Cost of Complying with the Proposed IDS Rule

Meeting at OMB, October 18, 2007

I have been asked to review certain aspects of USPTO's Proposed IDS Rule and a potentially related Information Collection Request -- specifically, matters related to costs, benefits and other effects, including costs associated with paperwork burden. The proposed Rule was published in July 2006,[1] and the draft final rule was submitted to OMB in July 2007. The request for comment on the ICR was published on August 21, 2007, in the preamble to the so-called "5-25 Rule.[2] The request for also mentions appeals, which may signal a relationship to a separate Notice of Proposed Rulemaking recently published by USPTO but not submitted to OMB for review.[3] Although the agenda for this meeting is strictly the draft final IDS Rule, I ask that USPTO and OMB treat this document as a provisional public comment on both the August 21st Federal Register notice and the September 26th ICR submission. It is not clear whether the ICR submission was intended to capture all paperwork burdens associated with this panoply of rulemakings. I believe it should.

I decline to reveal the identity of my clients. They have persuaded me that there is a reasonable expectation that revealing their identities could result in financially devastating retaliation with respect to patent applications now in process or which they would submit to USPTO in the future.

What Does USPTO Tell the Public about Costs, Benefits, and Other Effects?

NPRM. USPTO does not disclose any analysis of benefits, costs, or other effects in the NPRM. The entire relevant text reads as follows (71 Fed. Reg. 38819):

> *Executive Order 12866*
>
> This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

[1] "Changes To Information Disclosure Statement Requirements and Other Related Matters," 71 Fed. Reg. 38808.

[2] "Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications" ("5/25 Rule"), 72 Fed. Reg. 46835 (August 21, 2007).

[3] See "Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals," 72 Fed. Reg. 41472 (July 30, 2007). A fourth rule also might be implicated in this ICR: "Examination of Patent Applications That Include Claims Containing Alternative Language," 72 Fed. Reg. 44992 (August 10, 2007) ("proposed Markush Practice Rule").

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"Not significant" under EO 12866 normally is limited to regulatory actions that have minor consequences and elicit little or no controversy, such as housekeeping actions, and matters for which the agency is willing and able to perform internal oversight equivalent to that of OMB.

Regulations.gov. The NPRM is online at regulations.gov (PTO-P-2005-0024). However, no other USPTO documents or public comments are posted there.

USPTO website. No estimates of cost, benefits, or other effects are posted on USPTO's website. It contains only the following information:

- Executive Summary (1p)[4]
- Detailed Summary (5pp)[5]
- Slides (HTML format)[6]
- The Four Time Periods for Submitting an IDS and Their Corresponding Requirements (HTML)[7]
- Application Prosecution Timeline (HTML)[8]
- Public Comments[9]

Request for comment on ICR 0651-0031. The preamble to the 5-25 Rule asks for comment on substantive changes to this ICR. However, no specific ICR submission is referenced and the most apparently relevant ICR was not submitted to OMB until September 26, 2007. The request for comment concerns new information collection requirements resulting from the promulgation of the 5-25 Rule, but it also refers obliquely to elements related to information disclosure statements (IDSs) which are addressed by the draft final IDS Rule and the proposed Appeals and Markush Practice Rules.[10]

From the number of public comments submitted to USPTO (65), it is clear that the proposed IDS Rule is at least "significant" under EO 12866. From the contents of these comments, there is a *prima facie* case that the proposed IDS Rule has effects

[4] http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/idsexecsummary.pdf.
[5] http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/idsdetailedsummary.pdf.
[6] http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/idsnprslides.html.
[7] http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/idschart.html.
[8] http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/idsnprtimelineslides.html.
[9] http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab95/ids.htm.
[10] See Attachment B, excerpts highlighted in red underline for oblique references to the IDS and Appeals Rules. We cannot discern any connection to the proposed Markush Practice Rule (see footnote 3), but inasmuch as the proposed Markush Practice Rule also is economically significant but was not submitted to OMB for review under Executive Order 12,866, I prophylactically note the possible connection.

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exceeding $100 million in any one year, and thus is "economically significant." USPTO did not perform a Regulatory Impact Analysis (RIA), nor did it disclose the basis for its determination that the proposed rule is "not significant."

