Comment 10 Gary Colby

-----Original Message-----
From: Colby, Gary [SMTP:gcolby@AKINGUMP.com]
Sent: Wednesday, March 22, 2000 4:15 PM
To: 'stephen.walsh@uspto.gov'
Subject: Comments Regarding the December 21, 1999 Interim WrittenDescript ion Guidelines

Dear Mr. Walsh,

Attached to this message, please find a copy of a letter (in Microsoft Word 97 format) which includes my comments regarding the Interim Written Description Guidelines published in the Federal Register on December 21, 1999.

I would appreciate your consideration of these comments.

<<Comments_Regarding_Interim_Written_Description_Guidelines.DOC>>

Very truly yours,

Gary

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Gary D. Colby, Ph.D., J.D.
Akin, Gump, Strauss, Hauer & Feld, L.L.P.
One Commerce Square, Suite 2200
2005 Market Street
Philadelphia, PA 19103-7086
215-965-1200 (General Inquiries)
215-965-1285 (Direct to GDC)
215-965-1210 Fax
www.akingump.com
gcolby@akingump.com

April 12, 2000

VIA FACSIMILE
703-305-9373

Box 8
Attention: Stephen Walsh
Commissioner of Patents and Trademarks
Washington, DC 20231

Confirmation Copy by
Electronic Mail

Re: Comments Pertaining to
"Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 'Written Description' Requirement; Request for Comments" (Fed. Reg. 64(244):71427-71440; 21 Dec. 99)

Dear Mr. Walsh:

In response to the Request for Comments referenced above, please consider the following comments. The views expressed in this letter are my personal views, and do not necessarily represent the views of my colleagues at Akin, Gump, Strauss, Hauer & Feld, L.L.P. or the views of any client of that firm.

As used in this letter, "the Guidelines" refers to the Request for Comments referenced above, and not necessarily to any previous Request for Comments. In particular, these comments are not intended to respond to the interim guidelines published in the Federal Register on June 15, 1998 (63 Fed. Reg. 32,639). "The Office" refers to the U.S. Patent and Trademark Office.

As an initial matter, I support issuance of formal Written Description Guidelines which will, hopefully, harmonize how and when the Office's examiners reject claims on the basis of 35 U.S.C. § 112, ¶ 1. Furthermore, I believe that the Office's decision to couch the Guidelines in technology-neutral terms is imperative, in that the patent laws of this country do not include a "biotechnology version" of 35 U.S.C. § 112, ¶ 1 and a different version of this paragraph which is applicable to other arts. Given that the statutory and precedential law relating to the written description requirement (hereafter "WDR") is equally applicable to all technologies, except where explicitly stated otherwise, I believe that the Guidelines fail to comply with certain binding precedent and incorrectly apply other precedent. I set forth the deficiencies, as I see them, and suggested corrections below.

I. General Principles Governing Compliance With the WDR for Patent Applications

It is my opinion that, as a general matter, the existence of a WDR, entirely separate and distinct from the enablement and best mode requirements of 35 U.S.C. § 112, ¶ 1 cannot reasonably be questioned, the WDR having been manifested from the earliest period of U.S. patent law[1] through to the present[2]. Furthermore, the language of the statute could hardly make the distinctness of the three requirements more clear[3]. The Guidelines correctly identify the separateness and distinctness of the WDR from at least the enablement requirement of 35 U.S.C. § 112, ¶ 1.

The Goals of the WDR

The Guidelines, quoting a footnote in *In re Barker*[4], set forth that "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an

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[1] *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 5 L. Ed. 472 (1822), applying the Patent Act of 1793.

[2] *e.g.*, as discussed in *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 U.S.P.Q.2d 1111, 1114-1117 (Fed. Cir. 1991).

[3] "The specification shall contain a written description of the invention ***AND*** of the manner and process of making and using it..., ***AND*** shall set forth the best mode...". 35 U.S.C. § 112, ¶ 1 (Supp. May 1999; emphasis added).

