September 27, 2006

The Honorable Jon W. Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office
Mail Stop Comments-Patents
P.O. Box 1450
Alexandria, VA 22313–1450
Attention: Robert A. Clarke

Submitted by email to: AB95.comments@uspto.gov

Re: 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:

I am writing on behalf of Intellectual Property Owners Association (IPO) to comment on the proposed changes to Information Disclosure Statement Requirements as published in the Federal Register on July 10, 2006.

IPO is a national, U.S.-based trade association of more than 200 companies and a total of more than 8,500 individuals who are involved in the association either through their companies or as IPO inventor, author, executive, law firm or attorney members. Our corporate members file approximately 30 percent of the patent applications filed at the USPTO by U.S. nationals. We believe patent laws and rules should generally apply in the same way to all industries and technologies. Patent laws and rules should be designed to provide strong incentives for innovation while minimizing expenses for patent applicants and owners.

IPO supports the proposition that for quality patent examination it is necessary for the Examiner to consider all relevant prior art. We also understand the Office is concerned that relevant art may be buried in massive submissions and that Examiners may lack the time to adequately consider all that is submitted. We submit, however, that the proposed rules as a whole create more problems than they solve and urge a reconsideration of most of the proposals.

Our members are concerned that the proposed rules would:

(1) Impose a significant burden on all applicants to correct the perceived abuses of only a few; and

(2) Subject applicants and their counsel to an increased legal risk of a finding of inequitable conduct if any mistakes are made in the submission.

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USPTO statistics show that 85 percent of applications present 20 or fewer references in their disclosures. Some art areas, such as biotechnology, may require a larger number of submissions than other technology areas as a result of related academic publications to meet the applicant's disclosure obligation. We recommend that the USPTO further analyze the number of references submitted by applicants in each art unit. This data might support the proposition that the size of an adequate submission varies depending on the particular technology, and could support the formulation of rules to specifically address the problem.

The proposed rules, however, have a much broader reach imposing a burdensome obligation on all applicants rather than specifically addressing the perceived abuses of only a few. The proposed Rule 1.98 requires an "explanation" which includes an "identification" and "correlation" of all references if more than twenty are submitted or for any reference of more than 25 pages. The costs of these proposals are likely to be much greater than that suggested by the Office. Applicants and their attorneys are required by the rules to be absolutely correct in their analysis of each reference or else risk losing their patent rights due to inequitable conduct.

The proposed rules also require an affirmative statement that a reference is non-cumulative and impose an obligation on the applicant to review and update statements whenever an amendment is made. In the litigation context, the characterization of a reference as cumulative or the absence of an updated explanation could be the basis for an inequitable conduct charge. Whether a reference is cumulative or non-cumulative is a subjective question. Arguing this case could require substantial litigation to resolve and could result in severe consequences for a patentee who in hindsight made the wrong decision. Accordingly, we believe the requirements are overly burdensome and will increase both the cost of patent litigation and the risk that a patent will be found unenforceable due to inequitable conduct. Although the USPTO suggests creation of a "safe harbor" for good faith efforts, this safe harbor would not be binding on the courts absent legislation. IPO believes that a legislative change needs to precede such a substantive change to current rules.

Correlation of references to claims will constitute an admission on the part of the applicant, and it will serve as a limiting prosecution history statement. Although the proposal rules retain section 1.97(g), which states that disclosure does not admit materiality, the requirement that only relevant, non-cumulative art be disclosed appears to be in direct contradiction to this section.

The introduction to the proposed rules indicates that the intent is to encourage early submission of prior art, but the proposal leaves the applicant with late-discovered art no satisfactory option to file that art. When combined with the proposed rules limiting continuations, these rules may leave an applicant without a means to have its application properly examined.

Although related applications often generate prior art relevant to a particular application, the rules make no provision to encourage filing of information from related applications. This art has already been considered by the Office and should be exempt from any limitation on pages or number of references. It would be more expedient for examination and less costly if the USPTO proposed a means to combine related applications.

IPO would like to work with the USPTO to address the causes of information disclosure inefficiencies. We support efforts to curb disclosure abuse. In particular, we recommend that the objective of reducing disclosure volumes be achieved by adopting an increasing fee structure for larger disclosures or by combining related applications. This added fee should be used to enable the examiners to spend additional time on a case with a greater number of disclosures so that the application receives a quality examination. No limitation on the number of references should be specified.

