From: James Crowne [redacted]
Sent: Monday, April 11, 2011 4:53 PM

To: SEGuidelines112

Subject: AIPLA Comments: Supplementary Examiner Guidelines for Section 112

Please find attached the comments of the American Intellectual Property Law Association concerning the Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications. 76 Fed. Reg. 7162.

We appreciate the opportunity to convey our views and remain available for any further assistance.

Sincerely,

JIM CROWNE Director of Legal Affairs



AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION 241 18th Street South, Suite 700 ● Arlington, VA 22202 (p) 703.412.4353 ● (f) 703.415.0786 [redacted] | http://www.aipla.org



April 11, 2011

The Honorable David J. Kappos Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

Re: Comments on "Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications" 76 Federal Register 7162 (February 9, 2011)

Dear Under Secretary Kappos:

The American Intellectual Property Law Association (AIPLA) appreciates the opportunity to offer comments on the "Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications" ("Guidelines").

AIPLA is a national bar association with approximately 16,000 members who are primarily intellectual property lawyers and other practitioners in private and corporate practice, in government service, and in the academic community. AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Its members represent both owners and users of intellectual property.

AIPLA applauds the U.S. Patent and Trademark Office's (USPTO's) efforts to enhance the quality and consistency of patent application examination, and particularly this attempt to achieve some consistency in the application of Section 112.

The Federal Register Notice

The Federal Register notice sets forth examination guidelines to aid in the recognition and review of patentability issues under 35 U.S.C. §112, ¶¶ 2, 4, and 6, so-called "Markush" Practice, and functional language especially relating to the examination of computer-implemented inventions.

AIPLA recognizes that these areas raise questions not clearly answered by black letter law. Each patent application must be efficiently reviewed on a case-by-case basis for statutory compliance; ensuring consistency and quality in this process is essential to encouraging the innovative process. In this regard, AIPLA urges the USPTO to include a reminder in the examiner training materials related to this notice that rejections are to be based on the statutes, not based on these Guidelines or the Manual of Patent Examination and Procedures (MPEP).

Effective Date

AIPLA understands that the Guidelines became effective February 9, 2011, and that they are being applied to all patent applications filed before, on, or after the effective date. However, in view of at least the issues discussed below, we believe that implementation of these Guidelines is premature.

The Federal Register notice states that the Guidelines are a first step toward providing additional examination guidance in this area, and that they may be supplemented in later stages. However, it also states that the MPEP "will be updated *based on a final version of these guidelines.*" ¹

To the extent these Guidelines provide information that is supported by past practice and long-standing law, there is no reason to delay their use. However, some portions of the Guidelines set forth new policies and procedures that, for reasons discussed below, should cause them to be rescinded and revised before implementation.

General Comments

AIPLA recognizes the current administrative challenges facing the USPTO, including the backlog of unexamined applications and the need for full fee retention. While we have supported many of the initiatives that help address the USPTO's challenges, we do not support unnecessary efforts to limit the ability of applicants to freely claim their inventions as permitted by the statutes. Administrative burden is not an acceptable basis for limiting applicants' ability to claim their inventions under the law as they deem fit. We urge the careful consideration of the comments contained herein, and we invite the USPTO to work in close partnership with its users in seeking a way forward that is founded on law and based on the goal to "promote the Progress of Science and useful Arts."²

Interview Practice

AIPLA specifically notes and lauds the publication of examination directives that encourage the use of interviews "with the applicant or applicant's representative *at any point during pendency of an application*, if the interview can help further prosecution, shorten pendency, or provide a benefit to the examiner *or applicant*." We believe interviews can be a fruitful means for moving prosecution forward, particularly in facilitating efficient communication between the examiner and applicant on the substantive examination of patent applications.

Given the importance of interviews in aiding compact prosecution, we encourage the USPTO to enhance applicants' ability to obtain timely interviews.

¹ 76 Fed. Reg. at 7164, third column, last paragraph (emphasis added).

² U.S. Constitution, Article I, Section 8, paragraph 8.

³ 76 Fed. Reg. at 7169, third column, paragraph C.2 (emphasis added).

For example, some of our members report that examiners are increasingly requiring the applicant to submit an "Applicant Initiated Interview Request Form" (PTOL-413A) prior to any interview. We agree that the record should clearly reflect the prosecution history, including interviews. However, given that interviews are to be substantively summarized in writing, 4 we question the need to burden applicant and the examiner with the PTOL-413A form where applicants can sufficiently explain the purpose of the interview verbally when requesting the interview.