Because in all of the available modes USPTO revealed no useful information, my review required the use of alternative means to estimate costs.[11]

Developing a Third-Party Cost Estimate

I sought expert opinion from experienced patent attorneys. I specifically asked for an unbiased estimate – one that would adhere to applicable information quality standards published by OMB and USPTO.[12] One attorney agreed to provide me, *pro bono*, a cost estimate in the form of a declaration to which he was willing to swear under penalty of perjury.[13] This affiant is unrelated to my clients. However, to ensure that the affiant has the same protection from retaliation that my clients reasonably fear, I have redacted all personally identifiable information from the declaration.[14]

In this declaration, the affiant estimates that the cost of complying with the major provisions of the proposed IDS Rule is about $7.3 billion per year:[15]

- Applications in which more than 20 references are cited: $3.4 billion per year
- Additional explanations of foreign-language or moderately long references: $2.4 billion per year
- Requirements for citation of references after first Office action on the merits: $2.1 billion per year

Peer Review

Given the striking discrepancy between this cost estimate and USPTO's determination that the proposed IDS Rule is "not significant," I decided to seek

[11] I expended no effort at this time to estimate benefits. That would be an essential element of the Regulatory Impact Analysis that USPTO should have performed.

[12] See Office of Management and Budget, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication," 67 Fed. Reg. 8452 (February 22, 2002); and U.S. Patent and Trademark Office, "Information Quality Guidelines," http://www.uspto.gov/web/offices/ac/ido/infoqualityguide.html.

[13] See attached declaration of estimated cost of complying with the proposed IDS Rule.

[14] The affiant is willing to be identified. It is my professional judgment, based on facts unknown to the affiant, that it is prudent and necessary to redact the affiant's identity.

[15] The sub-estimates below total $7.9 billion. The discrepancy appears to be an error in addition. The arithmetic error is immaterial, however, as by itself exceeds by a factor of six the threshold for an economically significant regulatory action.

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independent and external peer review of the Declaration. I followed the procedures set forth by OMB in its final Bulletin on peer review for information quality.[16]

Selection of reviewers. Section II(3)(a) requires that reviewers be selected based on "expertise, experience and skills, including specialists from multiple disciplines, as necessary." I obtained reviews from four experienced patent attorneys with skills across multiple practice areas.

Conflicts of interest. Section II(3)(b) requires that peer reviewers be free of conflicts of interest except when the only expertise available is inherently conflicted, such as might occur in circumstances where the relevant expertise is highly classified. In this case, avoiding conflicts of interest was easy. None of the peer reviewers work for my clients or have any other embedded financial interest. Furthermore, while all peer reviewers would be affected by the proposed IDS Rule, the nature of that effect is coincident with their financial interest. That is, regulations making the practice of patent law more complex and more expensive also make their services more valuable. If they have a financial incentive to behave strategically, it is to understate rather than overstate costs.

Independence. Section II(3)(c) requires that peer reviewers not have authored or contributed to the work product they are asked to review. None of the peer reviewers authored or contributed to either the proposed IDS Rule or the independent third-party declaration. In addition, they could not have been influenced by the reputation of the affiant because they received only the redacted version of the declaration, and hence, do not know the affiant's identity.

Transparency. Section II(5) requires that the entity managing the peer review "shall instruct peer reviewers to prepare a report that describes the nature of their review and their findings and conclusions." One option for adhering to this requirement is to "include a verbatim copy of each reviewer's comments." This is the approach taken here; no additional summary or synthesis has been added, and nothing has been taken away. Three of the four individual reports include the text of the charge I provided them; the fourth supplied a response via email, which I have copied verbatim into a separate report.

Choice of Peer Review Mechanism. Section II(4) advises that the peer review mechanism be appropriate to the task, "based on the novelty and complexity of the information to be reviewed, the importance of the information to decision making, the extent of prior peer review, and the expected benefits and costs of review, as well as the factors regarding transparency described in II(5)." Under the circumstances, I judged a letter review to be a fully sufficient and cost-effective peer review mechanism.

[16] Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664-2677.

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Conclusion

Executive Order 12,866. Based on my expertise in regulatory analysis, and more than 20 years' experience reviewing such analyses (including 10 while employed as an economist at OMB), I am virtually certain that the proposed IDS Rule is economically significant and thus warranted the preparation of an RIA in accordance with the guidelines set forth in OMB Circular A-4. I am aware of no information suggesting that the draft final IDS Rule is so radically different that it would not also be economically significant.

