

**Is Your Patent Worth The Paper It's Printed On?
An Inventor's Duties Under The Law: "Best Mode",
"Enablement", and The Duty to Disclose the Prior Art**

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American Institute of Chemical Engineers
Spring National Meeting
Houston, Texas March 14-18

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JANUARY 27, 1999

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* "Conley, Rose & Tayon P.C. The author gratefully acknowledges the contributions to the preparation of this paper of Robert M. Gray, Chandran Kumar, Leslie V. Payne, and Charles A. Thomasian. The views expressed in this paper are those of the author and should not be attributed to the Firm or the clients of the Firm."

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**IS YOUR PATENT WORTH THE PAPER IT'S PRINTED ON?
AN INVENTOR'S DUTIES UNDER THE LAW: "BEST MODE",
"ENABLEMENT", AND THE DUTY TO DISCLOSE THE PRIOR ART**

I. EXECUTIVE SUMMARY

What is a patent worth to your company? The answer typically depends on whether, and for how much, your company can license its competitors who use (or want to use) its patented invention. Your competitors' decisions to take a license from you always include evaluations of how likely you would be to prevail against them in a patent infringement suit. Recent opinions of the Court of Appeals for the Federal Circuit, which hears all appeals in patent infringement cases, have given your competitors new - and stronger - weapons to use as defenses in such a lawsuit. This means that the value of existing patent assets has already been irreversibly degraded, to the extent that these Federal Circuit cases are followed. These recent changes in the law are reviewed, and suggestions are made by which both inventors and patent draftsmen can maintain the value of a developing patent portfolio.

II. INTRODUCTION

A review of Federal Circuit decisions over the past year indicates a trend towards greater number of patents found invalid for violations of 35 U.S.C. § 112, first paragraph¹. The Federal Circuit has changed the law. Accordingly, we must change the way that patent applications are drafted and prosecuted before the Patent Office. To maintain the value of your soon-to-be-patented technology, you must act now. The objective of this discussion is to describe these recent changes in the patent law and encourage your development of appropriate responses, both in how inventors and patent attorneys interact and in how patent applications are prosecuted. The value of

your patent assets can be maintained by increasing the awareness of inventors and patent attorneys to these changes in the law and by encouraging them to work together more closely to accommodate such changes.

III. THE RELEVANT STATUTE - 35 U.S.C. § 112, ¶ 1

The first paragraph of § 112 of the Patent Act includes the statutory recitation of the law defining what are known as the "written description", "enablement", and "best mode" requirements. Historically considered little more than a scribes' burden upon the patent draftsman, recent opinions of the Court of Appeals for the Federal Circuit have pushed these § 112 matters to the forefront of nearly every patent infringement defendant's case as potential infringement defenses, particularly in chemical cases.

Section 112, paragraph 1, of the Patent Act provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms 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.

The single sentence of the first paragraph of § 112 of the Patent Statute has given rise (so far) to three separate and distinct sets of issues, each of which may arise in both the prosecution and litigation of any United States Patent. Several issues are of current interest particularly in the litigation of chemical patents.

In the patent prosecution context, only the written description and enablement corners of the § 112 triangle have been pursued by the Patent and Trademark Office because evidence relevant to the best mode requirement is typically not available to the Office. In the context of

¹ See, e.g., *Nat'l Recovery Technologies, Inc. v. Magnetic Separation Systems, Inc.*, No. 98-1134, 1999 U.S. App. LEXIS 1671 (Fed. Cir. Feb. 4, 1999); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998); *Hyatt v. Boone*, 146 F.3d 1348 (Fed. Cir. 1998); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998).

patent infringement litigation, upon which we focus here, this evidentiary limitation is no burden at all. We therefore consider each of the § 112 defenses in turn.

A. The Written Description Requirement

1. The Statute

Recall that paragraph 1 of 35 U.S.C. § 112 provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it....

In 1998, there have been at least 3 cases applying the written description requirement: *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998); *Hyatt v. Boone*, 146 F.3d 1348 (Fed. Cir. 1998); and *Tronzo v. Biomet, Inc.*, 47 USPQ2d 1829 (Fed. Cir. 1998). Each of these cases applied the written description requirement of 35 U.S.C. § 112 and determined that the specification at issue failed to support at least one claim.

2. Brief History of the Written Description Requirement:

35 U.S.C. § 112 provides that: “The specification shall contain a written description of the invention...”. Reference to the policy underlying the written description requirement reveals that “adequate description of the invention guards against the inventor’s overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.”² This policy seems to demand some correspondence between the disclosed invention and the scope of the claims, although valid claims will still often be broader than the disclosed embodiment.³ Traditionally, however, the application of the written description

² *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991)

³ See *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996) (“*ipsis verbis* disclosure is not necessary to satisfy the written description requirement of § 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question.”) The demands of the written description requirement may be further gleaned from the following explanation of why an original patent specification describing simply “air or other gas which is inert to the liquid” did support a later-introduced claim directed toward a “fluid”, whose scope not only encompassed “air or other gas” but also (of course) encompassed a liquid: “We are not saying

requirement has arguably been narrower than this, with one commentator asserting that, “The description requirement comes into play when a claim is added by an applicant for a patent at some stage after the original filing date and the claim differs in scope from the original claims. If the added claim does not find support in the specification in the sense that it is for an invention not sufficiently described therein, the description requirement is not met, and the benefit of the original filing date is lost.”⁴ This is the heart of the “new matter” standard.⁵

3. Recent Cases

Gentry Gallery, Inc. v. Berkline Corp. The Federal Circuit reversed a finding of fact from the district court as clearly erroneous and held claims of the patent invalid under 35 U.S.C. § 112 because they failed to meet the written description requirement.⁶ The patent was directed toward a sectional sofa having two reclining units (*i.e.* reclining seats) with a console placed therebetween. The console accommodated recliner controls for both reclining units. This configuration allowed both reclining units to face the same direction. Claims 1-8, 11, and 16-18 of the patent were directed to sectional sofas in which the location of the recliner controls was not limited to the

that the disclosure of ‘air or other gas which is inert to the liquid’ sample *by itself* is a description of the use of all ‘inert fluid’ media. Rather, it is the description of the *properties and functions* of the ‘air or other gas’ segmentizing medium described in appellants’ specification which would suggest to a person skilled in the art that appellants’ invention includes the use of ‘inert fluid’ broadly ... A hypothetical situation may make our point clear. If the original specification of a patent application on the scales of justice disclosed only a 1-pound ‘lead weight’ as a counterbalance to determine the weight of a pound of flesh, we do not believe the applicant should be prevented, by the so-called ‘description requirement’ of the first paragraph of § 112, or the prohibition against new matter of § 132, from later claiming the counterbalance as a ‘metal weight’ or simply as a 1-pound ‘weight,’ although both ‘metal weight’ and ‘weight’ would indeed be progressively broader than ‘lead weight,’ including even such an undisclosed, but obviously art-recognized equivalent, ‘weight’ as a pound of feathers. The broader claim language would be permitted because the *description of the use and function* of the lead weight as a scale counterbalance in the *whole disclosure* would immediately convey to any person skilled in the scale art the knowledge that the applicant invented a scale with a 1-pound counterbalance weight, regardless of its composition.” *In re Smythe*, 480 F.2d 1376, 1384 (CCPA 1973).

⁴ Chisum, § 7.04, p. 7-137.

