United States Court of Appeals for the Federal Circuit

2008-1282

BAYER SCHERING PHARMA AG
and BAYER HEALTHCARE PHARMACEUTICALS, INC.,

Plaintiffs-Appellants,

v.

BARR LABORATORIES, INC.,

Defendant-Appellee.

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Appealed from: United States District Court for the District of New Jersey

Judge Peter G. Sheridan

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Appeal from the United States District Court for the District of New Jersey in case no. 05-CV-2308, Judge Peter G. Sheridan.

DECIDED: August 5, 2009

Before NEWMAN, FRIEDMAN, and MAYER, Circuit Judges.

Opinion for the court filed by Circuit Judge MAYER. Dissenting opinion filed by Circuit Judge NEWMAN.

MAYER, Circuit Judge.

Bayer Schering Pharma AG ("Bayer") appeals the judgment of the United States District Court for the District of New Jersey, holding U.S. Patent No. 6,787,531 ("'531 Patent") invalid due to obviousness. Bayer Schering Pharma AG v. Barr Labs., Inc., No. 05-CV-2308 (D.N.J March 3, 2008). Because we hold that the invention would have been obvious to try, we affirm.

BACKGROUND

Bayer is a large pharmaceutical company that produces the daily oral contraceptive, Yasmin®. One of the active ingredients in Yasmin, drospirenone, is a progestin that inhibits ovulation. Each of the invalidated claims requires drospirenone as the active ingredient. Drospirenone was known in the art at all times relevant. Its contraceptive qualities are particularly well suited for producing an oral contraceptive because, in addition to inhibiting ovulation, it is a diuretic which will diminish excess water retention arising from the estrogen component of oral contraceptives, and has anti-acne qualities to promote clear skin. These desirable qualities have led to Yasmin's success. Drospirenone is also acid-sensitive. When exposed to low-pH (highly acidic) environments such as found in the human stomach, drospirenone "isomerizes" – that is, the acid catalyzes a reaction that rearranges drospirenone's molecular structure while its molecular composition remains constant. The resulting isomer is non-antimineralocorticoidal, meaning it will not act as a diuretic, removing the desirable anti-bloating effect that sets drospirenone apart from other prior art progestins. Therefore, scientists working with drospirenone for use in an oral contraceptive must be aware of and work around the effects that the human stomach will have on the drug to ensure that its "bioavailability" – the amount of the active drug absorbed into the bloodstream and available to act on the body – is high enough to perform its contraceptive function.

Drospirenone is also a poorly water soluble hydrophobic composition. Because it will not easily dissolve into a volume of liquid, its bioavailability is degraded. To combat this, pharmaceutical producers commonly employ a technique called "micronization,"

whereby the drug's particle size is reduced, increasing its overall surface area. Often (but not always) with a larger surface area, the dissolution rate is also increased, ensuring that all of the poorly water soluble drug that can dissolve will dissolve in a given volume of liquid. With more of the drug dissolved, the drug will exhibit a higher bioavailability. Indeed, Bayer's expert testified at trial that this would be his first choice in attempting to increase the dissolution rate because, among the different ways to increase the dissolution rate, micronization presents the best chance of success. All commercially available oral contraceptives use micronized progestins and/or estrogens, so this technique was well known in the art.

While micronizing a poorly water soluble composition may result in increased bioavailability, micronizing an acid-sensitive composition may also increase its sensitivity to the acid. A drug that isomerizes when exposed to acid thus may isomerize at a faster rate if it is micronized.

One method pharmaceutical companies use to surmount an acid-sensitivity problem with a drug to be taken orally is to deliver the drug via an enteric-coated pill, as opposed to an immediate release pill, also called a "normal pill." An enteric coating is a pH-sensitive film that protects the drug from stomach acid, and only releases the drug when it has passed into the less acidic duodenum and small intestine. However, enteric coatings are not without drawbacks themselves. Coated tablets including enteric coated tablets present an obstacle to absorption, and thus reduce the drug's exhibited bioavailability. Additionally, as was known in the art at the time, they introduce a significant delay in the onset of therapeutic response while creating a considerable patient-to-patient variation of that onset. In fact, even for an individual taking the drug at

different times, the response time may vary considerably from dose to dose. Bayer scientists noticed these intra- and inter-individual bioavailability differences in practice in their studies on beagles and women. This presented a further complication because Bayer required the drug to be 99% effective, and work on all women at a single dose – "one dose must fit all." A normal pill may not present such variations, but will expose its contents to the stomach's highly acidic environment.

