

# FDAnews

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## Brand Companies Lose in Pepcid Patent Case

Merck, Johnson & Johnson and its operating unit, McNeil, lost their latest battle to prevent Perrigo from marketing a generic version of the heartburn drug Pepcid.

The U.S. Court of Appeals for the Federal Circuit affirmed a lower court's decision that invalidated as obvious the '340 patent related to the formulation of Pepcid Complete (famotidine/calcium carbonate/magnesium hydroxide). In the case, the plaintiffs sued Perrigo for infringing on the patent.

Perrigo now may sell a generic version of the OTC drug, which it said has annual retail sales of approximately \$90 million. Perrigo recently secured FDA approval of a generic version of Pepcid Complete, the chewable formulation of the OTC Pepcid heartburn franchise. The company has been waiting for the appeal to be resolved before launching its generic with 180-day market exclusivity in the third quarter of this year.