[4] 559 F.2d 588, 194 U.S.P.Q. 470, 473 at n.4 (C.C.P.A. 1977), referring to a conclusion drawn by the court, evidently from *In re Smith and Hubin*, 481 F.2d 910, 178 U.S.P.Q. 620, 624 (C.C.P.A.

applicant has invented the subject matter which is claimed"[5]. However, the Guidelines ignore the U.S. Supreme Court's guidance, referenced in the same footnote in *In re Barker* regarding the purposes of the portion of the Patent Act of 1793 corresponding to the first paragraph of 35 U.S.C. § 112. In *Evans*, the Supreme Court set forth that this section of the statute has as its purposes:

> [1] "to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans [*sic*] to make and use it, and thus to give the full benefit of the discovery after the expiration of the patent * * * [and]
> [2] to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented"[6].

The Federal Circuit has held that, in order to comply with the WDR, an 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*"[7]. As acknowledged in the Guidelines, an applicant shows possession of a claimed invention by describing the claimed invention with all of its limitations[8]. Per *Lockwood*,

> "One [satisfies the WDR] by such *descriptive* means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention."[9]

Thus, *Lockwood* indicates that the WDR is satisfied by describing to those skilled in the art (i.e. putting the public in possession of) the subject matter that is claimed, including every limitation of the claimed subject matter. Whether they be two truly separate requirements or merely two sides of the same requirement coin, two requirements for compliance seem to be identified by the courts for satisfying the WDR. To wit, an applicant must both

I. demonstrate possession of the claimed invention by the applicant and
II. put the public in possession of the claimed invention.

By describing the 'possession by the applicant' aspect of the WDR as its "essential goal" and the 'public possession' aspect of the WDR as merely "another objective,"[10] the Guidelines lead one to conclude that the WDR can be satisfied by demonstrating possession of a claimed invention without putting the public in possession of the invention. This conclusion is in conflict with the ultimate goal of the patent system, as articulated (albeit in *dicta*) by the Supreme Court in *Bonito Boats Inc. v. Thunder Craft Boats Inc.*[11]:

1973) and *In re Ruschig, Aumuller, Korger, Wagner, Scholz, and Bander*, 154 U.S.P.Q. 188, 123 (C.C.P.A. 1967).

[5] The Guidelines at p. 71,434.

[6] *Evans, supra* 20 U.S. (7 Wheat.) at 433-434, 5 L. Ed. at 491. (emphasis added).

[7] *Vas-Cath, supra*, 19 U.S.P.Q.2d at 1117.

[8] The Guidelines at 71,434, citing *Lockwood v. American Airlines Inc.*, 107 F.3d 1565, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997).

[9] *Lockwood, Id.* (emphasis added).

[10] The Guidelines at 71,434.

[11] 489 U.S. 141, 9 U.S.P.Q.2d 1847, 1852 (1989; emphasis added).

> "The federal patent system thus 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. ... Moreover, the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure"

and in *United States v. Dubilier Condenser Corp.*[12]:

> "[The inventor] may keep his invention secret and reap its fruits indefinitely. *In consideration of its disclosure*, [a] patent is granted. An exclusive enjoyment is guaranteed him for seventeen years, but, upon expiration of that period the knowledge of the invention inures to the people ...".

I respectfully suggest that the Guidelines should be modified to indicate that compliance with the WDR requires disclosure of information that both demonstrates that the applicant had possession of the invention as of the filing date and puts the public in possession of the invention upon issuance of the patent.

Compliance with the WDR

The Guidelines indicate that an applicant must demonstrate possession of the claimed invention in order to satisfy the WDR, and that the WDR requirement can be satisfied, per *Lockwood*, by describing the claimed invention with all of its limitations. Insofar as the Guidelines adhere to the holding in *Lockwood*, I am in agreement with the Guidelines. However, the Guidelines describe two alternatives by which an applicant may show possession of a claimed invention, namely by showing

1) actual reduction to practice or
2) that the invention was "ready for patenting," per *Pfaff v. Wells Electronics Inc.*[13].