Furthermore, based on my governmental experience it is inconceivable that USPTO could be unaware of the approximate magnitude of these costs, or that it employed any reasonable economic method or logic to determine that the proposed rule was "not significant." The Declaration gives a useful first-order approximation of cost that USPTO itself could have performed during the regulatory development process and long before the Office proposed it in 2006. Had the Office done so, it would have known with reasonable certainty that the proposed IDS Rule could not legitimately be classified as "not significant," and that an RIA containing the information required by Section 6(a)(3)(C) would be necessary. One can infer with reasonable certainty that USPTO deliberately evaded the requirements of Executive Order 12,866.

Information Quality. USPTO is required, pursuant to OMB's and is own information quality guidelines, to adhere to the principles of substantive and presentational objectivity in the dissemination of influential information. The proposed IDS Rule was covered by these guidelines, but USPTO did not disclose any credible information about its cost. This is *per se* a violation of both substantive and presentational objectivity. The agency could not reasonably have believed that the costs of the proposed IDS Rule were trivial and thus not worth mentioning, and its failure to disclose an unbiased cost estimate was knowingly misleading.

The third-party Declaration I am providing constitutes the best available information concerning the cost of the proposed IDS Rule. Furthermore, it has been reviewed in accordance with applicable pre-dissemination (i.e., peer review) procedures. Therefore, even if USPTO has the legal discretion to proceed without complying with any of the material requirements of Executive Order 12,866, it cannot legally choose not to comply with applicable information quality guidelines with respect to its characterization of the cost of compliance. USPTO must either include the analysis provided in the Declaration as the best available estimate of the cost of compliance, or produce and disseminate an alternative estimate, along with the final rule, that is superior with respect to its adherence to information quality principles, most notably the principle of objectivity.

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Paperwork Reduction Act. The costs estimated by the affiant consist of paperwork burdens that are subject to OMB's statutory oversight under the Paperwork Reduction Act.[17] The public is entitled to a full and complete opportunity to participate in OMB's review to ensure that the statutory requirements of the PRA are satisfied. If finalized, the proposed IDS Rule alone could increase threefold the Information Collection Budget of the entire Department of Commerce ($1,687 million[18]).

Each of the other proposed and final regulations mentioned herein also impose significant new paperwork burdens that so far have not been credibly estimated. I am willing to assist USPTO and OMB in the development of credible burden estimates for each of these regulations.

OMB's approval of ICR 0651-0031 appears to have lapsed on September 30, 2007. I would support a short emergency extension of the existing collection pending the development of corrected burden estimates. USPTO should be advised to refrain from taking any action that adversely affects patent applicants and owners for failure to submit information covered by an expired ICR.

[17] Economic costs, such as the value of lost innovation and invention that the proposed IDS Rule might cause, are not included.

[18] Information Collection Budget: FY 2006, Table 4. Commerce reported a 27% increase in department-wide burden in FY 2006 due to non-statutory program changes (Table 1). USPTO is responsible for most of this increase.

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Attachment A:

Final Information Quality Bulletin for Peer Review

70 Fed. Reg. 2664-2677, Section II

1. *In General:* To the extent permitted by law, each agency shall conduct a peer review on all influential scientific information that the agency intends to disseminate. Peer reviewers shall be charged with reviewing scientific and determinations for the agency. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the Federal laws governing information access and quality.

2. *Adequacy of Prior Peer Review:* For information subject to this section of the Bulletin, agencies need not have further peer review conducted on information that has already been subjected to adequate peer review. In determining whether prior peer review is adequate, agencies shall give due consideration to the novelty and complexity of the science to be reviewed, the importance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review. Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed.

3. *Selection of Reviewers:*

a. *Expertise and Balance:* Peer reviewers shall be selected based on expertise, experience and skills, including specialists from multiple disciplines, as necessary. The group of reviewers shall be sufficiently broad and diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge. Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers.

b. *Conflicts:* The agency—or the entity selecting the peer reviewers—shall

(i) ensure that those reviewers serving as federal employees (including special government employees) comply with applicable Federal ethics requirements;

(ii) in selecting peer reviewers who are not government employees, adopt or adapt the National Academy of Sciences policy for committee selection with respect to evaluating the potential for conflicts (*e.g.*, those arising from investments; agency, employer, and business affiliations; grants, contracts and consulting income). For scientific information relevant to specific regulations, the agency shall examine a reviewer's financial ties to regulated entities (*e.g.*, businesses), other stakeholders, and the agency.