⁵ See *In re Kaslow*, 717 F.2d 1366, 1375 (Fed. Cir. 1375) (addressing the written description requirement under the heading of new matter); See Manual of Patent Examining Procedure, § 2163 (“While the test or analysis of description requirement and new matter issues is the same, the examining procedure and statutory basis for addressing these issues differ”). But see *In re Rasmussen*, 650 F.2d 1212, 1214 (CCPA 1981) distinguishing § 112 and § 132.

⁶ *Gentry Gallery, Inc. v. Berkline Corp.* 134 F.3d 1473 (Fed. Cir. 1998)

console. These claims were held invalid by the Federal Circuit because they did not contain the critical “console” limitation.

Gentry filed suit against Berkline for manufacturing and selling sectional sofas having two recliner units facing in the same direction. The recliner units were separated by a tabletop, but no recliner controls were located on the tabletop. On appeal, “Berkline argued that claims 1-8, 11, and 16-18 are invalid because they are directed to sectional sofas in which the location of the recliner controls is not limited to the console.”⁷ Citing to the preferred embodiment, the objects of the invention, and inventor testimony, Berkline contended that the claims must be limited to sofas having controls on the console. Gentry responded with the axiom that claims may be broader than the preferred embodiment.⁸ Immediately thereafter, the Federal Circuit stated, “We agree with Berkline that the patent’s disclosure does not support claims in which the location of the recliner controls is other than on the console.”⁹

The Federal Circuit first laid out the guidelines for the written description requirement. “Whether a specification complies with the written description requirement of § 112, ¶ 1, is a question of fact, which we review for clear error on appeal from a bench trial. To fulfill the written description requirement, the patent specification ‘must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed.’ An applicant complies with the written description requirement ‘by describing *the invention*, with all its claimed limitations.”¹⁰

While acknowledging that a claim need not be limited to a preferred embodiment, the Federal Circuit asserted that “in a given case, the scope of the right to exclude may be limited by a

⁷ *Id.* at 1478.

⁸ *Id.* at 1478-79.

⁹ *Id.* at 1479.

¹⁰ *Id.* (emphasis in original; cites omitted).

narrow disclosure.”¹¹ The Federal Circuit then noted that, in this case, the original disclosure “clearly identifies the console as the only possible location for the controls. It provides for only the most minor variation in the location of the controls...Additionally, the only discernible purpose for the console is to house the controls” citing to the objects of the invention disclosed in the specification. The court also notes that the broadest original claim included the limitation that the control means were located on the center console. “Finally, although not dispositive, because one can add claims to a pending application directed to adequately described subject matter, [the inventor] admitted at trial that he did not consider placing the controls outside the console until he became aware that some of Gentry’s competitors were so locating the recliner controls. Accordingly, when viewed in its entirety, the disclosure is limited to sofas in which the recliner control is located on the console.”¹² Therefore, those claims not limiting the location of the recliner controls to the console (i.e. claims 1-8, 11, and 16-18) were invalid.

It should be noted that broadening claims were added during prosecution and thus this case fits neatly with the “new matter” paradigm mentioned by Chisum. However, it appears from the tone of *Gentry Gallery* and comments in the case that the broadening of claims during prosecution was not the most important point, although certainly the broadening of claims is one way to invoke written description concerns. This suggests that if a necessary feature for an invention (its necessity being apparent from the disclosure as a whole) is omitted from a claim, even as filed, that claim might be invalid for failure to comply with the written description requirement. At least one court has so interpreted *Gentry Gallery*.¹³ In *Reiffin v. Microsoft Corp.*,¹⁴ the district court found that a

¹¹ *Id.*

¹² *Id.*

¹³ For example, in distinguishing the cases argued by Gentry, the Federal Circuit stated that, “In sum, the cases on which Gentry relies do not stand for the proposition that an applicant can broaden his claims to the extent that they are effectively bounded only by the prior art. Rather, they make clear that claims may be no broader than the supporting disclosure, and therefore that a narrow disclosure will limit claim breadth.”

patent that omits from its claims elements essential to the invention as originally described is invalid for violating the written description requirement.¹⁵ The court noted that a patent owner cannot assert claims that omit elements of the invention as originally disclosed if a person skilled in the art would have understood those elements to be essential to the disclosed invention.¹⁶

Hyatt v. Boone. This case was an interference between two parties.¹⁷ The Board of Interferences applied the written description requirement of 35 U.S.C. § 112 and held that the patentee's earlier-filed application did not sufficiently describe the invention that was the subject of the interference count for the purpose of establishing priority. The Federal Circuit affirmed.

One of the parties, Hyatt, argued that the recitation of a "read only memory" in his claim sufficiently described the element in the interference count. The Federal Circuit first acknowledged that "The claims as filed are part of the specification, and may provide or contribute to compliance with § 112."¹⁸ It then laid out the applicable test: "Hyatt is correct that known details need not be included in a patent specification ... [However] when an explicit limitation in an interference count is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation...It is insufficient as written description, for purposes of establishing priority of invention, to provide a specification that does not unambiguously describe all limitations of the count."¹⁹ The Federal Circuit was unwilling to

¹⁴ *Reiffin v. Microsoft Corp.*, 48 U.S.P.Q.2d (BNA) 1274 (N.D. Cal. 1998).

¹⁵ *Id.* at 1277-78 (citing *Gentry Gallery*, 134 F.3d at 1479-80).

¹⁶ *Id.* at 1277 (citing *Gentry Gallery*, 134 F.3d at 1480).

¹⁷ *Hyatt v. Boone*, 146 F.3d 1348 (Fed. Cir. 1998)

¹⁸ *Hyatt*, 146 F.3d at 1352.

¹⁹ *Id.* at 1353-54.

reverse the Board's findings that the missing subject matter was not known details, but instead significant claim limitations.²⁰

The Federal Circuit also addressed the discrepancy between the apparently incongruous “reasonably conveys to the artisan” and “necessary and only reasonable construction” standards applied for the written description requirement. The court concluded that there exists no difference between these tests. “In all cases, the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.”²¹ However, this fancy bit of circular reasoning does not address how one determines whether the inventor had possession of the specific subject matter later claimed by him. The only thing that is certain is that “A disclosure in a parent application that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations.”²²

Tronzo v. Biomet, Inc. This recent case (August 28, 1998) of the Federal Circuit reversed the district court's determination that an earlier-filed application supported the claims of the patent at issue under the written description requirement.²³ Instead, these claims were held invalid. The patent issued from an earlier-filed parent application and a later-filed CIP application. Because a foreign filed application was published over one year before the filing of the CIP application, the claims at issue needed entitlement under 35 U.S.C. § 120 to the filing date of the parent application.

²⁰ *Id.* at 1354.

²¹ *Id.* at 1354.

²² *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565 (Fed. Cir. 1997).

