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The Disclosure Requirements of the 1952 Patent Act: Looking Back and a New Statute for the Next Fifty Years

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THE DISCLOSURE REQUIREMENTS OF THE 1952 PATENT ACT: LOOKING BACK AND A NEW STATUTE FOR THE NEXT FIFTY YEARS†

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I. OVERVIEW

The 1952 Patent Act was a major event in terms of cutting and pasting together the various patent laws from the previous eighty or so years into the first patent law codification of the twentieth century.[1] The great bulk was a mere codification of principles, going back in some cases to the earliest patent laws of the eighteenth century, that was the work of P. J. Federico.[2] Of the three major changes made to the patent law in 1952, each was primarily the work of the late Giles Sutherland Rich,[3] with his revision of Section 112 to introduce "means" claiming-perhaps

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1. For an excellent and contemporaneous review of the 1952 Patent Act by its principal draftsman, see P.J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. § 1 (1954), *reprinted in* 75 J. PAT. & TRADEMARK OFF. SOC'Y 162 (1993), which is a compendium of lectures shortly after enactment in Washington, D.C., Chicago, New York and elsewhere that for many years was found in the *United States Code Annotated*. For reasons unknown, West deleted this work from its recent editions of the *United States Code Annotated*, making the 1993 reprint a more accessible source.

2. *Id.*

3. Insofar as means claiming is concerned, see the negative of the author of these specific provisions in *In re* Donaldson Co., 16 F.3d 1189, 1194 n.3 (Fed. Cir. 1994):

> P.J. Federico's post-ACT "*Commentary on the New Patent Act*," 35 U.S.C.A. § 1 (1954 ed., West), *reprinted in* 75 JPOS 162 (1993), is not legislative history per se that may be relied upon to indicate Congressional intent. Even if it were, the comments contained therein do not suggest that Federico knew of any particular intent *by Congress* regarding the manner in which the sixth paragraph, then the third paragraph, should be applied. In this particular, he was merely stating his personal views.

Id.

representing the most problematic change in the patent law that still plagues practitioners, now, more than fifty years after the effective date of the new law.[4]

Interestingly, while this paper is not about harmonization of patent laws, it should be noted that the changes that were made to § 112 were done in a geographical vacuum, with unique and creative solutions sought that found no basis in the practice of any foreign country. Here, it is not for the sake of "harmonization" that corrections are needed, but more to help the American intellectual property community by providing simpler and better protection for the all-important innovators who create the promise of the new technologies for the twenty-first century. None of the key changes to § 112 has been adopted internationally, making our practice an arcane deviation from the rest of the world.[5]

The first portion of this paper deals with the first paragraph of 35 U.S.C. § 112. This section provides that:

> 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.[6]

The first problem here is the judicial activism from several panel opinions that created a "written description" requirement apart from the original "new matter" proscription.[7] The second major problem is the

4. The two other major changes were a statutory override of certain patent misuse cases via 35 U.S.C. § 271(d) and the creation of a statutory test of nonobviousness under what is today 35 U.S.C. § 103(a). While each represented a significant statutory change, the former was virtually ignored – but saved by a 5-4 vote that termed the provision a codification. *See* Dawson Chem. Co. v. Rohm and Haas Co., 448 U.S. 176, 179 (1980) ("Congress enacted [§ 271(d)] in 1952 to *codify* certain aspects of the doctrines of contributory infringement and patent misuse that previously had been developed by the judiciary." (emphasis added)). The latter was also deemed a codification. *See* Graham v. John Deere & Co., 383 U.S. 1, 3-4 (1966) ("[T]he 1952 [Patent] Act was intended to *codify* judicial precedents embracing the principle long ago announced by this Court in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1851), and that, while the clear language of § 103 places emphasis on an inquiry into obviousness, the general level of innovation necessary to sustain patentability remains the same." (emphasis added)).

5. A whole host of American initiatives in the patent law *have* been adopted by foreign countries, but the changes to the disclosure laws in the United States have – for good reason – not been adopted abroad.

6. *See infra* § II, *The First Paragraph of Section 112.*

7. *See infra* § II-A, *New Matter – Preview for "Written Description;"* Enzo Biochem, Inc. v. Gen-Probe, Inc. [*Enzo I*], 285 F.3d 1013 (Fed. Cir. 2002), *vacated on reh'g*, *Enzo II*, 296 F.3d 1316 (Fed. Cir. 2002) *and Enzo III*, 323 F.3d 956 (Fed. Cir. 2002); Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998); Gentry Gallery,

mistaken inclusion in the 1952 Patent Act of the requirement that the "best mode contemplated" be disclosed.[8]

The second portion of this paper deals with the final paragraph of 35 U.S.C. § 112 – originally the third but now the sixth paragraph – that provides for "means" claiming.[9]

The final section deals with the United States patent law as part of the global village: what statutory changes make sense for the United States to retain its leadership position in the world patent community?[10]

As an appendix, a new statutory scheme to modify the existing model of 35 U.S.C. § 112 is proposed.[11]

II. THE FIRST PARAGRAPH OF SECTION 112

A. New Matter – Preview for "Written Description"

One of the mistakes made in the creation of the 1952 Patent Act was the attempt to segregate substantive and procedural requirements into separate chapters – and the incomplete perfection of this task. In the area of disclosure requirements, a principal problem that would not crop up immediately is the proscription against the introduction of "new matter" after filing: one could not pull limitations for an invention out of thin air, after filing, and thereby redefine a broader (and sometimes narrower) generic definition. "New matter" dates back to the first half of the nineteenth century and was introduced as a statutory term in 1870,[12] while statutory reissue practice itself dates back to 1832.[13] The new matter

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

8. *See infra* § II-B, *Best Mode Trap for the Unwary*.