Dr. Johannes Tack, a Bayer scientist, began work in 1983 to develop drospirenone into an oral contraceptive. At the time, Bayer had been working with a related compound, spirorenone, as a diuretic. When consumed, spirorenone metabolizes into drospirenone, which is still a diuretic, but was found to have progestogenic (contraceptive) effects. Spirorenone itself had some contraceptive effects that Bayer concluded were the result of the appearance of drospirenone when it metabolized. Bayer decided to harness the diuretic effect of isolated drospirenone to create the new contraceptive. Tack consulted prior Bayer work with drospirenone including in vitro isomerization studies performed by a fellow Bayer scientist, Dr. Werner Krause. Krause had also performed in vivo studies with spirorenone, about which he published three articles. These studies, Krause I, II, and III, included the knowledge that drospirenone was a metabolite of spirorenone. Tack decided, however, that these in vivo studies garnered little information on the practice of drospirenone in vivo.

Tack tested the stability of drospirenone in acid at pH 1 to simulate the conditions of the stomach. He found that after 10 minutes, 21% of the drospirenone had

isomerized in the acid, and after 45 minutes, half had isomerized. He came to a critical conclusion:

> If the results obtained in vitro are applied to in vivo conditions, it can be presumed that, with an assumed gastric juice volume of 100ml, the majority of the dose (solubility of drospirenone 5-10 mg/l) passes into solution during passage through the stomach and consequently undergoes rapid isomerization. A clear reduction in the bioavailability of the unchanged active substance is to be expected as a result.
>
> The planned studies on the progestogenic efficacy of [drospirenone] should therefore be performed with an enteric-coated formulation.

Tack then moved into clinical studies with an enteric-coated formulation of drospirenone. For five years, Bayer used this coated pill in its studies, even reconfirming in 1988 that drospirenone needed an enteric coating because it isomerized quickly in a pH 1 acidic solution.

In 1988, Bayer also planned a study to determine how effectively its enteric-coated tablet delivered a formulation as compared to an intravenous injection of the same formulation. This study would thus measure the "absolute bioavailability" of the drug. Bayer added what it terms a "non-routine" element to the study, by which it added an unprotected (normal) drospirenone tablet and compared its bioavailability to that of the enteric-coated formulation and the intravenous delivery. Tack expected to find that the enteric-coated tablet would produce a lower bioavailability than an intravenous injection, while the normal pill would produce an even lower bioavailability than the enteric-coated tablet. However, he found that despite his observations that drospirenone would quickly isomerize in a highly acidic environment and his belief therefore that an enteric coating would be necessary to preserve bioavailability, the normal pill and the enteric-coated pill resulted in the same bioavailability. Following this

study, Bayer developed drospirenone in a normal pill, for which it would eventually receive the '531 patent.

Bayer relied on the finding that drospirenone would absorb with a normal pill to overcome an obviousness rejection in the Patent and Trademark Office. During prosecution, the examiner rejected the claims as obvious in view of a De Castro reference, which the examiner said taught to micronize poorly soluble drugs to increase their bioavailability. Bayer responded that another piece of prior art, the Nickisch reference, taught that micronizing drospirenone would increase its exposure to the highly acidic environment in the stomach, which would result in increased isomerization. The examiner allowed the claims, giving the specific reason that the prior art suggested that micronizing drospirenone would not work: "The micronized drospirenone will be degraded even more rapidly because the micronization of drospirenone expose [sic] the drug particles in the stomach (acidic). Therefore, to formulate an oral dosage forms [sic] containing the drospirenone particles, which exposed to the gastric environment upon dissolution, would be un[o]bvious in view of the data presented . . . ."