²³ *Tronzo v. Biomet, Inc.*, 47 USPQ2d 1829 (Fed. Cir. 1998)

The claims were directed toward a hip socket implant or prosthesis having a ball inside a cup. The earlier-filed parent application described a conical cup. Claims 1 and 9 of the patent were generic as to the shape of the cup. The Federal Circuit held that claims 1 and 9 of the patent were not entitled to the effective filing date of the parent application because they were not limited to a conical cup. In reaching this conclusion, the Federal Circuit first presented the standards for the written description requirement of 35 U.S.C. § 112: “To meet this requirement, the disclosure of the earlier application, the parent, must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the parent application was filed. A disclosure in a parent application that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations.”²⁴ Similarly, “in order for a disclosure to be inherent...the missing descriptive matter must necessarily be present in the parent application’s specification such that one skilled in the art would recognize such a disclosure.”²⁵

The Federal Circuit then reviewed the evidence. The patent disclosed only one embodiment (*i.e.* conical), and it specifically distinguished the prior art shapes as inferior and touted the conical shape of the patent. “Such statements make clear the [patent at issue] discloses only conical shaped cups and nothing broader. The disclosure in the [parent] specification, therefore, does not support the later-claimed, generic subject matter in claims 1 and 9 of the [patent at issue].”

²⁴ citing to *Vas-Cath, Hyatt, and Lockwood*.

²⁵ citing to *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). It is interesting to note that *Continental Can* did not address the written description requirement, but instead applied this rigorous standard to a prior art patent under § 102(b). It is also interesting that in that case Judge Newman found the patent at issue valid. To this author’s knowledge, this is the first time that the inherency standard established for § 102(b) has been quoted for the written description requirement of § 112.

It should be noted that because the patent at issue sprung from a CIP application, and because the parent application also issued as a patent, it might be inferred that the claims generic as to the shape of the cup were not filed with the parent application.²⁶ However, whether the claim scope was changed during prosecution was never specifically addressed in the opinion. This failure may represent another step away from any perceived paradigm that the written description requirement applies only when a claim is added by an applicant for a patent at some stage after the original filing date and the claim differs in scope from the original claims.

4. Emerging Trend For the Written Description Requirement:

These cases continue a recent (*i.e.* the last couple of years) trend by the Federal Circuit to invalidate claims based on the written description requirement. For example, the watershed case of *Vas-Cath Inc. v. Mahurkar* explained the distinction between enablement and written description, and found the claims at issue supported by the written description in the specification.²⁷ Other cases decided prior to the last couple of years and refusing to invalidate claims by using the written description requirement include: *In re Edwards*, 568 F.2d 1349 (CCPA 1978); *In re Rasmussen*, 6509 F.2d 1212 (CCPA 1981); *Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101 (Fed. Cir. 1986); *In re Wright*, 866 F.2d 422 (Fed. Cir. 1989); *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858 (Fed. Cir. 1993); *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545 (Fed. Cir. 1996); *In re Alton*, 76 F.3d 1168 (Fed. Cir. 1996). On the other hand, the following cases used the written description requirement, at least in part, to invalidate claims: *U.S. Environmental Products, Inc. v. Westall*, 911 F.2d 713 (Fed. Cir. 1990); *Martin v. Mayer*, 823 F.2d 500 (Fed. Cir. 1987); and

²⁶ This may also be supported by the Court's use of the term "later-claimed" subject matter, if "later-claimed" means "claims that are introduced subsequent to the filing of the patent application." However, if "later-claimed" simply denotes "that which is claimed at the time of the patent's issuance" then it the term "later-claimed" does not support this proposition.

²⁷ *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991)

Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570 (Fed. Cir. 1985). Nonetheless, a few years ago it seemed that a strong majority of cases discussing the written description requirement of 35 U.S.C. § 112 found it fully satisfied, or at the least refused to invalidate claims without first remanding to the district court.

By contrast, in the last year or two, the Federal Circuit used the written description requirement to hold that claims are not supported by corresponding specifications in *Fujikawa v. Wattanasin*, 93 F.3d 1559 (Fed. Cir. 1996), *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997) and *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997), in addition to the three cases in 1998.

It is now safe to declare that a trend has developed. Further, whereas in *Regents of UC* and *Lockwood* the Federal Circuit affirmed the factual findings of the district court that the claims were invalid, *Gentry Gallery* and *Tronzo* are even more aggressive in reversing as clearly erroneous the district court's factual determination that the written description requirement was met. The even more aggressive approach of the 1998 opinions may indicate that the Federal Circuit's hostility to patents on written description grounds is still accelerating.

These cases published in 1998 may also presage a change in approach to the written description requirement. As explained above, traditionally the written description requirement has been applied only where an allegation of new matter exists. However, the Federal Circuit seems to be receptive to using the written description requirement to impose a limitation on the breadth of claim scope so that claims are limited not only by the prior art, but also by distinguishing statements made in the specification. For the practitioner, this trend places a heavy burden on inventors and patent attorneys to explain and envision the possible permutations of their

inventions. (Also see *Renishaw*, September, 1998), a claim construction case that seems to apply many of the principles of the written description requirement.

An example of these principles is *U.S. Environmental Products, Inc. v. Westall*, 911 F.2d 713 (Fed. Cir. 1990). In *U.S. Environmental*, a first patent application disclosing a single-layer filter plate was filed in 1976.²⁸ A continuation-in-part application disclosing a multiple-layer filter plate was filed on August 2, 1978. The multiple-layer filter plate invention was offered for sale on September 29, 1976, after filing the first patent application, but over one year before filing the continuation-in-part.²⁹ As a result, the September 1976 offer for sale invalidated the patent under 35 U.S.C. § 102(b) if the multiple-layer filter plate was not supported by the written description in the first application.³⁰ Because only a single-layer filter plate, and not a multiple-layer filter plate, was disclosed in the first application, the CIP was not entitled to the filing date of the first application and the patent was invalid under 35 U.S.C. § 102(b).

B. The Enablement Requirement

1. The Statute

Patent claims are invalid unless the patent's specification meets the requirements of 35 U.S.C. § 112 which, in pertinent part, provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms 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

This longstanding requirement of U.S. patent law is the “*quid pro quo*” for the exclusive rights that are conferred on an inventor when he is granted a patent. The publication in an issued patent of a complete disclosure of how to make and use the invention immediately increases the

²⁸ *Id.* at 715.

²⁹ *Id.*

storehouse of public information that, in turn, may be further advanced through additional research and innovation. In this way, the patent system “embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.....”³¹ Thus, the enablement requirement is not merely a technical requirement having no real importance. Instead as the Supreme Court stated as early as 1832, it is the very “foundation” of our patent system.³²

2. Application in Chemical Cases

It can be easily argued that to be enabling under § 112, the patent specification must teach those skilled in the art how to make and use the “full scope” of the claimed invention without undue experimentation.³³ This section of the patent statute requires that the scope of the claims bear a reasonable correlation to the scope of enablement that is provided by the specification.³⁴

A defendant might easily contend that to be entitled to the valuable and exclusive rights that are accorded a patent owner, a patent specification must truly teach those skilled in the art what the invention is and how to make and use it. To wit: ... patent protection is granted only in return for an enabling disclosure of the invention, “not for vague intimations of general ideas that

³⁰ *Id.*

³¹ *Bonito Boats Inc. v. Thunder Craft Boats Inc.*, 489 U.S. 141, 150-51 (1989).

³² *See Grant v. Raymond*, 31 U.S. (6 Pet.) 218, 247 (1832)(a correct specification is necessary in order to give the public, after the [patent] privilege expires, the advantage for which the privilege is allowed, and is the foundation of the power to issue the patent.).

³³ *Harris Corp. v. Ixys Corp.*, 114 F.3d 1149, 1155-56 (Fed. Cir. 1997); *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997); *In re Wright*, 999 F.2d at 1561; *Amgen*, 927 F.2d at 1212-13.

