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Federal Circuit Patent Bulletin: *Allergan, Inc. v. Sandoz Inc.*

August 4, 2015

"[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, a relevant inquiry is whether there would have been a motivation to select the claimed composition from the prior art ranges [and] 'the burden of production falls upon the patentee to come forward with evidence that (1) the prior art taught away from the claimed invention; (2) there were new and unexpected results relative to the prior art; or (3) there are other pertinent secondary considerations.'"

On August 4, 2015, in *Allergan, Inc. v. Sandoz Inc.*, the U.S. Court of Appeals for the Federal Circuit (Lourie,* Linn, Hughes) affirmed the district court's judgment following a bench trial that U.S. Patents No. 7,851,504, No. 8,278,353, No. 8,299,118, No. 8,309,605, and No. 8,338,479, which related to bimatoprost ophthalmic solutions for treating open angle glaucoma and ocular hypertension (marketed by Allergan as LUMIGAN®), were not invalid for obviousness under 35 U.S.C. § 103, and that the '353 and '118 patents were not invalid for lack of an adequate written description under 35 U.S.C. § 112, ¶ 1. The Federal Circuit stated:

A patent claim is invalid as obvious if an alleged infringer proves that the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time of invention to a person having ordinary skill in the art. Obviousness is ultimately a question of law premised on underlying issues of fact, including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the pertinent art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence, such as commercial success, long-felt need, and the failure of others. [W]here there is a range disclosed in the prior art, and the

Authors

Lawrence M. Sung
Partner
202.719.4181
lsung@wiley.law

claimed invention falls within that range, a relevant inquiry is whether there would have been a motivation to select the claimed composition from the prior art ranges. In those circumstances, "the burden of production falls upon the patentee to come forward with evidence that (1) the prior art taught away from the claimed invention; (2) there were new and unexpected results relative to the prior art; or (3) there are other pertinent secondary considerations."

[Here] the record shows that the claimed amounts of the two different ingredients could and did materially and unpredictably alter the property of the claimed formulation. . . . It may also be true here that "the disclosed range[s are] so broad as to encompass a very large number of possible distinct compositions," such that they do not teach any specific amounts or combinations and that the burden of producing evidence of teaching away, unexpected results, and other pertinent secondary considerations did not shift to Allergan. But we need not decide that issue, as it would not affect our affirmance of the district court's conclusion of nonobviousness, because, as indicated infra, we conclude that the district court did not clearly err in finding that Allergan had produced ample evidence of teaching away and unexpected results, and that such evidence fully supports a conclusion of nonobviousness.

"Whether the prior art teaches away from the claimed invention is a question of fact." "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." The district court did not clearly err in finding that the prior art taught away from using 200 ppm BAK [(benzalkonium chloride)] in a bimatoprost formulation. As the district court found, the prior art taught that BAK should be minimized in ophthalmic formulations to avoid safety problems. Indeed, the Appellants' own expert summarized the prior art's widespread concern by describing BAK as "a natural-born killer" that was "from Satan." Specifically, as the district court found in great detail, BAK was known to cause increased IOP, hyperemia, dry eye, and damage to corneal cells, and to exacerbate other eye disorders. It is not clearly erroneous to find that those known side effects would have discouraged a person of ordinary skill from using higher concentrations of BAK in a bimatoprost formulation, especially when 50 ppm BAK was known to be an adequate preservative in Lumigan 0.03%. . . .

We also conclude that the district court did not clearly err in finding that the claimed formulation exhibited "unexpected results," which differed in kind, not just in degree, from the prior art. . . . The claimed formulation, which comprises 0.01% bimatoprost and 200 ppm BAK, unexpectedly maintained the IOP-lowering efficacy of Lumigan 0.03%, while exhibiting reduced incidence and severity of hyperemia, even though the prior art taught that BAK could cause hyperemia at high concentrations. Those results exhibited by the claimed formulation thus constitute an unexpected difference in kind, viz., the difference between an effective and safe drug and one with significant side effects that caused many patients to discontinue treatment. Finally, we reject the Appellants' argument that the unexpected results do not support nonobviousness because they are merely the inherent properties of an otherwise obvious formulation. . . . This is not a case where the claims merely recite the unknown properties of an otherwise obvious formulation. Here, the previously unknown and unexpected properties of a new and nonobvious formulation constitute additional, objective evidence of nonobviousness. . . .

The written description requirement is met when the disclosure "allow[s] one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." There is no rigid requirement that the disclosure contain "either examples or an actual reduction to practice"; the proper inquiry is whether the patentee has provided an adequate description that "in a definite way identifies the claimed invention" insufficient detail such that a person of ordinary skill would understand that the inventor had made the invention at the time of filing. That assessment "requires an objective inquiry into the four corners of the specification," as "the hallmark of written description is disclosure."

[T]he specifications of the asserted patents provide an adequate written description of the invention claimed by the Group II claims. The specifications specifically describe a formulation comprising 0.01% bimatoprost and 200 ppm BAK as one of the best modes of the invention. . . . A claim that recites a property that is necessarily inherent in a formulation that is adequately described is not invalid as lacking written description merely because the property itself is not explicitly described. On this particular record, we agree with the district court that the Appellants have failed to prove invalidity for lack of an adequate written description by clear and convincing evidence. We do find, however, that the district court erred by relying on the undisclosed clinical protocol to support its written description determination. As we have explained, "[i]t is the disclosures of the applications that count." The clinical protocol is not part of the specifications of the asserted patents. It should not form the basis of the written description inquiry, even if it shows that the inventors had invented the claimed invention before the time of filing. The written description requirement requires possession as shown in the specification, not as shown by prior experimental work. Nevertheless, as indicated, because the specifications contain an adequate disclosure of the claimed formulation, the district court's erroneous reliance on the clinical protocol does not affect the outcome of this case. . . .

To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without "undue experimentation." [T]he asserted claims are not invalid for lack of enablement. "[A] patent does not need to guarantee that the invention works for a claim to be enabled." And efficacy data are generally not required in a patent application. Only a sufficient description enabling a person of ordinary skill in the art to carry out an invention is needed. "Similarly, a patentee is not required to provide actual working examples; we have rejected enablement challenges based on the theory that there can be no guarantee that prophetic examples actually work." . . .

In a constructive example, the specifications teach that a formulation containing 0.015%bimatoprost and 125 ppm BAK would effectively reduce IOP and also exhibit less hyperemia than Lumigan 0.03%. In view of those disclosures, we agree with the district court that the skilled artisan would not have questioned the utility of the claimed formulation and would be able to make and use the claimed invention without undue experimentation.

Lupin argues that "if the asserted claims are non-obvious, they cannot possibly be enabled." We disagree. The obviousness inquiry turns on what the prior art would have taught a person of ordinary skill in the art and whether the claimed invention would have been obvious in view of the prior art. . . . In contrast, the enablement inquiry turns on whether the skilled artisan, after reading the specification, would be able to

make and use the claimed invention without undue experimentation, based on the ordinary skill in the art. Because the specifications here provide sufficient guidance to the skilled artisan, there is no tension in the district court's decision that the asserted claims would not have been obvious and also are not invalid for lack of enablement.