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United States District Court,
D. Delaware.

In re CYCLOBENZAPRINE HYDROCHLORIDE EXTENDED–RELEASE CAPSULE PATENT LITIGATION.

Civ. No. 09–MD–2118–SLR.
|
Sept. 21, 2010.

MEMORANDUM ORDER

SUE L. ROBINSON, District Judge.

***1** At Wilmington this 21st day of September, 2010, having considered defendants' motion to exclude plaintiff's admission of evidence of defendants' inability to obtain FDA approval as evidence of "failure of others" for purposes of non-obviousness, as well as the papers filed in connection therewith;

IT IS ORDERED that said motion (D.I. 200 at ¶ 107) is denied, as follows:

1. **Legal standard.** "All relevant evidence is admissible, except as otherwise provided ..." Fed. R Evid. 402. "Relevant evidence means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence ." Fed.R.Evid. 401. Rule 401's basic standard of relevance is a liberal one. *Daubert v. Merrell Dow Pharm., Inc.,* 509 U.S. 579, 587 (1993). The trial judge is obligated to act as a "gatekeeper" and has broad discretion to balance the probative value of the evidence against its potential prejudicial harm. *See Magnivision, Inc. v. Bonneau Co.,* 115 F.3d 956, 961 (Fed.Cir.1997).

2. "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." 35 U.S.C. § 103(a). Obviousness is a question of law, which depends on several underlying factual inquiries.

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1734 (2007) (quoting *Graham v. John Deere Co.,* 383 U.S. 1, 17–18 (1966)).

3. **Discussion.** The Federal Circuit has implicitly accepted that failure to obtain FDA approval is relevant evidence of failure of others. *Knoll Pharm. Co. v. Teva Pharm. USA, Inc.,* 367 F.3d 1381, 1385 (Fed.Cir.2004). In *Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.,* 460 F.Supp.2d 659, 662 (D.N.J.2006), the court went one step further, and expressly stated that "[n]ot getting to market with FDA approval is an appropriate benchmark for failure [of others]." Given this acceptance by other courts and the liberal standards of Rule 401, this court finds that failure to obtain FDA approval is relevant evidence of failure of others.

4. Defendants argue that, even if failure to obtain FDA approval is evidence of failure of others, the failure in question occurred after the issue date of the patent and should be excluded. (D.I. 200, ex. 3.2 at 18) However, this contradicts *Knoll* which explained that knowledge of an invention's advantages acquired after its patent application was filed is admissible in response to a litigation challenge. *Knoll,* 367 F.3d at 1385.

***2** 5. The most relevant case that defendants cite in support of their argument is *Eisai Co. v. Teva Pharmaceuticals USA, Inc.,* 247 F.R.D. 440 (D.N.J.2007). The *Eisai* court held that "failure of others is inherently limited to events pre-dating issuance of the patent." *Id.* at 444.

6. This court finds *Eisai* unpersuasive. The *Eisai* court reasoned that *Knoll* does not support the position that failure of others post-dating the patent's issuance date is relevant. *Id.* at 443. It discounted the argument that, because the *Knoll* court did not expressly limit the evidence of failure of others to a pre-invention time period, it was implicitly admissible. *Id.* In so holding, the *Eisai* court appears to ignore *Knoll's* direction that "[e]vidence developed after the patent grant is not excluded from consideration.... There is no requirement that an invention's properties and advantages were fully known before the patent application was filed ... in order for that [knowledge] to be introduced into evidence in response to litigation attack." *Knoll,* 367 F.3d at 1385.

7. Other secondary considerations such as commercial success and copying occur after a patent's issue date. *Application of Tiffin,* 443 F.2d 394, 398 (C.C.P.A.1971), *see also Santarus, Inc. v. Par Pharm., Inc.,* 720F.Supp.2d 427, 2010 WL 1506017 at * 24 (D.Del. Apr. 14, 2010) (reasoning that post-invention skepticism can be evidence of non-obviousness). Because science necessarily builds upon past discoveries, failure of others after a patent's issue date may be more persuasive than failures that occur before. *See generally* Kristen C. Buteau, *Denuterated Drugs: Unexpectedly Nonobvious,* 10 J. High Tech. L. 22 (2009). If others continue to fail despite having the patent as prior art, such failures may illustrate just how radically different the patent was from past discoveries. This would be highly relevant to a finding of non-obviousness.

8. Finally, at oral orgument, defendants argued the failure of others to obtain FDA approval is irrelevant because the FDA instituted a new testing methodology after the patent issued.[1] Even if this is true, any change to FDA testing procedures goes to the weight of the evidence and not its admissibility.

All Citations

Not Reported in F.Supp.2d, 2010 WL 3766530

Footnotes

1 The transcript has not yet been docketed.