9. *See infra* § III, *"Means" as Means to a Bad End*.

10. *See infra* § IV, *A Patent Law for the Global Village.*

11. *See infra* Appendix.

12. "New matter" may be traced back to the Patent Act of 1870. *See* Gill v. Wells, 89 U.S. 1, 25 (1874) ("[T]he description of the other combinations, beside the first, would constitute a new matter, the introduction of which into the specification of a reissued patent is expressly forbidden by the fifty-third section of that act."); Union Paper Collar Co. v. Van Dusen**,** 90 U.S. 530, 557 (1874) ("[B]y a recent act of Congress it is provided that no new matter shall be introduced into the specification."). "New Matter" was a term of art in the patent practice since the first half of the nineteenth century. Woodworth v. Hall**,** 30 F. Cas. 577, 580 (C.C.D. Mass. 1846) (No. 18,017) ("If new matter was inserted not originally contemplated . . . it is questionable whether they could relate back to the date of the letters-patent. . . .").

13. Sontag Chain Stores Co. v. Nat'l Nut Co.**,** 310 U.S. 281, 283-84 (1940) ("The provision concerning reissues in the present Patent Act, Section 4916 Revised Statutes, as amended by Act May 24, 1928, c. 730, 45 Stat. 732, U.S.C.A. Title 35, sec. 64 derives through the Acts July 3, 1832, c. 162, sec. 3, 4 Stat. 559; July 4, 1836, c. 357, sec. 13, 5 Stat. 117, 122; March 3, 1837, c. 45, sec. 5, 5 Stat. 191, 192; July 8, 1870, c. 230, sec. 53, 16 Stat. 198, 205.")

provision of the law prior to the 1952 Patent Act stated that "no *new matter* shall be introduced into the specification [of a reissue]."[14]

There was no harm seen to the legal fiction of a separate "written description" requirement as long as the requirement was seen strictly as a proscription against "new matter" being added by amendment. Clearly, there could never be a new matter problem with an *original* claim, because an original claim *is* a part of the written description.

The problem came to a head when panel opinions sought to judicially legislate that the "written description" requirement could be used against an *original claim*.[15] Here came the two *Enzo* opinions from 2002 (*Enzo I* and *Enzo II*)[16] that dramatically underscore a shortcoming of the 1952 Patent Act. They were foreshadowed by an obscure panel opinion from five years earlier.[17] Under the panel opinion majority in each of the *Enzo* opinions, priority based upon an original case – or maintenance of an

14. The reissue law evolved as Section 4916 Rev. Stat, as amended May 24, 1928, c. 730, 45 Stat. 732, 35 U.S.C. § 64, quoted in *Sontag*:

> [N]o *new matter* shall be introduced into the specification [of a reissue], nor in case of a machine patent shall the model or drawings be amended, except each by the other; but when there is neither model nor drawing, amendments may be made upon proof satisfactory to the commissioner that such *new matter* or amendment was a part of the original invention, and was omitted from the specification by inadvertence, accident, or mistake, as aforesaid.

Sontag Chain Stores, 310 U.S. at 283 n.1. (emphasis added).

15. Correctly citing *In re Gardner*, 480 F.2d 879 (C.C.P.A. 1973), Judge Lourie in his concurrence to denial of *en banc* consideration of *Enzo II* stated that "[t]here is no question that an original claim is part of the specification." Enzo Biochem, Inc. v. Gen-Probe, Inc. [*Enzo IV*], 42 Fed. Appx. 439, 441 (Fed. Cir. 2002) (Lourie, J., concurring) (published separately but accompanying the opinion of *Enzo II & III*). But here there is a disconnect as the paragraph concludes with the observation:

> [T]he question here is whether the disclosure, as an original claim, or in the specification, adequately describes the invention. It is incorrect that the mere appearance of vague claim language in an original claim or as part of the specification necessarily satisfies the written description requirement or shows possession of a generic invention.

Id. at 441-42.

16. There are three papers from the present writer in 2002 that relate to this issue all surrounding litigation involving an *Enzo* patent. The most recent paper in this series is Harold C. Wegner, *When a Written Description is Not a "Written Description": When* Enzo *Says it's Not*, 12 FED. CIR. B.J. 271, 271-283 (2002), which principally deals with *Enzo II.* The second paper is Harold C. Wegner, *An* Enzo *White Paper: A New Judicial Standard for a Biotechnology "Written Description" Under 35 U.S.C. § 112, ¶ 1*, 1 J. MARSHALL REV. INTELL. PROP. L. 254 (2002), *at* http://www.jmls.edu/ripl/vol1/issue2/wegner.html, which in turn is based upon the third of the three; the original version. The original was prepared for presentation to the American Intellectual Property Law Association Biotechnology Committee, Special Meeting on the *Enzo* Case, Waldorf Astoria Hotel, New York, April 19, 2002. These three papers dealt with the decision withdrawn on petition for reconsideration in *Enzo II*, the earlier decision being referred herein as *Enzo I*, but commonly referred to simply as *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 285 F.3d 1013 (Fed. Cir. 2002).

