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Client Alert

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LOW STANDARD FOR OBVIOUSNESS OF NEW FORMULATIONS OF KNOWN DRUGS

Many advances in treatment rely on new formulations of know drugs. As with most drugs, pharmaceutical companies consider patent-based recoupment of development and regulatory costs required to bring new formulations to market an essential prerequisite to pursuing a new formulation. Without effective patent protection, many new formulations would not be developed. A new decision from the Federal Circuit (the nation's main patent court) has applied the lowered standard for obviousness of inventions to invalidate the patent to a new formulation of a known drug.

As reported earlier (see Client Alert), the Supreme Court's decision in KSR v. Teleflex, 127 S. Ct. 1727 (2007), made it easier for courts to invalidate patents for obviousness. The KSR decision was expected to reduce the number of valid patents and to reduce the value of patents in general. Obviousness is one of the basic hurdles that an invention must avoid in order to be patentable. Put simply, if the new invention would have been obvious to workers in the technical field of the invention then the invention cannot get patent protection. Because what is obvious is a vague standard, prior courts had set up specific rules for testing obviousness—basically requiring evidence that workers in the field would have thought of the invention. In the KSR decision, the Supreme Court ruled that courts could not require any specific test of obviousness. Rather, the KSR decision asked courts to assess obviousness using common sense. The KSR decision was expected to reduce the number of valid patents and to reduce the value of patents in general because a common sense standard is lower and less objective.

We have been watching court decisions based on KSR and involving biomedical inventions to assess the impact of this decision. Now, the Federal Circuit has limited the ability of drug makers to patent new formulations of known drugs. In the new decision, Bayer Schering Pharma AG v. Barr Laboratories, Inc., -- F.3d -- (Fed. Cir. 2009), the Federal Circuit considered the obviousness of Yashmin®, Bayer's micronized, non-enterically coated formulation of the birth control drug drospirenone. A majority of the Federal Circuit panel agreed with Barr that it would have been obvious to try Bayer's formulation from among a limited set of formulation options. Dissenting Judge Newman criticized the majority's failure to consider evidence that the formulation was not obvious.

Whether an invention is or is not obvious depends of the what was known and what was expected by those in the relevant filed. These facts are applied by courts to the law of obviousness to determine whether a given invention is or is not obvious. The facts in the new Bayer decision illustrate the problems for patenting new formulations under the KSR obviousness standard.

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At the time the new formulation was invented, drospirenone was known to have low solubility in water and to be susceptible to inactivation by stomach acids. Both of these factors reduce the bioavailability of drospirenone. More than many drugs, it is essential that contraceptives have reliable and consistent bioavailability. This need was known and achieving it was a goal of Bayer scientists. It was known that micronization is one formulation strategy to increase the bioavailability of poorly soluble drugs. It was also known that covering acid-affected drugs with an enteric coating protected the drugs from inactivation by stomach acids. Finally, and in conflict with the goal, it was also known that enteric coatings reduced the bioavailability and the consistency of the effective dose of a drug.

Based on this, the Bayer scientists worked to develop a micronized, enterically coated formulation of drospirenone. The Bayer inventor testified that, at the time, he did not expect a non-enterically coated formulation to be an effective contraceptive because of the high rate of inactivation of drospirenone in an in vitro acid test and because he expected that the increased availability of drospirenone in the stomach made possible by micronization would further increase inactivation. The ultimate non-enterically coated formulation was only discovered by the inventor when Bayer scientists included a non-enterically coated formulation as a negative control in a test of bioavailability of injected drospirenone versus the enterically coated formulation under development. The scientists expected the bioavailability to be ineffectively low in the non-enterically coated formulation as a negative control. The inventor testified that they were surprised to find that the non-enterically coated formulation had an acceptable bioavailability. This led directly to Bayer's adoption of the ultimate formulation of Yashmin® and to issuance of a patent to that formulation.

In the Bayer decision, the Federal Circuit focused on the fact that the Bayer scientists had, in the court's view, a choice of only two, well-known options for drug formulation: enteric coating or no enteric coating. Because the Supreme Court's KSR decision emphasized that inventions that involve a choice of only a finite number of known options, the Federal Circuit concluded that selection of one of two well-known options for drug formulation of drospirenone was obvious.

However, at the dissenting Judge pointed out, the majority in Bayer failed to consider that neither the inventor nor those in the field of drug formulation would have expected non-enterically coated drospirenone to provide the necessary or reliable bioavailability for a contraceptive given the facts known about drospirenone at the time. This is important because another aspect of the law of obviousness requires that there be a "reasonable expectation of success" in doing what is allegedly obvious. The dissenting Judge argued that given the facts that those in the field of drug formulation would not have expected a non-enterically coated formulation of drospirenone to be an effective contraceptive. Based on this, the dissenting Judge concluded that the patented formulation should not have been considered obvious.

Both the majority and the dissenting Judge in Bayer missed another factor that supports nonobviousness for Bayer's drug formulation. Another aspect of obviousness law—an aspect not altered or limited by the Supreme Court in KSR—allows inventions that would otherwise be obvious to be patented if their are so-called "secondary considerations" on nonobviousness. Secondary considerations of nonobviousness include commercial success of the invention, long felt but unmet need in the field, failure of others to succeed where the inventor succeeded, and unexpected results. The unexpectedness of the success of Bayer's non-enterically coated formulation of drospirenone should have been a decisive factor in finding the formulation nonobvious.

The dissenting Judge seems to be correct, but the decision of the majority—and the limited rationale on which the majority decision is based—will likely influence future obviousness determinations of future drug formulations. By looking only at know and limited options—a common situation in the field of drug formulation—and by overlooking legitimate factors of nonobviousness, courts following the Bayer decision may deny patent protection to many drug formulations that should receive patent protection.