Some members continue to report being denied an interview after a final Office action. AIPLA agrees that it is desirable to address patentability issues as early in the prosecution process as possible. Nonetheless, denying interviews or putting administrative roadblocks up merely because it is late in prosecution, is unproductive as well. In addition, practice has shown that informal phone communications initiated either by the examiner or the applicant can speed prosecution and prevent the exchange of Office actions and responses that are based upon misunderstandings.

Some members report that they are having difficulties setting up multiple in-person interviews on the same day due to examiner scheduling conflicts. Many examiners, especially those more senior and of journeyman grade, have alternative work schedules and work from home. This creates logistical issues when attempting to set up several in-person interviews with different examiners on the same day. We appreciate the efficiency and flexibility provided by the judicial use of alternative schedules and workplaces, although we would encourage practices that would enhance access to examiners beyond that afforded by telephonic interviews (e.g., increased practical use of video conferencing).

Finally, some members report the absence of someone with signatory power at some interviews. We encourage the USPTO to ensure that an examiner having the ability to sign Office actions be present at all interviews. In the event of an unexpected absence or unavailability of an examiner with such authority who was to participate in a scheduled interview, a substitute with signatory authority should be required.

35 U.S.C. §112 ¶2: Markush Groups

The Guidelines set forth examination guidelines for so-called "Markush Groups." ⁵ It notes the difficulty of examining a Markush group that encompasses a massive number of distinct alternative species, and states that a claim to such a group may be rejected as indefinite under Section 112, ¶2 "if one skilled in the art cannot determine the metes and bounds of the claim due to an inability to envision all of the members of the Markush group." It also discusses the rejection of an "improper Markush grouping" under *In re Harnisch*, 631 F.2d 716 (CCPA 1980), i.e., where the species do not share a "single structural similarity" or a common use.

_

⁴ 37 CFR §1.133(b).

⁵ 76 Fed. Reg. 7162, 7163, first column, partial paragraph.

The use of a Markush format provides a means of claiming an invention that ranges from one embodiment (or species) to innumerable combinations of embodiments. For example, the use of Markush formats permits efficient recitation of chemical substitutions and equivalents on a functional core molecule, claiming multiple nucleic acids and proteins, and establishing alternative means for manifesting an inventive concept.

AIPLA recognizes that this section of the Guidelines addresses the long-felt need for an examination policy on claims that encompass large numbers of enumerated embodiments. AIPLA also recognizes that the USPTO has performed a significant review of the Office's restriction and election practices across all technologies. However, more work is needed here. As drafted, this section of the Guidelines is likely to cause significant confusion as to the correct manner of rejecting these types of claims, the proper interpretation of the reasoning in the Guidelines, and what actually constitutes an improper Markush group.

In particular, this section instructs examiners that, in addition to a rejection under 35 U.S.C. §112, ¶2, a Markush claim may be rejected "under the judicially approved 'improper Markush grouping' doctrine when claims contain an improper grouping of alternatively usable species," citing *In re Harnisch*, 631 F.2d 716, 719-20 (CCPA 1980). However, the *Harnisch* opinion addresses precisely the same position advanced by the PTO in 1980:

It is ... clear that Markush practice does not refer to a *single* rule. As may be seen from MPEP 706.03(y) set forth in the appendix, the PTO has one practice with respect to claims directed to compounds *per* se and a different one when they are directed to a process or a composition involving a combination of steps or ingredients where the Markush-type definition-by numeration is used in defining a process or composition.

In summary, there is no "doctrine" to be considered but only a body of case law emanating from both "higher" and "lower" authority, not altogether consistent, the latest decision tending to carry the most weight as precedent.⁷

As was the case when *Harnisch* was decided, there still is no "judicially created doctrine" for Markush claims in the sense of a rule, principle, theory, or tenet of law. Instead, the determination of whether claims are in proper form to be examined for patentability depends on an evolving collection of rules, principles, or tenets derivable from the cases. In its current form, the Guidelines misleadingly suggest a single rule.

The Guidelines also state that Markush claims "may be indefinite under §112, ¶2 second paragraph, if one skilled in the art cannot determine the metes and bounds of the claim due to an inability to envision all of the members of the Markush group."

