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From: Michael K. Kirk

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To: AB95 Comments

Subject: AIPLA Comments to Changes to Information Disclosure Statement Requirements

Hiram H. Bernstein

Senior Legal Advisor

Office of Patent Legal Administration

Office of the Deputy Commissioner for Patent Examination Policy

Dear Mr. Bernstein,

Attached are the comments of the American Intellectual Property Law Association on the proposed "Changes to Information Disclosure Statement Requirements."

An acknowledgment of receipt of these comments would be greatly appreciated.

Thank you.

Mike Kirk



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September 6, 2006

The Honorable Jon W. Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office
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Attn: Hiram H. Bernstein
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Comments on Notice of Proposed Rulemaking: "Changes to Information Disclosure Statement Requirements and Other Related Matters" 71 Fed. Reg. 38808 (July 10, 2006)

Dear Under Secretary Dudas:

The American Intellectual Property Law Association (AIPLA) appreciates the opportunity to offer comments regarding the U.S. Patent and Trademark Office ("PTO") proposed rules directed to Changes to Information Disclosure Statement Requirements and Other Related Matters, published at 71 Fed. Reg. 38808 (July 10, 2006).

AIPLA is a national bar association whose more than 16,000 members are primarily lawyers 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. Our members represent both patent owners and users of intellectual property.

GENERAL COMMENTS

The PTO has again proposed dramatic and complex changes to an important aspect of patent practice - the submission of information that may be relevant to a determination of patentability. Some of the proposals do have potential for improving the examination process and bringing greater clarity to patent practice before the PTO. In particular, AIPLA finds beneficial the proposed provisions on allowing withdrawal of a reexamination proceeding from the publication process upon filing a petition and paying a fee and eliminating some fees for submission of an Information Disclosure Statement (IDS) (§ 1.17), allowing a change in the order of the listing of the inventors (§ 1.48), allowing the entry of a claim for priority after the close of prosecution (§ 1.55), expanding the time during which third parties can submit prior art (§ 1.99), expanding the entry of amendments after allowance (§ 1.312), and filing of an IDS in a reexamination proceeding (§ 1.555). However, many of the most significant proposals regarding submissions in an IDS are problematic and unlikely to assist the Office in improving either the efficiency or quality of examination.

The proposed rules would impose substantial new analytical burdens on patent applicants seeking to bring information to the attention of the PTO to be considered during the prosecution of patent applications and reexamination proceedings. The proposed rules also would place unwarranted burdens on applicants bringing information to the attention of the PTO. These additional burdens would impose substantial costs on applicants, who would be motivated to seek to reduce those costs by reducing or eliminating activities (e.g., conducting a search of prior art) presently practiced to identify information that may be relevant to patentability. The proposed rules would also expose applicants to a substantially greater risk of having to defend against charges of inequitable conduct. The PTO has failed to justify the imposition of these burdens and risks in the great majority of applications.

The PTO survey described in the Notice states that IDS submissions in 85% of applications contain 20 documents or less, yet the PTO concludes that current IDS requirements are ineffective. Imposition of the proposed unduly burdensome disclosure requirements on the 85% of patent applicants who do not disclose in excess of 20 documents would be unjustified. Consideration should be given to alternative approaches that might more directly address the concerns of the PTO. For example, the Office might introduce an "excess document fee" analogous to the excess claim fee. This could be accompanied by a procedure allowing Examiners who received excess document citations additional time for reviewing such documents.

While the new burdens and complexities of patent prosecution contained in the proposed rules would fall on all patent applicants, they would be especially damaging to small entities. Public respect for the PTO and confidence in issued patents would be diminished if applicants are required to act as a filter for information considered during the examination process. The PTO has failed to take into consideration the significant burdens, problems, and complexities that it proposes to introduce in attempting to address problems that its own data show exist in less than 15% of applications. It would appear that the PTO may not appreciate the potential adverse effects of its proposals on inventors, patent owners, and investors when it states: "Noncompliance with these rules results only in the Office possibly not considering information in an information disclosure statement." 71 Fed. Reg. at 38818.

The patent system and PTO would be better served by addressing specific problems with the submission of IDSs in a specific way rather than imposing substantial new burdens on every patent applicant, forcing them to pay for the alleged excesses of a few. Most of the new disclosure requirements would create new pitfalls that would only diminish the utility of the patent system, thereby disserving the national interests in innovation and industrial growth.

The current system allows applicants to submit an unlimited number of references without any explanation until the application is allowed or finally rejected. The Examiner may briefly review the submission to locate relevant documents that would not have turned up in the Examiner's search, and then review in detail those that seem especially relevant. When the patent issues, all the references submitted during prosecution are listed, so the public has knowledge of them. References that were only cursorily reviewed and not discussed substantively in the file can still form the basis of a reexamination request, and raise a substantial new question of patentability, if material. They can also be used by those writing opinions on the validity of the patent. If there is material prior art in the submission that the Examiner has missed, it can be found easily by those having an interest.

