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Federal Circuit Patent Bulletin: *Braintree Labs., Inc. v. Novel Labs.*

April 22, 2014

"[A] preamble is not limiting 'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.'"

On April 22, 2014, in *Braintree Labs., Inc. v. Novel Labs.*, the U.S. Court of Appeals for the Federal Circuit (Dyk, Prost,* Moore) affirmed-in-part, reversed-in-part, vacated-in-part, and remanded the district court's summary judgment that Novel infringed U.S. Patent No. 6,946,149, which related to a magnesium sulfate, potassium sulfate, and sodium sulfate composition for colonic purging without causing clinically significant electrolyte shifts that Braintree markets as SUPREP® Bowel Prep Kit, and that the '149 patent was not invalid. The Federal Circuit stated:

"In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" The asserted claims here only require that the compositions "induce" (i.e., bring about or start) diarrhea. The claims do not contain language that requires achieving a fully cleansed colon for a colonoscopy. Thus, while cleansing is the goal specifically articulated in the specification, it is not a claim requirement. . . . Although the specification contemplates a scenario in which an effective amount could produce a full cleansing, it does so only in terms of a preferred embodiment. [W]e affirm the district court's construction of the claim term "purgation." . . .

[T]he patentee's lexicography must govern the claim construction analysis. Therefore, we disagree with the district court's modification of the clear language found in the specification. We reverse the district court's claim construction and construe "clinically significant electrolyte shifts" to be "alterations in blood chemistry that are outside the normal upper or lower limits of their normal range or other untoward effects." . . . Based on its construction of "purgation," which does not require a full cleanse, the district court found that one bottle of SUPREP meets the "purgation" claim limitation, as it will induce an evacuation of a copious amount of stool from the bowels and is a composition comprising 473 mL of an aqueous hypertonic solution. We affirm the

district court's construction of this term, and we likewise affirm the district court's finding that one (half-dose) bottle of SUPREP practices this claim limitation. . . .

"[I]f the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." Conversely, a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." [I]n this case, the district court's definition of "a patient" is incorrect. In view of the proper claim construction of "clinically significant electrolyte shifts," the district court's application of the claim terms "a patient" leads to the absurd result of infringement even if a composition causes clinically significant electrolyte shifts in a large percentage of patients. Therefore, we instead interpret "a patient" to mean the general class of persons to whom the patented compositions are directed, i.e., a patient population. [T]here is evidence in the record that at least some patients experienced alterations in blood chemistry that are outside the normal upper or lower limits of their normal range. Therefore, we conclude that there remains a genuine dispute as to whether SUPREP avoids producing any clinically significant electrolyte shifts in a patient population. We vacate the district court's grant of summary judgment of infringement, and we remand this matter to the district court for further factual findings concerning whether such alterations qualify as "clinically significant electrolyte shifts" in accordance with the proper claim construction articulated here within. . . .

Novel alleges that the asserted claims "'simply arrange[] old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, [so] the combination is obvious." . . . We disagree. As the district court correctly noted, Novel did not prove that one of skill in the art would have been motivated to combine so many references. In other words, it failed to prove a "plausible rational[e] as to why the prior art references would have worked together." Further, in building its obviousness case, Novel relies on expert testimony which the district court found to be less credible. And the prior art, including Hechter, taught that safe bowel preps should be isotonic, not hypertonic like the claimed compositions. Therefore, we conclude that the district court did not err in finding that Novel failed to demonstrate that the asserted claims of the '149 patent would have been obvious at the time of the invention.