I respectfully contend that neither of these two proposed alternatives to the *Lockwood* test for demonstrating compliance with the WDR is authorized by the statute or by precedent. To the extent that these two proposed alternatives extend beyond the holding in *Lockwood*, I do not believe the Office can justify their inclusion in the Guidelines.

1) Actual Reduction to Practice

With regard to demonstrating possession of a claimed invention by showing actual reduction to practice, the Guidelines indicate[14] that actual reduction to practice can be shown in at least two ways.

a) First, the Guidelines indicate that one may describe "testing of the claimed invention." No authority is cited for this proposition. I am at a loss to understand what sort of testing might be considered sufficient to replace the sort of description required in *Lockwood*. Would description of testing that demonstrates that a non-disclosed, but claimed compound has a utility asserted in an application be considered a sufficient replacement for description of the compound itself? Certainly this cannot be what the Office has in mind. Could description of testing that demonstrates that an applicant actually has possession of a claimed, but otherwise non-described invention satisfy the WDR? Surely this could not be intended either[15].

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[12] 289 U.S. 178, 53 S. Ct. 554, 77 L. Ed. 1114, 17 U.S.P.Q. 154, 157-158 (1933; emphasis added)

[13] 525 U.S. 55, 119 S. Ct. 304, 48 U.S.P.Q.2d 1641 (1998).

[14] at footnote 6.

[15] Were this the case, then one should, I suppose, be able to obtain allowance of a claim directed to 'a nucleic acid encoding human protein X' by demonstrating that one had isolated an otherwise-

If, by "testing of the claimed invention", the Office intends to indicate, per *Fiers v. Revel*[16], that the WDR may be satisfied for a claimed invention by setting forth properties or characteristics[17] that uniquely identify the claimed invention, rather than a definition of the invention in an art-accepted formulaic or schematic form, then I do not believe that the Office has done so clearly. However, even if this is what the Office intends to indicate, disclosure of "testing of the claimed invention" is merely a way of satisfying the *Lockwood* test for satisfaction of the WDR, not a substitute for satisfying that test. To the extent the Office wishes to suggest in the Guidelines that one may comply with the WDR by describing "testing of the claimed invention" in an application, the Office should emphasize that the requirements of *Lockwood* must be satisfied, regardless of the form of the description provided in the specification.

b) The Guidelines indicate that actual reduction to practice (and thereby "possession") of an invention by an applicant can be shown by specifically describing a deposit of biological material made in accordance with 37 C.F.R. 1.801 *et seq.* I respectfully suggest that a specific description of a deposit of biological material is also not a substitute for satisfying the WDR in the method set forth in *Lockwood*, but rather a way by which the *Lockwood* requirements can be met. The Guidelines should be modified to indicate that, even if a deposit of biological material is made, that deposit alone will not necessarily satisfy the WDR unless the *Lockwood* test is satisfied.

In summary, it is my opinion that neither disclosure of "testing of the claimed invention" nor disclosure of a deposit of biological material is a substitute for describing the claimed invention with all of its limitations (thereby demonstrating possession of the invention by the applicant and disclosure of the invention to the public). Instead, these disclosures represent ways in which the WDR can (but will not necessarily) be met. The Guidelines should be modified accordingly.

2) Demonstrating that an Invention is "Ready for Patenting"

The Guidelines indicate that an applicant can demonstrate possession of a claimed invention (and thereby presumably comply with the WDR) by showing that (presumably as of the filing date) the invention was "ready for patenting," citing *Pfaff*. I respectfully contend that the Office's citation of *Pfaff* in this context is inappropriate.

The *Pfaff* decision relates to the preclusive effect that a patent applicant's sales-related activities prior to filing an application can have on the allowability of claims in that application, pursuant to 35 U.S.C. § 102(b). In contrast, the WDR (as well as the other portions of 35 U.S.C. § 112) relates to what the patent specification must contain. Very different policy considerations underlie 35 U.S.C. §§ 102(b) and 112, ¶ 1.