In contrast, the proposed system would discourage applicants from searching and finding references that they would be obliged to evaluate and discuss in detail. This could be a significant loss and would deprive the public of the benefits it receives from the current system. The proposed rules should not be adopted in their present form. If adopted in any form, they should apply only to applications filed on or after the effective date of the new rules.

COMMENTS ON SPECIFIC CONTENT

The following comments address the specific provisions in the Notice of Proposed Rulemaking along with alternative suggestions.

Duty to Review Documents

The PTO has stated that § 1.56 “neither authorizes nor requires anyone to file unreviewed or irrelevant documents with the Office.” 71 Fed. Reg. at 38809. We can certainly agree that § 1.56 contains no such requirement. Any document filed in an IDS must be reviewed to some extent so that someone associated with the preparation and prosecution of the patent application can make a connection between the subject matter contained in a document and an application. However, that review may sometimes be limited to the title of the article or the content of an abstract and, in these situations, it would not be necessary to review the entire contents of a document to make a connection between the possible relevance of that document to the examination of a particular application.

To our knowledge, the PTO has not previously made clear what degree of review of a document is required under current practice. Under current practice, if the inventor supplies a document to a practitioner following an explanation of his duty of disclosure in his patent application, that practitioner has been able to provide that document to the PTO in an IDS without the slightest hesitation or concern that its submission would cause “unnecessary delay or increase the costs of examination.” To date, the PTO has encouraged applicants to submit information that may be relevant to patentability. As noted in the Notice of Final Rulemaking related to IDS practice in 1992:

If information is not material, there is no duty to disclose the information to the Office. The Office believes that most applicants will wish to submit the information, however, even though they may not be required to do so, to strengthen the patent and avoid the risks of an incorrect judgment on their part on materiality or that it may be held that there was an intent to deceive the Office.

Reply to comment 3, 57 Fed. Reg. 2021, 2023 (January 17, 1992).

Contrary to its position reflected in the current proposals, the PTO has previously expressed the view that:

It is in the best interest of the Office and the public to permit and encourage individuals to cite information to the Office without fear of making an admission against interest.

57 Fed. Reg. 2021, 2022 (January 17, 1992).

Similarly, it was expected that applicants would submit information for consideration by the Office rather than making and relying on their own determinations of materiality. *Id.* at 2024. Indeed, the Office has specifically stated that Rule 1.56 itself does not place a burden on the practitioner to analyze references. *Id.* at 2026, Reply to comment 26.

The PTO is free, of course, to propose and adopt changes to its policies and practices. It would be manifestly unfair, however, to retroactively reinterpret its past policies and practices, and would create more uncertainty in an area of critical concern to the patent community, i.e., the doctrine of inequitable conduct.

If the PTO wishes to require a particular level of review, or to require that the review be performed by a particular person, those requirements should be pointed out with particularity. While the proposed rules and commentary provide specifics, they are, in our view, based on improper assumptions about the proper roles of applicants and the PTO in producing valid and enforceable patents.

“Applicant” is Intended to Cover the “Patent Owner”

The PTO should reconsider and clarify the statement (71 Fed. Reg. at 38809) that the term “applicant” is intended to cover the “patent owner” in regard to IDS submissions in reexamination proceedings. An applicant for a patent application is generally considered to be the named inventor(s). 37 C.F.R. § 1.41. The patent owner may be the patentee, but more typically is the assignee of the patent. The duty of disclosure in reexamination proceedings should not apply to every employee or person associated with the patent owner, but only those individuals who are substantively involved on behalf of the patent owner. Please clarify this statement and consider appropriate clarifying amendments to 37 C.F.R. § 1.555.

Section 1.17 Patent Application and Reexamination Processing Fees

The PTO has proposed to amend this section to require a petition fee for a petition to withdraw a reexamination proceeding from the publication process under proposed § 1.98(a)(3)(iii)(B). AIPLA supports this proposal.

The Office also proposes to delete the requirement to pay a fee with the submission of an IDS after a first Office action where a § 1.97(e) certification cannot be filed, and for consideration of an IDS after the close of prosecution but before payment of the issue fee. While AIPLA can agree to the general principle that the payment of a fee should not excuse an intentional delay in submitting information to the PTO that is potentially relevant to patentability, the effects of the proposed changes, along with proposed changes to continuing application and RCE practice, are likely to reduce opportunities to present potentially material information to the PTO and to have adverse consequences on the quality of examination.

