

“[A] proper Rule 59(e) motion . . . must rely on one of three grounds: (1) an intervening change in controlling law; (2) the availability of new evidence; or (3) the need to correct clear error of law or prevent manifest injustice.” Wiest v. Lynch, 710 F.3d 121, 128 (3d Cir. 2013).

Plaintiffs first argue that, on the issue of obviousness, the trial judge engaged in hindsight reasoning which was a clear error of law. Yet the arguments Plaintiffs offer in support do not appear to support this contention. Plaintiffs begin by stating that the trial judge failed to acknowledge that the PTO recognized the evidence of teaching away during prosecution. This makes it sound like the trial judge ignored the evidence of teaching away, which is untrue. The Opinion provides a detailed analysis of the evidence of teaching away. Opinion at *48-*62. Plaintiffs may disagree with the trial judge’s analysis of the evidence, but they have failed to persuade this Court that any material evidence of teaching away was ignored.

Similarly, Plaintiffs contend that “the Court ignored the significant challenges and obstacles faced by the inventors.” (Pls.’ Br. 13.) The brief does not, however, point out what specific evidence, of which specific obstacles, Plaintiffs believe the trial judge ignored. The paragraph which begins with this assertion does not identify any challenge or obstacle faced by the inventors. (Id. at 13-14.) The preceding paragraph does present some history of the development of Atelvia®. (Id. at 12-13.) This paragraph does identify one event that seems to show an obstacle faced by the inventors: a study in beagles was conducted, but the “results were disappointing and P&G’s development partner Sanofi abandoned the project.” (Id. at 12.) The trial judge did not ignore or overlook this evidence; to the contrary, the Opinion specifically cites the evidence of this, and explains why the Court found it to be of little significance (there was no evidence of the reason why Sanofi abandoned the project). Opinion at *73.

Plaintiffs' brief next contends that the trial judge used the patents in suit to confirm that EDTA would be effective to achieve pharmaceutically effective absorption. (Pls.' Br. 13-14.) The brief then cites at length a few portions from the Opinion – but all are taken from the section on anticipation, not from the obviousness analysis. This does not demonstrate improper use of hindsight in the obviousness analysis.

Plaintiffs argue that the trial judge “embraced hindsight.” This Court, having reviewed the trial judge’s analysis, is unpersuaded that it reflects such a clear error of law or fact warranting relief.

This Court is not in a position to comprehensively review the trial judge’s obviousness analysis, but if it is tainted by hindsight, the defect is not glaring. Plaintiffs do not dispute the Court’s statement in the Opinion that the parties agreed that all the elements of the claims at issue could be found somewhere within the Brazilian Application, with the exception of the element of pharmaceutically effective absorption. Opinion at *20. A 35mg risedronate sodium pharmaceutical medication for the treatment of osteoporosis, Actonel®, was in the prior art. Opinion at *21. The question is whether it would be obvious to modify this, creating a combination with 100 mg EDTA, to solve the bisphosphonate food effect problem. Opinion at *39-*41. The use of EDTA as a chelator of calcium was known in the prior art. Opinion at *43-*46. “The 1978 *Poiger Reference* used disodium EDTA as a chelating agent to eliminate the food effect in humans observed with a drug called tetracycline.” Opinion at *44. “A skilled artisan would recognize that Poiger disclosed a formula—an equimolar ratio of EDTA to expected calcium . . .—for a formulation that would significantly bind to metal ions in food without significantly altering absorption, leading to similar bioavailability irrespective of diet.”

Opinion at *46. The skilled artisan could apply the Poiger formula to risedronate and compute a range of EDTA dosages that includes the 100mg dose in the claims at issue. Opinion at *89.

These points are the building blocks of the trial judge's obviousness analysis. The decision contains a careful exploration of the motivations to combine the references, and the basis for the trial Court's conclusion that the skilled artisan would have had a reasonable expectation of success in using a 100mg dose of EDTA to solve the bisphosphonate food effect problem. The Opinion provides a detailed explanation supporting the conclusion that the skilled artisan would have had a reasonable expectation of success that the modifications of Actonel® would work for the intended purpose. Opinion at *88-*98. Under Federal Circuit law, when this is based on clear and convincing evidence, this provides a basis for a conclusion of obviousness. Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1364 (Fed. Cir. 2007).