17. *Regents of the Univ. of Cal*., 119 F.3d at 1559.

original claim – may depend *in biotechnology only* – upon whether there is a sufficient possession of the invention under judicially legislated standards for a written description.[18]

1. The *Gentry Gallery* Case

While *Enzo* was the most extreme case of misconstruing the first paragraph of 35 U.S.C. § 112, it was not the first. Perhaps the most notorious case in this regard deals with the characterization of features in the specification as critical or not – something that has no statutory basis but which has recently been interpreted to the contrary. Under a new line of case law, if there is a feature in a claim that is characterized in the specification as "important" or "critical," then broadening the claim to delete this feature goes against the written description requirement of 35 U.S.C. § 112.[19]

Careful patent draftsmanship requires as a best practice drafting a specification that *discloses* all features of an invention but which does not *characterize* the importance of one or more of the features, and which also – particularly in biotechnology and chemistry – fully discloses the features in a manner that the Examiner and a judge can understand. To say that one feature in the specification is "critical" or the "heart of the invention" adds nothing in terms of meeting any statutory requirement, yet may well prejudice the case in terms of an unwanted rejection or ground for invalidity under *Gentry Gallery*.[20] Failure to have a full disclosure of examples in the biotechnology field may invite a rejection for want of "possession" of the invention, and hence lack of a "written description."[21]

18. *Id.*

19. Consider the case where the original claims are all directed to a combination of A and B. If there are features A and B in a combination invention and A, *alone*, is novel, then the applicant has the right to a generic claim that comprises A, *alone* – which means that it may cover A by itself or with B or anything else. Perhaps the specification says that B is a critical component to a successful commercial realization of the invention. This may enhance the patentability of a claim to a combination of A and B, but the patent applicant should be entitled to claim A, alone – in addition to whatever claims he or she may or not wish to present to B.

20. Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479 (Fed. Cir. 1997) (legislating a "written description" requirement that proscribed presenting a generic claim that was *fully supported by the specification* where the specification indicated that a subgeneric embodiment was considered to be the invention of the application).

21. There *are* situations where the full scope of a claimed invention is not supported by a representative teaching to enable the full practice of the invention. This is, however, an entirely different situation where the patent law provides a complete remedy. Thirty-two years ago in *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970), a "scope of enablement" test was formulated – one that continues as a viable test even today. *See* Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315

2. The *Enzo* Cases

Following *Gentry Gallery,* a panel of the court in *Enzo* continued to tinker with the written description requirement of 35 U.S.C. § 112, ¶ 1. Any study of the history of this section of the patent law will show that in the 1952 Patent Act there was no "written description" requirement apart from enablement or best mode, and that instead there was a parallel requirement that a new claim introducing new language be free from "new matter" under 35 U.S.C. § 132. Then, in the 1960's, the late Giles S. Rich invented the concept that the "new matter" proscription was better housed within the ambit of the "written description" requirement.[22] The original intention of such judicial legislation was to merely *substitute* the "written description" requirement for the "new matter" requirement of the 1952 Patent Act. *Enzo* was perhaps the worst example of judicial legislation from the Federal Circuit in recent years: the case made news twice in 2002, in a first panel opinion[23] and then on reconsideration in a second panel opinion[24] – which was met by strident dissent when the court concurrently failed to grant a petition for *en banc* reconsideration.[25]

Already, far too much energy has been expended on the aberrations of the panel opinions in *Gentry Gallery* and *Enzo*. In early 2003, some hope was shown for a repudiation of this line of case law. While paying lip service to *Enzo*, a panel of the court sharply repudiated much if not all of

F.3d 1335, 1339 (Fed. Cir. 2003) (quoting *In re Fisher*, 427 F.2d at 839 ("The first paragraph of 35 U.S.C. § 112 effectively requires that 'the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.'")).

22. It is without controversy that prior to *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967), there had never been a single precedent from the CCPA that had considered the "written description" wording of 35 U.S.C. § 112, ¶ 1, to be anything other than a modifier of the requirement for enablement. *See* Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991) ("With respect to the first paragraph of § 112 the severability of its 'written description' provision from its enablement ('make and use') provision was recognized . . . as early as *In re Ruschig*.").

23. *Enzo I*, 285 F.3d at 1013. For a critique of this opinion, *see* Wegner, *An* Enzo *White Paper*, *supra* note 16.

24. *Enzo II*, 296 F.3d at 1316.

25. In a procedurally bizarre release of the denial of the *en banc* request, the official website of the court initially took the action of *separately* issuing the panel opinion's decision on reconsideration as a "precedential" opinion on an M.S. Word document and then concurrently posted an Adobe PDF file with the *order* denying *en banc* consideration having a heading that indicated that it was a nonprecedential *opinion* – and then lumping together the several concurring and dissenting opinions of the court on denial of *en banc* as attachments. Within a day, the PDF file was replaced with a regular Word file. For whatever reason, the odd procedure slipped past the *Federal Reporter* which failed to include the opinions accompanying the denial of *en banc* hearing into their main volumes, instead reporting these separate opinions as *Enzo IV*. Enzo Biochem, Inc. v. Gen-Probe, Inc., 42 Fed.Appx. 439, 441, 63 U.S.P.Q.2d 161B (Fed.Cir. 2002). *See* Wegner, *When Written Description*, *supra* note 20, at 271-283.

Gentry Gallery. In *Amgen v. Hoechst,*[26] the court denied the precedential value of *Gentry Gallery*:

> [The accused infringer] would have us view *Gentry* as a watershed case, in reliance on an isolated statement—probably only dicta—that one of ordinary skill in the art would clearly understand that the location of the reclining controls on the claimed sectional sofa 'was not only important, but essential to [the] invention.'"[27] But, the court noted that "we did not announce [in *Gentry*] a new 'essential element' test mandating an inquiry into what an inventor considers to be essential to his invention and requiring that the claims incorporate those elements.[28]

Judge Clevenger in his strongly phrased dissent in *Amgen* underscored the virtually express repudiation of *Gentry Gallery* by the panel majority.[29]

So, what should be done? Are *Gentry Gallery* and the two *Enzo* cases the mere aberrant panel opinions of one judge? Or, are they to be followed? If the latter, then they need to be legislatively overruled as part of any further legislative recodification.

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26. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Fed. Cir. 2003).

27. *Id.* at 1333 (citation omitted).