The '531 patent issued on September 7, 2004. Claim 1 is representative:

> 1. A pharmaceutical composition comprising
> from about 2 mg to about 4 mg of micronized drospirenone particles,
> about 0.01 mg to about 0.05 mg of 17.alpha.-ethinylestradiol, and
> one or more pharmaceutically acceptable carriers,
> the composition being in an oral dose form exposed to the gastric environment upon dissolution,
> and the composition being effective for oral contraception in a human female.

Barr Laboratories ("Barr") makes generic pharmaceuticals, and filed an Abbreviated New Drug Application with the Food and Drug Administration seeking approval to market a generic version of Yasmin®. Bayer promptly filed a patent

infringement suit against Barr. The parties agreed that if the '531 patent is valid, Barr infringes claims 1, 5, 8, 27, 29, 36, 49, and 50. Barr then alleged that these claims are obvious, among other invalidity and unenforceability arguments. At trial, the two parties agreed that 2-4 mg drospirenone was well known in the art, as well as its combination with 0.01-0.05 mg 17α-ethinylestradiol, a pharmaceutically acceptable carrier, and a kit containing 21 such tablets with active ingredients and 7 placebos, to be used as an effective oral contraceptive in human females. Bayer claimed that its innovation was that the drospirenone could be micronized to increase its bioavailability, and that the micronized drospirenone would not need to be enteric coated for protection against the highly acidic gastric environment.

The district court ruled that these claims were invalid as obvious, and rejected Barr's other theories. The court found that a person having ordinary skill in the art would have considered the Krause I, II, and III studies' results that spirorenone though acid-sensitive would nevertheless absorb in vivo because drospirenone is closely related to spirorenone. It also found that while the Nickisch reference did teach that drospirenone isomerizes in vitro when exposed to acid simulating the human stomach, a person of ordinary skill would be aware of the study's shortcomings, and would verify whether drospirenone absorbed or isomerized with precise in vivo and in vitro testing as suggested by the Robert Aulton treatise, Pharmaceutrics: The Science of Dosage Form Design (1988). It then held that under KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007), it would have been obvious to a person having ordinary skill in pharmaceutical formulation to try a normal pill in formulating drospirenone as an oral

contraceptive. Bayer timely appeals this ruling; Barr does not cross-appeal its adverse rulings. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

Obviousness under 35 U.S.C. § 103 is the sole issue in this appeal. Whether an invention would have been obvious at the time the invention was made is a question of law, which we review de novo, based on underlying facts, which we review for clear error. Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1355 (Fed. Cir. 2007). A district court's finding is clearly erroneous when, despite some supporting evidence, we are "left with the definite and firm conviction that a mistake has been committed." Forest Labs., Inc. v. Abbott Labs., 339 F.3d 1324, 1328 (Fed. Cir. 2003) (quoting United States v. U.S. Gypsum Co., 333 U.S. 364, 395 (1948)).

A patent may not be obtained if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. § 103(a). An obviousness analysis is based on several factual inquiries. A court must examine the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). At that point, a court may consider secondary objective evidence of non-obviousness, such as commercial success, long felt but unsolved need, failure of others, and the like. Id.

In KSR, the Supreme Court stated that an invention may be found obvious if it would have been obvious to a person having ordinary skill to try a course of conduct:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

550 U.S. at 421. This approach is consistent with our methodology in In re O'Farrell, 853 F.2d 894 (Fed. Cir. 1988). See Procter & Gamble Co. v Teva Pharms. USA, Inc., 566 F.3d 989, 996-97 (Fed. Cir. 2009); In re Kubin, 561 F.3d 1351, 1359, (Fed. Cir. 2009). O'Farrell observed that most inventions that are obvious were also obvious to try, but found two classes where that rule of thumb did not obtain.

First, an invention would not have been obvious to try when the inventor would have had to try all possibilities in a field unreduced by direction of the prior art. When "what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful" an invention would not have been obvious. O'Farrell, 853 F.2d at 903. This is another way to express the KSR prong requiring the field of search to be among a "finite number of identified" solutions. 550 U.S. at 421; see also Procter & Gamble, 566 F.3d at 996; Kubin, 561 F.3d at 1359. It is also consistent with our interpretation that KSR requires the number of options to be "small or easily traversed." Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1364 (Fed. Cir. 2008).