⁶ 76 Fed. Reg. at 7166, first column, paragraph 4.

⁷ 631 F.2d at 720 (emphasis in original).

⁸ 76 Fed. Reg. at 7166, first column, paragraph 4.

While we agree that such a standard sets forth a *prima facie* legal standard for analysis under the cited statute, ⁹ the instruction provides little practical advice for either the examiner or the applicant. Establishment of an objective standard for determination of indefiniteness requires more than a restatement of the legal conclusion.

In particular, the Guidelines set forth an inquiry under 35 U.S.C. §112, ¶2 that directs examiners to determine, *a priori*, whether one skilled in the art could have determined the metes and bounds of the invention based on whether one could "envision all the members of the Markush group." Unfortunately, there is a long history of confusing broad claim scope with indefiniteness. Here, it seems that issues of claim breadth, properly addressed under the well-established 35 U.S.C. §112, ¶1 standards, are being moved to second paragraph. There is a risk that this instruction could encourage examiners to avoid more complex examination issues in favor of a difficult to overcome *per se* pronouncement of lack of clarity.

While it is desirable to find a more efficient and effective way to examine so-called "Markush Group" claims, AIPLA believes that the solution outlined in the Guidelines does not adequately address the concerns raised in these comments, and that the USPTO can work with its stakeholders to find a better solution. AIPLA urges the Office to reconsider and rescind a policy of making "Improper Markush" rejections.

35 U.S.C. §112 ¶6

Section 112 ¶6 expressly authorizes claim elements to be expressed as a means or step for performing a function, requiring that such a claim be construed to cover the structure, material, or acts (and their equivalents) described in the specification for performing the claimed function.

The Guidelines describe several areas where examination of means/step-plus-function claims may encounter ambiguity sufficient to subject the claim to a rejection under \$112, \$6 and potentially under \$112, \$1. Some examples include determining if a claim limitation invokes \$112, \$6 (e.g., includes means/step/substitute term-plus linked function); if the corresponding structure, material, or acts are insufficiently described in the specification; and if the corresponding structure, material, or acts are not sufficiently linked or associated with the claimed function.

The Guidelines cite to case law interpreting §112, ¶6 claims and suggesting types of language that may be ambiguous and lack clarity under §112, ¶2. In particular, Section C-3 of the Guidelines, entitled "Computer-Implemented Means-Plus Function Limitations" refers to the Federal Circuit opinions in *Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328 (Fed. Cir. 2008), *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339 (Fed. Cir. 1999), and the recent opinion in *In re Katz Interactive Call Processing Patent Litigation v American Airlines et al.*, decided February 18, 2011.

⁹ "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." 35 U.S.C. §112 ¶2.

One criticism of the new Guidelines is their unnecessary complexity as compared to the simplicity of MPEP §2181's explanation of the 3-prong analysis and its exceptions. Use of traditional language or exceptions to provide a simpler view of the requirements for invoking §112, ¶6 might make the analysis easier to follow and generate more consistent prosecution.

Determining Whether a Claim Limitation Invokes §112, ¶6

The Guidelines set out a process for interpreting claim limitations under §112, ¶6 that would modify the analysis recited in MPEP § 2181 to identify not only traditional "means for" or "step for" language to invoke §112, ¶6, but also non-structural terms deemed suitable substitutes, such as: mechanism for, device for, system for, apparatus for, and others. Although such substitute terms were previously recognized as potentially invoking §112, ¶6, the applicant had been required to either amend the claims to include the "means/step for" language or make a showing that the substitute language was suitable (i.e., written as a function to be performed and lacking recitation of structure/materials/acts for performing the function).

The Guidelines now suggest that, upon encountering a claim with a limitation reciting a term and associated functional language, the examiner should proactively consider whether the language potentially invokes §112, ¶6 and further analyze the claim language for compliance with that provision. However, this is contrary to statements in the Guidelines recognizing that claim limitations containing the traditional "means/step for" language are presumed to invoke §112, ¶6, and that there is a rebuttable presumption that §112, ¶6 does not apply where the traditional language is not used. ¹⁰

AIPLA suggests that this inconsistency can lead to confusion, causing examiners to needlessly follow multiple steps to interpret the alternate language in deciding whether the §112, ¶6 requirements are met. The better process would be to simply apply the presumption.