As discussed above, the purpose of 35 U.S.C. § 112, ¶ 1, is to ensure that a patent applicant possesses the claimed invention as of the filing date and that the public is put into

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non-disclosed nucleic acid from a human genome, expressed the nucleic acid, and obtained human protein X by expressing it. The patentee would then be able to exclude others from making and using the nucleic acid, and, even after expiration of the patent, the public would not know the identity of the nucleic acid.

[16] 984 F.2d 1164, 25 U.S.P.Q.2d 1601, 1606 (Fed. Cir. 1993). (Satisfaction of the WDR for a DNA requires "a precise definition, such as by structure, formula, chemical name, or physical properties").

[17] *e.g.*, infrared spectra by which a claimed product is characterized, as in the patents at issue in *Glaxo Inc. v. TorPharm Inc.*, 153 F.3d 1366, 47 U.S.P.Q.2d 1836 (Fed. Cir. 1998).

possession of the invention as of the issue date. In contrast, the purpose of the 'on-sale bar' of 35 U.S.C. § 102(b) is to prevent commercial exploitation of a claimed invention for more than one year prior to filing a corresponding patent application, thereby substantially confining the duration of the patent franchise to the statutory term[18]. Notably, the 'on-sale bar' does not require that the claimed invention be made known to the public[19].

In *Pfaff*, the Supreme Court indicated that a sale of an embodiment of an invention claimed in a later-filed patent application can be found if the invention had been reduced to practice at the time of the sale or if the invention was "ready for patenting" at the time of the sale. The Court suggested at least two ways in which an invention may be found to be "ready for patenting," namely by proof of reduction to practice or by proof that the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention"[20]. Thus, according to the Supreme Court's test, an invention can be "ready for patenting" if it is reduced to practice, even if the embodiment of the invention is not disclosed to anyone, and 35 U.S.C. § 102(b) will bar claims to the invention if the embodiment is the subject of a commercial offer for sale (*i.e.*, regardless of whether the embodiment is disclosed to the potential purchaser or to anyone else) more than one year prior to the filing date of a patent application including such claims.

If satisfaction of the *Pfaff* "ready for patenting" test were sufficient to satisfy the WDR, then the WDR could be satisfied by reducing a claimed invention to practice and not disclosing the claimed invention to anyone, including the Office. Thus, permitting an applicant to satisfy the WDR by demonstrating that a claimed invention is "ready for patenting" would permit satisfaction of the WDR in the complete absence of any written description of the invention itself[21] - a result which I believe would be, at best, disquieting.

It may be that a disclosure which describes, in a manner which satisfies 35 U.S.C. § 112, ¶ 1, subject matter which is claimed in a later-filed patent application will necessarily satisfy the requirements of 35 U.S.C. § 102(b) if that subject matter is the subject of a commercial offer for sale more than one year prior to the filing date of the application. However, I do not believe that it follows that any activity by an applicant that satisfies the "ready for patenting" test of *Pfaff* will necessarily satisfy the WDR. Furthermore, it seems to me that the test for whether such activity satisfies the WDR is that set forth in *Lockwood*, as discussed above. For this reason, discussing the *Pfaff* decision in the Guidelines does not appear to inform applicants how they might comply with the WDR. Indeed, it seems to me that discussion of *Pfaff* in the Guidelines is likely to confuse or mislead applicants. I suggest that *Pfaff* not be mentioned in the Guidelines for this reason.

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[18] *See, e.g., Gould Inc., v. United States*, 579 F.2d 571, 195 U.S.P.Q. 112 (Ct. Cl. 1977) and *Frantz Mfg. Co. v. Phenix Mfg. Co.*, 457 F.2d 314, 173 U.S.P.Q. 266 (7th Cir. 1972).