³⁴ *In re Wright*, 999 F.2d at 1561; *Amgen*, 927 F.2d at 1212-13 (“The essential question here is whether the scope of enablement of claim 7 is as broad as the scope of the claim.”); *In re Vaeck*, 947 F.2d 488, 495-96 (Fed. Cir. 1991)(claims held invalid where there was “no reasonable correlation between the narrow disclosure in applicants’ specification and the broad scope of protection sought in the claims”).

may or may not be workable”.³⁵ This fatal defect cannot be dismissed by the argument that the missing disclosure is within the skill in the art:

[A] failure to meet the enablement requirement ... cannot be rectified by asserting that all the disclosure related to the [claimed] process is within the skill of the art. It is the specification, not the knowledge of one of skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

Genentech, 108 F.3d at 1366 (emphasis added). It has become increasingly apparent that the *Genentech* case is not an aberration. The Court of Appeals for the Federal Circuit and its predecessor court, the Court of Customs and Patent Appeals (CCPA), have often determined patents to be invalid for failing to provide an enabling description **in the specification**.³⁶

The law is quite clear that when the **specification** provides no guidance to enable one of skill in the art to make the invention, the claims are invalid.³⁷ The **specification itself** is evidence of its own insufficiency with respect to § 112.³⁸

Recent indications from the Federal Circuit (as discussed below) are that information missing from a chemical patent disclosure, such as -- (1) the identity of a claimed compound; (2) a teaching of how to make such a claimed compound; (3) a teaching of how to use such a claimed

³⁵ *Genentech*, 108 F.3d at 1366 (“Tossing out the mere germ of an idea does not constitute enabling disclosure.”). “[W]hen there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; [and] there is a failure to meet the enablement requirement.”

³⁶ See, e.g., *In re Wright*, 999 F.2d at 1562 (“The general description and the single example in Wright’s specification ... did nothing more ... than invite experimentation to determine whether other vaccines having in vivo immunoprotective activity could be constructed for other RNA viruses.”); *Amgen*, 927 F.2d at 1217 (specification determined not enabling where patent “does not contain any procedures ... for purifying rEPO”); *In re Glass*, 492 F.2d at 1233 (disclosure insufficient under § 112 where specification failed to disclose temperatures, temperature gradients, ingredients, pressures, flow rates and other matters needed to practice the claimed invention, leaving the court with the “strong feeling” that the patent applicant either “did not have possession of the details of a single operative process or, if he did, he chose not to divulge them.”)

³⁷ *Harris Corp.*, 114 F.3d at 1156 (reversing summary judgment that specification was enabling where patent “contains no discussion of how to make or use the claimed invention”); *Genentech*, 108 F.3d at 1367 n. 4 (experimentation is to be described in the specification “if it is to contribute to an enabling disclosure”).

³⁸ *Amgen*, 927 F.2d at 1217(citing *In re Rainer*, 377 F.2d 1006, 1012 (CCPA 1967)).

compound -- cannot be dismissed simply as “minor details” as might permit the patent’s specification to be supplemented by the general knowledge of those of ordinary skill in the art:

[T]hat general, oft-repeated statement [that the specification need not disclose what is well known in the art] is merely a rule of supplementation, **not a substitute for a basic enabling disclosure**. It means that the omission of **minor details** does not cause a specification to fail to meet the enablement requirement.³⁹ Clearly, the Enablement Requirement has acquired new vitality as an infringement defense

under recent interpretations of the statute by the Federal Circuit.

C. The Best Mode Requirement

1. The Statutory Law, 35 U.S.C. § 112, ¶ 1

The statutory basis for the best mode requirement lies in 35 U.S.C. § 112. The first paragraph of that section provides:

“The specification shall . . . set forth the best mode contemplated by the inventor of carrying out his invention.”

The Best Mode requirement is unique among the requirements of paragraph one of 35 U.S.C. § 112 of the Patent Statute in that it is not, and cannot be, evaluated by the patent Examiner during prosecution of a patent. The statute stands, nevertheless, as a requirement to issuance of a valid United States Patent. As we shall see, this requirement has created, over time, interesting questions as to the validity of U.S. Patents, particularly as regards patents issuing from continuation-in-part ("CIP") patent applications.

Violation of the Best Mode requirement has become a favorite defense of the defendant in a patent infringement suit, and there are indications that this defense is increasingly favored by the Federal Circuit. The question therefore naturally arises: what items must an alleged infringer show in order to prove a best mode violation by a patentee? The short answer is that the alleged infringer must show that the inventor of the patent did not disclose in the application his preferred

³⁹ *Genentech*, 108 F.3d at 1366 (emphasis added).

embodiment of the claimed invention in sufficient detail so that one of ordinary skill could routinely practice it.

Under appropriate facts, certain preferred details relevant to the claimed invention may not be present in the patent application as originally filed. Whether this constitutes a best mode violation relies on the following inquiries:

a) Who is the focus of the best mode inquiry?

The inventor's knowledge is the sole focus for the best mode inquiry.⁴⁰ Strictly speaking, then, the knowledge of an employer is irrelevant.⁴¹ However, because evidence of the inventor's knowledge at the time the patent application was filed is paramount for this inquiry, evidence of the employer's knowledge may be relevant to rebut an inventor's assertion of ignorance regarding the non-disclosed best mode.

b) When is the date of interest for the best mode inquiry?

The crucial date is the date of filing the patent application. For a continuation application, the crucial date is the date of filing the earliest parent application.⁴²

c) What invention is the focus of the best mode inquiry?

The best mode of the claimed invention must be disclosed.⁴³ This requires that details of the preferred embodiment must be disclosed where "necessary to satisfactory performance" of the

⁴⁰ *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043 (Fed. Cir. 1995) (no best mode violation where inventor kept intentionally ignorant of the best mode by the employer)

⁴¹ With the possible exception of special circumstances. The Federal Circuit, in an unpublished opinion, affirmed the district court of Delaware's holding that a best mode violation was committed in a case where years after the inventor's initial conception, the manufacturer dusted off the invention, another employee made the improvements to the preferred use of the invention, and the inventor was minimally involved in the drafting and filing of the patent application. This affirmance was in spite of the inventor's ignorance at the time of filing of this preferred embodiment. *CPC Int'l Inc. v. Archer Daniels Midland Co.*, 831 F.Supp. 1091 (D. Del. 1993), *aff'd*, 31 F.3d 1176 (Fed. Cir. 1994)(unpublished).

⁴² See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551 (Fed. Cir. 1994).

⁴³ *Chemcast Corp. v. Arco Industries Corp.*, 913 F.2d 923 (Fed. Cir. 1990) quoting *Randomex, Inc. v. Scopus Corp.*, 849 F.2d 585, 588 (Fed. Cir. 1988) ("It is concealment of the best mode of practicing the *claimed invention* that § 112 ¶ 1 is designed to prohibit") (emphasis in original).

claimed invention, and not just when “the preferred embodiment of the claimed invention.”⁴⁴ On the other hand, the Federal Circuit has also recently held that when an invention relates solely to a *part* of a device, the best mode for a *non-claimed* element needed in the overall device need not be disclosed.⁴⁵

d) What is the test to establish whether the best mode requirement has been satisfied?

