BRAINTREE LABORATORIES, INC. v. NOVEL LABORATORIES INC., Appeal No. 2013-1438 (Fed. Cir. April 22, 2014). Before Dyk, Prost, and Moore. Appealed from D.N.J. (Judge Sheridan).

Background:

Plaintiff owns a patent directed to a composition (drug) for inducing "*purgation* of the colon of *a patient*," where the composition does not produce any "*clinically significant electrolyte shifts*." Defendant filed an abbreviated new drug application ("ANDA") for a generic version of the drug. The ANDA limits the dose regimen of the generic version of the drug to a dose requiring administration of two bottles of oral solution. Plaintiff filed a declaratory judgment action seeking a declaration that Defendant's product infringes the claims of its patent. Specifically, Plaintiff asserted that one (half-dose) bottle of Defendant's ANDA product infringes the claims of its patent. Defendant asserted a counterclaim of non-infringement.

After construing claim terms, the district court granted summary judgment of infringement in Plaintiff's favor and denied Defendant's motion for reconsideration. The district court rejected Defendant's argument that the disputed claim term "purgation" means cleansing, concluding that although cleansing is a term in the specification of the patent, the asserted claims clearly adopt purgation as the methodology to improve visualization of the colon, which can be accomplished with a half-dose of the Defendant's ANDA product. In reaching its determination, the district court modified its original construction of the term "clinically significant electrolyte shifts" to depart from an express definition of this term in the specification. The district court also found that the administration of the composition and evaluation of the electrolyte levels in the asserted claims were meant to be done on a per patient basis, with the district court construing the preamble term "a patient" to mean "one or more patients." Defendant appealed.

Issue/Holding:

Did the district court err in granting summary judgment of infringement in Plaintiff's favor? Yes, vacated and remanded.

Discussion:

The Federal Circuit held that the claims contain no language that requires achieving a fully cleansed colon for a colonoscopy. While cleansing is a goal stated in the specification, it is not a claim requirement. The Federal Circuit also determined that a post-issuance statement (equating cleansing and purging) did not modify the plain meaning of the word "purgation." The district court's construction and findings that Defendant practiced this feature were thus affirmed.

The Federal Circuit reversed the district court's claim construction of the term "clinically significant electrolyte shifts" because the district court ignored the inventor's clear definition of this term in the specification. Additionally, instead of defining the term "a patient" to mean "one or more patients," the Federal Circuit held that the term "a patient" should be construed to mean a general class of persons to whom the patented compositions are directed, i.e., a patient population. The Federal Circuit determined that the district court's application of the claim term "a patient" to be one or more patients individually leads to an absurd result of infringement (i.e., infringement even if a composition causes clinically significant electrolyte shifts in a large percentage of patients, but little or no shift in only a single patient). The Federal circuit also explained that the revised definition of "a patient" is consistent with the invention the patentee intended to define and protect.