



# THINK FORWARD

## Federal Circuit: Written Description of Claimed Result Requires More Than Recitation of Claim Language

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The Federal Circuit recently issued a precedential opinion in [Nuvo Pharmaceuticals v. Dr. Reddy's Laboratories \(2017-2473\)](#). The court held Nuvo's asserted claims invalid for lack of written description, notwithstanding a verbatim recitation of the disputed claim language in the specification of the patents-in-suit.

The patent claims at issue were directed to a pharmaceutical composition for treating pain comprising: (1) a non-steroidal anti-inflammatory drug (NSAID) to control pain; and (2) a proton pump inhibitor (PPI) to increase the pH in the gastrointestinal tract, thereby minimizing side effects of the NSAID, such as ulcers, erosions, and other lesions. The claims specifically required an amount of PPI that is *effective* to raise the gastric pH of the patient. Nuvo argued, and the district court found, that the claims were nonobvious because the prior art taught that an uncoated PPI would be *ineffective* to raise gastric pH due to degradation of the uncoated PPI in the stomach. The district court also rejected the defendants' written description arguments.

On appeal, the Federal Circuit held that the asserted claims were invalid for lack of written description because the specification did not demonstrate that the inventor possessed and actually invented an amount of uncoated PPI that is *effective* to raise gastric pH. The court found that it was not sufficient that the disputed claim language appeared in the specification *in ipsius verbis* (i.e., "in the same words"). Because the inventor expressly claimed a result – therapeutic effectiveness of uncoated PPI to raise gastric pH – and because a person of ordinary skill would not have expected uncoated PPI to achieve the claimed result, the specification was required to provide "adequate disclosure" supporting the claimed result. The specification provided no experimental results or supporting theory demonstrating that an uncoated PPI would be effective to raise gastric pH. Accordingly, the court held that the asserted claims were invalid for lack of written description.

The *Nuvo* decision provides a cautionary tale about the importance of providing adequate support when claiming a result that allegedly runs counter to the expectations of a person of ordinary skill in the art. Patent applicants should consider including supportive experimental data or a technical explanation when claiming such results. Conversely, patent challengers should evaluate whether a written description defense is appropriate when the patentability of an asserted patent is based on a claimed result that allegedly runs counter to the teachings of the art.

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