

B.4.2 Validity—Adequacy of Patent Specification

4.2b ENABLEMENT

The patent law contains certain requirements for the part of the patent called the specification. One of those requirements is called the enablement requirement. [Alleged infringer] contends that claim(s) [] of [patent holder]’s [] patent [is/are] invalid because the specification does not “enable” the full scope of the claimed invention. To succeed, [alleged infringer] must show by clear and convincing evidence that the [] patent specification does not contain a sufficiently full and clear description to have allowed a person having ordinary skill in the field of technology of the patent to make and use the full scope of the claimed invention as of the effective filing date, here [insert date], without undue experimentation. If a patent claim is not enabled, it is invalid.

The question of undue experimentation is a matter of degree, and what is required is that the amount of experimentation not be “unduly extensive.” Some amount of experimentation to make and use the invention is allowable. In deciding whether a person having ordinary skill would have to experiment unduly in order to make and use the invention, you may consider several factors:

- (1) the time and cost of any necessary experimentation;
- (2) how routine any necessary experimentation is in the field of [identify field];
- (3) whether the patent discloses specific working examples of the claimed invention;
- (4) the amount of guidance presented in the patent;
- (5) the nature and predictability of the field of [identify field];
- (6) the level of ordinary skill in the field of [identify field]; and
- (7) the nature and scope of the claimed invention.

No one or more of these factors is alone dispositive. Rather, you must make your decision about whether or not the degree of experimentation required is undue based upon all of the evidence presented to you. You should weigh these factors and determine whether or not, in the context of this invention and the state of the art at the time of the effective filing date, a person having ordinary skill would need to experiment unduly to make and use the full scope of the claimed invention.

Authorities

35 U.S.C. § 112(a); Pre-AIA 35 U.S.C. § 112, ¶ 1; *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019); *Promega Corp. v. Life Techs. Corp.*, 773 F.3d 1338 (Fed. Cir. 2014), *rev’d and remanded on other grounds*, 137 S. Ct. 734 (2017); *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380 (Fed. Cir. 2013) (“The question of undue experimentation is a matter of degree, and what is required is that the amount of experimentation not be ‘unduly extensive.’” (quoting *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004) and *PPG Indus.*,