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c. *Independence:* Peer reviewers shall not have participated in development of the work product. Agencies are encouraged to rotate membership on standing panels across the pool of qualified reviewers. Research grants that were awarded to scientists based on investigator-initiated, competitive, peer-reviewed proposals generally do not raise issues as to independence or conflicts.

4. *Choice of Peer Review Mechanism:* The choice of a peer review mechanism (for example, letter reviews or ad hoc panels) for influential scientific information shall be based on the novelty and complexity of the information to be reviewed, the importance of the information to decision making, the extent of prior peer review, and the expected benefits and costs of review, as well as the factors regarding transparency described in II(5).

5. *Transparency:* The agency—or entity managing the peer review—shall instruct peer reviewers to prepare a report that describes the nature of their review and their findings and conclusions. The peer review report shall either

(a) include a verbatim copy of each reviewer's comments (either with or without specific attributions) or

(b) represent the views of the group as a whole, including any disparate and dissenting views. The agency shall disclose the names of the reviewers and their organizational affiliations in the report. Reviewers shall be notified in advance regarding the extent of disclosure and attribution planned by the agency. The agency shall disseminate the final peer review report on the agency's Web site along with all materials related to the peer review (any charge statement, the peer review report, and any agency response). The peer review report shall be discussed in the preamble to any related rulemaking and included in the administrative record for any related agency action.

6. *Management of Peer Review Process and Reviewer Selection:* The agency may commission independent entities to manage the peer review process, including the selection of peer reviewers, in accordance with this Bulletin.

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Attachment B:

Public Comment Request on Paperwork Burden
August 21, 2007 (72 Fed. Reg. 46835)[19]

N. Paperwork Reduction Act

This final rule involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The collection of information involved in this final rule has been reviewed and approved by OMB under OMB control number 0651-0031. This final rule provides that: (1) A third or subsequent continuation or continuation-in-part application or any second or subsequent request for continued examination must include a showing that the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution after a first and second continuation or continuation-in-part application and a request for continued examination; (2) an application that contains or is amended to contain more than five independent claims or more than twenty-five total claims must include an examination support document under 37 CFR 1.265 that covers each claim (whether in independent or dependent form) before the issuance of a first Office action on the merits; and (3) multiple applications that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and a common assignee must include either an explanation of how the claims are patentably distinct, or a terminal disclaimer and explanation of why patentably indistinct claims have been filed in multiple applications. The United States Patent and Trademark Office has resubmitted an information collection package to OMB for its review and approval because the changes in this notice do affect the information collection requirements associated with the information collection under OMB control number 0651-0031.

The title, description and respondent description of the information collection under OMB control number 0651-0031 is shown below with an estimate of the annual reporting burdens. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Number: 0651-0031.

Title: Patent Processing (Updating).

[19] "Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications" ("5/25 Rule"), excerpt. Emphasis added.

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Form Numbers: PTO/SB/08, PTO/SB/17i, PTO/SB/17p, PTO/SB/21-27, PTO/SB/24B, PTO/SB/30-32, PTO/SB/35-39, PTO/SB/42-43, PTO/SB/61-64, PTO/SB/64a, PTO/SB/67-68, PTO/SB/91-92, PTO/SB/96-97, PTO-2053-A/B, PTO-2054-A/B, PTO-2055-A/B, PTOL-413A.

Type of Review: Approved through September of 2007.

Affected Public: Individuals or households, business or other for-profit institutions, not-for-profit institutions, farms, Federal Government and State, Local and Tribal Governments.

Estimated Number of Respondents: 2,508,139.

Estimated Time Per Response: 1 minute and 48 seconds to 24 hours.

Estimated Total Annual Burden Hours: 3,724,791 hours.

Needs and Uses: During the processing of an application for a patent, the applicant or applicant's representative may be required or desire to submit additional information to the United States Patent and Trademark Office concerning the examination of a specific application. The specific information required or which may be submitted includes: information disclosure statement and citation, examination support documents, requests for extensions of time, the establishment of small entity status, abandonment and revival of abandoned applications, disclaimers, appeals, petitions, expedited examination of design applications, transmittal forms, requests to inspect, copy and access patent applications, publication requests, and certificates of mailing, transmittals, and submission of priority documents and amendments.

Comments are invited on: (1) Whether the collection of information is necessary for proper performance of the functions of the agency; (2) the accuracy of the agency's estimate of the burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information to respondents.

