



Associate Elese Hanson Speaks With Wolters Kluwer on Section 10609 of the ACA

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Elese Hanson, an associate in the Intellectual Property practice, spoke with Wolters Kluwer regarding the Congressional intent behind Section 10609 of the Affordable Care Act. Intended to provide for faster approval of generic drugs and prevent brand name drug manufacturers from delaying approval of generic versions, Section 10609 will require labeling changes in relation to the generic drugs. Elese stated that she believes that Section 10609 strikes an appropriate balance of not discouraging legitimate labeling amendments by a brand company, which may serve to benefit the physician and/or patient, while also protecting the generic company in its right to bring its product to the market without further unnecessary delay. ([“Strategic Perspectives: FDA's Implementation of the ACA Moves Slowly, Behind Schedule,”](#) March 11, 2014)