[19] Indeed, it has been held that an invention is 'on-sale' even if the invention was maintained in secrecy during and after the sale *Robine v. Apco Inc.*, 227 F. Supp. 512, 141 U.S.P.Q. 17 (S.D. N.Y. 1964), *aff'd* 386 F.2d 267, 156 U.S.P.Q. 1 (2nd Cir 1967).

[20] *Pfaff*, 48 U.S.P.Q.2d at 1647.

[21] For example, which reduction to practice of an isolated DNA encoding human insulin might be demonstrated by demonstrating a very high degree of homology of a human cDNA with a rat cDNA encoding insulin, coupled with a demonstration of a complete lack of mismatching between the human cDNA and human genomic DNA - without disclosing what the sequence of the human cDNA might be.

Applicability of the WDR to Original Claims and to New or Amended Claims

In parts A and B of section I of the Guidelines, applicability of the WDR to originally filed claims is discussed separately from its applicability to new or amended claims. I respectfully suggest that this discussion be removed from the guidelines. Just as there is not one WDR for biotechnology inventions and a different WDR for inventions in other arts, there is not one WDR for originally filed claims and a different WDR for new or amended claims. I respectfully contend that the Office is confusing the WDR and the 35 U.S.C. § 132 prohibition against adding new matter to a patent application.

WDR Support of Claims

The Guidelines state that "[t]here is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. The Guidelines cite *In re Wertheim*[22] for this proposition. I respectfully suggest that the Office is misinterpreting the holding of the court in that case.

In *In re Wertheim*, the court recognized that the claim at issue was an originally filed claim, and that the claim was, for that reason, its own written description[23]. Similarly, it was held in *In re Gardner*[24] that a particular originally filed claim, in itself, "constituted a description in the original disclosure equivalent in scope and identical in language to the total subject matter now being claimed." In neither *In re Wertheim* nor *In re Gardner* is the broad assertion that is set forth in the Guidelines supported. In each of these two cases, the court made a factual finding that the words of each of the particular claims at issue constituted a sufficient description of the subject matter that was encompassed by the claim and that, as a part of the original disclosure, the words in the originally filed claim satisfied the WDR.

In neither *In re Wertheim* nor *In re Gardner*, nor in any other case of which I am aware, has a precedential court set forth, as a general rule, that there is any presumption (let alone a "strong" presumption, as indicated in the Guidelines) that the text of an originally-filed claim constitutes an adequate written description of the subject matter of that claim. Reference in the comments accompanying the Guidelines[25] to *In re Koller*[26] is inapposite. In *In re Koller*, the court simply found that the meaning of a term used in the originally-filed specification of an earlier patent application (albeit in a claim) adequately described subject matter claimed in a later patent application which claimed priority to the earlier application[27]. *In re Koller* neither created nor

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[22] *In re Wertheim, et al.,* 541 F.2d 541, 191 U.S.P.Q. 90 (C.C.P.A. 1976).

[23] *See, e.g., In re Wertheim,* 191 U.S.P.Q. at 97-98.

[24] *In re Gardner,* 475 F.2d 1389, 177 U.S.P.Q. 396, 397 (C.C.P.A. 1973).

[25] Particularly comment 9 in the Guidelines at 71,429.

[26] *In re Koller, Hartl, and Kirchner,* 613 F.2d 819, 204 U.S.P.Q. 702 (C.C.P.A 1980).

[27] The court held that the term "liquid medium" in the earlier application would have been understood by the ordinarily-skilled artisan to include water-immiscible solvents, which were recited in a claim in the later application. Although the court suggested in *dicta* that *In re Gardner* stood for the proposition that originally filed claims constitute their own description, the holding of the court was that

> "the circumstances here do not fit any exception to the general rule that the language in a *specification* is to be understood for what it meant to one having ordinary skill in the art at the time the application was filed." *In re Koller,* 204 U.S.P.Q. at 706. (emphasis added).

extended a presumption that the words of an originally filed claim constitute an adequate written description of the subject matter of that claim.

