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The Federal Circuit's Evolving Obviousness Analysis

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The Federal Circuit continues to take some of the bite out of the Supreme Court's KSR decision (*KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)) that broadened the basis for determining that patent claims are obvious by, among other things, avoiding overly rigorous application of the TSM (teaching, suggestion, motivation) test. In *Unigene Labs. and Upsher-Smith Labs. v. Apotex* (Fed. Cir. August 25, 2011) (available at <http://www.ca9.uscourts.gov/images/stories/opinions-orders/10-1006.pdf>), the Federal Circuit held that use of 20 mM citric acid as an absorption-enhancing agent and surfactant in a nasal spray composition was not obvious in view of the combination of an otherwise similar formulation using BZK (benzalkonium chloride) for that purpose and a reference using citric acid as a buffer in a nasal spray composition.

Unigene Laboratories is the owner of Reissue Patent No. __?__, "the '812 patent," which claims the liquid formulation used in the product Fortical®, which is administered as a nasal spray. The Fortical® formulation was developed to design around a former product, Miacalcin®. Miacalcin® is a liquid formulation for nasal administration of salmon calcitonin that includes BZK as a preservative, absorption enhancer and surfactant. Claim 19 of the '812 patent recites a formulation for nasal administration that includes about 20mM citric acid. Among the references considered by the court were the '014 patent, which describes a solid oral formulation of salmon calcitonin that includes citric acid as an absorption enhancer, and the '315 patent that describes peptide formulations that use citric acid as the acidic component of a buffer.

The Federal Circuit acknowledged that KSR broadly held that the motivation to combine references need not necessarily come from a teaching in the references themselves, but can also come from "common sense and [the] appropriate perspective" of a person in the art. The court recognized that the desire to create a formulation that is bioequivalent to an existing formulation provides motivation to develop new formulations. However, the court then qualified its interpretation of reasoning behind KSR, stating that "[t]o render a claim obvious, prior art cannot be 'vague' and must collectively, although not explicitly, *guide an artisan of ordinary skill* towards a particular solution." (emphasis added)

To apply this obviousness standard, the Federal Circuit first defined Miacalcin® as a "reference composition," the basis for a starting point for inventing a new drug formulation. The court frequently uses similar methodology to define a reference or lead compound when analyzing the obviousness of new chemical entities. The court then looked at whether the prior art would lead one to modify the reference composition to arrive at the claimed composition. In doing so, the court observed that the '014 patent differed by describing "citric acid for bioavailability in the context of a liquid injection into a rat duodenum, not a human use in a liquid pharmaceutical formulation." Further, the '315 patent "makes clear [] that 'citric acid was not used as an absorption enhancing agent, but it is merely the acidic component of the buffer.'" (quoting the District Court opinion). Thus, in the court's view, "[t]o a person of ordinary skill in the art, citric acid, even at about 20 mM concentrations, would not be an obvious substitute for BZK's functions as an absorption enhancer and as a surfactant because citric acid has a vague role in even the closest prior art."

There are a number of important observations about this decision. First, the court uses a "reference composition" for the first time in looking at obviousness of a formulation. It is difficult to tell whether this use of a starting point can be applied to other technology areas, such as electronics or mechanical inventions, but the court here broadens its use in the chemical and medical fields. Second, the purpose of citric acid is not identified in the claim, although it was defined during prosecution as being significant. While not claiming the specific purpose is consistent with existing law, patent applicants and patent owners are often challenged when the claim itself does not define the advantage or use of a particular component. This opinion can serve as a reminder to examiners and litigants that reciting the purpose or advantage is not required in the claim. Third, in its prior art analysis, the court takes a hard look for a suggestion, motivation or teaching to combine references,

and finds reasons why there are none. This view seems to cast a stone at the Supreme Court's urging to find broad reasons for combining references, suggesting once again that the Federal Circuit will continue to use some version of the TSM test. Finally, although not discussed here, the court held the claim nonobvious because a person of ordinary skill would not have considered using the particular amount of citric acid together with the narrowly claimed amounts of the other ingredients and expected to obtain a properly performing formulation. This stresses the importance of including narrowly drafted patent claims directed to a specific commercial embodiment that can be upheld as valid. Narrow claims are particularly useful where the product is subject to regulatory approval, such as for a drug, where there is less latitude for subsequent variations.

The Federal Circuit continues to develop its obviousness jurisprudence in view of KSR. In the chemical arts, the court tends to apply a modified TSM analysis by looking at a starting point and determining whether there is some teaching, suggestion or motivation in the art, that would lead to the claimed composition. As has been noted widely, this results in a greater tendency to find nonobviousness in the chemical arts than in other technology areas. As a result, claims for new compounds and, now, new formulations are held valid. It remains to be seen whether a similar analysis applied to other technologies might meet with similar success.