A Rule 59(e) motion is essentially a motion for reconsideration. The question is not whether this Court would have arrived at the same decision, but whether there are clear errors of law in the trial judge's obviousness analysis. The careful analysis in the Opinion does not support Plaintiffs' position that the trial judge embraced hindsight.

Plaintiffs next argue that Teva provided no evidence that a skilled artisan would have been motivated to modify the Brazilian Application. As Teva notes, this argument appears to attack a conclusion of fact, rather than one of law. Par Pharm., Inc. v. TWi Pharms., Inc., 773 F.3d 1186, 1196 (Fed. Cir. 2014) ("The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact.") Factual determinations are reviewed by the Federal Circuit for clear error. Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 835 (2015).

Yet there is another problem for Plaintiffs, who aptly cite KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007). KSR stands for, *inter alia*, the proposition that “[t]he obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation . . .” Id. at 419. The Supreme Court further held:

The flaws in the analysis of the Court of Appeals relate for the most part to the court’s narrow conception of the obviousness inquiry reflected in its application of the TSM test. In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103. One of the ways in which a patent’s subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent’s claims.

Id. at 419-20. KSR makes clear that the obviousness analysis must be flexible, and that the particular motivation to combine does not control.² Rather, it is sufficient to show that there was a known problem for which there was an obvious solution encompassed by the patent’s claims. This is what the trial judge appears to have concluded.

Plaintiffs next argue that the trial judge committed a clear error of law by concluding that a skilled artisan would be motivated to modify the Brazilian Application based on Poiger, and then discuss what Poiger would have taught the skilled artisan. (Pls.’ Br. 19-21.) Under Par, however, motivation to modify is a question of fact, not law. 773 F.3d at 1196. These comments apply as well to Plaintiffs’ arguments about the WO ‘111 reference: Plaintiffs identify

² The Federal Circuit has more recently stated:

While an analysis of any teaching, suggestion, or motivation to combine elements from different prior art references is useful in an obviousness analysis, the overall inquiry must be expansive and flexible.

Kinetic Concepts, Inc. v. Smith & Nephew, Inc., 688 F.3d 1342, 1360 (Fed. Cir. 2012).

no error of law, and the matter is a factual one.

Plaintiffs argue that the trial judge overlooked objective evidence of non-obviousness. Yet the Opinion contains a lengthy discussion of the objective evidence of non-obviousness. Opinion at *47-*75. Although Plaintiffs contend that this constitutes a clear error of law, again, they are simply disagreeing with the trial judge's factual determinations about the objective evidence of non-obviousness.

Lastly, Plaintiffs argue that the judgment should be altered to prevent the manifest injustice to Plaintiffs caused by the use of the "hot tub" format during the trial. This Court is not persuaded that the use of the "hot tub" format resulted in manifest injustice.

Plaintiffs' motion does not persuade this Court of a need to correct clear errors of law in the Opinion or to prevent manifest injustice. As Teva contends, Plaintiffs' motion largely disagrees with the trial judge's factual determinations. Plaintiffs have failed to persuade this Court, however, that any factual determinations are clearly erroneous. To the extent that Plaintiffs advance arguments already presented to the trial court, such arguments cannot be a basis for a Rule 59(e) motion. Lazaridis v. Wehmer, 591 F.3d 666, 669 (3d Cir. Del. 2010).

Plaintiffs have failed to persuade this Court of the need to correct any clear error of law or fact or to prevent manifest injustice. The motion to amend the judgment will be denied.

For these reasons,

IT IS on this 23rd day of April, 2015 hereby

ORDERED that Plaintiffs' motion to alter or amend a judgment, pursuant to Federal Rule of Civil Procedure 59(e), (Docket Entry No. 330) is **DENIED**.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.