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Janssen Biotech vs. Celltrion: The balance between the BPCIA and litigation

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On March 6, 2013, Janssen Biotech, Inc. and New York University filed suit against Cell-trion Healthcare Co., LTD, Cell-trion, Inc, and Hospira in the Federal District of Massachusetts. Janssen filed the suit as an attempt to assert its intellectual property rights for the drug Remicade® (Infliximab). The patents in dispute are US Patent No. 6,284,471, which covers the infliximab cA2 monoclonal antibody; US Patent No. 7,223,396, which covers novel uses of infliximab to treat disease; and US Patent No. 5,807,715, which covers methods of producing functional antibodies that are capable of specifically binding antigens. Cell-trion submitted a Biologic License Application in August of 2014, which the FDA accepted for review in October of 2014. However, Cell-trion indicated that they would begin commercial marketing of their proposed biosimilar product as early as August 5, 2015. The question at hand is was Cell-trion's notice of commercial marketing premature, and how does a biosimilar company properly serve notice of commercial marketing?

Biography

Kerisha A Bowen is a Registered Patent Agent in Dentons' Intellectual Property and Technology practice. She has a Doctorate in Organic Chemistry and her practice focuses on patent prosecution in chemical and biological arts. Prior to joining Dentons, she held several Assistant Professorships and research positions at prestigious universities including the University of Pennsylvania and Penn State University. She was a Patent Analytic Intern at the Union Station Technology Center where she assessed patent cost estimates of orphan drug research. She was also on the Editorial Staff of the *Journal of Chemical and Engineering Data*. As a Postdoctoral Fellow at the University of Pennsylvania, School of Veterinary Medicine, her research focused on the P13K signaling pathway and the link between cancer and diabetes. Her Doctoral Research was concentrated on the synthesis of nitrogen-based pharmaceuticals from sulfinimines.

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