Thank you for the opportunity to comment on these proposed rules. We hope to continue to discuss such proposed changes with the USPTO in a frank and constructive way to improve the system for all users. A more detailed discussion of the issues can be found in the APPENDIX.

Sincerely,

Marc S. Adler
President

(APPENDIX attached)

APPENDIX
Detailed Comments on Notice of Proposed Rulemaking, "Changes To Information Disclosure Statement Requirements and Other Related Matters," 71 Fed. Reg. 38808 (July 10, 2006)

Introduction

IPO supports the proposition that patent quality requires the Examiner to consider all relevant art during examination. We also understand the Office concern that relevant art may be buried in massive submissions. We submit, however, that the proposed rules create more problems than they solve and urge a reconsideration of many of the proposals.

Under existing law, a patent applicant must provide the U.S. Patent and Trademark Office (USPTO) with any type of material information. An applicant provides a simple list of documents or other items of information that are being submitted, the Examiner reviews the information, checks off the list and sends a copy back to the applicant. The issued patent then lists the information that was considered. The courts have long noted that providing this information is an affirmative duty and breach of that duty renders the patent unenforceable. The USPTO charges a fee to consider the information, unless the information is provided to the USPTO before the USPTO begins to examine the application for the first time.

The Information Disclosure Statement (IDS) process has been a well integrated, procedurally-balanced system. An imbalance in the system is that the USPTO has under-priced the fee that charged for reviewing prior art submitted after examination. That fee should probably increase from $180, where it has been for almost fifteen years. The additional funds generated by this change could be used by the USPTO to provide the examining corps additional time to review applications with atypically large numbers of submitted references and/or large numbers of pages in such submitted references.

The proposed rules upset this settled practice, and make it extraordinarily difficult for applicants to meet their duties. The problems are especially acute for (a) patent applications for which a preliminary patentability search has been conducted, as is often the case with larger corporations (thus penalizing such corporations for likely making the examination process more efficient by pre-locating many of the most relevant references), (b) patent applications in a "crowded field" where the field might contain more than 20 relevant prior art patents or scholarly articles (especially biotech and computers), and (c) when information becomes known to an applicant after the USPTO's first consideration of the application, for example, where several related applications are pending before several different examiners, each of which has a different view of what prior art is most relevant.

The proposed rules require some applicants to submit an extraordinarily onerous discussion of every such piece of information. This discussion must make a number of admissions that may be damaging to patent rights, and each discussion must be 100 percent accurate, to avoid a risk of losing enforceability of the patent. (Under the "duty of candor and good faith" that requires applicants to disclose the information in the first place, a misstatement can have the same consequences as non-disclosure.) The proposed rules would require that this discussion must be updated every time the application is amended.

The proposed rules do include helpful provision that will (1) lengthen the period for third-parties to submit prior art from two months after publication until six months after publication (proposed rule 1.99) and (2) enable an applicant to voluntarily permit a third party submitter of prior art to file a protest that discusses in detail the relevance of any prior art they choose to submit (proposed rule 1.291).

The Proposed Rules are Overly Burdensome and Unclear

1) The USPTO proposes an "explanation" for "any English-language document over 25 pages." As defined by the USPTO, an "explanation" comprises both an "identification" of relevant portions and a "correlation" to the pending claims. The requirement for a "correlation" is burdensome and not needed if the "identification" is succinct, i.e. references less than 25 pages of the document.

2) There are two items in proposed Rule 1.98 which need to be clarified.

    a) Proposed rule 1.98(a)(1)(iii) specifies that each page of the IDS must include a "heading that clearly indicates that the list is an information disclosure statement." This phrase is not clear and it is suggested that the Office offer an example since the IDS could be technically not accepted because of an improper heading.

    b) In proposed Rule 1.98(a)(3)(c), the purpose and need of the expression "calculated cumulatively" is not understood.