Second, an invention is not obvious to try where vague prior art does not guide an inventor toward a particular solution. A finding of obviousness would not obtain

where "what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." O'Farrell, 853 F.2d at 903. This expresses the same idea as the KSR requirement that the identified solutions be "predictable." 550 U.S. at 421; see also Procter & Gamble, 566 F.3d at 996-97; Kubin, 561 F.3d at 1359-60.

Because the use of drospirenone with 17α-ethinylestradiol as an oral contraceptive was known prior art, Bayer represented that the innovation was to micronize the drospirenone to increase its bioavailability, and that the micronized drospirenone would absorb with a normal pill, against the teachings of the prior art. The district court analyzed the prior art and determined that micronizing drospirenone was taught, and that using a normal pill would have been obvious to try.

The court first determined how the person having ordinary skill in the art of pharmaceutical formulation would consider the correlation of in vitro and in vivo tests. It relied principally on Robert Aulton's pharmacologist textbook, Pharmaceutics: The Science of Dosage Form Design, which, as the court found, teaches that "dissolution rate data when combined with solubility . . . provide an insight to the formulator into the potential in vivo absorption characteristics of a drug. However, in vitro tests only have significance if they can be related to in vivo results. Once such a relationship has been established, in vitro dissolution tests can be used as a quality control test. (Aulton, p. 9)." The court concluded that the person of ordinary skill would not accept in vitro testing as valid without a correlation to in vivo tests.

With that knowledge, the court then turned to micronization. It found that Aulton cut both ways on this point, because it taught both that micronizing a poorly water soluble substance like drospirenone may increase its absorption rate, but may also increase the rate of degradation. However, Aulton stated, and other evidence corroborated, that "it is now generally recognized that poorly soluble drugs showing a dissolution rate limiting step in the absorption process will be more readily bioavailable when administered in a finely subdivided [micronized] form with larger surfaces than as the coarse material. . . . The fine material often in micronized form with larger specific surface dissolves at faster rates which can lead to improved drug absorption by passive diffusion." The district court acknowledged that the prior art suggested that there would be concern about the dissolution of a poorly water soluble acid-sensitive drug, but found that the prior art generally suggests that micronization could improve the dissolution of drospirenone. It concluded that a person having ordinary skill would have seen it as a viable option.

Bayer argues that this is clear error because the court relied on one piece of prior art to show that micronization has been shown to work on acid-sensitive compounds. The court reviewed the Hargrove reference, which was a study on micronizing progesterone, concluding that "it confirms that not all acid-sensitive drugs require enteric coating." This is incorrect, as Barr agrees, because progesterone is not an acid-sensitive drug. However, Bayer's own expert, Dr. James McGinity, testified that micronization is the first choice solution because it presents the best chance for success. So there remains adequate support for the conclusion that micronization was a viable option.

The district court then moved to Bayer's second alleged non-obvious aspect of the invention, whether the formulation should use an enteric-coated or normal tablet delivery. The court considered Bayer's argument that prior art taught formulation scientists to employ an enteric coating on drospirenone, and Barr's argument that an enteric coating is so complicated, expensive, cumbersome to manufacture, and prone to variability that it only would be used as a last resort by formulation scientists working with an acid-sensitive drug. The court found neither side persuasive, and considered the prior art as the center, again focusing on the Aulton textbook. It found that Aulton recognizes the necessity of an enteric coating to the formulation of acid-sensitive drugs, but that an enteric coating also introduces drawbacks, including that enteric coated tablets have the lowest bioavailability of all drug delivery forms. Poor bioavailability of drospirenone is the major problem that Tack sought to solve. The district court further found that Aulton teaches that there is variability in bioavailability both intra- and inter-subject when using enteric coated tablets, which is a significant obstacle to Bayer's requirement that the drug must be 99% effective for all women.