Generally, the best mode requirement is satisfied “if [the inventor] does not conceal what he feels is a preferred embodiment of his [claimed] invention.”⁴⁶ This means that “the record must show that the inventor considered an alternative mode superior to the disclosed mode.”⁴⁷ More specifically, the best mode inquiry has been broken down into two sub-inquiries:

“In short, a proper best mode analysis has two components. The first is whether, at the time the inventor filed his patent application, he knew of a mode of practicing his claimed invention that he considered to be better than any other. This part of the inquiry is wholly subjective, and resolves whether the inventor must disclose any facts in addition to those sufficient for enablement. If the inventor in fact contemplated such a preferred mode, the second part of the analysis compares what he knew with that he disclosed – is the disclosure adequate to enable one skilled in the art to practice the best mode or, in other words, has the inventor ‘concealed’ his preferred mode from the ‘public’? Assessing the *adequacy* of the disclosure, as opposed to its *necessity*, is largely an objective inquiry that depends upon the scope of the claimed invention and the level of skill in the art.”⁴⁸

Thus, “both the level of skill in the art and the scope of the claimed invention [are] additional, objective metes and bounds of a best mode disclosure.”⁴⁹

⁴⁴ *Chemcast*, 913 F.2d at 928. See *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1532 (Fed. Cir. 1987).

⁴⁵ *Applied Med. Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 1377-78 (Fed. Cir. 1998).

⁴⁶ *In re Gay*, 309 F.2d 769 (CCPA 1962).

⁴⁷ *Minco, Inc. v. Combustion Engineering, Inc.*, 95 F.3d 1109, 1115-16 (Fed. Cir. 1996). It should be noted that “superior” does not equate to “best” in an objective sense; this portion of the best mode inquiry is wholly subjective. The presence of the inventor’s preferred embodiment may be established on summary judgment or JMOL by inventor testimony. See *U.S. Gypsum Co. v. National Gypsum Co.*, 74 F.3d 1209, 1212 (Fed. Cir. 1996); *Nobelpharma AB v. Implant Innovations, Inc.*, ___ F.3d ___, ___ USPQ2d ___ (Fed. Cir., Mar. 20, 1998).

⁴⁸ *Chemcast*, 913 F.2d at 927-28.

⁴⁹ *Id.* at 926.

e) **What is the “mode” to which 35 U.S.C. 112 is referring?**

The Federal Circuit has stated that the question “What is a ‘mode’ of the ‘invention?’” cannot be answered by a mechanical rule.⁵⁰ Broadly, however, the Federal Circuit has explained that if “the applicant develops specific instrumentalities or techniques which are recognized at the time of filing as the best way of carrying out the invention, then the best mode requirement imposes an obligation to disclose that information to the public.”⁵¹

f) **Is there an *intent* requirement for concealment of the best mode?**

No. Accidental or deliberate, the focus here is whether the best mode, as appreciated by the inventor as of the date of filing, was included in the patent application.⁵² If it was not included, it is irrelevant whether the absence of the preferred embodiment was intentional or not.⁵³

g) **How much detail of disclosure is required to adequately disclose the best mode?**

The exact level of detail required in order to determine whether “the disclosure [is] adequate to enable one skilled in the art to practice the best mode” is unclear. One unassailable proposition is that “the best mode requirement may not be met *solely* by reference to what was known in the prior art.”⁵⁴ Further, details of the best mode may not be provided by a patentee’s outside activities.⁵⁵

⁵⁰ *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1567 (Fed. Cir. 1996).

⁵¹ *Spectra-Physics*, 827 F.2d at 1532. Once again, this refers to “best” in a purely subjective sense.

⁵² *U.S. Gypsum*, 74 F.3d at 1213-14 (“failure to find intentional concealment does not preclude a finding that the best mode requirement has been violated. ... Inquiry into intent to conceal ... is not part of that analysis”).

⁵³ However, an intentional withholding of the best mode combined with disclosure of a false mode of practicing an invention may be grounds for a charge of inequitable conduct. *Consolidated Aluminum Corp. v. Foseco Int’l, Ltd.*, 910 F.2d 804 (Fed. Cir. 1990).

⁵⁴ *Chemcast*, 913 F.2d at 927 quoting *Dana Corp. v. IPC Limited Partnership*, 860 F.2d 415, 418 (Fed. Cir. 1988)

⁵⁵ For example, a patentee’s sale of a product conforming to the preferred embodiment does not absolve the failure to disclose the preferred embodiment upon filing the patent application. See *U.S. Gypsum*, 74 F.3d at 1215 (“Compliance with § 112 cannot depend on whether a patentee later commercializes the invention”); *Chemcast*, 913 F.2d at 930

On the other hand, the Federal Circuit has opined that the best mode requirement does not require that the patentee provide:

“production details so long as the means to carry out the invention are disclosed.”⁵⁶ “Our cases ... employ the term ‘production detail’ in two senses. ... We have used the term to refer to commercial considerations such as the equipment on hand, or prior relationships with suppliers that were satisfactory. Such commercial considerations do not constitute a best mode of practicing the claimed invention because they do not relate to the quality or nature of the invention. Our cases have also used ‘production details’ to refer to details which do relate to the quality or nature of the invention but which need not be disclosed because they are routine – i.e. details of production about which those of ordinary skill in the art would already know. In this latter scenario, the omitted detail constitutes a best mode but the disclosure is deemed adequate because the detail is routine. According to our precedent, then, ... we must determine whether the [details at issue] relate to the claimed invention or to commercial considerations.”⁵⁷

Thus, this paragraph appears to suggest that where a detail is relevant to the claimed invention, it should be disclosed absent its being “routine”. For instance “supplier/trade name information must be provided only when a skilled artisan could not practice the best mode of the claimed invention absent this information.”⁵⁸

A later case, *U.S. Gypsum Co. v. National Gypsum Co.*,⁵⁹ enunciates a “well-known” standard: “the evidence indicates, however, that the material was *not* well-known in the art in December 1982.”⁶⁰ More important to the *Gypsum* Court, however, was that fact that although the referenced material “was sold commercially, the [] specification does not disclose it and, at the time the [] application was filed, no one in the art except [the inventor] and [the assignee] knew

(“whether and to whom [the patentee] chooses to sell its products cannot control the extent to which [the patentee] must disclose his best mode”).

⁵⁶ *Transco Products*, 38 F.3d at 560.

⁵⁷ *Great Northern Corp. v. Henry Molded Products, Inc.*, 94 F.3d 1569, 1572 (Fed. Cir. 1996).

⁵⁸ *Transco Products*, 38 F.3d at 560.

⁵⁹ 74 F.3d 1209 (Fed. Cir. 1996).

⁶⁰ *Id.* at 1214.

that the [material] should be used in [the invention].”⁶¹ As such, it seems that even where a supplier or trade name for a material would not be required, the specification must adequately point an artisan in the field in the right direction by disclosing necessary parameters, etc. If this is not done, a best mode violation may result.

D. So Who Cares? Typical Application - 35 U.S.C. § 112 Defenses

The trio of § 112 defenses find fascinating, if occasional, application in the situation of defense to an infringement charge based upon a U.S Patent issuing immediately from a C-I-P application. From the defendant's perspective, interesting issues develop from the occasions when the Patent Office generally does not consider, during prosecution, the question of whether the (eventually) issued claims are entitled to the filing date of the patent application from which the issued claims claim priority.

We may frame the issue as follows: what are the criteria a party must demonstrate for the issued claims of a continuation-in-part application to be entitled to the original or parent filing date? This issue can safely be considered to be of consequence in every case where the patent-in-suit issued from a CIP application and, when raised, may implicate *all* of the § 112 defenses.