28. *Id.* (quoting *Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1323 (Fed. Cir. 2002)). Also following the quotation is the statement: "*See also Vas-Cath*, 935 F.2d at 1565; *cf. Aro Mfg. Co. v. Convertible Top Replacement Co*., 365 U.S. 336, 345 (1961) ('[T]here is no legally recognizable or protected 'essential element,' 'gist' or 'heart' of the invention in a combination patent.'). *Id.* Understood in this light, one sees the holding in *Gentry* for what it really was: an application of the settled principle that a broadly drafted claim must be fully supported by the written description and drawings. *See Cooper Cameron*, 291 F.3d at 1323." *Amgen*, 314 F.3d at 1333.

29. *Id.*, at 1360-61 (Clevenger, J., dissenting).

> I must also disagree with the majority that the district court's approach was faithful to this court's articulation of the written description requirement of section 112, as expressed in *Regents of the University of California v. Eli Lilly & Co*., 119 F.3d 1559, 43 USPQ2d 1398 (Fed.Cir.1997) and *Gentry Gallery, Inc. v. Berkline Corp*., 134 F.3d 1473, 45 USPQ2d 1498 (Fed.Cir.1998). Eli Lilly articulated two principles of the written description requirement: that in haec verba description of broadly described generic subject matter may not suffice to describe the subject matter of that particular claim, 119 F.3d at 1567, 43 USPQ2d at 1404-05, and that disclosure of a species may not suffice to describe a genus, id. at 1568-69, 43 USPQ2d at 1405-06. The district court followed neither of these principles here, and the majority, dismissing *Eli Lilly* on the grounds that no undisclosed DNA molecule appears in this case, verges on confining *Eli Lilly* to its facts.

Id.

B. Best Mode Trap for the Unwary

The requirement to set forth the "best mode contemplated" under 35 U.S.C. § 112, ¶ 1, is easily met by anyone who *timely* drafts his or her patent application before or shortly after the invention has been reduced to practice. Typically, there is at most only a small number of pages of laboratory notebooks, barely enough to fill out a patent application. All this material is used to draft the patent application, and then there can be no concealment of the best mode contemplated.[30] (If there is a protracted prosecution with a continuing application with all claims entitled to priority under 35 U.S.C. § 120, there is no problem for intervening developments;[31] but, if a claim in a continuing application is filed after a best mode is developed, and the claim is not supported in the patent, there may be a best mode violation.[32])

Problems may crop up from time to time, however, where there are parallel, related inventions in separate cases with differing disclosures: if the disclosure in one case provides a better mode for a second case and is known to the inventor of the second case, a problem may be present. But, if the *claims* of the cases do not read on the disclosures of the different cases, then the problem should not be there.

Circuit Judge Linn provides a tutorial on the "best mode contemplated" in his opinion in *Teleflex*,[33] entitled *Contours of the Best Mode Requirement*, which covers the requirements of the "best mode contemplated" requirement.[34] Judge Linn explains that the law only requires a disclosure of a best mode of the *claimed* invention – citing numerous cases that make this point.[35]

30. If, however, a patent application is first filed even after commercialization (but before the expiration of the grace period), then there may be literally thousands of pages of notes, pilot plant drawings and specifications, and countless preferences that have been developed by dozens of coworkers, all *known* to the inventor at the time of filing, all possible best mode traps for the unwary.

31. Transco Prod. Inc. v. Performance Contracting, Inc., 38 F.3d 551, 559 (Fed. Cir. 1994) ("[T]he relevant date for evaluating a best mode disclosure is the date of the parent application.").

32. *Id.* at 557 n.6 (quoting MPEP § 201.11).

> Any claim in a continuation-in-part application which is directed *solely* to subject matter adequately disclosed under 35 U.S.C. 112 in the parent application is entitled to the benefit of the filing date of the parent application. However, if a claim in a continuation-in-part application recites a feature which was not disclosed or adequately supported by a proper disclosure under 35 U.S.C. 112 in the parent application, but which was first introduced or adequately supported in the continuation-in-part application such a claim is entitled only to the filing date of the continuation-in-part application.

Id.

33. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313 (Fed. Cir. 2002).

34. *Id.* at 1331-32.

35. *Id.* at 1330-31. The court cited:

Yet, shortly after *Teleflex,* in *Bayer* – a case where there was a *holding* that there was no violation of the best mode requirement because what was alleged to have been concealed was *unclaimed* – Judge Clevenger issued dicta that seemingly would (for at least the author of the opinion) keep the door open to a best mode violation for concealment of *unclaimed* matter.[36] However, the concurring opinion in *Bayer* clearly shows the correctness of the majority view as expressed by Judge Linn.[37] Indeed, "[w]hen extended beyond the scope of the claimed invention [as suggested in dicta in the majority opinion], the best mode requirement becomes as insidious and destructive as a hidden land mine."[38]

As long as Judge Linn's interpretation of the "best mode" requirement is seen as that of the majority view of the Federal Circuit, there is little harm with the "best mode" requirement. Applicants who simply disclose everything they know about their claimed invention will be in good shape. To the extent that the Clevenger dictum is a true reflection of the possible direction of the best mode requirement, this creates a slippery slope for safe disclosure.