While most applicants strive to be diligent in presenting known information to the PTO, it is a practical reality that potentially relevant prior art may be overlooked by both examiners and applicants. Under the proposed rules, it would appear that if applicants discover a potentially relevant document known to an inventor at the time the application was first filed, there would be no opportunity to present that information to the PTO after a first Office action in a continuation or an application in which an RCE has been filed. The proposed rules require a § 1.97(e) certification which could not be filed, and the proposed continuing prosecution rules would appear to bar the filing of a further continuation because the information could have been presented earlier. Surely the grant of a U.S. patent without consideration of potentially relevant prior art would not be in the best interest of either the applicant or the public, and most certainly would not contribute to the Office’s goal of improved quality of examination.

Unless the PTO makes allowance for situations where the identification or relevance of a known document is belatedly discovered, the quality and reliability of the PTO’s work product will suffer. The frequency of these situations is likely to increase if the PTO goes forward with its proposal to make applicants a filter for information that may be considered cumulative to information already of record in an application or reexamination proceeding. Reasonable people will differ on what is cumulative, and it is easy to second guess the judgment of others made earlier in prosecution. The PTO should consider alternative mechanisms and procedures for allowing for consideration of potentially relevant prior art before a patent is granted. These mechanisms could include a substantial fee where a § 1.97(e) certification could not be filed, or a requirement that new information be considered in a continuing application that would require the sacrifice of any patent term extension or adjustment accumulated in an existing application.

Section 1.48 Correction of Inventorship

The proposed revisions to § 1.48 include a clarification that these procedures do not apply to correction of inventorship via reexamination or reissue, and provide explicit provisions for changing the order or spelling of inventors' names, and updating an inventor's name in pending or abandoned applications. AIPLA supports these changes that both simplify and reduce the cost of requesting the PTO to make these largely technical changes to a patent application.

Section 1.55 Claim for Foreign Priority

The proposed changes to this section are consistent with the proposed changes to § 1.312, which would provide an expanded opportunity for applicants to have certain technical amendments entered after the close of prosecution without withdrawal of the application from issue. AIPLA supports these proposals because they would both clarify and simplify the procedures available to make certain technical amendments in applications at an advanced stage of prosecution without withdrawal of the application from issue. It is in the best interest of both applicants and the PTO that these procedures be both simplified and clarified, so long as the PTO provides the staff necessary to process the technical amendments when made so that they can appear in the patent grant. While we recognize that these changes cannot always be made before the patent grant, it is important to provide the staff necessary to promptly and efficiently process any request for a certificate of correction because any amendment adding a priority claim that is not printed in the patent would not be effective unless corrected by a certificate of correction under 35 U.S.C. § 255 and § 1.323.

Section 1.56 Duty to Disclose Information Material to Patentability

The PTO has proposed to amend this section by the addition of paragraph (f) that would provide a so-called "safe harbor" for individuals attempting to comply with the additional disclosure requirements of proposed § 1.98(a)(3). It is clear the PTO recognizes this proposal would create substantial new pitfalls and vulnerabilities for both practitioners and patent owners. However, the PTO also acknowledges that the proposed "safe harbor" is an illusion, stating in the notice that the court is not bound by any duty of disclosure standard established by the Office. *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1316, 77 USPQ2d 1823, 1829 (Fed. Cir. 2006). In addition, the court has declined to honor the "safe harbor" for canceled claims in § 1.56(a). *PerSeptive BioSystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1322, 56 USPQ2d 1001, 1006 (Fed. Cir. 2000). Despite the PTO's expressed hope that a court, in deciding a duty of disclosure issue, would take the proposed safe harbor into account, a practitioner or patent owner cannot derive any comfort or safety from this proposed addition to § 1.56.

The proposed "safe harbor" does not provide any safety not already accorded by court decisions. We are not aware of any case where an individual has been successfully accused of inequitable conduct where a court has found that the individual made a reasonable inquiry regarding the information cited, and acted in good faith in providing any information to the PTO. The problem with the PTO's proposal is not that a court that makes the factual findings and conclusions contained in proposed paragraph (f) is likely to find an individual accountable for inequitable conduct. Rather, the PTO proposal would magnify the opportunities for an entity challenging a patent to question whether an individual's actions were reasonable or conducted in good faith, and would necessarily diminish the value of the patent and increase the cost of enforcing it. Not only would patent owners face additional costs and pitfalls based on an individual's activities directed to complying with the new disclosure requirements, but the costs associated with complying with the new disclosure requirements and trying to avoid challenges to those activities in the future would substantially increase the costs of prosecution. While AIPLA has no objection to this proposed addition per se, it is unnecessary and meaningless.

Section 1.97 Filing of Information Disclosure Statements

The PTO is proposing to amend this section to redefine the requirements for having an IDS considered during different segments of the examination process, and to make these time periods applicable to reexamination proceedings. The proposed four time periods are clearly set forth, and the

application of these time periods to reexamination proceedings would bring greater clarity, transparency, and certainty to the consideration of an IDS in reexamination proceedings. Accordingly, AIPLA supports these reexamination aspects of the proposed revisions of § 1.97.