The Guidelines instruct the examiner to determine whether the limitation contains a non-structural substitute for the traditional "means/step-for" language, and to apply §112, ¶6, if that is the case. Where the substitute term is modified by structural language or is understood to be the name of a structure that performs the function, such as filters, brakes, or screwdriver (and is therefore no longer a non-structural substitute), §112, ¶6 would not be applied.

We suggest that examiners use the former practice of recognizing the lack of traditional "means/step plus" language where the applicant may have intended a §112, ¶6 claim. In such a case, any confusion and ambiguity would be better resolved by requiring the patent applicant either to amend the claim to include the explicit "means/step-for" language, or to clarify on the record that the recited claim language provides a non-structural substitute for §112, ¶6.

¹⁰ "The claim limitation is presumed to invoke § 112, ¶6 when it explicitly uses the phrase 'means for' or 'step for' and includes functional language. That presumption is overcome when the limitation further includes the structure necessary to perform the recited function." See 76 Fed. Reg. at 7167, first column, under "C. Interpreting Claim Limitations Under §112 ¶6."

The applicant may also choose to amend the claim language to clarify that the functional claim limitation is not intended to invoke §112, ¶6, for example, by including a structure for carrying out the recited function. This practice would likely provide more clarity and certainty for claim prosecution and post-grant construction.

If the claim limitation language (1) is consistent with invoking §112, ¶6, (2) contains the required functional language (prong B, MPEP §2181), and (3) is not modified by sufficient structure, material, or acts for achieving the specified function (prong C, MPEP §2181), the examiner should state in the record that §112, ¶6, will be applied.

When the examiner is uncertain about whether or not a claim limitation is sufficient to invoke §112, ¶6, an objection or a clarity rejection under §112, ¶2 may be used to require the applicant to remove the ambiguity by amending the claim so that the examination can proceed with a full understanding of its status under §112, ¶6. This procedure appears to be in keeping with past practice and would alleviate needless work by the examiner where it is unclear whether §112, ¶6 applies. In the interest of efficient prosecution, the examiner may consider a telephone or video conference to inform the applicant of the ambiguity and provide the applicant the opportunity to clarify the claim language prior to the examiner's written action. Early resolution of §112, ¶6 claims at the outset of prosecution would appear to foster greater clarity and not induce ambiguity in the prosecution record, as well as prevent needless effort by the examiner and by the applicant.

<u>Rejections Under §112, Second Paragraph When Examining</u> <u>Means-Plus-Function Limitations Under §112, Sixth Paragraph</u>

The Guidelines indicate that a clarity rejection under §112, ¶2 may be appropriate when it is unclear: that a claim limitation invokes §112, ¶6; that sufficient structure, material, or acts are recited to perform the claimed function; or that the disclosed structure, material, or acts are clearly linked to the claimed function.

Although such a §112, ¶2 rejection is appropriate in prosecution when the claim language is not understood or is ambiguous, this practice differs from the judiciary's treatment of issued patents which enjoy a presumption of validity. Under Federal Circuit law, a patent is invalid for indefiniteness only if reasonable efforts at claim construction prove futile and the claim is "insolubly ambiguous." The Board of Appeals has found this test inapplicable to patentability determinations in prosecution, ¹² and the question on the proper standard may be reviewed by the Supreme Court. Accordingly, a practical procedure for clarifying §112, ¶6 language during prosecution is preferred for both prosecution and judicial efficiency.

¹

¹¹ Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001); Honeywell Int'l, Inc. v. Int'l Trade Comm'n, 341 F.3d 1332, 1338-39 (Fed. Cir. 2003).

¹² Ex parte Miyazaki, No. 2007-3300, 2008 WL 5105055, at *5 (B.P.A.I. Nov. 19, 2008).

¹³ Applera Corp. v. Enzo Biochem, Inc., U.S. No. 10-426, petition for certiorari filed 9/23/2010, views of the Solicitor General invited 12/13/2010.

In this section, the Guidelines specify that the description of structure supporting a §112, ¶6 must be more than "simply a general purpose computer or processor." The Guidelines require disclosure of an "algorithm" to transform the general purpose computer/microprocessor into a special purpose machine that performs the disclosed algorithm. The algorithm provides the needed "structure" in the specification, and is defined in the Guidelines as, for example, "a finite sequence of steps for solving a logical or mathematical problem or performing a task." The absence or insufficiency of the disclosed structure (here, algorithm) or failure to link the disclosed algorithm with the recited function can result in a rejection under §112, ¶2.

