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US biosimilars taking flight: Discussion of the key events and cases shaping the US biosimilar landscape

Timothy J Shea

Sterne Kessler Goldstein & Fox PLLC, USA

The bio-similar era has arrived in the US! The past few months have seen the first ever FDA approval of a biologic deemed biosimilar to a previously approved biologic, the first cases of the Federal Circuit addressing the scope and interpretation of the US biosimilars statute, and the first patent battles between biosimilar challengers and brand companies. Against this backdrop the broad contours of the US biosimilar landscape is taking shape, and the early strategies of both brand companies and biosimilar developers are being put to the test. This session will highlight the key legal developments in the US biosimilar industry over the past year with particular focus on the patent issues. The session will also outline the strategies being implemented by biosimilar developers to gain an advantages in the critical patent disputes that are central to any biosimilar launch, as well as the strategies of brand companies in attempting hold off biosimilar competition for as long as possible. We will also discuss which of these strategies are working, and whether they are applicable only to this “first wave” of biosimilar development, or whether they will have long term applicability.

Biography

Timothy J Shea is Director of the Biotechnology/Chemical Practice Group at Sterne, Kessler, Goldstein & Fox P.L.L.C., where he has practiced for 20 years. He specializes in advising biopharmaceutical companies and research institutions on complex legal issues relating to the protection, enforcement and transfer of their intellectual property. He practices primarily in the fields of immunology, molecular biology, genetic and medical diagnostics and bio-therapeutics and drug delivery. He has extensive experience advising clients on the creation and management of strategic patent portfolios, freedom-to-operate and patentability issues, complex prosecution strategies, validity and infringement issues, and due diligence investigations in connection with acquisitions and investments. He has published and spoken extensively on IP issues related to therapeutic antibodies and biosimilars. He received his BS in Biology from Washington and Lee University in 1988 and his JD from Chicago-Kent College of Law (with High Honors, Order of the Coif) in 1995. He served as a Judicial Extern to the Honorable Rebecca Pallmeyer of the U.S. District Court for the Northern District of Illinois. Prior to attending law school, he worked for several years in the biotech industry in the areas of genetic diagnostics.

TSHEA@skgf.com

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