That the "strong presumption" of compliance with the WDR set forth in the Guidelines is ill advised can be demonstrated with a simple example of a patent application, listed below in its entirety.

> U.S. Patent Application
>
> CANCER CURE
>
> We claim:
>
> 1. A naturally-occurring composition which cures cancer in a human when administered to a human afflicted with cancer.
> 2. A method of curing cancer in a human, the method comprising administering the composition of claim 1 to a human afflicted with cancer.
> 3. A method of determining whether a naturally-occurring composition is useful for curing cancer in a human, the method comprising administering the composition to a human afflicted with cancer and assessing whether the human's cancer is cured, wherein if the cancer is cured then the composition is useful for curing cancer.

According to the Guidelines, the patent application listed above would be entitled to a strong presumption of compliance with the WDR, despite the fact that absolutely nothing of consequence is disclosed therein.

I respectfully submit that the proper rule regarding the disclosure provided by originally filed claims is that the text of originally-filed claims disclose no more and no less than the same text would disclose if it were located at any other point in the originally-filed disclosure. Thus, a claim which specifically describes an embodiment of an invention (*e.g.*, "A composition consisting of 2-hydroxytoluene.") can, standing alone, provide adequate written description support for the subject matter of the claim. In contrast, a claim which provides no meaningful description of the subject matter it encompasses (*e.g.*, "A composition which cures cancer in a human.") provides only the written description support that the same words would provide if incorporated into another portion of the specification (*i.e.*, for the example above, substantially no written description support). Put another way, compliance with the WDR must be determined by assessing what is described in the entire specification (*i.e.*, including the claims originally filed therewith).

I respectfully suggest that the Office abolish all mention of a presumption of compliance with the WDR from the Guidelines and instead set forth that for each claim (*i.e.*, including both originally filed claims and new or amended claims), the Examiner has the burden of making a *prima facie* showing that a person of ordinary skill in the art would not recognize that the claim does complies with the WDR, in view of the entire originally-filed specification.

The court further explained its reasoning as follows:

> "If a *specification* provides a statutory description via a generic expression which is understandable, the presence of specific examples cannot, in ex parte practice, be said to limit that expression." *Id*. (emphasis added).

Thus, the court in *In re Koller* did not rely on the fact that the term in question appeared in a claim of the earlier application, only that it appeared in the specification of the earlier application.

New Matter in a Patent Application

35 U.S.C. § 132 provides that, "[n]o amendment shall introduce new matter into the disclosure of the invention." Pursuant to this section, an applicant should not be permitted to amend a patent application so as to introduce subject matter that was not described (explicitly, implicitly, or inherently) in the application as originally filed. It is therefore true that originally filed claims cannot constitute new matter, since the words of those claims were present in the original application. There is therefore no basis upon which an examiner can reject an originally filed claims as including new matter.

A new or amended claim, on the other hand, can include new matter if the subject matter of that claim was not among the subject matter disclosed in the original application. A claim which is added or amended in a manner which introduces new matter into the application should not be rejected by an examiner. Instead, the examiner should, pursuant to 35 U.S.C. § 132, refuse to add or amend the claim in the manner requested by the applicant. Compliance with the WDR of a claim which the examiner believes to include new matter should not be considered. Avoidance of such refusals by examiners to enter amendments is one reason that an applicant should indicate to the examiner why or how amendments to the specification (including the claims) do not include new matter[28].

A conclusion drawn by an examiner that an amended or added claim does not include new matter is a separate matter from whether the amended or added claims complies with the WDR. An added or amended claim may include subject matter that was not originally claimed, and yet does not constitute new matter[29]. However, the added or amended claim may nonetheless fail to comply with the written description requirement[30].