Particular problems arise for the applicant who files a continuation application where at least one of the claims does not provide a "written

> The best mode inquiry is directed to what the applicant regards as the invention, which in turn is measured by the claims.' *Engel Indus., Inc. v. Lockformer Co.,* 946 F.2d 1528, 1531, 20 U.S.P.Q.2d (BNA) 1300, 1302 (Fed. Cir. 1991). *Accord N. Telecom [Ltd. V. Samsung Elecs. Co.]*, 215 F.3d at 1286, [1297] 55 U.S.P.Q.2d (BNA) at 1068 ("As we have repeatedly held, the contours of the best mode requirement are defined by the scope of the *claimed* invention . . . . [T]he party asserting invalidity must show that the asserted best mode relates directly to the claimed invention."); *Eli Lilly [& Co. v. Barr Labs., Inc.]*, 251 F.3d [955] at 963, 58 U.S.P.Q.2d (BNA) [1869] at 1874 ("[T]he extent of information that an inventor must disclose depends on the scope of the claimed invention."); *Chemcast [Corp. v. Arco Indus. Corp.]*, 913 F.2d [923] at 927, 16 U.S.P.Q.2d (BNA) [1033] at 1036 ("The other objective limitation on the extent of the disclosure required to comply with the best mode requirement is, of course, the scope of the claimed invention."); *Randomex, Inc. v. Scopus Corp.,* 849 F.2d 585, 588, 7 U.S.P.Q.2d (BNA) 1050, 1053 (Fed. Cir. 1988) ("It is concealment of the best mode of practicing the *claimed invention* that section 112 ¶ 1 is designed to prohibit."); *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1567, 38 U.S.P.Q.2d (BNA) 1281, 1284 (Fed. Cir. 1996) ("The focus of a section 112 inquiry is not what a particular user decides to make and sell or even in what field the invention is most likely to find success. Rather, in keeping with the statutory mandate, our precedent is clear that the parameters of a section 112 inquiry are set by the *claims*."); *Christianson v. GH Indus. Operating Corp.]*, 822 F.2d [1544] at 1563, 3 U.S.P.Q.2d (BNA) [1241] at 1255 ("[T]he 'best mode' is that of practicing the *claimed* invention .")

Id.

36. Bayer AG v. Schein Pharm., Inc., 301 F.3d 1306 (Fed. Cir. 2002).
37. *Id.* at 1325 (Rader, J., concurring).
38. *Id*.

description" basis in the patent.[39]

In the end, the United States is the *only* country in the world that punishes its applicant community with a best mode requirement. To the extent that the objective disclosure requirement of an enabling disclosure satisfies the *quid pro quo* of the patent system that the inventor fully disclose his invention to the public, erasure of the best mode experiment of the 1952 Patent Act would be a worthwhile event as part of any general codification.

III. "MEANS" AS MEANS TO A BAD END

Perhaps the most problematic part of the 1952 Patent Act was the creation of a unique test of "means" claiming. The entire legislative exercise was merely designed to avoid a Supreme Court holding.[40] Instead of overruling the holding that certain broad functional claims are invalid – as held in *Halliburton*[41] – the new law permitted a *bypass* of *Halliburton* by use of the magic word, "means:"

An element in a claim for a combination may be expressed as a means

39. Here, it may be necessary to update the best mode to the time of filing the continuation. But, if all claims have priority basis in the patent case, this is not the case. *See* Harold C. Wegner, *Continued Prosecution in a Continuation Application, or a* Transco *Best Mode Trap for the Unwary?* 75 J. PAT. & TRADEMARK OFF. SOC'Y 837 (1993) (urging reversal of trial court opinion on best mode with such result adopted); *Transco*, 38 F.3d 551, (Fed. Cir. 1994), *discussed* P.T. Mansfield, *Letter to the Editor*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 276 (1994) (discussing contrasting views of author and Commissioner on discriminatory aspects of patent system toward foreign inventors); Roy E. Hofer & L. Ann Fitzgerald, *New Rules for Old Problems: Defining the Contours of the Best Mode Requirement in Patent Law*, 44 AM. U. L. REV. 2309 (1996); Todd R. Miller, *The Public's Right to Know? Or a Red-tape Nightmare? Demanding that Best Mode Disclosure be Updated*, 35 IDEA 261 (1995).

40. *See* Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 958 n.4 (Fed. Cir. 1987) (*en banc*) (Newman, J., commentary):

> 35 U.S.C. § 112 ¶ 6 provides that a functional claim shall be construed to cover the means described in the specification and equivalents . . .In 1946 the Court had held, Halliburton Oil Well Cementing Company v. Walker, 329 U.S. 1, 12, 67 S.Ct. 6, 11, 91 L.Ed. 3[, 11] (1946), that this form of claim was not limited to "actual equivalents" of the means disclosed, and therefore was invalid. Section 112 ¶ 6 was enacted to reverse that ruling. P.J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. 1, 25 (1954).

Id. See also In re Donaldson, 16 F.3d 1189, 1194 (Fed. Cir. 1994):

> In *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946), the Supreme Court held that means-plus-function language could not be employed at the exact point of novelty in a combination claim. Congress enacted paragraph six, originally paragraph three, to statutorily overrule that holding. *See In re* Fuetterer, 319 F.2d 259, 264 n.11, 138 USPQ 217, 222 n.11 (CCPA 1963) (noting that it was Congress's intent to restore the law regarding broad functional language in combination claims to its state prior to *Halliburton*).

Id.

41. Halliburton Oil Well Cementing Co. v. Walker, 329 U.S. 1, 12 (1946).

> or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim *shall be construed* to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.[42]

There are several problems with the "means" law:

A. Narrowing – not Broadening – the Scope

The statute permits claiming an element as a "means" for performing a function, which will be given *a narrower* interpretation than if the function, alone, had been stated. The statute says:

> An element in a claim for a combination may be expressed as a means . . . for performing a specified function without the recital of structure . . . in support thereof, and such claim shall be construed to cover the *corresponding structure* . . . described in the specification *and equivalents thereof*.[43]

By invoking the "means" provision of the statute, the applicant automatically *excludes* from the scope of protection every possible means for performing that function *except*: (a) the specific structure disclosed in the specification; and (b) equivalents of *that specifically disclosed* structure.