In effect, while Bayer argued that prior art teaches away from using micronized drospirenone in a normal tablet, Barr argued that the prior art teaches away from using an enteric coating. What the parties have done, however, is present the options available to a pharmaceutical formulator having ordinary skill to solve the problem of acid-sensitive but hydrophobic drospirenone.

Barr argued that the Krause series on spirorenone is controlling because of the great similarity between spirorenone and drospirenone. The Krause series tested the bioavailability of spirorenone in vivo in humans and monkeys to determine whether

there was need to develop a "pharmaceutical formulation resistant to gastric juice." The studies each found no spirorenone isomers in the subjects' blood streams, and concluded that spirorenone is absorbed before it isomerizes. Furthermore, an in vitro comparison found that drospirenone isomerized in pH 1 acid with a profile similar to spirorenone. The court found that the drugs were closely related in that they are both (1) acid-sensitive at similar rates, (2) steroids having the same pharmacological properties, (3) derivatives of the same drug, (4) of the same chemical composition except for one bond, and (5) from the same family of substances. The court then concluded that a person of ordinary skill would find the drugs closely related, and would therefore access these studies when formulating drospirenone. He would be led to believe that drospirenone, like spirorenone, may absorb in vivo, but isomerize in vitro.

Bayer argues now that the district court ignored key differences between drospirenone and spirorenone, such as that the former isomerizes 40% faster than the latter, and that drospirenone is more soluble and thus could dissolve and isomerize in acid faster. This is irrelevant because the Krause series prior art is not an anticipatory reference. It can be used to show that a drug formulator having ordinary skill had a viable known option to consider with micronized, unprotected drospirenone, and a reasonable expectation that drospirenone would perform similarly (even if not identically) to the spirorenone in the Krause series. See O'Farrell, 853 F.2d at 903-904 ("Obviousness does not require absolute predictability of success . . . all that is required is a reasonable expectation of success.").

Similarly, Bayer argued that the Nickisch article teaches that drospirenone isomerizes when exposed to acid in vitro, teaching away from allowing exposure to the

gastric environment, and thus suggesting the need for an enteric coating. Barr attacked the merits of the study as it would apply to the practice of drospirenone in vivo, noting that Nickisch did not test drospirenone in vivo to correlate its in vitro findings. Barr also challenged the Nickisch reference on the grounds that drospirenone was found to isomerize slowly and would not have isomerized before the stomach emptied, that the in vitro environment was too extreme to be compared to an in vivo practice, and that it did not explain its testing protocols. The court found that a person of ordinary skill in the art would recognize that Nickisch establishes that drospirenone isomerizes in vitro, but would be alerted to the study's shortcomings when used in vivo.

At this point, a person having ordinary skill in the art has reached a crossroads where he must choose between two known options: delivery of micronized drospirenone by a normal pill following the spirorenone analogy in the Krause series, or delivery of drospirenone by an enteric-coated pill following the Nickisch teaching that the drug needs to be protected from the stomach. This is a finite number of identified, predictable solutions. See KSR. 550 U.S. at 421. The prior art would have funneled the formulator toward these two options; he would not have been required to try all possibilities in a field unreduced by the prior art, thus avoiding the first pitfall of O'Farrell, 853 F.2d at 903. Additionally, the prior art was not vague in pointing toward a general approach or area of exploration, but rather guided the formulator precisely to the use of either a normal pill or an enteric-coated pill, thus avoiding the second pitfall of O'Farrell. Id. Because the selection of micronized drospirenone in a normal pill led to the result anticipated by the Krause series, the invention would have been obvious. See KSR, 550 U.S. at 421.

CONCLUSION

Accordingly, the judgment of the United States District Court for the District of New Jersey is affirmed.

AFFIRMED

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NEWMAN, Circuit Judge, dissenting.

