NUVO PHARMACUETICALS v. DR. REDDY'S LABORATORIES INC., Appeal No. 2017-2473 (Fed. Cir. May 15, 2019). Before Prost, Clevenger, and Wallach. Appealed from D.N.J. (Judge Cooper).

Background:

Nuvo sued Dr. Reddy's for infringement of patent claims covering its pain relief drug, Vimovo®, after Dr. Reddy's filed an ANDA seeking to market a generic version of the drug. The drug is a combination of a non-steroidal anti-inflammatory drug (NSAID) for treating pain and an acid inhibitor for reducing acidity in the gastrointestinal tract. In order to prevent gastrointestinal problems thought to be caused by the combination of the NSAID and acid in the stomach and upper small intestine, the drug is designed to release the acid inhibitor first to increase the pH in the gastrointestinal tract to a desired level before the NSAID is released.

Dr. Reddy's stipulated to infringement, but alleged that the patent claims were invalid on various grounds, including lack of an adequate written description. The district court disagreed, finding that the claims satisfied the written description requirement. Dr. Reddy's appealed.

Issue/Holding:

Did the district court err by holding that the claims satisfied the written description requirement? Yes, reversed.

Discussion:

The Federal Circuit disagreed with the district court that the specification adequately supported claim limitations requiring an amount of an uncoated acid inhibitor *effective* to raise the gastric pH to at least 3.5. The specification recognized that uncoated acid inhibitors were known to be problematic due to their risk of destruction by stomach acid. In fact, in its obviousness analysis, the district court found that persons of ordinary skill in the art would not have expected an uncoated acid inhibitor to be effective. Yet there was no disclosure in the specification explaining how an uncoated acid inhibitor in any amount could be effective to raise pH, let alone any experimental evidence demonstrating effectiveness.

The Federal Circuit acknowledged that experimental evidence of effectiveness is normally not required for pharmaceutical composition claims. But, here, because the claims recited the therapeutic effectiveness, the court found that the effectiveness must be adequately supported by the specification to demonstrate that the inventor possessed and actually invented the claimed composition. In view of the lack of any explanation or evidence of the effectiveness of uncoated acid inhibitors, the Federal Circuit concluded that the specification provided nothing more than the mere wish that uncoated acid inhibitors would work.

The district court had held that the written description requirement was satisfied by the disclosure of uncoated acid inhibitors for immediate release and preferred amounts thereof in combination with the knowledge that coated formulations sometimes work too slowly. But the Federal Circuit disagreed that this was sufficient to support claims to the effectiveness of uncoated acid inhibitors to increase the pH to at least 3.5.