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Dosing, double patenting and the US biosimilars landscape

Nabeela Rasheed
McAndrews, Held & Malloy, Ltd, USA

The US Biosimilars landscape is developing in parallel to that of Europe. With the advent of the relatively new *Inter Partes Review* proceedings at the United States Patent and Trademark Office (USPTO), Biosimilar applicants are provided with a new forum to clear the path for early Biosimilar entry. Currently, the USPTO is reviewing a number of key patents that could impact the early entry of biosimilar versions several blockbuster drugs into the United States market. Key in this review is patents that claim dosing regimens and formulations. How the USPTO and the Courts view such regimens and formulations patents will be crucial in the question of early US Biosimilar entry. In parallel, obviousness-type double patenting, a once arcane judicially-created doctrine has become an extremely prominent defense against various patents in the biologics arena. This session will focus on dosing, formulations, and double patenting and the future of the biosimilar landscape. A comparison of strategies used at the USPTO with those used at the EPO also will be provided.

Biography

Nabeela Rasheed obtained her PhD from University of Liverpool, United Kingdom and after completing two Postdoctoral fellowships, she joined a law practice. She has been practicing in the area of Biotechnology patent law for over 20 years. As a licensed US attorney, she counsels in all areas of patent law and has particular experience in working with antibodies and other biologics. She is currently a shareholder at McAndrews, Held & Malloy.

nrasheed@mcandrews-ip.com

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