FOREST LABS., LLC v. SIGMAPHARM LABS., LLC, Appeal Nos. 2017-2369, -2370, -2372, -2373, -2374, -2375, -2376, -2389, -2412, -2436, -2438, -2440, -2441 (Fed. Cir. March 14, 2019). Before Prost, Dyk, and Moore. Appealed from D. Del. (Judge Robinson).

Background:

Forest Laboratories sued several drug manufacturers that had filed Abbreviated New Drug Applications to market generic versions of Forest's patented antipsychotic drug. The representative product claim was directed to "a pharmaceutical composition comprising ["Compound X"], wherein . . . the composition disintegrates within 30 seconds in water at 37ºC."

The district court construed the claim to be limited to buccal and sublingual formulations when read in view of the specification, and found that the claim was valid and had been infringed. The defendant drug manufacturers appealed, arguing that the district court's claim construction was improper, and that the claimed composition would have been obvious.

Issues/Holdings:

(i) Did the district court err in its claim construction? No, affirmed.

(ii) Did the district court err in holding that the claimed composition was not obvious? Yes, vacated and remanded.

Discussion:

The Federal Circuit held that the district court did not clearly err in its claim construction. Although the claim did not expressly refer to buccal or sublingual administration, the district court properly construed the claim to be limited to these types of formulations in view of language in the specification. Specifically, the Federal Circuit highlighted the following points:

- The specification stated that "the invention relates to a sublingual or buccal pharmaceutical composition."
- The specification described the benefits of sublingual and buccal administration over the prior art.
- The patent was titled "Sublingual or Buccal Pharmaceutical Composition."
- The specification described preferred pharmaceutical compositions as those which "rapidly disintegrate in the mouth of the subject" by sublingual or buccal placement, and defined "rapid disintegration" as "disintegration within 30 seconds in water at 37ºC."

The Federal Circuit also reviewed several of the district court's findings relating to obviousness. Although it upheld most of the district court's findings, the Federal Circuit held that the district court did not set forth a clear finding with respect to whether it would have been obvious to develop sublingual or buccal formulations of the drug in order to address compliance concerns. Instead, the district court only summarized testimony showing that sublingual and buccal administration would have been expected to be more burdensome to the target population. The Federal Circuit therefore vacated the validity judgment and remanded to the district court to further address this particular issue.