Short Answer: The issued claims must find support in the patent application, as filed. It must be understood that the introduction of a new best mode disclosure in a continuation application would constitute the injection of ‘new matter’ into the application and automatically deprive the applicant of the benefit of the earlier filing date of the parent or original application for any claim whose validity rests on the new best mode disclosure.⁶²

⁶¹ *Id.* at 1215.

⁶² *Transco*, 38 F.3d at 557.

The explanation is as follows:

“To secure the benefit of the filing date of an earlier filed (‘parent’) application, 35 U.S.C. § 120 requires that the claimed invention be disclosed in the manner provided by the first paragraph of § 112, which requires 1) a written description of the invention, 2) enablement, and 3) disclosure of the best mode for practicing the invention. Each of these disclosures is separately required before the later application is entitled to the filing date of the parent.”⁶³

This really is the same requirement for any continuation application because “no matter what term is used to describe a continuing application, that application is entitled to the benefit of the filing date of an earlier application only as to common subject matter.”⁶⁴ The oft-repeated requirement that claims introduced to a C-I-P may not depend on “new matter” if they are to rely on the parent application’s filing date is not inconsistent with the above, because as explained below the standard for “new matter” is derived from, intertwined with, or consonant with the written description requirement.⁶⁵

Consequently, whether these criteria are satisfied depends on a separate inquiry into each of the written description, enablement and best mode requirements of 35 U.S.C. § 112.

1. Written Description

“The description requirement comes into play when a claim is added by an applicant for a patent at some stage after the original filing date and the claim differs in scope from the original claims. If the added claim does not find support in the specification in the sense that it is for an invention not sufficiently described therein, the description requirement is not met, and the benefit

⁶³ *Applied Materials v. Advanced Semiconductor Materials America, Inc.*, 98 F.3d 1563, 1579 (Fed. Cir. 1996) (Mayer, J. concurring). See *Transco Products Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 556-57 (Fed. Cir. 1994) (“§ 120 does not exempt the best mode requirement from its reach, and therefore this court must accept the plain and precise language of § 120 as encompassing the same. Accordingly, the date for evaluating a best mode disclosure in a continuing application is the date of the earlier application with respect to common subject matter”). *Accord* Ex parte *Engelhardt*, 208 USPQ 343 (P.T.O. Bd. App. 1980) (“[Because] the 1959 application did not comply with the best mode requirement, appellant’s 1967 application cannot be accorded the benefit of the filing of its parent application”).

⁶⁴ *Transco*, 38 F.3d at 556.

of the original filing date is lost.”⁶⁶ Reference to the policy underlying the written description requirement reveals that “adequate description of the invention guards against the inventor’s overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.”⁶⁷ Similarly, “in patent law, the translation from invention in a scientific sense to the legal description of the invention is important, because the law establishes a system of deadlines that could be subverted by allowing the scientific sense to control. Unless it conveys a sense of which features matter, a diagram could enable later filings on the entire genus of which it is a species, a process that would substantially enlarge the time for filing the real patent application.” As such, the touchstone of the written description requirement is that “the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.”⁶⁸ This is the heart of the “new matter” standard.⁶⁹

The fact specificity of the written description requirement has been stressed and thus the analysis varies on a case-by-case basis.⁷⁰ One complicating factor is that “the precedential value of cases in this area is extremely limited.”⁷¹ Nonetheless, some signposts have been provided to offer guidance. For instance, one-to-one correspondence between the specification and the newly

⁶⁵ The wellspring of the “new matter” standard is unclear (*e.g.* the written description requirement, 35 U.S.C. § 132), but it really doesn’t matter for this discussion.

⁶⁶ Chisum, § 7.04, p. 7-137.

⁶⁷ *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991)

⁶⁸ *Id.* at 1564.

⁶⁹ See *In re Kaslow*, 717 F.2d 1366, 1375 (Fed. Cir. 1375)

⁷⁰ *Vas-Cath*, 935 F.2d at 1562.

⁷¹ *In re Driscoll*, 562 F.2d 1245, 1250 (CCPA 1977)

introduced claims is not required.⁷² “Rather, it is a question whether the application necessarily discloses that particular device. It is not required that the application describe the claim limitations in greater detail than the invention warrants. The description must be sufficiently clear that persons of skill in the art will recognize that the applicant made the invention having those limitations ... [The] specification must ‘convey clearly to those skilled in the art to whom it is addressed ... the information that [the inventor] has invented the specific subject matter later claimed.’”⁷³

The limits of this doctrine may be further gleaned from the following explanation of why an original patent specification describing simply “air or other gas which is inert to the liquid” did support a later-introduced claim directed toward a “fluid”, whose scope not only encompassed “air or other gas” but also (of course) encompassed a liquid:

“We are not saying that the disclosure of ‘air or other gas which is inert to the liquid’ sample by itself is a description of the use of all ‘inert fluid’ media. Rather, it is the description of the properties and functions of the ‘air or other gas’ segmentizing medium described in appellants’ specification which would suggest to a person skilled in the art that appellants’ invention includes the use of ‘inert fluid’ broadly ... A hypothetical situation may make our point clear. If the original specification of a patent application on the scales of justice disclosed only a 1-pound ‘lead weight’ as a counterbalance to determine the weight of a pound of flesh, we do not believe the applicant should be prevented, by the so-called ‘description requirement’ of the first paragraph of § 112, or the prohibition against new matter of § 132, from later claiming the counterbalance as a ‘metal weight’ or simply as a 1-pound ‘weight,’ although both ‘metal weight’ and ‘weight’ would indeed be progressively broader than ‘lead weight,’ including even such an undisclosed, but obviously art-recognized equivalent, ‘weight’ as a pound of feathers. The broader claim language would be permitted because the description of the use and function of the lead weight as a scale counterbalance in the whole disclosure would immediately convey to any person skilled in the scale

⁷² See *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996) (“*ipsis verbis* disclosure is not necessary to satisfy the written description requirement of § 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question.”)

⁷³ *Martin v. Mayer*, 823 F.2d 500, 505 (Fed. Cir. 1987)

*art the knowledge that the applicant invented a scale with a 1-pound counterbalance weight, regardless of its composition.”*⁷⁴

Note that the question is not whether the later-claimed subject matter is *obvious* in light of the specification, but rather did the “disclosure of the application relied upon reasonably convey to the artisan that the *inventor had possession* at that time of the later claimed subject matter?”⁷⁵ “[T]he test for the written description is not whether a skilled artisan *would have known* that lithium iodide was ‘suitable’ in similar processes; the test is whether the artisan would have known, from reading the description, that the *inventor ...did know* of this suitability – and hence had possession of this invention.”⁷⁶ The practical impact of this distinction is unknown, however. Perhaps where a patent specification states that something is necessary to the invention, but one of ordinary skill in the art would appreciate that it is not, nonetheless later introduced claims without such a limitation would constitute new matter outside the scope of the written description.

