

## Procter & Gamble Co. v. Teva Pharms. USA, Inc.

Nos. 08-1404, -1405, -1406, Fed. Cir. (Mayer, Dyk, Huff\*)

***[To the extent that] researchers can only “vary all parameters or try each of numerous possible choices until one possibly arrive[s] at a successful result, where the prior art [gives] either no indication of which parameters [are] critical or no direction as to which of many possible choices is likely to be successful”. . . “courts should not succumb to hindsight claims of obviousness.”***

On May 13, 2009, the Federal Circuit affirmed the district court’s judgment that U.S. Patent No. 5,583,122, which related to risedronate, the active ingredient of P&G’s osteoporosis drug Actonel®, was not invalid for obviousness or obviousness-type double patenting in view of U.S. Patent 4,761,406. The Federal Circuit stated:

The question of obviousness “often turns on the structural similarities and differences between the claimed compound and the prior art compound[.]” In this case, risedronate and 2-pyr EHDP are positional isomers; they each contain the same atoms arranged in different ways. . . . To successfully argue that a new compound is obvious, the challenger may show “that the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention.” “In keeping with the flexible nature of the obviousness inquiry, the requisite motivation [to modify] can come from any number of sources.” Thus, in addition to structural similarity between the compounds, a prima facie case of obviousness may be shown by “adequate support in the prior art” for the change in structure. . . . “To the extent an art is unpredictable, as the chemical arts often are, KSR’s focus on [ ] ‘identified, predictable solutions’ may present a difficult hurdle because potential solutions are less likely to be genuinely predictable.” The district court found that Teva failed to clear that hurdle, establishing insufficient motivation for a person of ordinary skill to synthesize and test risedronate. This finding was not clearly erroneous.

Additionally, there was an insufficient showing that a person of ordinary skill in the art would have had a “reasonable expectation of success” in synthesizing and testing risedronate. In KSR, the Supreme Court stated that when an obvious modification “leads to the anticipated success,” the invention is likely the product of ordinary skill and is obvious under 35 U.S.C. § 103. “[O]bviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.” Here, the district court’s findings indicate

that there was no reasonable expectation in 1985 that risedronate would be a successful compound.

Cases following KSR have considered whether a given molecular modification would have been carried out as part of routine testing. When a person of ordinary skill is faced with “a finite number of identified, predictable solutions” to a problem and pursues “the known options within his or her technical grasp,” the resulting discovery “is likely the product not of innovation but of ordinary skill and common sense.” So too, “[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress.” In other cases, though, researchers can only “vary all parameters or try each of numerous possible choices until one possibly arrive[s] at a successful result, where the prior art [gives] either no indication of which parameters [are] critical or no direction as to which of many possible choices is likely to be successful.” In such cases, “courts should not succumb to hindsight claims of obviousness.” Similarly, patents are not barred just because it was obvious “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.”

In this case, there is no credible evidence that the structural modification was routine. The district court found that the appellee’s expert was evasive on this topic, stating that the witness “did not directly respond to most questions posed to him about whether it would be common for a chemist who develops a pyridine compound to conceive of and make [2-pyr EHDP, 3-pyr EHDP, and 4-pyr EHDP] isomers.” But evidence of evasion is not necessarily evidence that the testimony would otherwise have been favorable. The only direct evidence that the structural modification was routine was presented by an expert witness that the district court judge discredited. Accordingly, we conclude that the district court did not clearly err in finding that Teva had not established a prima facie case of obviousness as to the challenged claims of the ’122 patent.

...

In addition to its obviousness defense, Teva also asserted that the ’122 patent was invalid for double patenting. The double patenting doctrine is designed to prevent a patent owner from extending his exclusive rights to an invention through claims in a later-filed patent that are not patentably distinct from claims in the earlier filed patent. In general, the obviousness analysis applies to double patenting, except for three distinctions. First, statutory obviousness compares claimed subject matter to the prior art, while non-statutory double patenting compares claims in an earlier patent to claims in a later patent or application. Second, double patenting does not require

inquiry into a motivation to modify the prior art. Finally, double patenting does not require inquiry into objective criteria suggesting non-obviousness. Having concluded that risedronate was not obvious under 35 U.S.C. § 103, we similarly conclude that the '122 patent is not invalid for obviousness-type double patenting. . . . Teva failed to present clear and convincing evidence of overlap between the claims of the two patents to invalidate the '122 patent based on obviousness-type double patenting.

*The previous statements are for information purposes only, and do not constitute legal advice. Questions regarding the matters discussed above, and any requests to be subscribed to the free electronic distribution of this publication, may be directed to Lawrence M. Sung, Ph.D., at +1 202.346.7850 or lsung@dl.com, or to any other Dewey & LeBoeuf LLP attorney with whom you regularly consult.*

NEW YORK | LONDON MULTINATIONAL PARTNERSHIP | WASHINGTON, DC  
ALBANY | ALMATY | BEIJING | BOSTON | BRUSSELS | CHICAGO | DOHA | DUBAI  
FRANKFURT | HONG KONG | HOUSTON | JOHANNESBURG (PTY) LTD. | LOS ANGELES | MILAN | MOSCOW  
PARIS MULTINATIONAL PARTNERSHIP | RIYADH AFFILIATED OFFICE | ROME | SAN FRANCISCO | SILICON VALLEY | WARSAW