

The Enablement Requirement of 35U.S.C.§112

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35U.S.C.§112 Paragraph 1 reads as follows:

“The specifications shall contain a written description of the invention, and of the manner and process in making and using it, in such full, clear, concise, and exact turns as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.”

History

Early in the history of the United States the Supreme Court heard many patent cases. Today the number of cases is relatively small with a great deal of fanfare accompanying each decision. The enablement requirement was considered by the Supreme Court as early as 1832.

In *Grant v. Raymond*¹ The Supreme Court held that an insufficient specification was an appropriate defense to an infringement suit even though there was no intent to deceive the public. Chief Justice Marshall noted that a correct specification is necessary in order to give the public what it had bargained for in the grant of the patent monopoly.

Later in *Wood v. Underhill*,² the patent was on a process of using anthracite coal to make bricks and tiles. The inventor had indicated that the exact quantity would be dependant upon the kind of clay used to make the brick, indicating the clay which required the most burning would require the greatest amount of coal dust. There was a disclosure of “in general 3/4 of a bushel of coal dust to 1000 brick would be correct.”

At the trial level there was a jury instruction that the specification was to vague. However, the Supreme Court reversed indicating that the specific reference given avoided the general rule regarding use of the invention without undue experimentation.

¹31 U.S.(6 Pet.) 218 (1832).

² 46 U.S. (5How.) 1 (1847).

“35U.S.C. §112 requires the specification “enable” only to a person skilled in the art to which it pertains, or with which it is most nearly connected.” The Supreme Court in *Webster Loom Co. v. Higgins*³ indicated that the specification need not be enabling to “unskilled” persons. This raises the question,

Who Is One Skilled in the Art?

The decisions are scarce considering this issue. There is an assumption that the “person skilled in the art” within the meaning of §112 is the same as the “person having ordinary skill in the art” of §103 regarding non obviousness. Section 103 defines the pertinent art in terms of the problem to be solved rather than in term of the specific industry of trade which the problem is encountered and the invention used. One decision adopting this approach for §112 is *American Stainless Steel Co.v. Ludlum Steel Co.*⁴ The plaintiff’s patent claimed metal tools and cutlery made from a specific range of low carbon iron-chromium alloys which were to have a stainless quality. The defendant sold an alloy and promoted it as having a stainless quality. The defendant’s “stainless” quality was achieved only if the alloys were heated to a temperature higher than normally employed for hardening of a cutlery.

Precise temperature was not recited within the patent. The District Court then construed the patent narrowly to cover only the range of alloys in which it was enabling i.e. alloys that were heated at the normal hardening temperature for cutlery.

The Second Circuit Court reversed indicating that the relevant art was steel making and not cutlery making and that the higher temperature was well within the range of professional knowledge of a metallurgist or steel maker. Under this approach the person in §103 and §112 seem to be the same.

A question arises, however with regard to “person skilled in the art” is how much of the prior art is such a person deemed to know when judging the enabling quality of the specification. Under §103 the person with ordinary skill in the art is presumed to know the teachings of all the material in the prior art. Does this carry forward to §112? This question was addressed *In re Howarth*⁵ This case involved a rejection for inadequate disclosure based upon a failure to disclose certain starting materials. The applicant pulled together materials laid open for public inspection in Rhodesia, Panama, and Luxembourg prior to the application filing date. The court affirmed such rejection for failure to meet the enabling requirement noting that the prior art under §102 is not to be equated with common knowledge for purposed with §112 enablement.

The court distinguished between basic knowledge and the knowledge of where to search out information.

³105 U.S..(15Otto.) 580 (1881).

⁴290 F 103 (2nd. Cir.1923).

⁵210 USPQ 689 (CCPA 1981)

“ Well known textbooks in English are obvious research materials. Similarly, public records concerning U.S. patents are likely to be checked, and information therein is reasonably accessible in view of the published abstracts and our classification system. Thus, common U.S. patents are considered pertinent evidence of what is likely to be known by persons of ordinary skill in the art—We do not exclude the possibility that foreign patents and foreign language printed publications may also be relevant to the inquiry of what is likely to be known but we do not ipso facto give all patent and printed publication the same evidentiary weight for purposes of showing enablement under §112, even though such references are treated the same for prior art purposes under §102.”

The court in essence held that only those sources of information which one skilled in the art would reasonably be expected to check, and find with no more than ordinary diligence could be relied upon to establish enablement. In essence, the court held certain materials are clearly part of the “prior art” for purposes of §103, but not part of the “skilled in the art” for purposes of §112.

What Is the Time Frame for Prior Art?

U.S. patent application by operation of §102e are prior art under § 103 as of the filing date of the application. However, applications are secret and not available to the public until the patent issues. Moreover, a patent can not be relied upon as of its filing date in determining the enabling quality of a subsequent specification. In, *In re Glass*⁶ such treatment was argued to be unfair but the CCPA disagreed pointing out that §102e rested upon a different foundation and served a different purpose with regard to the question of time frame.

When must a Specification Be Enabling?

Courts have held that the application must be enabling as of the filing date and that information which becomes available after the date can not be considered in determining the sufficiency of the enablement.

