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Choosing between patents and trade secrets for protecting biotech products or bio-production processes

The choice of trade secrets versus patent protection has taken on renewed importance in the biotechnology sector with the advent of biosimilar biologics. From an originator perspective, increasing importance is being placed on secondary patent protection, i.e., patents that cover manufacturing processes, formulations, etc. The goal of these filings is to extend protection of the original composition and method, and use of patents by covering production methods or the commercial formulation. However, there are many originator companies which can bypass filing for patent protection, and the disclosure of their bioprocess that comes with it, in favor of keeping some of their critical processes secret. Factors that weigh in favor of patent or trade secret protection will be outlined in the context of products versus processes.

Biography

Paul A Calvo is the Director of the Biotechnology/Chemical Group at the Washington, DC-based law firm Sterne Kessler Goldstein & Fox which represents a diverse group of US and international companies innovating in the field of Biotechnology and Pharmaceuticals Industries. He provides counsel with regard to global patent portfolio strategy, licensing, patent validity, infringement, and design around strategies. He also has extensive expertise in prosecuting and investigating patents related to bio-production methods and therapeutic formulations. He has extensive technical expertise in the areas of vaccines, therapeutic antibodies, cellular immunology, and bio-therapeutics during his graduate studies and Post-doctoral fellowships at the University of Pennsylvania and National Institutes of Health.

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