It is thus immediately seen that the statutory "means" claiming system has absolutely nothing to do with the doctrine of equivalents that was reined in by *Festo*: whereas *Festo* deals with limitations on broadening the scope of protection *beyond* the literal scope of the claim, the statutory equivalents determination under the "means" provision is a component of determining the *literal* scope of protection that is afforded to a claim. This determination therefore has absolutely nothing to do with the *Festo*-based inquiry on limitations to expansion of protection beyond the literal scope of the claim.

A principal author of the 1952 Patent Act and the key person credited with the creation of what is now 35 U.S.C. § 112, ¶ 6, has explained:

> The record is clear on why paragraph six was enacted. In *Halliburton Oil Well Cementing Co. v. Walker,* the Supreme Court held that means-plus-function language could not be employed at the exact point of novelty in a combination claim. Congress enacted paragraph six,

42. 35 U.S.C. § 112, ¶ 3, in the original 1952 Patent Act, 66 Stat. 798 (1952), later ¶ 6 with the addition of three additional sections before this still final paragraph of § 112.

43. 35 U.S.C. § 112, ¶ 6 (2000) (emphasis added).

originally paragraph three, to statutorily overrule that holding.[44]

B. Prosecution History to Limit the Scope

Even though the equivalents determination under 35 U.S.C. § 112, ¶ 6, is used to flesh out the *literal* scope of protection – which in any event is narrower than if the functional term without "means" interpretation had been used in the first place – one will not always get the full scope of even the equivalents of the structure defined in the specification if there has been prosecution history to show a narrowed interpretation. This is *not* prosecution history estoppel in the classic sense, because prosecution history estoppel is used to deny the broadening of the effective scope of protection beyond the literal scope of protection. Yet, the Federal Circuit has made it clear that prosecution history may be used to block the full scope of equivalents in the determination of the *literal* scope of protection. As explained by Judge Archer, "[p]rosecution history is relevant to the construction of a claim written in means-plus-function form."[45] Thus, "just as prosecution history estoppel may act to estop an equivalence argument under the doctrine of equivalents, positions taken before the PTO may bar an inconsistent position on claim construction under § 112, ¶ 6."[46] Therefore, "[c]lear assertions made in support of patentability thus may affect the range of equivalents under § 112, ¶ 6."[47]

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44. *In re* Donaldson Co., 16 F.3d 1189, 1194 (Fed. Cir. 1994) (citations omitted) (citing *In re Fuetterer*, 319 F.2d 259, 264, n.11 (C.C.P.A. 1963) (noting that it was Congress's intent to restore the law regarding broad functional language in combination claims to its state prior to *Halliburton*)); *see also* Dawn Equip. Co. v. Ky. Farms Inc., 140 F.3d 1009, 1021 (Fed. Cir. 1998).

> It should be remembered that § 112, ¶ 6 was a legislative solution to a problem in claiming – broadly stated claims using means-plus-function language were too vague to be judicially enforced. *See* Valmont [Indus., Inc. v. Reinke Manufacturing Co., Inc.], 983 F.2d [1039] at 1042 (noting that § 112, ¶ 6 was enacted in response to the Supreme Court prohibiting certain use of means-plus-function language in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 67 S.Ct. 6, 91 L.Ed. 3 (1946)). The purpose of § 112, ¶ 6 was to provide clear parameters within which means-plus-function claims could be drawn and sensibly construed.

Dawn Equip. Co., 130 F.3d at 1021.

45. Cybor Corp. v. FAS Tech., Inc., 138 F.3d 1448, 1457 (Fed. Cir. 1998) (citing *United States v. Telectronics, Inc.*, 857 F.2d 778, 782 (Fed. Cir. 1988) and *Rite-Hite Corp. v. Kelley Co.*, 819 F.2d 1120, 1123 (Fed. Cir. 1987)).

46. *Id.* (quoting *Alpex Computer Corp. v. Nintendo Co.*, 102 F.3d 1214, 1221 (Fed. Cir. 1996)).

47. *Cybor*, 138 F.3d at 1457 (citing *Am. Permahedge, Inc. v. Barcana, Inc.*, 105 F.3d 1441, 1446 (Fed. Cir. 1997) and *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1582 (Fed. Cir. 1996)). The court continued, citing *Insituform Techs., Inc., v. Cat Contracting, Inc.*, 99 F.3d 1098, 1107-08 (Fed. Cir. 1996), by stating that "[t]he relevant inquiry is whether a competitor

In the *Alpex* case,[48] specific assertions were made during prosecution to contradict a broad scope of equivalents. There, the court stated that "[i]f an applicant specifically distinguishes a structure from what is claimed during prosecution, the applicant will be estopped from asserting a scope for the same claim that covers that structure."[49]

C. An Invariable Narrowing of Literal Scope

The Supreme Court in *Warner-Jenkinson* has expressly recognized that 35 U.S.C. § 112, ¶ 6, "*narrow[s]* the application of broad literal claim elements."[50] Thus, perhaps the cruelest hoax to proponents of means claiming is the myth that one gets broader protection by using means definitions for elements.

The late Helen Wilson Nies unequivocally stated more than ten years ago that if one uses the 'means' formula for definition of an element, one is obtaining protection not for every possible structure that performs a stated function, *but only for the very specific structure recited in the specification*. To be sure, equivalents *of the specific structure* are also covered, but in total this will always be less than if one claimed the structure broadly without resort to 'means' terminology.[51]

She points out that "section 112, ¶ 6 does not, in any event, *expand* the scope of the claim. An element of a claim described as a means for performing a function, if read literally, would encompass *any* means for performing the function."[52] This is not the way the statute is to be read: "But section 112, ¶ 6 operates to *cut back* on the types of *means* which could literally satisfy the claim language."[53]

The only way to get a broadening interpretation out of the use of

would reasonably believe that the applicant had surrendered the relevant subject matter."