In, *In re Wright*⁷ the applicant sought to site subsequently filed applications resulting in patents to show the state of the crystal growing art at the time. The court held that the patents can not be relied upon, pointing out that the filing date becomes the date of constructive reduction of practice in determining priority of invention and this should not be the case unless at the time, without waiting for subsequent disclosure, any person skilled in the art could practice the invention from the disclosure of the application.

⁶181 USPQ 31(CCPA).

⁷27 USPQ2d.1510 (Fed. Cir. 1993)

This results in a situation where the filing of an application at one point of time may result in the holding of non-enablement where as a second filing of the subsequent date of the identical application would result in a holding enablement.

Is a Disclosure Enabling When Some Experimentation Is Required to Carry out the Invention?

As was discussed earlier in *Wood V. Underhill*⁸ the Supreme Court assumed that a specification would be defective if it required one of skill of the art to experiment in order to practice the invention.

The Court in *Mineral Separation v. Hyde*⁹ emphasized the issue was not with regard to experimentation per se, but whether the experimentation required was undue or unreasonable under the circumstances having regard to the subject matter, noting that some inventions can not be practiced without adjustment being made to adapt them to the particular context. There are many many cases on this particular point.

In *In re Gardner*¹⁰ the application claimed a method of using certain compounds to produce an anti depressant activity. There was no disclosure as to whether it was to be used on humans or animals, or what the proper dosage should be. The only disclosure was that the dosage would fall within the range of 10 milligrams to 450 milligrams. The applicant argued that experimentation could easily be carried out to determine a proper dosage. The CCPA however, stated that “there is not a single specific embodiment by way of an illustration of how the invention is to be practiced on any kind of host. We deem it to be in the category an invitation to experiment in order to determine how to make use of appellants alleged discovery of the anti-depressant activity— but our view is that the law requires that the disclosure in the application shall inform how to use, not how to find out how to use for themselves.”

This case was distinguished in *In re. Bundy*¹¹ when it was disclosed that compounds in a subgenus contain certain pharmacological properties but gave no specific example of dosages for human or even animal tests. The court reversed a rejection based upon the how to use requirement of §112 and in doing so it clearly looked at the claimed subject matter stating:

“we do not consider that one of ordinary skill in the art would not know how to use these anodal analogs to determine that the specific dosages for the various biological purposes. We are persuaded that sufficient guidelines as to use are given in the disclosure here. This is not the same situation as in *In re. Gardner* —here only the compound is being claimed and not their therapeutic use.”---

⁸N.S ibid 2

⁹ 242 U.S. 261 (1916)

¹⁰166 USPQ 138 (CCPA 1970)

¹¹2019 USPQ 48 (CCPA 1981)

Early filing of an application with its disclosure of novel compounds which possess significant therapeutic use is to be encouraged. Requiring specific testing of the thousands of prostaglandin analogs encompassed by the present claim in order to satisfy the how-to-use requirement of §112 with delay disclosure and would frustrate, rather than further, the interests of the public”

Without going into all the specifics required in biotechnology technology cases, it should be noted that the enablement requirement is largely satisfied by the deposit of one or more specimens of biological material. This addresses both the undue experimentation issue as well as the relationship of the deposit to the breadth of the claimed subject matter.

How to Use

There is a close relationship between the how to use aspect of paragraph 1 §112 and the utility requirement of §101. It is clear that an application having a disclosure with no utility would fail the how-to-use aspect of enablement but the converse is not necessarily so. The issues were addressed in *Hughes Aircraft Co. v. US*¹²

The patent in suit was filed by Williams in 1960 which disclosed and claimed a control system for properly orienting a satellite that hovers over a fixed point on earth. In 1962 Williams described this invention in a paper to a professional society.

In April of 1964 Williams filed a CIP application that added one new item to the disclosure of the original application; a ground control device receiving and transmitting signals with the satellite.

In a compensation suit, the U.S. argued that the claims were only entitled to the 1964 filing date of the CIP because the CIP added essential support for how to use the claimed subject matter. This position would result in invalidity because of the statutory bar effect of the 1962 paper. The court disagreed and construed the claims of the patent as directed only to the equipment of the satellite that is, not embodying any specific devices or process outside the satellite. Critics¹³ have questioned this section as avoiding § 112 requirement of how to make and use. Chisum indicates that this may require disclosure of methods, materials and machines not mentioned in or not constituting elements of the claims. Chisum concludes that this holding can only be justified if:

1. The original specification did disclose a minimally operable system, or,
2. A person of ordinary skill in the pertinent art could have at the time the specification was filed and in the light the disclosures, constructed a suitable ground control device.

¹² 208 USPQ 785 (Ct.Cl.1980), appeal after remand 219 USPQ 473 (Fed. Cir. 1983)

¹³ Chisum on Patents § 703[6]

Conclusion

In order to assure that specification possesses the appropriate enablement under §112 one must look at:

1. The disclosure at the time of filing.
2. The prior art and what one of ordinary art would have actually known or known where to look at that point in time.
3. The degree of experimentation deemed reasonable in relevant art and,
4. How the invention is claimed in considering the experimentation.