3) Proposed rule 1.98(a)(3)(i) would require additional disclosure in the form of an explanation if more than 20 documents are submitted and/or if any document is over 25 pages. The proposed rule requires an explanation and non-cumulative description of the information which would render any such information *prima facie* material by admission. The "updating" section requires a review and updating for any and all amendments. While the rule as proposed states "where necessary in view of the amendment(s)", what substantive amendment would not require an update? Moreover, the proposed rule requires the practitioner to make a statement "to the effect that updating of the previous explanation(s) submitted with information disclosure statement(s) is not needed."

4) The cumulative documents provision in Section 1.98(c) should be withdrawn. As proposed, it would impose an additional burden on applicants to compare each document not only to the claimed subject matter, but also to all other documents cited.

5) Applicants are encouraged to submit references early. However, applicant must not submit "too many," as the USPTO warns about "burying" relevant references and the looming presence of inequitable conduct, p. 38809, col. 2, citing *Molins PLC v. Textron, Inc*., 48 F.3d 1172, 1184 (Fed. Cir. 1995) which lends to imprecise interpretations what is "too many."

6) The USPTO's proposal appears to indicate that the examiner will review the references in order "where review of an IDS reveals the presence of a pattern of merely cumulative information to such extent that the utility of further review of the IDS is called into question, the office may terminate **further review** of the IDS." This imposes an unjustified burden associated with the order in which documents are listed and subjects applicants to unreasonable attacks during litigation.

7) Additional disclosure exceptions based on citation by a foreign patent office in a counterpart application apply only during the first two stages (up to receipt of Notice of Allowance). It is not clear how an applicant would be expected to handle a situation where foreign prosecution lags U.S. prosecution. How should citation of a reference not disclosed in the U.S. case be handled after receipt of a Notice of Allowance?

8) Early and potentially limiting interpretations of references and the application must be placed on the record by applicants, either explicitly or impliedly possibly before all art has been developed.

    a) Regarding Identification (first part of Explanation requirement, proposed CFR 1.98(a)(iv)(A)): Applicant must point to a specific teaching in a submitted reference.

Since only one occurrence needs to be pointed to, is this subject to inquiry, e.g., that the more pertinent occurrence was hidden?

b) Regarding Correlation (second part of explanation requirement, proposed CFR 1.98(a)(iv)(B)): Applicant must correlate the specific teaching in submitted reference to a corresponding specific claim language (or portion of specification) in application. Will this requirement serve as an entrapment for the inadvertent failure to point out **all** relevant claims?

c) Regarding Non-cumulative Description (proposed CFR 1.98(a)(v)): Applicant must determine the specific teaching in reference that is not found in any of previously submitted references. A reference's teaching could be quite expansive and complex – one could foresee finding a new reference cumulative in most areas but not cumulative in terms of one claimed element.

9) The failure to submit a reference supposedly implies that the reference is cumulative. However, applicant may have decided not to cite a reference for other reasons, such as non-relevance to claimed subject matter.

10) How does developing technology that changes the routine skill level of one of ordinary skill affect the analysis of prior art? Could situations arise where an applicant considers a reference as cumulative or marginal, but, due to developing technology, that reference becomes non-cumulative or not marginal? Are applicants at risk of inequitable conduct because they did not initially submit this reference? Is there a continuous obligation to re-evaluate references relative to this cumulative aspect?

11) During the 3rd and 4th stages (after Notice of Allowance), what is the likelihood that an applicant will place on the record positions of patentability based on newly-found, non-cumulative art? If a non-cumulative reference is found during these later stages of prosecution, many practitioners would likely file a continuation application and abandon current application rather than put patentability reasons on the record. This would increase filings, which would go counter to the recent proposed rule on reducing filings of continuation applications.

12) Even if the proposed safe harbor is recognized by the courts (or implemented by Congress), applicants will still have concerns regarding the impact of their statements placed in the record concerning:

a) characterization of prior art;

b) correlation of specific teachings in prior art to specific claim language; and

c) patentability and unpatentability positions.

13) The proposals will lead to more uncertainty in patent litigation and possibly increase the amount and cost of such litigation. The Notice discusses only obligations under the USPTO's Rule 56, but is silent about the judicially-created equitable doctrine of "inequitable conduct." The two bodies of law are distinct. They originate from different heads of authority, they have different scope, different threshold standards apply, different tribunals have subject matter jurisdiction, and the consequences are different. Most importantly, the USPTO can amend Rule 56 on its own authority, but has no authority to alter the substantive law of inequitable conduct. The rules introduce new obligations on applicant and counsel which can serve as a basis for charges of inequitable conduct in any subsequent litigation. The characterization of references as cumulative (or not) is likely to be a ripe source of inequitable conduct allegations.