One of the most recent cases on point is *Gentry Gallery, Inc. v. The Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998), decided January 27, 1998, where the patent’s broader claims were found invalid for violation of the written description requirement. The technology at issue pertained to reclining sectional sofas, and in particular the patent taught to provide a “console” upon which were located controls for adjusting the reclining sectional seats. The patentee alleged infringement of its claims by competitors who were not placing their sofa controls upon a console. As explained by the court, “the original disclosure clearly identifies the console as the only possible location for the controls.” Consonant with this statement, the broadest original claim was

⁷⁴ *In re Smythe*, 480 F.2d 1376, 1384 (CCPA 1973)

⁷⁵ *Waldemar Link, GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 558-59 (Fed. Cir. 1994)

⁷⁶ *Hoechst Celanese Corp. v. BP Chemical Ltd.*, 844 F.Supp. 336, 340 (S.D. Tex. 1994) (Kent, J.); *Dana Corp. v. IPC Limited Partnership*, 860 F.2d 415, 419 (Fed. Cir. 1988) (“The best mode requirement is not satisfied by reference to the level of skill in the art, but entails a comparison of the facts known to the inventor regarding the invention at the time the application was filed and the disclosure in the specification.”) (emphasis in original).

directed to control means located on a center console. As issued, however, the claims were “invalid because they are directed to sectional sofas in which the location of the recliner controls is not limited to the console.” As such, broadening claims were added during prosecution that constituted new matter and thus were invalid.

Although this analysis fits neatly with the paradigm provided by Chisum and quoted above, it appears from the tone of *Gentry Gallery* that the broadening of claims during prosecution was not the most important point. Instead, *Gentry Gallery* repeatedly discussed how the specification suggests that the console must be located in the center console, and pointed to the inventor’s testimony that he “did not consider placing the controls outside the console until he became aware that some of Gentry’s competitors were so locating the recliner controls.” Further, the Federal Circuit emphasized that “when viewed in its entirety, the disclosure is limited to sofas in which the recliner control is located on the console.” This suggests that if a necessary feature for an invention (its necessity being apparent from the disclosure as a whole) is omitted from a claim, even as filed, that claim might be invalid for failure to comply with the written description requirement.

2. Enablement

§ 112 requires the specification to be enabling to a person “skilled in the art to which it pertains, or with which it is most nearly connected.” This may be broken down into a number of different sub-inquiries:

- a) ***What is the scope of the relevant art (i.e. how do we define “art to which it pertains” under § 112?***

The specification is directed toward the field whose adepts have the best chance of being enabled to carry out the aspect proper to their specialty.⁷⁷

⁷⁷ *In re Naquin*, 398 F.2d 863, 866 (CCPA 1968)

b) ***How much prior art is the person skilled in the art presumed to know?***

Unlike the legal construct of “one of ordinary skill in the art” under § 103, the “person skilled in the art” of § 112 is not presumed to know everything in his field. On the other hand, “a patent need not disclose what is well known in the art.”⁷⁸ In discussing the § 112 enablement standard, the United States Court of Customs and Patent Appeals appears to have adopted a somewhat lower standard than “well known.” It states: “U.S. patents are considered pertinent evidence of what is likely to be known by persons of ordinary skill in the art.”⁷⁹ Thus, for any particular piece of knowledge alleged to be within the purview of the person skilled in the art, “an applicant must show that anyone skilled in the art would have actually possessed the requisite knowledge or would reasonably be expected to check the source which the applicant relies upon to complete his disclosure and would be able to locate the information with no more than reasonable diligence.”⁸⁰ This has been referred to as an “all prior art which is generally and reasonably available to the public” standard.⁸¹

c) ***As of what time do we judge whether the patent is enabling?***

The specification must be enabling as of the specification’s filing date.⁸²

⁷⁸ *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988); *Webster Loom Co. v. Higgins et al.*, 105 U.S. 580, 586 (1881) (“That which is common and well known is as if it were written out in the patent and delineated in the drawings”).

⁷⁹ *In re Howarth*, 654 F.2d 103, 106 (CCPA 1981). Note: specifically, the court was discussing the requirements for an applicant to supplement a specification that on its face appears deficient under § 112

⁸⁰ *Id.* at 107

⁸¹ Chisum, § 7.03[2], p. 7-30

⁸² *In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993)

d) *How much detail must be included in the specification?*

The 35 U.S.C. § 112 enablement requirement implicitly tolerates a disclosure requiring “experimentation” to make or use the claimed invention so long as the experimentation is not “undue” or “unreasonable.”⁸³

3. *Best Mode*

It is important to note that *Transco* instructs that “the date for evaluating a best mode disclosure in a continuing application is the date of the earlier application with respect to common subject matter.”⁸⁴ “It must be understood that the introduction of a new best mode disclosure [in a continuation application] would constitute the injection of ‘new matter’ into the application and automatically deprive the applicant of the benefit of the earlier filing date of the parent or original application for any claim whose validity rests on the new best mode disclosure.”⁸⁵ This statement was made in the context where no new matter would be introduced to the continuation other than a new best mode. This statement was also used, in part, to conclude that there is no obligation to update best mode in a continuation application. Thus, when the court refers to “validity” it must necessarily be referring to any claimed subject matter that would be covered by the new best mode. As such, where no best-mode violation occurs in the parent application, and the verbiage introduced in a continuation-in-part application finds support in the parent application under the enablement and written description requirements, the mere introduction of a new best mode in the C-I-P forecloses dependency on the parent application’s filing date.⁸⁶ However, it could also be

⁸³ *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1212 (Fed. Cir. 1991) (“That some experimentation is necessary does not constitute a lack of enablement; the amount of experimentation, however, must not be unduly extensive”).

⁸⁴ *Transco*, 38 F.3d at 557.

⁸⁵ *Id.* at 559.

⁸⁶ *In re Gostelli*, 872 F.2d 1008, 1011 (Fed. Cir. 1989), cited to by analogy by the *Transco* court when making the quoted statement, involved a best-mode analysis for an application claiming foreign priority under § 119.

argued that where claims introduced in a C-I-P would have been valid were the new best mode disclosure not made (because there is no obligation to update the best mode), then those claims' validity does not rest on the new best mode disclosure. Further, not giving the newly introduced claims the parent's filing date seems incongruent with the result where a continuation application is filed, rather than a continuation-in-part, and no new best mode is introduced into the continuation specification. Under these circumstances, any claims newly introduced in the continuation application would be entitled to the parent's filing date (once again, assuming that the enablement and written description requirements for the new claims were satisfied by the parent's specification). Penalizing the applicant for voluntarily updating his best mode, as contrasted to requiring the best mode disclosure to be updated, seems to undermine having the best mode requirement in the first place. Therefore, it may be important not to rely solely on this proposition to force a plaintiff to rely on its later C-I-P filing date, although certainly the statements of *Transco* are favorable to defendants.

IV. INEQUITABLE CONDUCT

An inventor's dealings with the U.S. Patent and Trademark Office are entirely *ex parte* and have all the well-recognized dangers of *ex parte* proceedings. Therefore, every inventor has an absolute duty of candor, good faith, and honesty when dealing with the Patent and Trademark Office (PTO). In fact, every inventor is required to sign a declaration promising to disclose all information relevant to the patentability of his invention. A breach of this duty is called inequitable conduct.

By thorough consideration of patent applications, the patent examiner attempts to protect the public from invalid patents. However, the examiner's communications with the patent applicant are entirely *ex parte* and thus only the inventor's interpretation of documents and events

is presented to the examiner. The dangers of this are clear. Therefore, every person who is involved with any patent application has an absolute duty of candor, good faith, and honesty when dealing with the U.S. Patent and Trademark Office (PTO). This duty is codified in 37 CFR § 1.56:

...Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability...⁸⁷

Accordingly, the PTO requires every inventor to sign a declaration that he will disclose all information relevant to the patentability of his patent application. This declaration is made under penalty of fine, imprisonment, and the unenforceability of the patent. 37 C.F.R. § 1.63.