Interested persons are requested to send comments regarding these information collections, including suggestions for reducing this burden, to: (1) The Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10202, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Patent and Trademark Office; and (2) Robert A. Clarke, Director, Office of Patent Legal Administration, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of

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information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

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IN THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS
OFFICE OF MANAGEMENT AND BUDGET

In re United States Patent and Trademark Office proposed "Changes to Information Disclosure Statement Requirements and Other Related Matters," 71 Fed. Reg. 38808 (Jul 10, 2006)	Docket No. RIN 0651-AB95 **DECLARATION OF** [redacted]

I, [redacted] declare that the following is true and correct:

BACKGROUND AND EXPERIENCE

1. I am a registered patent attorney in private practice [redacted]. I have been practicing in the field of intellectual property, with emphasis on patent or related matters, for over 20 years. My practice has included work at a relatively large law firm, a small law firm, in a practice group of affiliated lawyers, and in a solo practice. I have also worked with and for in-house practitioners in corporations.

2. I have worked on dozens of patent lawsuits or prospective lawsuits, mostly but not exclusively representing patent-holders.

3. I have prosecuted hundreds of patent applications for scores of different clients, directly and through oversights of several patent lawyers and patent agents.

4. I have been active in licensing and selling patents and understand their value and valuation issues.

5. I have written or been the principal author for approximately a dozen sets of comments on PTO rules and procedures. I have assisted various Congressional offices in connection with patent-legislation matters.

6. In connection with recent PTO rule proposals, including this one, I have been in close contact with and have gathered information from a large number of fellow patent-prosecution lawyers and patent agents in various settings, including in-house, large firms, small practices, and mid-size firms.

7. I am an active contributor and regular reader of a number of patent-related mail lists and blogs. I have attended many patent-related conferences and heard various PTO officials speak on the rationales for recent rule-making initiatives.

8. [redacted]

9. I have reviewed and formed certain opinions, and can provide evidence, concerning the PTO's 2006 rule-making proposal for additional requirements for Information Disclosure Statements ("IDS") and specifically the cost of that proposed regulation. I have studied that proposal carefully. I understand that this information is being sought by the OMB to evaluate the cost of the proposed rules, and I am willing to donate my time to assist OMB in any fashion in connection with this matter, including

providing it with my opinions in any other form, or to any person interested in discussing the matter.

10. My opinions below are based in part on my personal experiences connected to IDS and related matters. I have personally filed or overseen the filing of IDS papers in essentially all of the hundreds of patent applications that I have handled. I have handled IDS papers that have cited references that arose from litigation parents.

11. I have defended litigation challenges to charges of inequitable conduct made against practitioners who have prosecuted patents of my clients. I have billed clients for significant work on inequitable-conduct issues and other litigation and prosecution matters, including in complex and simple cases.

12. I have gathered information related to the subject of IDS filings and their costs, including facts and estimates, from other practitioners, as well, including through some of the activities described in my background above.

13. I am well aware of the charges and time expended on various issues by other practitioners, including from my discussions, reading postings on mail lists and blog entries, and through attention that I have paid to surveys such as the AIPLA's surveys of practitioner charges and patent-litigation costs.

14. I have a significant background in statistical analysis and estimation, including college-level courses and work experience in those subjects.

15. I have prepared this declaration on a *pro bono* basis, and I am receiving no compensation for the work in doing this effort. I have not discussed this report with any of my clients, and none of my clients even know that I have done this work or have requested that I become involved with this effort. My work also is independent of any other organization with which I am involved, [redacted].

PARTS OF THE PROPOSAL THAT WILL IMPOSE COST ON THE PUBLIC

16. My study of the proposed regulation leads me to the opinion that there are four main areas that will lead to new costs on the public in securing and enforcing patents, which collectively are significant. Those new costs would arise from the following requirements in the proposed rule:

a. The proposal would add new requirements to provide detailed explanations of all references cited in those applications in which more than 20 references were provided (with a few narrow exceptions for a few types of references, which would not be counted towards the threshold);

b. The proposal would add new requirements to explain IDS-cited references that are either in foreign languages or are at least 25 pages long;

c. The proposal would add new requirements to explain and compare references cited after the first Office Action on the merits (FAOM); and

d. The proposal would add and adjust the requirements for citation of references after notices of allowance and after issue-fee payments.

17. The costs of each of those parts of the rule that are estimated in this declaration arise mainly from two factors (although there are a few others discussed below too):

a. Practitioner charges to produce the paperwork required to comply with the rules during patent prosecution; and

b. Increased litigation costs that would result from added opportunities to allege inequitable conduct during patent-enforcement lawsuits, in the fraction of applications that result in issued patents that are involved in lawsuits.

