



[PFIZER, INC. v. APOTEX, INC.](#) Case Brief

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[Official Cite] No. 2006-1261, May 21, 2007

**JUDGES:** Before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, Circuit Judges.

**DISSENTS BY:** NEWMAN, LOURIE, and RADER

**Procedural Posture:**

Pfizer, Inc. filed a combined petition for panel rehearing and rehearing en banc of its April 2007 decision (*Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007).) finding a new salt form of a composition obvious in view of the prior art and holding that a motivation to combine references can be gleaned from the nature of the problem to be solved. The CAFC denied the request for panel rehearing and rehearing en banc. Three circuit judges provide three separate dissents against the majority opinion.

**Overview:**

Is your firm doing all it can to strengthen each of your patents? PFIZER, INC. was recently handed a heavy defeat, when the Court of Appeals for the Federal Circuit ruled that its Norvasc® product was invented through “routine...testing.” Recent decisions like this one have left patent filers scrambling to present their products as unpredictable discoveries, and to embolden examiners to summarily reject claims as obvious-to-try rather than performing a more balanced “reasonable expectation of success analysis.” Patent practitioners must present their inventions as more of an unexpected result and remove it from something that can be considered obvious to try.

**Facts:**

- Pfizer’s amlodipine besylate (known as Norvasc®) is prescribed for the treatment of hypertension and angina. Pfizer instituted this infringement action in response to generic manufacturer Apotex filing an Abbreviated New Drug Application (ANDA) with the FDA, before expiration of Pfizer’s U.S. Patent No. 4,879,303 (the '303 patent), seeking approval to sell generic amlodipibe besylate tablets.
- Apotex certified in its ANDA that it believed the '303 patent was invalid and unenforceable, and sought approval to market and sell its amlodipine besylate tablets before September 25, 2007 (i.e., the expiration date of the '303 patent plus an additional six months of pediatric exclusivity) pursuant to 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

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- Apotex asserted that Pfizer's '303 patent was obvious in view of U.S. Patent No. 4,572,909 (the '909 patent) and Berge, 1977, "Pharmaceutical Salts," *J. Pharm. Sci.*, 66:1-19 (Berge). Pfizer's '303 patent relates to amlodipine besylate, an acid addition salt of amlodipine that does not exhibit the instability and stickiness in tablet form of amlodipine maleate (an acid addition salt of amlodipine disclosed in Pfizer's '909 patent).
- The District Court concluded that amlodipine besylate was nonobvious, stating that "[t]here is no reliable way of predicting the influence of a particular salt species on the behavior of a parent compound," and further, that amlodipine besylate "clearly and unexpectedly illustrates a superior combination of properties when compared to [amlodipine maleate]."
- On appeal, a panel consisting of Chief Judge Michel and Judges Mayer and Linn reversed, stating that "[a]t most . . . Pfizer engaged in routine, verification testing to optimize selection of one of several known and clearly suggested pharmaceutically-acceptable salts to ease its commercial manufacturing and marketing of the tablet form of the therapeutic amlodipine."

**Issue:** Whether obviousness in view of *KSR* is settled in the eyes of the CAFC – Is the CAFC improperly applying an overly rigid *KSR* analysis for a mechanical device to an inherently unpredictable technology area, such as pharmaceutical inventions? Should the panel's "obvious to try" analysis for predictable technology areas also apply equally to unpredictable technology areas? Or should the CAFC employ a reasonable expectation of success analysis for unpredictable technology areas, such as pharmaceutical inventions?

**Dissent:** Although *en banc* rehearing was denied, three judges dissented, thereby providing fodder for future arguments in support of a diverse interpretation of *KSR* with for diverse technologies. All three dissents stressed how unpredictable technologies (i.e., pharmaceutical and chemical arts) should not be held to the same obviousness standard applied to a mechanical invention.

Judge Newman accused the panel of misapplying the obvious-to-try standard as well as declining to consider the unexpected result represented by the stability and lack of stickiness of the besylate salt. Judge Newman alleged that the panel changed "the criteria and analysis of patentability."

Judge Lourie, in his dissent, charged the panel with erring in its legal determinations and predicted that the panel's errors will confuse the law relating to the rebuttal of a *prima facie* case of obviousness for a chemical compound.

Judge Rader, in the final dissent, noted that three separate district courts held trials involving the patent in suit and came to the same factual conclusion regarding the non-

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obviousness of amlodipine besylate. Echoing Judge Lourie's dissent, Judge Rader concluded that, given that the district court's factual determinations were not clearly erroneous, the panel should have deferred to those factual findings. With regard to the panel's "obvious to try" analysis, Judge Rader noted that "[w]ith unpredictable pharmaceutical inventions, this court more wisely employs a reasonable expectation of success analysis," and since salt selection is unpredictable, there would be no reasonable expectation of success in this case.

**Lessons:** It appears a battle is brewing over how KSR should be applied in the more unpredictable technologies of the pharmaceutical and chemical arts. Pfizer appealed the CAFC's decision to the Supreme Court on May 31, 2007. We shall see if the Supreme Court will choose to clarify the application of KSR and Graham to more unpredictable pharmaceutical arts.

- Patent practitioners should counterbalance the PTO's move toward "obvious to try" by showing unpredictability and applying a reasonable expectation of success analysis.

**Client message:** Especially in the chemical, pharmaceutical, and biotechnology arts, identify how your new inventions have overcome unpredictability in the art, and why others may not have had a reasonable expectation of succeeding.

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