Similarly, it is not sufficient to reference a specialized computer, logic, code, or black box elements as there must be some explanation of how the computer or computer component performs the claimed function. Arguments that one skilled in the art is capable of writing suitable software to permit a general purpose computer to perform the claimed function, according to the Guidelines, are insufficient to relieve the patentee of the duty to disclose in the specification sufficient structure to support the means-plus-function claims. Where the means-plus-function claim limitation is supported by software and not hardware, the Guidelines indicate a definiteness rejection under §112, ¶2 is appropriate, except when other claim limitations provide the needed structural limitations.

AIPLA agrees that some description of a specific algorithm is generally needed to support a claim to specialized function. However, the implementation details of the algorithm should not be needed when such details would be known to the skilled person. In many situations, a very high level description would suffice to describe and enable a specific algorithm.

The Guidelines in part are consistent with recent case law, particularly the *In re Katz* decision. In *Katz*, the court held that reciting a general purpose computer without disclosing an algorithm or programming was insufficient structure to support the functions claimed under §112, ¶6. Those claims, according to the court, were therefore invalid for indefiniteness because the function claims without adequate corresponding structure lack the required public notice and are subject to being overly broad, a feature inherent in open-ended function claims.

However, the *Katz* opinion also found the disclosure of a general purpose computer without algorithms to be *sufficient structure* for other claims to the functions of "processing," "receiving," and "storing." The court explained as follows:

Absent a possible narrower construction of the terms "processing," "receiving," and "storing," discussed below, those functions can be achieved by any general purpose computer without special programming. As such, it was not necessary to disclose more structure than the general purpose processor that performs those functions. Those seven claims do not run afoul of the rule against purely functional claiming, because the functions of "processing," "receiving," and "storing" are coextensive with the structure disclosed, i.e., a general purpose processor. ¹⁵

¹⁴ 76 Fed. Reg. at 7168, second column, paragraph 1.

¹⁵ Slip op., pp. 20-21.

The cases requiring the disclosure of algorithms, according to the court, involved specialized functions that had to be carried out by specially programmed computers. *Katz* was remanded for a further construction of the "processing," "receiving," and "storing" functions to confirm that they were not specialized functions.

The Guidelines attempt to impose a bright-line test to computer-implemented \$112, \$6 claims that Katz does not support. Rather than apply a special rule for computer implemented claims, the \$112, \$6 test is the same for such claims as for any other: the disclosed structure must be coextensive with the claimed function. There is no categorical test that applies when a general purpose computer is involved. Examiners must evaluate the claimed functions and decide whether there is a structure disclosed that will carry out those functions. With respect to certain Katz claims, an unprogrammed general purpose computer was enough.

Computer Implemented Functional Claim Limitations

AIPLA applauds the USPTO for summarizing the law regarding §112, ¶¶4 and 6 for the examining corps. However we do not agree that there should be any special treatment for computer implemented functional claim limitations. Whether or not an invention is implemented on a computer is irrelevant as long as the requirements of Sections 101, 102, 103 and 112 are met.

Rather than having a special section on computer-implemented functional claim limitations, these Guidelines instead should cite specific examples dealing with computer-implemented inventions in the discussion of each of the paragraphs of Section 112. Having separate considerations for computer-implemented inventions may cause an examiner to believe that these inventions should be subject to additional or stricter rules than those that apply to other technologies.

We do not believe that the Guidelines adequately describe the role of the knowledge of the skilled person in determining whether the written description requirement has been met. For example, the Guidelines cite *Lizardtech v Earth Resources Mapping*, 424 F.3d 1336 (Fed Cir. 2005) as requiring a patent specification to enable a claimed invention over its entire scope. While this use of *Lizardtech* is appropriate, the material quoted in the Guidelines is deficient because it does not explain the role of the knowledge of the person of ordinary skill in the art in making this determination. In addition to the *Lizardtech* passage quoted in the Guidelines, the opinion includes the following:

A claim will not be invalidated on *section 112* grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. See *Union Oil Co. v. Atl. Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000). That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Placed in that context, it is unnecessary to spell out every detail of the

invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation.¹⁶

Thus, if the Discrete Wavelet Transform (DWT) in *Lizardtech* were a well-known operation and the skilled person would know different ways to perform the transform operation, the claim may have satisfied the written description requirement even though the specification did not disclose every known method for performing a DWT. If a genus is supported by an example and the skilled person would immediately know other examples, there should be no problem supporting a broad genus with a single example. Indeed, *Ariad v. Eli Lilly* explicitly declines to set out any bright-line rules as to what is needed to satisfy the written description requirement for a genus claim.