With all respect to my colleagues, I do not share their view that it would have been obvious to do that which was indisputably unobvious to the experienced formulation scientists whose assignment was to formulate the known product drospirenone. The evidence showed, without contradiction, that it was known that micronized drospirenone rapidly degraded at the acidity of stomach acid. The evidence showed, without contradiction, that the Bayer scientists working in this field believed that the product required an enteric coating in order to prevent degradation in the stomach, upon ingestion as an oral contraceptive. Yet my colleagues, employing their own expertise, hold that since

the scientists working in this field turned out to be mistaken, it would have been obvious that it was not necessary to take steps to prevent acid degradation. The court discounts the testimony of the scientists themselves, ignores the knowledge concerning this product and its instability in acid, ignores the textbook teachings, and finds that this unlikely process obviously should have been tried. That is not the law of obviousness.

The statutory criterion is whether the invention would have been obvious to persons of ordinary skill at the time of the invention, not whether it is sufficiently simple to appear obvious to judges after the discovery is finally made, despite the years of contrary belief among the scientists charged with the project. At the time that the Bayer scientists were attempting to formulate drospirenone as an oral contraceptive, the textbook teaching was that micronizing acid-sensitive products would accelerate their acid-induced degradation. See, e.g., Aulton's Pharmaceutics: The Design and Manufacture of Medicines (advising against micronizing acid-sensitive drugs because it reduces the drug's bioavailability). My colleagues criticize these specialists, and rule that it was nonetheless obvious to conduct experiments that they believed would not work. The court rules that the scientists should have "tried" that which they believed would fail, and that when they eventually did try this unlikely formulation, and it succeeded, it was obvious to do so.

The unusual physiological behavior of drospirenone in the stomach was not known; this knowledge followed as scientific explanation; it did not precede the invention in suit. There was no evidence to reasonably suggest that micronized drospirenone was likely to be usable, with 99+ percent consistency of effectiveness, without any protection from degradation by stomach acid. A usable contraceptive requires virtually complete effectiveness, and the standard confronting the Bayer scientists was high. Unlike the

unrelated drugs cited by the panel majority, contraceptives require complete effectiveness. Previously known oral contraceptives such as progesterone and spironolactone are not acid sensitive, and drospirenone presented a highly specific challenge to the formulation scientists. The Bayer scientists believed that the way of avoiding the known acid degradation of drospirenone was to protect it from acid. My colleagues, however, find that it would have been obvious to expose it to acid, although it was not obvious to the scientists working on the project.

"Obviousness" requires that the subject matter was obvious to persons of ordinary skill in the field of the invention. The law does not hold it "obvious to try" experiments that contravene conventional knowledge, and that are not deemed reasonably likely to succeed. The evidence in this case is a better measure of obviousness than is the hindsight science of judges, for the scientists who eventually made this discovery testified, without dispute, that they did not believe an uncoated micronized product would meet the demanding criteria of contraceptive effectiveness. The Court in KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007) explained that the standard for "obvious to try" is whether there was a "reasonable expectation of success" at the time. It was undisputed that there was not. It was undisputed that it was not reasonably expected that uncoated micronized drospirenone would be 99+% effective as an oral contraceptive when ingested into the acidic stomach, when it was known to degrade rapidly in acid.

The district court stated that micronization was a "viable" option, and that although success was "uncertain," the invention was obvious to try. However, "viability" is not the standard. "Viability" implies that the experiment may or may not succeed. What the law requires is not guesswork, not dumb luck, but a reasonable degree of predictability of

success. My colleagues depart from the statutory standard, in ruling that persons of ordinary skill would have conducted experiments that were expected to fail. Nothing in the prior art teaches the likelihood of success of ingestion of uncoated micronized drospirenone; what is taught is the likelihood of failure.

The invention must be viewed as a whole. With the existing knowledge that drospirenone is both hydrophobic and that it degrades rapidly in acid, and the existing knowledge that micronization, although useful to counteract a drug's hydrophobic properties, renders the drug even more susceptible to acid degradation, it was not shown that a person of ordinary skill in this field would have had a reasonable expectation of achieving complete contraceptive bioavailability and effectiveness with uncoated micronized drospirenone. The contrary view has surfaced only in this litigation-induced argument. The exercise of judicial expertise to override the clear evidence of how persons of skill in this field actually behaved, is inappropriate.

I respectfully dissent.