

## Generic Pharmaceutical Company, Which Had Filed an ANDA With a Paragraph III Certification, Had Standing to Pursue *Inter Partes* Review to Invalidate the Patent

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*Amerigen Pharmaceuticals Ltd. v. UCB Pharma GMBH*, No. 2017-2596 (Fed. Cir. Jan. 11, 2019)

A generic pharmaceutical company filed an Abbreviated New Drug Application (ANDA) to make a generic version of a brand drug. The patent-at-issue was listed in the Orange Book, and a generic pharmaceutical company made a paragraph III certification indicating that it would not enter the market until after the patent expired. The generic pharmaceutical company filed an *inter partes* review (IPR) seeking to invalidate the patent. On appeal, the patentee argued that the generic pharmaceutical company did not have standing because by filing a paragraph III certification, the generic pharmaceutical company had agreed not to enter the market until after the patent expired. The Federal Circuit found standing.

A party seeking judicial review has the burden of proving standing. To establish standing, a party must show an injury in fact traceable to the challenged conduct, which can be redressed by a favorable judicial decision. In this case, even though a paragraph III certification was filed, the listing of the patent in the Orange Book delays the launch of the generic pharmaceutical company's product. If the generic pharmaceutical company succeeds in the IPR and invalidates the patent, the patent would have to be removed from the Orange Book, and the generic pharmaceutical company's product could be approved. Thus, a favorable IPR would have made it possible for the generic pharmaceutical company's product to enter the market.

[A copy of the opinion can be found here.](#)

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