The PTO proposes to delete § 1.97(b)(4), which would mean that any IDS filed with a Request for Continued Examination (RCE) under § 1.114 would need to comply with the new disclosure requirements that would be applicable to an IDS filed in the time period in which the RCE is filed. Thus, if an RCE is filed after a notice of allowance is mailed, an applicant would have to include a patentability justification with any IDS filed as a submission with the RCE.

The PTO should reconsider and withdraw its proposal to delete § 1.97(b)(4), since it may motivate applicants to elect to file a continuing application rather than an RCE to restart prosecution. The RCE procedure is much simpler, avoids additional work for both applicants and the PTO in preparing and processing a new application, and is docketed for more prompt examination than most continuation applications. Applicants and their representatives are very familiar with the current RCE practice, and the proposed imposition of additional limitations and requirements on its use would most certainly cause confusion and errors, and would not contribute to the PTO goal of improved efficiency of examination.

Section 1.97(h) provides that the filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability. This text appears to be inconsistent with the new requirements for submitting a document in an IDS after the first period, which would require a non-cumulative description for each document contained in the IDS. If these proposed non-cumulative description requirements are not inconsistent with the current provisions of § 1.97(h), please explain. As more fully developed below, AIPLA would support the retention of § 1.97(h) in its current form, together with the withdrawal of the proposed requirements that would necessarily require not only an admission, but an identification of some portion of the document that correlates to specific claim language or to a specific portion of the specification that is not cumulative to the teachings of any document of record in the file.

Proposed new § 1.97(j) would be added to make clear that an IDS filed during the fourth time period (after the issue fee is paid or the NIRC is mailed) would not be effective to withdraw the application from issue or to withdraw a reexamination proceeding from the publication procedure. This proposal would be consistent with present practice, but compliance with the proposed new disclosure requirements would add complexity, delay, and uncertainty to the ability to restart the examination or reexamination process. The current process of withdrawing an application from issue for consideration of an IDS is ably handled by staff in the Office of Petitions. The procedures are clear, the requirements are simple, and the staff is both competent and reliable. The proposed addition of new disclosure requirements would introduce a new element (compliance with the patentability justification requirement) that is both complex and uncertain, and would likely require evaluation by different staff than currently handles these processes. This is a recipe for delay, confusion, and wasted resources that could otherwise be effectively used for improving patent examination quality and efficiency.

Section 1.98 Content of Information Disclosure Statements

As proposed, this section would be substantially revised to add additional and onerous disclosure requirements that would apply to selected documents submitted before a first Office action and to all documents supplied after the first action. The amount of information required from applicants in an IDS would increase during the examination process. Failure to comply with these new requirements may result in the PTO's failure to consider the IDS. In some instances, compliance with some of these new requirements would not be required where a document is identified as a result of a foreign search or examination report and is timely supplied to the PTO, or the document is submitted in reply to a requirement for information pursuant to § 1.105.

The proposed new requirements are complex, would be largely wasteful of scarce examining resources, and would create burdens, costs, and risks for applicants that would far outweigh any benefit that might be derived by the PTO. These new requirements would also significantly raise the barrier for small businesses and independent inventors to obtain meaningful patent protection.

AIPLA suggests that these proposed disclosure requirements be substantially revised or withdrawn.

Section 1.98(a)(3)(i)

This proposed section would require an explanation in compliance with paragraph (a)(3)(4) of this section (hereinafter "Explanation") for any document submitted before a first Office action that was (a) in a foreign language or (b) over 25 pages, or (c) for all of the documents if more than 20 documents are submitted, calculated cumulatively. Documents that result from a foreign search or examination report where a copy of the report is submitted with the IDS, and documents submitted in reply to a requirement for information pursuant to § 1.105, would be exempted from these requirements and not count toward the 20 document threshold.

An Explanation would require identification of a specific feature or teaching that caused a document to be cited and a representative portion of the document where the specific feature or teaching may be found, together with a statement correlating the specific feature or teaching to corresponding specific claim language or to a specific portion of the specification that provides support for the claimed invention. While we think there is some justification for this requirement as applied to documents that are not word-searchable and that are over 25 pages in length, or volumes of documents that exceed a reasonably high number (not 20, but more like 50), there is little justification for imposing these requirements on U.S. patent documents that are published, patented, or otherwise contained on a word-searchable database.

It is not clear whether the required correlation to claim language can be limited to a single claim or to only those claims designated for examination (if the PTO adopts its proposed piecemeal examination proposal), or if it applies to all claims. Please clarify. The proposed Explanation requirement should not apply to a foreign-language document if an English-language translation is supplied.