A. A Breach of the Duty of Candor is Known as Inequitable Conduct

The test for inequitable conduct requires two things: a misrepresentation or omission that a reasonable examiner might find important; and an intent to deceive the Patent and Trademark Office. A breach of the duty of candor, good faith, and honesty by an inventor or his representative is called inequitable conduct.⁸⁸ The existence of inequitable conduct is a question of law for the Court.

The test for inequitable conduct requires two elements:

- (1) a material misrepresentation or omission; and
- (2) an intent to deceive the PTO.

Id. at 1256.

Materiality does not depend on whether an examiner actually relied on the misrepresentation or omission. Instead, “information is material when there is a substantial

⁸⁷ 37 C.F.R. § 1.56.

⁸⁸ *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995).

likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent.”⁸⁹

“Direct proof of wrongful intent is rarely available.”⁹⁰ Instead, deceptive intent must be inferred using the truism that the natural consequences of acts are presumed to be intended by the actor.⁹¹ Thus, intent to deceive “may be inferred where a patent applicant knew, or should have known, that information would be relevant to the PTO’s consideration of the patent application.”⁹²

If both materiality and intent are found, the court balances them in light of all the evidence and determines whether inequitable conduct occurred.⁹³ The more material the misrepresentation or omission, the lower the level of intent required for inequitable conduct, and vice versa.⁹⁴ If inequitable conduct is found, then every claim of the patent is unenforceable.⁹⁵ A complete discussion of how to avoid an eventual assertion of inequitable conduct is properly the subject of another paper. Some highlights may be noted, however. Particularly interesting, are applications of the duty of disclosure as applied to cases where a patent has issued from a C-I-P application, and items embodying claim elements supported by newly added disclosure are arguably publicly used, sold, or offered for sale.

⁸⁹ *Fox Industries, Inc. v. Structural Preservation Systems, Inc.*, 922 F.2d 801, 803 (Fed. Cir. 1990).

⁹⁰ *LaBounty Mfg., Inc. v. U.S. International Trade Commission*, 958 F.2d 1066, 1076 (Fed. Cir. 1992).

⁹¹ *Molins PLC*, 48 F.3d at 1180.

⁹² *Critikon v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997).

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Critikon*, 120 F.3d at 1259.

B. Sales and Public Uses of the Invention One Year Before Filing.

35 U.S.C. § 102(b) prohibits filing for a patent more than one year after a sale of the invention. This same statute also prohibits filing for a patent more than one year after a public display of the invention.⁹⁶ The day one year before the filing date of the application is called the “statutory bar date” or “critical date” of the patent -- “critical” because a sale or public display prior to the “critical date” invalidates the patent. Thus, by their nature, sales and public uses before the critical date are material to patentability. In fact, the declaration signed by the inventor includes the representation that the invention has not been on sale or in public use more than one year prior to filing of the patent application.

However, unless the inventor tells the examiner of these sales or public uses, the examiner has no way of knowing they took place. Thus, the Federal Circuit warns that “The concealment of sales information can be particularly egregious because, unlike the applicant’s failure to disclose, for example, a material patent reference, the examiner has no way of securing the information on his own.”⁹⁷

In *Paragon Podiatry*, the Federal Circuit affirmed a summary judgment of inequitable conduct. Over one year before filing the patent application, the patentee sold items that embodied certain claims of the patent.⁹⁸ These sales made those claims invalid on summary judgment for violation of 35 U.S.C. § 102(b).⁹⁹ A summary judgment holding of inequitable conduct was also appropriate because invalidating sales satisfy the most stringent standard of materiality.¹⁰⁰ Further, intent to deceive could be inferred because “the evidence of a knowing failure to disclose sales that

⁹⁶ 35 U.S.C. § 102(b).

⁹⁷ *Paragon Podiatry Laboratory v. KLM Laboratories, Inc.*, 984 F.2d 1182, 1193 (Fed. Cir. 1993).

⁹⁸ *Id.* at 1185.

⁹⁹ *Id.*

¹⁰⁰ *See Fox*, 922 F.2d at 804; *Paragon Podiatry*, 984 F.2d at 1188; *Labounty*, 958 F.2d at 1075-76

bear all the earmarks of commercialization reasonably supports an inference that the inventor's attorney intended to mislead the PTO."¹⁰¹ Thus, *none* of the claims of the patent were enforceable.

C. Example - An Applicant For Patent Cannot Hold Back Evidence of Sales When Filing a Continuation-In-Part Application

A continuation-in-part (CIP) application is exactly what it says: a second patent application that continues the first application only "in-part." By filing a continuation-in-part application, a patentee adds new product or feature descriptions to his invention in the form of drawings and specifications. By law, when added, these new product or feature descriptions are entitled only to the patent application filing date of when the additions were added.¹⁰² Thus, each CIP application has its own CIP "critical" date. As such, the duty of candor, good faith, and honesty requires the inventors to disclose all sales that occurred before the critical date, having new features introduced in the CIP application.

V. CONCLUSION

The bottom line to protecting the value of developing intellectual property via patent must now include increasing your awareness of the requirements imposed by 35 U.S.C. § 112. As mentioned above, this increased awareness is mandated not by any change to the statute itself but by the heightened emphasis recently given to this section of the statute by the Federal Circuit. Your particular response to this emphasis must be guided by your response to the relevant Federal Circuit opinions, but some general guidelines may be suggested as follows.

As an inventor, to try make sure that: the description of your invention in the patent specification is commensurate in scope with what you recite in the claims; remember that the specification of your patent must be sufficiently detailed to teach someone of *ordinary* skill in the

¹⁰¹ *Paragon Podiatry*, 984 F.2d at 1193.

¹⁰² *U.S. Environmental Products v. Westall*, 911 F.2d 713 (Fed. Cir. 1990).

relevant field (not necessarily someone with *your* skill) how to make and use your invention as recited in the claims. If you know of a better way to make, use, or build your invention than you see described in the draft patent application that your patent attorney asks you to approve, *make sure you include that "better way" in the patent specification before it is filed with the Patent Office; give your patent attorney the best of everything that everybody else has done that you know of* - the closer the prior art is to your invention the stronger your patent will be when it issues.

As an in-house patent attorney recognize that: recent Federal Circuit cases appear to have given the 35 U.S.C. § 112 defenses to infringement renewed vitality, particularly in non-chemical cases; *In re McGrew* appears to have created a new "late claiming" defense, enlarging the scope of the relevant prior art when claims are broadened during prosecution. As part of the services you provide to the research groups you support, you might well want to: increase the frequency of the patenting seminars you give to research technologists; schedule a special discussion to emphasize the requirements of 35 U.S.C. § 112 (especially § 112, first paragraph); and critically review the invention disclosures you've already drafted but not yet filed after reviewing some of the Federal Circuit discussed above.

Finally, as a manager, supervisor, or group leader, you may believe that you are already doing everything you can to foster interaction between your inventors and in-house patent attorneys; most of you are probably are. Somebody out there however, has more work to do: 1998 was a banner year for invalidating patents on the basis of § 112 violations during patent prosecution that could have been avoided.

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