

# Navigating Patent Potholes Along the FDA's Proposed ANDA / 505(b)(2) Pathway

Fitch, Even, Tabin & Flannery LLP will hold a **complimentary webinar**, "Navigating Patent Potholes Along the FDA's Proposed ANDA / 505(b)(2) Pathway," presented by Kendrew Colton and James Zak. The webinar will be Wednesday, Dec. 2, 2015, at 9 am PST / 10 am MST / 11 am CST / 12 noon EST.

The FDA has released new rules regarding the procedures for approval of ANDA and 505(b)(2) applications implementing the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). The U.S. Patent and Trademark Office in turn has created new procedures and other ways by which they cancel, modify, and administer patent rights. The USPTO's actions have created potholes along the FDA-proposed pathways for pharmaceuticals companies and generics manufacturers attempting to maintain monopolies. Their activities may also provide an express lane for new startups in the pharmaceutical space.

The webinar will cover these topics and more:

- Newly listed patents in the Orange Book and the ability to catch up to first applicants
- Breaking through settlement roadblocks with AIA post-grant procedures
- Newly listed and issued patents downshifting ANDAs into tentative approvals
- Express lane for 505(b)(2) applicants

The speakers will be Fitch Even attorneys Kendrew H. Colton and James A. Zak. Colton has extensive IP counseling and litigation experience, with a focus on designing strategies to achieve market exclusivity and freedom to operate for clients

working with chemical and biochemical technologies. Zak chiefly focuses his practice on the intersection of intellectual property and FDA law, often working with startups in FDA-regulated industries to develop and align their IP and FDA market approval strategies while simultaneously developing robust patent portfolios.

CLE credit has been approved for California and Illinois and is pending in Nebraska. Other states may also award CLE credit upon attendee request. There is no fee to attend, but please note registration is required.

Following the live event, a recording of the webinar will be available to view for one year at [fitcheven.com](https://fitcheven.com).

**Register for the webinar.**