We think that the designation of the 21st document as the trigger for additional disclosure requirements is far too low, since it represents a small fraction of the number of documents found in a single average subclass of the U.S. patent classification system and cannot unduly burden an examiner. We further do not understand the implication that the citation of the 21st document would trigger a requirement to provide an explanation for all documents that were cited. We recommend that the triggering mechanism, if adopted, should apply only to documents in excess of 50 and should be applied to only those documents that are not word-searchable. We further recommend that the Explanation requirement apply only to those documents in excess of the threshold number so that applicants would not be further discouraged from submitting potentially relevant prior art.

As to the proposed threshold document count of 20, to what extent will applicants be able to withdraw a document and substitute a new document? Assume an applicant has submitted 20 references, including reference A. A new reference B is found that is non-cumulative because it discloses everything in A, plus some more relevant information. Can applicants withdraw A (assuming it has not already been considered) and substitute B, rather than simply adding B, which would trigger the Explanation requirement for all 21 documents?

Depending on the scope and content of a patent application, the 20 document threshold may encourage an applicant to delay the filing of an IDS in contemplation of a restriction requirement, contrary to the goals of the PTO. When making an election, the IDS can be filed with documents that relate to the elected invention that would be less likely to exceed the 20 document threshold. While this choice is

perhaps risky, it would be less risky and less costly in the long run than trying to comply with the proposed enhanced disclosure requirements. This is but one example of the strategies that practitioners would develop and employ to avoid the harmful effects of the proposed rules.

AIPLA further recommends that the exceptions to the proposed requirement for an explanation be expanded to include those documents cited in a related U.S. application, including the PTO actions that the Federal Circuit has determined may be material to patentability. *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 66 USPQ2d 1801 (Fed. Cir. 2003). The lower courts have indicated that documents cited in a foreign search or examination report may create an especially strong inference that the documents are material when they are cited or used in a rejection. MPEP 2001.06(a). Similarly, and even more strongly, the courts have held that the rejection of a claim in a related application is material to patentability of a similar claim in a second application. MPEP 2001.06(b). Since the courts have not defined how “similar” a claim has to be to trigger this requirement, applicants require a wide latitude in submitting information cited and applied in related applications.

In addition, AIPLA recommends that the continuing duty to apprise the PTO of the actions of examiners in applications with “similar” claims can be expeditiously handled by instructing examiners to update their consideration of cited applications, which information is currently available to each examiner in electronic form, whenever the search is updated. This would avoid supplemental IDSs in all related applications whenever an action is issued or an amendment filed in a related application.

AIPLA also recommends that the PTO explore other mechanisms for addressing the submission of an IDS that cites non-word searchable documents in excess of 50. For example, applicants could be required to pay a fee to compensate the PTO for the additional work required for consideration of an excessive number of documents, and/or the examiner could receive compensation for cases or dockets in which applicants file an excessive number of documents in an IDS.

Section 1.98(a)(3)(ii)

This proposed section would require that any document cited in the second time period between a first Office action and a notice of allowability would be required to be accompanied by an Explanation and a non-cumulative description in compliance with paragraph (a)(3)(v) of this section (hereinafter “Non-Cumulative Description”), except for documents that were cited in a foreign search or examination report and submitted with a § 1.97(e)(1) certification or cited in reply to a requirement for information pursuant to § 1.105. The requirement for a Non-Cumulative Description would require a description of how each document cited is not merely cumulative of any other document in the record of the application, whether cited in a previous IDS, cited by an examiner, or cited under §§ 1.99 or 1.291.

As readily acknowledged by the PTO in proposed § 1.98(c), this requirement is intended to place the burden on applicants to eliminate the citation of documents that are merely cumulative of other documents in the record of the application or reexamination proceeding. This requirement would place applicants in the untenable position of filtering out information for submission to the PTO that the courts have repeatedly held should be submitted to the PTO for consideration. The Federal Circuit has repeatedly emphasized that when the question of materiality is close, a patent applicant should err on the side of disclosure. *LNP Engineering Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1360-61, 61 USPQ2d 1193, 1203 (Fed. Cir. 2001), citing *La Bounty Mfg. v. US Int’l Trade Comm’n*, 958 F.2d 1066, 1076, 22 USPQ2d 1025, 1033 (Fed. Cir. 1992). A chilling reminder of the difficulty, in many cases, of determining what is a close case or when information is cumulative can be found in *Loral Fairchild Corp. v. Victor Co. of Japan Ltd.*, 61 USPQ2d 1943, 1947 (E.D. NY 2002) where the court held that:

An applicant may not, however, withhold what he considers cumulative information where a reasonable examiner might likely arrive at an opposite determination. The applicant must disclose the information to the examiner who will then determine whether the information is cumulative.

