HZNP MEDICINES LLC v. ACTAVIS LABORATORIES UT, INC., Appeal Nos. 2017-2149, -2152, -2153, -2202, -2203, -2206 (Fed. Cir. October 10, 2019). Before Prost, Newman, and Reyna. Appealed from D.N.J. (Judge Hillman).

Background:

HZNP ("Horizon") owns a number of patents that relate to formulations and methods of using a topical agent marketed as PENNSAID® 2%. Actavis sought to market a generic version of PENNSAID 2% and filed an ANDA along with a Paragraph IV certification. Horizon brought suit alleging infringement. Claim construction ensued at the district court and a number of patents were found invalid on the grounds that the phrase "consisting essentially of" was indefinite. Horizon appealed.

Issue/Holding:

Did the district court err in finding "consisting essentially of" indefinite? No, affirmed.

Discussion:

The phrase "consisting essentially of" reflects intent to include (a) the listed ingredients that follow the phrase, and (b) unlisted ingredients that do not materially affect the basic and novel properties of the invention. Because the parties disputed the basic and novel properties, the district court determined that identification of those properties was required, and that, because these properties were part of the claim construction, the *Nautilus* standard applied to the assessment of the properties.

The specification described several properties including better drying time. The district court held that this property was indefinite because the specification described two different methods for evaluation that provided inconsistent results. In light of expert testimony that a POSITA would not know which standard to use to evaluate the drying rate, the district court found that a POSITA would not have had a "reasonable certainty" about the scope of the property, thereby rendering "consisting essentially of" indefinite.

On appeal, Actavis argued that the district court's evaluation of the basic and novel properties under the *Nautilus* standard was legal error. It asserted that the *Nautilus* definiteness standard focuses on the claims and therefore does not apply to such properties. But the Federal Circuit disagreed, finding that by using the phrase "consisting essentially of," the inventor incorporated into the scope of the claims an evaluation of the basic and novel properties. The Federal Circuit reasoned that having used "consisting essentially of," and thereby incorporated unlisted ingredients or steps that do not materially affect the basic and novel properties, a drafter cannot later escape the definiteness requirement by arguing that the properties are in the specification, not the claims.

The Federal Circuit noted that "consisting essentially of" is not *per se* indefinite, and that a patentee can surely claim unnamed ingredients by employing "consisting essentially of" so long as the basic and novel properties are definite. The Federal Circuit held that, in order to determine if an unlisted ingredient materially alters the basic and novel properties, the *Nautilus* standard requires that the properties be known and definite. Based on this premise, the Federal Circuit agreed with the district court that the specification's drying time property, and therefore the claims, were indefinite.