The law must be applied to each invention at the time it enters the patent process, for each patented advance has a novel relationship with the state of the art from which it emerges. Thus, we do not try here to predict and adjudicate all the factual scenarios to which the written description requirement could be applied. Nor do we set out any bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field.¹⁷

Thus, we urge the USPTO to revise the Guidelines to emphasize the role of the person of ordinary skill in the art, and to indicate that the written description requirement is met when the person of ordinary skill in the art, after reading the claims and the specification, understands that the applicant was in possession of the invention.

The knowledge of the skilled person is also relevant to the discussion of the sufficiency of the disclosure for computer related inventions. The Guidelines require an inquiry into both the sufficiency of not only the disclosed hardware but also the disclosed software. This statement should be tempered with a recognition that, in order to satisfy the written description and enablement requirements, the application need not describe well-known hardware elements or software algorithms as long as they are referenced in the specification. In these instances, the written description requirement is met by the reference to the algorithm, and the enablement requirement is met by the knowledge of the skilled artisan.

We are also concerned about the statement in the Guidelines that "the scope of the claims must be less than or equal to the scope of enablement provided by the specification." While we agree with the statement, we are concerned that it may mislead examiners into believing that the specification must fully describe every element of every claim. This interpretation would be at odds with the statement from *Ariad*, referenced above. As set forth in *Ariad*, the amount of disclosure needed to satisfy the written description may be different for each invention.

¹⁶ 424 F.3d at 1345 (emphasis in original).

¹⁷ Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

¹⁸ 76 Fed. Reg. at 7171, second column, third paragraph.

"Thus, we have recognized that determining whether a patent complies with the written description requirement will necessarily vary depending on the context. Specifically, the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." ¹⁹

Further, the statement in the Guidelines that "the specification must contain the information necessary to enable the novel aspects of the claimed invention," may also be misleading and should be amended to read, "the specification must contain the information necessary to enable the skilled person to make and use the novel aspects of the claimed invention." While the knowledge of the skilled artisan cannot be used to provide an element that is missing from an application, once a well-known element is referenced in the specification or claim, it does not need to be described in detail. The mere mention of the element should be sufficient if both the structure and use of that element in the particular invention would be known to the skilled person.

Finally, we do not agree with the statement in the Guidelines that, "if the prior art discloses a device that can inherently perform the claimed function, a rejection under § 102 or § 103 may be appropriate." In particular, the word "can" should be removed and "inherently" should be defined. Inherency, as it relates to prior art, requires more than just an examiner's opinion.

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.²¹

Thus, an examiner asserting that a reference inherently performs a claimed function should be required to take Official Notice of the fact, which can be rebutted by the applicant.

Reasons for Allowance

The Guidelines remind examiners to establish a clear prosecution record with regard to rejections under $\S112$, $\P2$. The Guidelines also advise examiners to use a Statement of Reasons for Allowance as provided under 37 CFR 1.104 (e), if necessary, to establish such a clear record with regard to the claim interpretation that was used in allowing a claim. 23

While these instructions are welcomed, AIPLA encourages the USPTO to include a reminder in the training materials for these Guidelines that examiners should not include a Statement of Reasons for Allowance unless necessary to complete the record.

²⁰ 76 Fed. Reg. at 7172, column 1, paragraph 1.

¹⁹ Id. (citations omitted).

²¹ Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991) (citations omitted).

²² 76 Fed. Reg. at 7169, column 3, Section C-2.

²³ 76 Fed. Reg. at 7170, column 1, Section D-1.

That is, where the record is clear as to why the case was allowed, the inclusion of a Statement of Reasons for Allowance is unnecessary may cloud rather than clarify the record. For example, if an applicant has responded to an Office action with argument or amendment, and the claims are then allowed in view of that argument or amendment, the record is inherently clear as to why the claims were allowed, and there is no need for a Statement of Reasons for Allowance.