In my opinion, the Officer's examiners should determine compliance of originally filed claims with the WDR in the same manner in which compliance of added or amended claims with the WDR is determined. The only significant difference in this determination between the two types of claims should be that added or amended claims will first be examined to ensure that their addition or amendment does not include subject matter (i.e. 'new matter') that was not originally disclosed in the application, as filed. This preliminary examination is not properly considered examination for compliance with the WDR, but rather examination for compliance with 35 U.S.C. § 132. Thus, the only meaningful difference between applying the WDR to originally filed claims and to added or amended claims should be that the WDR is not applied to added or amended claims that include new matter, because such additions or amendments are properly refused entry and the added or amended claims are not examined.

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[28] *See, e.g.*, M.P.E.P. §§ 714.02 and 2163.06 (7th Ed., July 1998)

[29] For example, a specification may describe a genus which encompasses many hundreds or thousands of compounds. Addition of a claim which recites one of those compounds is not new matter, since that the specific compound is included within the subject matter disclosed in the specification.

[30] For example, a claim which recites a particular species within a broad genus disclosed in a patent application does not necessarily satisfy the WDR if the particular species is not described specifically as something the applicant has invented. *C.f. In re Ruschig*, 154 U.S.P.Q. at 123.

II. Methodology for Determining Adequacy of Written Description

In section II of the Guidelines, the Office set forth a recommended procedure by which examiners should analyze compliance with the WDR. The section designated "A" in section II of the Guidelines is directed to analysis of "the Specification" with respect to the WDR. In the two ensuing paragraphs, the Guidelines suggest that examiners should analyze:

- whether the "written description provides support for the claims",
- whether an applicant shows support in the original disclosure for new or amended claims, and
- whether "the claim as a whole * * * [is] sufficiently described in the specification".

I respectfully suggest that these statements do not provide proper guidance to examiner with regard to what must be analyzed in order to assess compliance with the WDR.

Applicants are, of course, permitted to disclose whatever they wish in a patent application, and are also permitted to withhold whatever disclosure they wish from the application. Of course, the scope of claims that will be allowed depends on what is disclosed in the application. The requirement that the specification include a written description of the invention. For the purposes of determining compliance with the WDR, the invention is "whatever is now claimed"[31]. Thus, it is not sensible to discuss compliance of the specification with the WDR. It is compliance of the claims with the WDR which must be analyzed.

Compliance of the claims with the WDR does not entail inclusion of a sufficient written description of the claims themselves, but rather a sufficient written description (i.e. per *Lockwood*, *supra*) of the subject matter encompassed by the claims. As the Guidelines indicate, each claim must be given its broadest reasonable interpretation. Compliance of a claim with the WDR must be considered in view of whether the specification provides an adequate written description of the entire scope of subject matter encompassed by the claim[32].

With regard to the Guidelines at section II, part A, including item 1, I believe that the language used should be more carefully selected. "Support" for a claim, pursuant to 35 U.S.C. § 112, ¶ 1, encompasses not only compliance with the WDR, but also enablement and best mode issues. I believe it would be more helpful to refer simply to compliance of a claim with the WDR.

For the reasons discussed above, the suggestion should be removed that originally filed claims have a greater presumption of compliance with the WDR than amended claims, added claims, or claims for which priority to an earlier-filed application is asserted.

It seems to me that the second paragraph of the Guidelines at section II, part A, item 1, relates more nearly to compliance of the claims with 35 U.S.C. § 112, ¶ 2. For this reason, this paragraph should probably be removed from the Guidelines. I believe that the prohibition against

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[31] *Vas-Cath*, *supra*, 19 U.S.P.Q.2d at 1117.

[32] *See, e.g., California v. Lilly*, *supra*, 43 U.S.P.Q.2d at 1406.

importing limitations into the claims from other portions of the specification is best discussed in the context of assessing compliance of claims, throughout their entire scope, with the WDR.