The Safe Harbor Provision May Be Ineffective To Protect Applicant

1) The Notice indicates at several points that an essential *quid pro quo* for the entire rule package is the creation of a "safe harbor" for an individual that states that he or she "acted in good faith to comply with the disclosure requirements by having a reasonable good faith basis," (proposed 37 C.F.R. § 1.56(f)), and that "the Office is hopeful that a court in deciding a duty of disclosure issue will take the proposed safe harbor into account." The Notice identifies no basis for the USPTO's "hope." It is expected that in a litigation situation, one party will likely share the USPTO's "hope," while the opposing party is likely to have a different "hope."

2) A practitioner may unintentionally mischaracterize a reference to the USPTO if he or she: (i) misreads a reference; or (ii) fails to appreciate the significance of the reference because of information buried in the reference. In such a situation, allegations of inequitable conduct could be made and the fact that the reference was submitted under the proposed rules may establish by admission in court that the reference is material, notwithstanding rule 1. 97(h), which would make it much easier to prove inequitable conduct. The alleged infringer might only need to provide some evidence of intent such as the practitioner knowing of the reference and therefore being chargeable with knowledge of its content. The courts may not accept the above listed reasons for mischaracterization as supporting a "good faith" defense argument. They are likely to require contemporaneous evidence of "good faith" review which may not be readily available.

3) Further, in such a situation, the practitioner could be subject to the USPTO Disciplinary Rules. USPTO Disciplinary Rule 10.23(b)(4) only requires that the practitioner engage in a misrepresentation. There is no requirement that he or she know at the time that he or she was making a misrepresentation. If a practitioner does not take the time to update and review the IDS and makes the required statement, then under USPTO Disciplinary Rule 10.23(d) the Office could regard this as acting in reckless indifference as to whether the statement is true or false and under the Disciplinary Rule the Office would take the position that the practitioner would be charged with knowledge of its falsity. The practitioner could make a "good faith" argument, but this would require some contemporaneous evidence, which he or she may not have.

4) As a practical matter, the proposed IDS rules will require applicants to risk breaching the requirements of substantive law, or surrendering substantial patent coverage when interpreting references.

Time Period Comments

Regarding the various time periods laid out for filing an IDS, we make the following comments:

First Period

- The new IDS requirements impose a heavy burden on applicants. With respect to the twenty-document limit, applicants may have to choose between not citing a reference, which may open up the resulting patent to an inequitable conduct challenge in subsequent litigation, or providing an "explanation" to the Patent Office, which may also raise a charge of inequitable conduct for misleading the Office or otherwise weaken the validity of the patent in subsequent litigation.

- The requirement of an "explanation" for documents over 25 pages is unduly burdensome. Applicants have no control of the size of the documents that end up being submitted in an

IDS. In particular, patent documents are routinely more than 25 pages in some technologies. Although applicants are permitted and encouraged by the Office to submit only portions of documents to avoid submitting documents over 25 pages, such selective submission will almost certainly result in increased charges of inequitable conduct during subsequent litigation. The selection of the "relevant" portions of a document will in many cases be unclear and non-routine.

- The requirement of an "explanation" for a foreign language document is also burdensome. Non-English language documents accompanied by an English language abstract are routinely found in the results of in-house novelty searches. Preparation of the "explanation" would virtually always require obtaining and carefully reading an English translation which would substantially increase the cost and time required in the preparation of an IDS.

Second Period

- Applicants may need to submit documents during the second period that were not cited by a foreign patent office in a counterpart application. The requirement of an "explanation" and "non-cumulative description" is unduly burdensome on applicants and will almost certainly result in increased charges of inequitable conduct during any subsequent litigation. Coupled with the proposed rules limiting continuation practice, applicants are left with no good options for making such documents of record.