Further, when an examiner provides a Statement of Reasons for Allowance that includes rationale not previously raised during prosecution, other than a statement that says "The art of record does not teach or suggest," followed by the entire language of the relevant independent claim(s), the record can become clouded by one-sided assertions. Under these circumstances, the examiner must address each and every relevant independent claim. Where an examiner simply states a reason for allowance and quotes only one of the independent claims, this practice can imply undue significance for the quoted language of that claim. If other independent claims include the modified language, the record can incorrectly suggest that those other claims can only overcome the reference if that language is interpreted exactly as in the quoted claim. In any event, it is suggested that, when an examiner includes rationale in a Statement of Reasons for Allowance not previously raised during prosecution that may cloud the record, the examiner call the applicant to discuss the proposed reason, and thereby allow the record to be further developed and clarified.

In addition, while "[t]he examiner's statement should not create *an estoppel*,"²⁴ such a statement is, nevertheless, an important source of prosecution history.²⁵ However, if an examiner issues a Statement of Reasons for Allowance which sets forth an inaccurate claim interpretation, in the course of allowing the application, the applicant is then presented with a number of difficulties.

First, if the applicant is dissatisfied with such a statement, he cannot appeal it, because none of his claims have been rejected. Second, while the applicant can file a comment on a Statement of Reasons for Allowance, the failure of an examiner to respond to said comment does not give rise to *any* implication. Indeed, the examiner has no obligation to respond to the applicant's comments on a Statement of Reasons for Allowance. Third, if the applicant comments on the statement, his comments risk creating estoppels. Fourth, if the applicant files a continuing application in the hope of "correcting" the misleading impression left by the examiner's original statement, such a course of action is problematic for the reason that it delays the issuance of the patent and further because the application may well come before the same examiner who issued the original Statement of Reasons for Allowance. Fifth, if the applicant files a Request for Continued Examination (RCE) or a continuing application in order to clarify the record, it could negatively impact patent term adjustment under 35 U.S.C. § 154.

²⁴ MPEP §1302.14, Section V (emphasis added).

²⁵ See Zenith Labs., Inc. v. Bristol-Myers Squibb Co. 19 F.3d 1418 (Fed. Cir. 1994).

²⁶ 35 U.S.C. 134 (a).

²⁷ 37 CFR 1.104 (e).

²⁸ MPEP §1302.14, Section I.

Even Salazar v. Procter & Gamble Co., 414 F.3d 1342 (Fed. Cir. 2005), which held that an applicant's silence in the face of a Statement of Reasons for Allowance should not be treated as an acquiescence to the examiner's statement, does not assure the issuance of a quality patent. In Salazar, the examiner issued a Statement of Reasons for Allowance, asserting that the claims to a certain toothbrush were allowable for the reason that nylon for the bristles was not covered by the claims, which referred to "elastic" bristles. The majority in Salazar held that the applicant's silence in the face of this statement did not alter claim scope and did not bar the applicant from asserting infringement by nylon bristle toothbrushes under the doctrine of equivalents, because such silence was not a clear disavowal of claim scope by the applicant. However, the dissent in Salazar pointed to the specification which called nylon bristles "conventional" and a feature of prior art toothbrushes. The dissent asserted that the applicant's silence in the face of a distinction that was central to patentability indicated that the applicant was estopped from asserting that the nylon bristles were within the scope of the claims under the doctrine of equivalents.

A similar problem could arise where the examiner in the course of "resolving" a rejection under 35 U.S.C. §112, second paragraph, makes an improperly narrowing interpretation of the claims. Namely, the examiner, with his improper statement, could leave the impression in the prosecution history, that the claims were narrower in scope than they really should be.

Perhaps, the best description of the effect of a Statement of Reasons for Allowance on claim scope is that "Any inferences or presumption [created by such a statement and the comments thereon] are to be determined on a case-by-case basis by the court reviewing the patent." Therefore, while it is appreciated that examiners are being instructed to clarify the record with such statements in the Guidelines, it is extremely important such statements be accurate and absolutely necessary.

We appreciate the opportunity to provide these comments on the "Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications," and we would be pleased to answer any questions about our comments that may arise.

Sincerely

Q. Todd Dickinson Executive Director

²⁹ MPEP 1302.14 Section V.