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Clearing the biosimilar patent thicket with IPRs

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Abstract

It is well recognized that most licensed biologic products are covered by a multitude of patents. The biosimilars regime created a defined pathway to identify and litigate the patents covering a licensed product as part of a biosimilar challenge. The recent implementation of the America Invents Act provide further mechanisms to challenge patents outside of the courts. These mechanisms, notably an inter partes review or post grant review, have many advantages that should be understood by those contemplating or expecting a biosimilars challenge.

Biography

Kevin W. McCabe is a Director in the Biotechnology practice group at Washington, DC based IP law firm Sterne, Kessler, Goldstein & Fox. Mr. McCabe specializes in complex client counseling issues, such as product clearance opinions, patent validity and infringement opinions, performing due diligence investigations, and drafting and negotiating agreements. He has extensive experience in drafting and prosecuting patent applications across a broad range of technologies; has represented a broad range of clients, from Fortune 100 companies and large international conglomerates to non-profit foundations and small start-up companies; has represented clients in complex multi-jurisdiction, multi-party, and multi-patent litigations, including Paragraph IV ANDA litigations; and has argued interference cases before The Board of Patent Appeals and Interferences and has participated in appeals to the Federal Circuit. In sum, Mr. McCabe is the quintessential renaissance IP lawyer, having gained significant experience across many facets of IP law.