The courts simply do not agree that information that may be cumulative should not be submitted for consideration by the PTO, particularly where the question of materiality may be close. It is manifestly unfair and untenable for the PTO to suggest that documents may not be submitted to the PTO that courts require to be submitted for an appropriate determination by the PTO.

In addition to conflicting with established case law, there are other good reasons why the PTO should not use applicants as a filter to eliminate the submission of cumulative information. Materiality is determined from the viewpoint of a reasonable patent examiner, and not the subjective beliefs of the patentee. *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer Inc.*, 326 F.3d 1226, 1238, 66 USPQ2d 1481, 1488 (Fed. Cir. 2003). In this case, the views of an inventor regarding materiality were dismissed as unpersuasive because they were regarded as the self-serving testimony of an interested witness, supported by neither objective evidence nor by the testimony of an independent expert. A patent examiner is in a much better position to objectively judge whether a teaching is cumulative.

It would be a waste of resources to spend the time and effort to make a determination of whether information is cumulative to information already present in the record of an application, unless necessary for a finding of materiality in an inequitable conduct determination. Requiring USPTO examiners to police this requirement would waste resources, and if the examiners are not going to police this requirement, the requirement should not be imposed. Accordingly, the PTO should withdraw the requirement for a Non-Cumulative Description of a document submitted at any point in the examination process. In the unfortunate event that the PTO retains this requirement, for the reasons presented above, the PTO should add an exception for documents cited in a related application containing similar claims.

Section 1.98(a)(3)(iii)

This proposed section would require that all documents cited in an IDS submitted after a notice of allowance would require both a certification pursuant to § 1.97(e) and a patentability justification pursuant to either paragraph (a)(3)(vi)(A) or (a)(3)(vi)(B) of this section (hereinafter "Patentability Justification"). A Patentability Justification submitted before the payment of the issue fee would require that each document be accompanied by an Explanation, a Non-Cumulative Description, and reasons why the claims are patentable over the information in the IDS considered alone, or in combination with any information already of record. A Patentability Justification supplied after the issue fee was paid would have to satisfy similar requirements, but in addition contain an admission that at least one claim was unpatentable over the information in the submitted IDS, either alone or in combination with any information already of record, an amendment, and the reasons why the amendment causes the claims to now be patentable over the information. A Patentability Justification submitted after the payment of the issue fee also would have to be accompanied by a petition to withdraw the application from issue or a reexamination proceeding from publication.

As we understand these proposed provisions, after a notice of allowance is mailed the Office would only consider documents for which a certification pursuant to § 1.97(e) can be made and when accompanied by the appropriate Patentability Justification. This would prevent the PTO from considering information that was belatedly discovered or where the potential materiality was belatedly appreciated. The observations made above with respect to the requirement for a Non-Cumulative Description are incorporated herein. The proposed requirements may make some sense, at least in the context of the production system at the PTO, if an applicant were given an opportunity to file an RCE or a continuation application to have new information considered after the notice of allowance is mailed. However, given the proposed limitations on applicants to continue the prosecution of subject matter beyond the first continuation or RCE, the PTO would be denied the opportunity to assess the materiality of information that cannot meet the requirements of this proposed section. Such a barrier to the submission of potentially important information would not contribute to the quality of examination or the reliability of patents or decisions made by the PTO in the examination process.

If the proposed rule were modified so that a certification under § 1.97(e) could be made where the information was belatedly discovered or where the potential materiality was belatedly appreciated, it could be beneficial. In particular, by filing a Patentability Justification, the applicant could have prior art

considered without withdrawing a case from issuance and filing an RCE. This would be an improvement in the office's processing of cases to issues, would be less expensive for the applicant, and would allow the applicant, to receive the patent in less time.

Section 1.98(a)(3)(vii)

This proposed paragraph would establish the principle that unless an IDS is submitted in compliance with new requirements, the Office may decline to consider the IDS. We acknowledge that, if the PTO is going to adopt these new requirements, there must be some consequence associated with failing to comply with the requirements. However, the PTO must recognize that whether or not a particular IDS is determined to meet all the new requirements is going to be subject to a great deal of variability among practitioners and patent examiners. This variability, aggravated by requirements that are themselves vague and uncertain, would not contribute to the efficiency of the examination process. The imposition of new requirements and the administrative review that would be necessary to ensure meaningful compliance undoubtedly would diminish the efficiency of the examination process and direct examining resources away from substantive examination. The PTO's recent management of restriction practice, entry of amendments after final Office action, and Rule 1.105 requests for information, strongly suggests that the proposed practice may not be beneficial to either examiners or practitioners. The complexity of the new proposals alone would make it more difficult for examiners and practitioners, acting in good faith, to follow the rules as adopted at a time that the PTO might better focus its attention on the determination of patentability.