Third & Fourth Periods

- Applicants have no control over the timing of search reports issued from foreign patent offices for counterpart applications. If such a search report issues during period three, applicants are required to provide a very burdensome "patentability justification." During period four, the "patentability justification" must include an unequivocal statement that one or more claims are "unpatentable" in view of the cited art. When faced with a foreign patent office citation during periods three or four, the timing of which is totally outside applicants' control, there is no good option for getting the information before the Office.

The Proposed Rules Undermine the Objectives of the Information Disclosure Statement

1) The Proposal Makes No Provision for Prior Art Developed in Companion U.S. Applications

   a) The Notice correctly notes that prior art often comes to light after the first Office Action, and makes allowances. However, the Notice fails to recognize the single largest source of late-developed prior art: related U.S. applications. Applicants are obligated to disclose such prior art to all other related applications, even if it arises after the first Office Action. *Elk Corp. of Dallas v. GAF Building Materials Corp.*, 168 F.3d 28, 31, 49 USPQ2d 1853, 1856 (Fed. Cir. 1999) (rendering a patent unenforceable when prior art developed in a daughter application was not disclosed to the examiner of the parent application).

   b) This omission from this IDS rule package is especially of concern in view of the "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" (71 Fed. Reg. 48, January 3, 2006) rule package. The "Continuing Applications" rule package would require all claims for all contemporaneous inventions to be filed

together, and allow the USPTO to divide them. The effect of the "Continuing Applications" rule package will be more applications that are linked by direct priority claims. Yet this IDS rule package makes it extraordinarily costly to cross-cite art that arises from the situation that the "Continuing Applications" rule package proposes to create.

2) The actual costs of the rule package are likely to be much greater than suggested in the rule proposal. The costs appear to reflect the time an Examiner might spend on such an analysis. Applicant will need to spend more time because:

    a) An examiner is allowed to be wrong. An applicant must be 100 percent right.

    b) As noted in the PTO's public forum in April in New York, examiners have no liability and face no repercussions for being wrong. On the other hand, if an applicant makes an incorrect concession in an IDS discussion, the patentee will be bound by that admission. If an applicant admits too little, the patentee faces charges of inequitable conduct. The IDS discussion that the Office proposes will require great care, and some IPO members have asserted it may take up to 30 hours *per reference*. If the average application subject to the rule has 30 references, an average response could take about two months of full time work to prepare, and could reach a cost of $200,000. If the rule is applied to 10,000 applications per year, the cost could be over one billion dollars. The USPTO states no basis for its "Estimated Time Per Response" of "1.8 minutes to 12 hours" per application.

The Costs of the IDS Rules Harm Small Entities

1) The Rules package ignores the economics that drive applicant behavior.

    a) First, patent applications with lots of references arise out of only one circumstance: a patent application to cover a valuable invention. Applicants and potential infringers need to have these applications searched and examined thoroughly. Applicants will pay the USPTO's costs for doing so. If the USPTO sets its fee levels to match its costs the USPTO will find that applicants will provide the resources necessary to examine applications properly.

    b) Second, important patent applications frequently arise from small entities: when a small entity invests in a patent, the small entity hopes to build a business around that invention. Small entities cannot afford to litigate – the strength of the patent must be thoroughly vetted during prosecution, typically by doing a thorough patentability search and filing many of the references discovered.

2) The proposal penalizes the inventors of the most economically-important inventions. The proposed IDS rules are bad public policy, and could violate the Regulatory Flexibility Act and Executive Order 13272.

3) Eliminating the IDS Fee is inefficient and bad policy:

    a) In 1992, the Office noted that the fee for after-first-action IDS filings was intended to compensate for the added costs of later examination. Matching revenues to costs is fundamental to the financial freedoms the USPTO was given in 2000 when it was made a "Performance Based Organization." Decoupling costs and fees will create perverse incentives, and further skew the misallocation of examining resources.

    b) Current practice recognizes that examiners are in the best position to evaluate references efficiently. When a reference is of only marginal relevance requiring a written discussion of it is simply inefficient "busy work" for the applicant and will require examiners to spend time reading non-relevant discussions. Examiners are well-situated to look at a

reference, note its marginal relevance, and move on, without spending inordinate and unproductive time documenting that fact.

c) Requiring the applicant pay a higher fee for large IDS submissions (as proposed below) would further the objective of quality patent examination.