In item 2 of part A of section II of the Guidelines, the Office asserts that examiners should review the specification in order to "understand what applicant has identified as the essential distinguishing characteristics of the invention." The Guidelines explain that the "essential identifying characteristic features of the invention"[33] can be equated with "what the applicant has demonstrated possession of." Compliance of a claim with the WDR is to be considered in light of whether the "essential identifying characteristic features of the invention" correspond with what is claimed. Thus, the test for compliance with the WDR applied in the Guidelines appears to equate with nothing more than whether an applicant has demonstrated possession of what is claimed. If my understanding of the test set forth in the Guidelines is accurate, then the test does not comply with the test set forth in *Lockwood*, as set forth above, in that the test does not require that the public be put into possession of the claimed invention. To the extent that the WDR compliance test in the Guidelines is inconsistent with *Lockwood*, I believe it should be revised.

It seems to me that the following sequence of analysis should be employed by the Office's examiners in order to determine compliance with the WDR:

1) Read the claim in order to form an initial approximation of what is claimed.
2) Read the remainder of the specification in order to determine:
   A) how, if at all, the remainder of the specification informs the scope and meaning of the claim (keeping in mind the prohibition against importing limitations from the remainder of the specification into the claim;
   B) whether the claim includes new matter, relative to the originally filed specification (note that because an originally filed claim is a part of the specification, such a claim never constitutes new matter); and
   C) whether the disclosure in the originally filed specification meets the requirements of the WDR, namely that the disclosure would convince one of ordinary skill in the art to which the claim most nearly relates that
      i) the applicant was in possession of the claimed invention at the time the application was filed, and
      ii) the public will be put into possession of the invention upon issuance of the specification and the claim as a patent.

As a specific example of a type of claim which has been routinely allowed by the Office and for which I question compliance with the WDR, please consider the following. It is not an uncommon practice for the Office to allow a claim which recites an antibody which binds specifically with a novel and non-obvious protein disclosed in a patent application, at least where the specification discloses the protein in a manner which would satisfy the WDR for a claim directed to the isolated protein. Such a patent application might disclose, explicitly or by reference,

[33] It is unclear whether "essential distinguishing characteristics of the invention" and "essential identifying characteristic features of the invention" are intended to be the same or different in the Guidelines.

one or more well known methods of making an antibody which binds specifically with an isolated protein, and may even disclose one or more examples of antibodies which have been reduced to practice.

Although enablement of claims to such antibodies seems clear enough, I question whether a claim directed broadly to an antibody (i.e. any antibody) which binds specifically with the isolated protein can possibly comply with the WDR requirement. I believe it is clear that the method of making an antibody is adequately described that a claim to that method should be allowed. However, because the sequences of the complementarity-determining regions of the antibody are essentially unpredictable, I doubt that disclosure of such a method, even coupled with disclosure of one, two, ten, or one hundred examples of antibodies so generated, could provide a written description:

- that sufficiently places the applicant in possession (actually or constructively) or
- that sufficiently places the public in possession

of every antibody which would specifically bind with the isolated protein. Thus, it seems to me that claims directed to such antibodies *per se*, including product-by-process claims, cannot comply with the WDR. To my knowledge, no precedential court has yet ruled on compliance of such claims with the WDR[34]. Because the Office appears to regularly allow such claims, and because allowance of these claims seems to me to be at variance with consistent application of the WDR, I would appreciate it if the Office would clarify the position it will take with regard to compliance with the WDR of product and product-by-process claims directed to antibodies which bind specifically with a disclosed, isolated protein.

The Office's efforts to harmonize application of the WDR by issuing guidelines is much appreciated. However, I suggest that the modifications to the Guidelines disclosed above be made before the Guidelines are formally adopted or once again submitted for public comment.

If the Office would consider it helpful to contact me in order to clarify or further elaborate issues raised in this letter, I would be pleased to assist. I can usually be reached using the information atop this letter during ordinary business hours.

Very truly yours,

Gary D. Colby, Ph.D., J.D.

[34] *But cf. Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 47 U.S.P.Q.2d 1705, 1719-1720 (Fed. Cir. 1998) (explicitly declining to address this issue on the grounds that the issue was raised for the first time on appeal).