Section 1.98(a)(3)(ix)

This proposed section would impose a new requirement for applicants when presenting an amendment to the claims or to the specification affecting the scope of the claims, other than an examiner's amendment after submitting an IDS. This proposal would require an applicant to review any previously filed Explanation for all previous IDS citations, and update them where necessary in view of the amendment(s). As an alternative, a statement would have to be supplied to the effect that updating of the previous Explanation(s) submitted with an IDS of record is not needed. As we understand this proposal, only a statement indicating that updating is not required needs to be supplied when none of the cited documents required an Explanation, e.g., where there were fewer than 21 documents cited, all were in the English language, and none exceeded the 25 page limit. Please clarify this provision.

The PTO has not made clear the consequences for failure to provide either an updated statement or a statement that no updating is needed. If this proposal is adopted, the PTO should treat such an omission as inadvertent, and provide additional time to comply with this requirement. This is another administrative task that would cause delay in the examination process and divert scarce examination resources from the primary task of determining patentability.

The proposed updating requirement is unnecessary because the required Explanation requires only an identification of a specific feature, showing, or teaching that caused a document to be cited. This is not understood to be a requirement for an exhaustive identification of all potentially relevant teachings in that document. In any event, any subsequent amendment to the claims or specification would not alter the specific feature, showing, or teaching that caused the document to be cited. If the PTO is suggesting that all documents cited in any existing IDS be reviewed to identify the presence of any limitation or text added by amendment, it should provide a more clear statement of that intent.

Section 1.98(a)(3)(xi)

This proposed paragraph would adopt the existing requirement for a translation of a non-English language document where a translation is within the possession, custody, or control of, or is readily available to, any individual having a duty to disclose information to the PTO. Although it does not appear that the PTO intends any change in this requirement, a question has been raised as to whether machine translations, for example, as available from the JPO for Japanese language patent documents, would be considered readily available and within the scope of this requirement. It is our understanding that the

machine translations do not yet enjoy a reputation for accuracy. If such a translation were supplied to the PTO, the practitioner would not be in a position to state that it was either complete or accurate. Please clarify the PTO's position on this issue.

Continuing Application Policy/Practice

Please clarify the meaning of the paragraph bridging pages 38813-14 of the Federal Register Notice pertaining to continuing applications. As we understand the paragraph, documents cited in any IDS filed in a parent application would not be considered as part of the cumulative total in a continuing application unless the documents were resubmitted in the continuing application so that they would appear on the face of the patent that issues from the continuing application. Thus, an examiner would be required to consider the documents cited in a parent application in any IDS filed in a parent application that complied with the requirements that were applicable at the time it was filed, but would not consider documents cited in a non-compliant IDS unless the documents were resubmitted in the continuing application.

If our understanding is correct, this proposal would discourage applicants from citing documents in a continuing application that had been cited in a compliant IDS in a parent application, because they would then be counted toward the threshold number of 20 that would trigger additional disclosure requirements. This would be both unfortunate and unfair to applicants who may cite documents from a parent application in a continuing application to obtain confirmation from the examiner that documents they are expected to consider have been considered. Examiners are expected to record in the file wrapper that they have reviewed the art cited in a parent application. MPEP 719.05(E). Examiners are further expected to indicate in the first Office action in a continuing application whether the prior art in a related earlier application has been reviewed. MPEP 2001.06(b).

We are aware of cases that have ruled that it cannot be inequitable conduct for an applicant not to resubmit, in a divisional application, the information that was cited or submitted in the parent application. *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 547, 48 USPQ2d 1321, 1330 (Fed. Cir. 1998). On the other hand, we are also aware of cases that have held that the lack of any objective evidence that the examiner reviewed an article in connection with his review of the patent application supports a finding that the article was not before the PTO. *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1236, 66 USPQ2d 1481, 1487 (Fed. Cir. 2003). How will a court view a record that does not acknowledge that an examiner has considered documents cited in a parent application?

In short, confirmation by the PTO that the examiner has performed the obligation expected is better practice. If the PTO adopts proposals that further complicate the IDS process, AIPLA requests that the PTO develop a simple mechanism (e.g., a separate listing entitled "Parent Application Citations") that would permit the citation of documents, supplied in a compliant IDS in a parent case, in a continuing application without counting toward the threshold number of documents that would trigger additional disclosure requirements.

Section 1.99 Third Party Submission in Published Application

This section is proposed to be amended to expand the period during which a third party may submit information in the form of patents or publications relevant to a pending published application. The period would be extended from two months from the date of publication to six months from the date of publication of the application or prior to the mailing of a notice of allowance, whichever is earlier. AIPLA supports the expansion of this time period, but suggests that the period extend up to the mailing of the first action on the merits. For applications that are not examined for several years, it seems unnecessary to limit the opportunity for third parties to submit relevant information to six months from the publication date. Permitting information to be supplied before the mailing of the first action on the merits would also promote the PTO's efforts to obtain the most relevant prior art before the first substantive action.