Alternative Proposals

1) A workable long term solution should include these elements:

   a) Patent applications must be examined by the USPTO. Applicants may be required to identify the most relevant references, but comparing references to claims is an examination task for examiners, not an application task for applicants. Applicants might be encouraged to identify the particular portions of a large reference that caused it to be cited[1], but should not be required to identify "specific feature(s), showing(s), or teaching(s)."

   b) The USPTO should measure the costs associated with certain services provided by the USPTO, and set its fee levels accordingly. For example, the fee schedule for an IDS might be as follows (the numbers are pure first "guesstimates"):

      i) for each reference first disclosed after the first twenty (or fifteen) references and/or for any reference disclosed after the first Office Action (and not cited by a foreign patent authority or by the USPTO in a related application issued within three months of filing the IDS): $30;

      ii) for each X1 pages by which a reference exceeds X2 pages: $20;

      iii) the above fees are eliminated if an applicant provides the discussion requested in the rule package; and

      iv) the above fees double if the reference is filed after prosecution is closed.

   c) The fees charged by the USPTO for "extra examination" (whether of excess claims, large specifications, or numerous references) could be passed through to examiners in the form of extra examination time. For example, the USPTO could estimate the additional examining time required for applications having atypically large numbers of submitted references and/or large amounts of pages within submitted references. Based on this estimation, the USPTO could use the additional funds that would be charged for such references to provide such necessary additional examining time to the examining corps as it deems appropriate.

2) The abuses identified in the Notice are more amenable to adjudication on a case-by-case basis under Rule 56 than by the types of rules proposed. Any USPTO rulemaking should be narrowly tailored to the abuses. Applicants who are making a bona fide effort to secure strong patent protection for an important invention should pay the costs of that examination, but should not face "collective punishment" for the sins of a few.

3) Place no limit on the number of references submitted during the first period, to encourage applicants to submit all references prior to substantive examination and address the Office's concerns about applicants' delays.

4) Clarify the Office's standard of materiality under Rule 56. Limits on the number of references are in conflict with the duty to disclose under Rule 56.

[1] This should be satisfied by a statement of a reason that the reference is cited, for example, that it was made of record but not applied in a related application, even if it is not known to be relevant to this application.

5) The prior art cited in a **parent** application should be exempt from the 25 page rule and should not count towards the 20 document rule since this prior art has already been cited and fully considered by the USPTO in the **parent** application. MPEP 609.02 already provides that "[t]he examiner will consider information which has been considered by the Office in a parent application when examining (A) a continuation application filed under 37 CFR 1.53(b) (B) a divisional application filed under 37 CFR 1.53(b) or (C) a continuation-in-part application filed under 37 CFR 1.53(b). A listing of the information need not be resubmitted in the continuing application unless the applicant desires the information to be printed on the patent."

6) Prior art cited by a USPTO examiner in an Office Action in a related application should be treated at least the same, if not better than, prior art cited by an examiner in an Office Action in a related application in a foreign patent office. Therefore, all prior art cited by a USPTO examiner in an Office Action in a related application filed within three months of the Office Action should be exempted from the 25 page rule, should not count towards the 20 document rule, and should be exempted from the explanation and non-cumulative description requirements.

7) A "Listing of Related Applications" filed pursuant to 37 CFR 1.78 to inform the examiner of those related applications is not an IDS and therefore the applications listed on the "Listing of Related Applications" should not count towards the 20 document rule.

Conclusion

The proposed rules add considerable uncertainty and increased workload to the obligation to disclose relevant information to the USPTO. Disclosure of relevant information should be encouraged, but this proposal discourages disclosure. The risk of inequitable conduct allegations to the applicant and attorney is greatly increased. Enforcement mechanisms available under the current rules should be used to curb any abuses of the IDS system.

IPO recommends that the USPTO structure the IDS process to maximize the relevant information disclosed and set fees at the level necessary to support consideration of relevant information by the Examiners. Creating a workload-based fee allows the applicants to make better economic tradeoffs in the disclosure filing process.

IPO favors the proposals that would lengthen the period for third parties to submit prior art and permit an applicant to authorize a third party submitter of prior art to file a protest that discusses in detail the relevance of any prior art they choose to submit.

The remainder of the IDS rule package should be withdrawn.

** END **