

3rd International Conference and Exhibition on **Biowaivers, Biologics & Biosimilars**

October 27-29, 2014 Hyderabad International Convention Centre, Hyderabad, India

Patent issues in biopharmaceutical industry

Vijay Kumar

BioBridge Healthcare Solutions Pvt. Ltd., India

Intellectual property law enables and gives proper direction along with the rules that individuals and organizations can use when conducting business and making business plans. Unfortunately, the present state of intellectual property laws around the world has created an environment that imposes timing issues ambiguities that are vexing to decision makers in every industry, including the biomanufacturing industry. In United States, courts have defined a 'Super' enablement standard that patent application must meet in order to mature into valid, issued patents. European and Japanese courts appear to be following the lead of the US, by embracing the 'Super' enablement standard. The timing of intellectual property protection and public notice frequently acts as an impediment to developing global strategy and in making changes in the strategy. This talk describes basic considerations and intellectual property law during development and scaling up biomanufacturing processes, including barrier imposed by the law. This talk also describes intellectual property law tools and strategy for protecting assets of a biomanufacturer engaged in development and scale-up operations.

vijay@biobridge.in