48. *Alpex Computer*, 102 F.3d at 1214.

49. *Id.* at 1221 (citing *Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1220 (Fed. Cir. 1996)).

50. Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 28 (1997) (emphasis added). *Warner-Jenkinson* held:

> Section 112, ¶ 6, now expressly allows so-called "means" claims, with the proviso that application of the broad literal language of such claims must be limited to only those means that are 'equivalent' to the actual means shown in the patent specification. This is an application of the doctrine of equivalents in a restrictive role, narrowing the application of broad literal claim elements.

Id.

51. Johnston v. IVAC Corp., 885 F.2d 1574, 1580 (Fed. Cir. 1989).

52. *Id.* (citing *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987) (*en banc*), *cert. denied*, 485 U.S. 961, 1009 (1988)) (emphasis in original).

53. *Id. See also* Data Line Corp. v. Micro Tech., Inc., 813 F.2d 1196, 1201 (Fed. Cir. 1987) (emphasis in original).

means claiming would be if the overall *function* stated in the claim could be broadened through equivalents, instead of simply the specific examples given for the means. This is clearly not the way the statute is interpreted: "[S]ection [112, ¶ 6] has no effect on the function specified – it does not extend the element to equivalent functions. Properly understood section 112, ¶ 6 operates more like the reverse doctrine of equivalents than the doctrine of equivalents because it restricts the scope of the literal claim language."[54]

D. "Means" is not a General Equivalents Trigger

Some have proposed that if there are several elements in a claim and if there is any recitation of the word "means," then this triggers a claim-wide determination of equivalents. At best, there is a determination of equivalent *elements* but only to the elements defined in means format. Thus, "[s]ection 112, ¶ 6 provides direction with respect to how the part of a claim framed in means-plus-function language must be interpreted within an infringement analysis."[55] But:

> That part of a claim contains means-plus-function language does not make section 112, ¶ 6 applicable to the entirety of the claim. Thus, contrary to [the patentee]'s understanding, section 112, ¶ 6 is clearly not a separate *test* for infringement inasmuch as an infringement determination necessarily involves all parts of the claim.[56]

E. A Fatal Lack of Means Correspondence

The patentee who drafts means language with a specified function tied to the means must be careful that the two match up with the reality of the science or engineering disclosed in the specification. If one has a means term in a claim tied to a particular function yet the specific structure of the examples is tied to a different function, then the means element is not interpreted as corresponding to the particular structure in hand.

Judge Linn, in *Budde v. Harley-Davidson*, explains this particular pitfall of means claiming:

> In construing means-plus-function claim limitations, a court must first

54. *IVAC*, 885 F.2d at 1580 (citing *Pennwalt*, 833 F.2d at 934.; *cf. D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1575 (Fed. Cir. 1985)).

55. *IVAC*, 885 F.2d at 1580.

56. *Id.* (citing *Perkin- Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1533 (Fed. Cir. 1987)).

> define the particular function claimed. Thereafter, the court must identify 'the corresponding structure, material, or acts described in the specification.' *It is not until the structure corresponding to the claimed function in a means-plus-function limitation is identified and considered that the scope of coverage of the limitation can be measured.*[57]

But, if a sloppy case is filed either without any structure being shown at all or showing structure that does not tie to the function stated in the claim, the courts are not there to bail out the negligent applicant at the expense of the public: "failure to disclose adequate structure corresponding to the recited function in accordance with 35 U.S.C. §112, paragraph [6], results in the claim being of indefinite scope, and thus invalid, under 35 U.S.C. §12, paragraph 2."[58] Thus:

> For a court to hold that a claim containing a means-plus-function limitation lacks a disclosure of structure in the patent specification that performs the claimed function, necessarily means that the court finds the claim in question indefinite, and thus invalid. Because the claims of a patent are afforded a statutory presumption of validity, overcoming the presumption of validity requires that any facts supporting a holding of invalidity must be proved by clear and convincing evidence. Thus, a challenge to a claim containing a means-plus-function limitation as lacking structural support requires a finding, by clear and convincing evidence, that the specification lacks disclosure of structure sufficient to be understood by one skilled in the art as being adequate to perform the recited function."[59]

While the lessons from Judge Linn on the need to correlate structure with function are clear, they are even more graphically underscored in the holding of invalidity in the *Cardiac Pacemakers* case,[60] where there *are* means disclosed in the specification, but such means just do not line up with the stated function of the claims. In

57. Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1376 (Fed. Cir. 2001) (emphasis added) (citing 35 U.S.C. § 112, ¶ 6; *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1428 (Fed. Cir.1997); *In re Donaldson Co.*, 16 F.3d 1189, 1195 (Fed. Cir. 1994) (*en banc*) (Rich, J.) ("[I]f one employs means-plus-function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by the language.")).

58. *Budde*, 250 F.3d at 1376 (citing *In re Dossel*, 115 F.3d 942, 945 (Fed. Cir. 1997)).

59. *Id*. at 1376-77 (citations omitted) (citing *Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co.*, 204 F.3d 1360, 1367 (Fed. Cir. 2000); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1570 (Fed. Cir. 1987) (stating that the presumption mandated by § 282 is applicable to all of the many bases for challenging a patent's validity)).

60. Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 296 F.3d 1106 (Fed. Cir. 2002) (Gajarsa, J.).

holding the claims invalid for indefiniteness, Judge Gajarsa sums up the case against the use of means claiming:

> After identifying the claimed function, the court must then determine what structure, if any, disclosed in the specification corresponds to the claimed function. [*Lockheed Martin,* 249 F.3d at 1324.] In order to qualify as corresponding, the structure must not only perform the claimed function, but the specification must clearly associate the structure with performance of the function. *Medtronic,* 248 F.3d at 1311 (quoting *B Braun Med., Inc. v. Abbott Labs.,* 124 F.3d 1419, 1424 (Fed. Cir. 1997)). This inquiry is undertaken from the perspective of a person of ordinary skill in the art. *Amtel Corp. v. Info. Storage Devices, Inc.,* 198 F.3d 1374, 1378-79 (Fed. Cir. 1999). Alternative embodiments may disclose different corresponding structure, and the claim is valid even if only one embodiment discloses corresponding structure. *See Ishida Co. v. Taylor,* 221 F.3d 1310, 1316 (Fed. Cir. 2000). If, however, this inquiry reveals that no embodiment discloses corresponding structure, the claim is invalid for failure to satisfy the definiteness requirement of §112, ¶ 2 *Budde v. Harley-Davidson, Inc.,* 250 F.3d 1369, 1376 (Fed. Cir. 2001) (citing *In re Dossel,* 115 F.3d 942, 945 (Fed. Cir. 1997)).[61]

The ruling by Judge Gajarsa is seemingly harsh, but is consistent with the view of the author of this provision in the 1952 Patent Act, the late Giles Sutherland Rich. He wrote in the *Donaldson* case:

> [T]he sixth paragraph of section 112 does not exempt an applicant from the requirements of the first two paragraphs of that section. Although paragraph six statutorily provides that one may use means-plus-function language in a claim, one is still subject to the requirement that a claim 'particularly point out and distinctly claim' the invention. Therefore, if one employs means-plus-function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.[62]

F. No "Means" in Foreign Practice

Americans have introduced "means" claiming practice around the world through the simple expedient of directing their foreign associates

61. *Id.* at 1113-14.

62. *In re Donaldson*, 16 F.3d at 1195.

to file literal translations of home country American patent applications as foreign counterparts. Thus, "means" terminology has come to be used in many countries of the world. But, 35 U.S.C. § 112, ¶ 6, is an arcane domestic statute that was implemented fifty years ago at home *but has never been adopted in any other country of the world*. Expecting to have a foreign tribunal resort to American statutory interpretation schemes is a nonstarter. The word "means" obtains no special interpretation abroad.

IV. A PATENT LAW FOR THE GLOBAL VILLAGE

The United States has shifted from a largely domestic patent community to a global one where the inclusion of foreign interests in the United States is a condition precedent to our better introduction of American patent principles into foreign systems. Since the quirks of the United States law are either unique to the 1952 Patent Act – unique both *vis a vis* foreign countries but also to our own previous law that went back for more than a full century – we would do well to rid ourselves of these ill-conceived oddities of practice. Furthermore, some of the changes in the law have been judicially engrafted onto the shaky framework of the "written description" requirement that is now said to be housed in the first paragraph of 35 U.S.C. § 112 as a requirement *per se*. Worst of all, the most recent changes are said to provide a special disclosure requirement for biotechnology[63] – something that is completely contrary to our obligations under the TRIPs[64] that requires that "patents shall be available for any inventions . . . in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[65] The treaty underscores the

63. It is beyond dispute that there is a special patent law set forth from *Enzo* for biotechnology, setting a unique and higher bar to patentability under 35 U.S.C. § 112, para. 1, than in other areas. Professors Burk and Lemley have studied this in some detail and reach this conclusion:

> In theory . . . we have a unified patent system that provides technology-neutral protection to all kinds of technologies. Of late, however, we have noticed an increasing divergence between the rules themselves and the application of the rules to different industries. The best examples are biotechnology and computer software. . . .[The Federal Circuit] has imposed stringent enablement and written description requirements on biotechnology patents that do not show up in other disciplines. . . . As a practical matter, it appears that while patent law is technology-neutral in theory, it is technology-specific in application.

Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology Specific?*, 17 BERKELEY TECH. L.J. 1155, 1156 (2002).

64. *See Agreement on Trade-Related Aspects of Intellectual Property Rights*, Apr. 15, 1994, INT'L LEGAL MATERIALS [hereinafter TRIPs].

65. *TRIPs*, *supra* note 64, at 93 n.5, art. 27.1, first sentence, states: "For the purposes of this

requirement that there may not be any discrimination against an invention in a particular technology: "patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology."[66] The discrimination against biotechnology inventions is widely appreciated.[67]

It is important that as the United States seeks to overhaul its patent system it should do so with a recognition that it is in the self-interest of America to have a strong and fair system for *all* innovators in *all* technologies – and that to do this the law should be technology-blind in its requirements and be compliant with the international treaty obligations that we so much need the rest of the world to honor as well.

Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively." Thus, the first sentence of Art. 27.1 may be read as follows: "[P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, [are nonobvious] and are [useful]." *Id*.

66. *TRIPs*, *supra* note 64, at 94, art. 27.1.

67. *See* Mark D. Janis, *On Courts Herding Cats: Contending with the 'Written Description' Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J. L. & POL'Y 55 (2000); Arti Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827 (1999); Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615 (1998).

Appendix
Statutory Changes for 35 U.S.C. § 112 - Specification

Rewritten to compare the old and new versions of the statute, with bold indicating additions and strike-out indicating deletions.

~~(a)~~ The specification shall contain ~~(1)~~ a written description **of the invention, and** of the manner and process of making and using **it** ~~the invention~~, 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** ~~and (2) no new matter shall be introduced into the disclosure of the invention~~.*

~~(b)~~ The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

~~(c)~~ Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

~~(d)~~ A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

* The second clause parallels the final sentence of 35 U.S.C. § 132: "No amendment shall introduce new matter into the disclosure of the invention".