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Federal Circuit Patent Bulletin: *Merck Sharp & Dohme Corp. v. Hospira, Inc.*

November 20, 2017

"[M]ultiple patents do not necessarily detract from evidence of commercial success of a product or process, which speaks to the merits of the invention, not to how many patents are owned by a patentee."

On October 26, 2017, in *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Newman, Lourie,* Hughes) affirmed the district court's judgment after a bench trial that the asserted claims of U.S. Patent No. 6,486,150, which related to preparing a stable formulation of the antibiotic ertapenem (marketed by Merck as Invanz®), were invalid for obviousness under 35 U.S.C. § 103. The Federal Circuit stated:

Obviousness is a question of law, based on underlying factual findings, including what a reference teaches, whether a person of ordinary skill in the art would have been motivated to combine references, and any relevant objective indicia of nonobviousness. On appeal, Merck argues that the district court erred in finding that the claims would have been obvious over either [U.S. Patent No. 5,952,323] or Almarsson because it is undisputed that none of the claimed steps is disclosed in the prior art. Merck contends that the court erred in relying solely on the "knowledge, creativity, and common sense" of a skilled artisan because "common sense" is properly invoked to provide a motivation to combine, not to supply a missing claim limitation. Furthermore, Merck continues, the prior art focused solely on degradation by dimerization, not hydrolysis. In that way, Merck argues, the prior art taught away from the claimed invention because pH values favorable for reducing dimerization result in increased hydrolysis, and vice versa. Merck also argues that the narrow ranges recited in the dependent claims are the result of

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the inventors' extensive research efforts, belying the court's finding that routine experimentation would have led to their discovery. . . .

We agree with Hospira that the district court did not err in finding that the claimed process would have been obvious at the time the invention was made. The court found that both references expressly taught minimizing dimerization by forming the carbon dioxide adduct of ertapenem at pH 6.0–9.0, that sodium hydroxide could be used to adjust the pH, and that the final adduct was to be obtained using "standard lyophilization techniques." The court also found that, while the claimed temperature range was not explicitly taught in the prior art, it was understood that degradation is minimized at low temperatures, so one of ordinary skill would have wanted to keep the temperature as low as possible without freezing. Those findings are supported by substantial record evidence. . . . [It] was reasonable for the district court to deduce from the evidence that the order and detail of the steps, if not already known, would have been discovered by routine experimentation while implementing known principles. The court's analysis thus involved no legal error.

We next address the district court's treatment of Merck's objective evidence. Merck maintains that the court improperly discounted Merck's objective evidence, which it found to be persuasive, when weighing the obviousness factors. . . . The district court found that there was commercial success of Merck's Invanz® product, and that it was sufficiently linked to the asserted claims of the '150 patent. However, the court found that this evidence was "weak[ened]"by the "blocking effect" of the '820 patent, which is directed to ertapenem itself, the point being that commercial success was not due to the qualities of ertapenem, but rather to the fact that Merck had control of another patent that precluded competition from others. Merck's evidence of commercial success should not have been discounted simply because of the existence of another patent of which Merck was the exclusive licensee. We have previously held that where "market entry was precluded" by another patent and by exclusive statutory rights stemming from FDA marketing approvals, "the inference of nonobviousness . . . from evidence of commercial success[] is weak."

But developers of new compounds often obtain a package of patents protecting the product, including compound, formulation, use, and process patents. Often such patents result from Patent Office restriction requirements relating to the technicalities of patent classifications and rulings that various aspects of claiming an invention cannot be claimed in the same patent. Or they may result from continuing improvements in a product or process. Thus, multiple patents do not necessarily detract from evidence of commercial success of a product or process, which speaks to the merits of the invention, not to how many patents are owned by a patentee. Commercial success is thus a fact-specific inquiry that may be relevant to an inference of nonobviousness, even given the existence of other relevant patents.

Nonetheless, we do not discern clear error in the district court's determination that Merck's evidence of commercial success could not overcome the weight of the evidence that the claimed process was substantially described in the prior art and required only improvement by the use of established variations. Thus, even giving the evidence of commercial success its full and proper weight, the court did not err in concluding that the claims would have been obvious at the time the invention was made in light of the merely ordinary experimentation required to arrive at the '150 patent, starting from either the '323 patent or Almarsson, for the reasons discussed above.

Second, the district court found that there was evidence of copying by others because Hospira tried five alternative formulations in an attempt to avoid copying the '150 patent, but ultimately had to rely on the accused process, which the court found would infringe the '150 patent. Hospira argues that "evidence of copying is not compelling in the context of ANDA cases because the [Hatch-Waxman Act] requires generic drug manufacturers to copy the approved drug." We do not agree with Hospira's argument, nor did the district court. The Act does not, as the court noted, require the generic manufacturer to copy the NDA holder's process of manufacturing the drug. In any event, as with the evidence of commercial success, the district court found that the evidence of copying could not overcome the weight of the competing evidence of obviousness of the claimed process. We agree with the district court. The claimed process differs from the disclosure of the '323 patent only in routine details, the implementation of which would have been well within the capabilities of one of ordinary skill in the art. Thus, we conclude that the district court did not err in its conclusion of obviousness.