Section 1.291 Protests by the Public Against Pending Applications

Revisions of this section have been proposed to clarify and rearrange the procedures and requirements for filing a protest against a pending application. Proposed paragraph (b)(3) would highlight the options that an applicant currently has in treating unsolicited information received from someone who is not associated with the patent applicant or those individuals substantively involved with the preparation or prosecution of the application. According to this paragraph, applicants have the wholly unsatisfactory options of submitting the information as an IDS in compliance with the proposed new requirements, providing written consent to file a protest in the PTO to the party that has supplied the unsolicited information, if known, or submitting the unsolicited information in the form of a protest in compliance with § 1.291(c) on behalf of the person supplying the unsolicited information.

An applicant who does not want to spend the resources and take the risks necessary to file an IDS or a protest on behalf of the third party (which would require providing a concise explanation of the relevance of each document and an English language translation of any foreign language document) should be required to consent to submission of a protest by the third party within a reasonable period of time. However, failure of the third party to accept that invitation should not place an applicant in a position that would necessitate the filing of an IDS or a protest on behalf of the third party. Failure to provide other relief to an applicant in possession of unsolicited information places the PTO in the position of aiding an effort by the third party to burden the applicant with the costs and risks that would necessarily follow from the remaining options. This is another proposal that would be especially prejudicial to small entity applicants.

AIPLA recommends that the PTO provide a fourth option to an applicant in possession of unsolicited information. If an applicant does not choose to file an IDS or a protest on behalf of the third party, the applicant must provide consent to the third party to file the unsolicited information with the PTO as a protest. However, if the third party does not file the protest, the applicant should have the option of filing the unsolicited information with the PTO, along with any commentary on that information supplied by the third party, without needing to satisfy any additional IDS requirements. The examiner would be expected to consider the items filed in this manner in the same manner as any other document supplied in an IDS - i.e., by making an initial brief review to determine whether the items warrant a more in-depth study, coupled with a more thorough review of any items of particular interest.

In its commentary on the proposed rules, the PTO suggests that applicant's knowledge of prior art gained during litigation or through license negotiations "may qualify...as receiving unsolicited information." 71 Fed. Reg. at 38817. Why the uncertainty? What are the factors that will permit applicants to determine, without another costly, time-consuming, wasteful interaction with the PTO, whether such material qualifies as "unsolicited information?" In the unfortunate event that these provisions are adopted, the PTO is requested to provide guidance that would reduce the difficulties and ambiguities created by these situations.

Paragraph (c)(2) would be revised to set forth that items in a compliant protest would be considered by the examiner, at least to the extent of the provided explanations. AIPLA suggests that items in a compliant protest should be considered for all that they reasonably teach to a person of ordinary skill in the relevant art, and not only to the extent that a protestor provides an explanation of the portions of any document that it relies upon in asserting a position of unpatentability. Whatever the depth of consideration by the examiner, the document as a whole should be considered rather than only those portions deemed relevant by a protestor.

Section 312 Amendments After Allowance

This section is proposed to be amended to permit certain amendments filed after mailing of a notice of allowance to be entered without withdrawal of the application from issue. AIPLA supports these amendments that both clarify the practice and provide an explicit authorization to file amendments after

the date the issue fee is paid. We understand that if the patent does not include the amendment filed after payment of the issue fee, the amendment would not be effective unless the patent is corrected by a Certificate of Correction or other post-issuance proceeding. As noted above, we encourage the PTO to provide the staff necessary to process these amendments before the patent is granted, and to process requests for Certificates of Correction when the patent does not contain the requested amendments.

Section 1.555 Information Material to Patentability in Reexamination Proceedings

This section is proposed to be amended to make explicit that information disclosure statements may be filed during a reexamination proceeding so long as they comply with §§ 1.97 and 1.98. As noted above, AIPLA supports this revision to the extent that it provides greater clarity and transparency for the consideration of an IDS submitted in a reexamination proceeding. However, our reservations and concerns about most of the new requirements in proposed § 1.98 would apply equally to their applicability in reexamination proceedings.

Section 1.948 Limitations on Submission of Prior Art by Third Party Requester Following the Order for Inter Partes Reexamination

This section is proposed to be amended to set forth that the provisions of § 1.98 would apply to a third party requester of an *inter partes* reexamination. AIPLA supports this revision.

We appreciate the opportunity to provide comments on the proposed rules and stand ready to assist the PTO in further developing patent practice and procedures.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael K. Kirk". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Michael K. Kirk
Executive Director