

## Obsolete Best Mode Requirement Should Be Repealed

**Current Law:** The Best Mode requirement has no counterpart in foreign law. Under this requirement, a patent specification must “set forth the best mode contemplated by the inventor of carrying out his invention” at the time the patent application was filed, in addition to a complete and precise description of how to make and use the invention. During the patent examination process the examiner must assume that the best mode is disclosed unless there is evidence to the contrary. According to the PTO’s Manual of Patent Examining Procedures (MPEP), it is extremely rare that a best mode rejection properly would be made in *ex parte* prosecution. The information that is necessary to form the basis for a rejection based on the failure to set forth the best mode is rarely accessible to the examiner, but is generally uncovered during discovery procedures in interference, litigation, or other *inter partes* proceedings.

The Patent Reform Act of 2007 would perpetuate this requirement.

- The Best Mode requirement has outlived its usefulness as a requirement of patentability, and is now often used in modern patent litigation to attack the state of mind of the inventor at the time the patent application was filed, in order to undermine the validity of infringed patents.
- The National Academies of Science has recommended eliminating or reforming subjective elements in patent litigation, including Best Mode. According to NAS, “Given the cost and inefficiency of this defense, its limited contribution to the inventor’s motivation to disclose beyond that already provided by the enablement provisions of Section 112, its dependence on a system of pretrial discovery, and its inconsistencies with the European and Japanese patent laws, the committee recommends that the best mode requirement be eliminated. (page 121, A Patent System for the 21<sup>st</sup> Century, National Research Council)
- As currently used in patent litigation, the Best Mode attack on the validity of a patent applies only to information and beliefs of the inventor her- or himself, rather than on objective aspects of the invention. It is therefore highly subjective and heavily depends on the discovery of historical facts used as circumstantial evidence of the inventor’s past state of mind, making such litigation expensive, acrimonious, and time-consuming.
- Further, quite frequently the company suing for infringement acquired the patent years after patent was granted, through assignment, licensing or other transfer mechanism, and is therefore held responsible for how the inventor prosecuted the otherwise valid patent.
- As with other invalidity defenses, establishing best mode requires a clear and convincing evidence and is applied only on a claim by claim basis. However, if intent to deceive is shown, the same proof can establish “inequitable conduct” and

the entire patent may be unenforceable. This is why in many cases where there is an allegation of inequitable conduct, there are also allegations that the inventor has not fulfilled his/her requirement for best mode requirement.

- Moreover, such litigation has nothing to do with the central questions of whether the invention was truly new, non-obvious, and adequately described, and has little relation to the ways in which the invention was later actually developed into a marketable product.
- Retaining the Best Mode requirement also would create problems in the efficient administration of any new administrative post-grant patent review system. Best Mode issues are highly discovery-intensive and often involve complex privilege and evidentiary issues that the Patent Office is poorly equipped to resolve, and that, in any case, would be contrary to the goal of making this new administrative proceeding simple, quick, and cost-effective.
- Foreign patent systems operate effectively without a Best Mode requirement, relying instead on high-quality technical patent disclosures alone. In the spirit of making U.S. patent law more objective and efficient, Best Mode should be repealed as recommended by the National Academies of Science.

### **Examples of Best Mode cases**

#### *Amgen v. Chugai*

The method of making a biotech product, (protein, DNA, cell line etc) is very often integral in the practice of the biotechnology invention. 35 USC 112 requires that an applicant show how to make and use the claimed invention in such a way that one of skill in the art can practice the claimed invention. 35 USC 112 also requires that the applicant disclose the best mode for practicing his invention. For all intents and purposes, the PTO believes an inventor when he says that he has disclosed the best mode, unless of course, the PTO has evidence to the contrary. As a result, the best mode requirement is rarely used as a basis to deny a patent. In *Amgen v. Chugai*, Amgen disclosed how to prepare a few DNA analogs encoding erythropoietin ("EPO"), a protein that "stimulates the production of red blood cells." One of the claims, however, covered "every possible analog of [the] gene." The defendants (Chugai) maintained that Amgen had failed to disclose the best mammalian cell line for making the product, when they failed to deposit CHO cells. The Patent Office accepted Amgen's description in the specification as being sufficient to enable those desiring to practice the claimed invention. The court ultimately agreed with Amgen that the best mode requirement was fulfilled, however, certain of the claims of Amgen were held to be invalid. However, Chugai's assertion that Amgen had concealed best mode could have led to the unenforceability of the entire patent, had the court decided that Amgen had indeed withheld the best mode for making EPO. Amgen's

seminal patent would have been rendered unenforceable, which would make it likely that the biotechnology industry would be in a very different position today.

*Lilly v. Barr*

In the biopharmaceutical area it is often the case that there is no prior art associated with an invention. This is because often times, the inventor is often the researcher who discovered the biotechnology invention (DNA, protein, cell line etc.). This dearth of prior art therefore, forces competitors to resort to employing subjective elements of patent law, such as best mode in attempting to invalidate patents. In *Lilly v. Barr*, Lilly sued Barr and other generic drug manufacturers for patent infringement in 1996, when the rivals first sought FDA approval to make a generic form of Prozac. Specifically, Lilly claimed that Barr's application infringed certain of Lilly's claims to fluoxetine hydrochloride. Barr alleged that Lilly failed to disclose their best method of preparing p-trifluoromethylphenol (a starting material) and failed to disclose their preferred solvent used in the recrystallization process for removing impurities from the fluoxetine hydrochloride. The Federal Circuit found that because section 112 requires only "an adequate disclosure of the best mode," a patent-holder need not disclose a "routine detail" of production because one skilled in the art would be familiar with alternative means to accomplish the same result. As other generic drug makers could independently perform the two processes above, Lilly's best mode disclosure was adequate. While the court agreed with Lilly on best mode, it held one of Lilly's patent claims as invalid over obviousness double patenting. Lilly's Prozac patent expired in August 2001.