of disease conditions, biosimilars based on such prominent drugs are slowly making their way into regulatory approvals. This presentation looks at a variety of options that this marked area of new technology has created in protecting invaluable intellectual property rights (IPR) and also, how this new technology provides avenues to enter into new business opportunities that address unmet societal needs. The presentation will also look briefly into the creation of IPR and ways in which to capitalize it under current regulatory practices in the US with some case studies.

Biography

Balu Gupta is a seasoned patent attorney and is currently the in-house Patent Counsel at Promerus LLC. Before joining Promerus LLC, he held a variety of positions of increasing responsibilities in his many years of illustrious career at Sanofi. Over the years at Sanofi, he headed both the Global Immuno-inflammation and CNS/Oncology patent groups and was responsible for all patent and regulatory matters. He holds a doctorate degree in organic chemistry from University of Southern California (Nobel Laureate, George Olah as Thesis Adviser) and a law degree from Seton Hall University. Balu is admitted to practice law in New Jersey and Texas and is a registered patent attorney. Prior to entering his legal career, he was a bench chemist for about ten years, holding about 30 patents, and has successfully prosecuted over 330 US patents.

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