The proposed IDS rule would, if adopted, impose additional costs that are described qualitatively but not estimated quantitatively in this declaration, as a result of a number of other factors, including, but not limited to, (i) reduction in patent asset value to reflect the increased risk that particular patents would be rendered unenforceable or constrained in scope because of statements made in or omitted from "patentability justification" or less comprehensive documents filed to meet the proposed requirements or because of references that practitioners decide not to submit to avoid filing such documents, and (ii) increased costs on members of the public investigating the file histories and scope of issued patents.

18. In the sections that follow, I provide evidence commenting on all but one of the areas of new costs listed in the previous paragraph. The exception is part (d), related to citation of references after allowance or payment of issue fees. In my experience, that part of the rule concerns relatively rarely occurring situations, ones that I have rarely faced in my personal practice, and I have no comments concerning that part of the proposed rule.

APPLICATIONS IN WHICH MORE THAN 20 REFERENCES ARE CITED

19. The PTO reports statistics, cited in the proposal itself, pp. 38809-10, based on a sample of "a six-week period of allowed applications," from which it estimates that about three out of every 20 patent applications (~15%) cite more than 20 references.

20. To test the PTO's statistic, I drew a random sample, across technology fields, consisting of 25 patents of the 2,896 regular patents (or about 1%) that issued the week of this report (*i.e.*, not counting design patents, plant patents, reissue patents, or statutory invention registrations). I found that fully 11 of the 25 (44%) contained citations of more than 20 references.

21. I cannot explain why this figure resulted in a rate that is three times higher than the PTO sample, but I urge OMB to examine the PTO data supporting the comment in the rule proposal very carefully, including checking its methodology for possible bias. For example, the PTO does not identify the dates of the allowed applications in its study, but if it used applications allowed some years ago, that could explain the discrepancy, because I believe that modern applications are far more likely to cite large number of references.

22. Despite my suspicions of the PTO statistic, I have used, for purposes of this report, the PTO's own reported estimate of 15% of applications that would be subject to this rule. Even that figure is nearly one in six applications.

23. Certain PTO studies, including PTO's current strategic plan, report that about 420,000 patent applications (not counting international applications filed under the Patent Cooperation Treaty (PCT) or design applications) were filed in FY06 and further estimate an expected annual growth through 2012 of approximately 8%.

24. Thus, the PTO estimates that the total number of new applications filed over the next five years will be about 2.875 million. In addition, the PTO reports that it has nearly 700,000 unexamined applications in the PTO's current backlog (I am uncertain whether that statistic includes partially examined applications as well as ones that have not had the first action). The proposed IDS rule contains no transitional provision, so it would apply by its terms to all IDS filings made in those pending applications as well. In sum, over 3.5 million applications are potentially subject to the proposed IDS rule.

25. Thus, saying that the first part of the new proposal will impose the extra cost on about 15% of applications results in *more than a half million patent applications* over the next five years or so being subject to the rule and its costs. If the PTO's 15% estimate is low, as may be the case, the number would be proportionately higher.

26. The proposed IDS rule would require, for each application having 20 or more references, that the practitioner, on behalf of applicant, explain all references, identify the parts of the reference thought most material, and correlate the reference to each claim. Those requirements represent a huge effort and expense in cases to which they would apply.

27. I have reviewed the PTO's "Certification Analysis Under the Regulatory Flexibility Act" dated June 29, 2007, prepared by ICF International, relating to the Examination Support Documents (ESD) required by the PTO's recent "Continuations" rule. I consider that report's quality as easily falling within the term "junk science" (to the extent that the report qualifies for use of the term "science" at all). I am prepared to support that strong statement with specific criticisms of flawed methodology and unfounded or unreasonable assumptions in that study upon request.

28. The ESD estimate has some pertinence to the IDS rule-making discussed here, because the proposed requirements for a "patentability justification" document, for applications in which more than 20 prior art references are filed, are similar to those required in ESDs. The PTO's consultant apparently did not make, or at least failed to report, any effort to survey practitioners to estimate actual attorneys' or agents' expected costs for meeting the ESD requirements. Nevertheless, the consultant provided estimates ranging from $2,563 to $13,121 per application for an ESD.

29. My own surveys, personal experiences, and discussions with other practitioners lead me to opine that the consultant estimates are unrealistically low. I believe that the actual figures would range from the highest end of the range, or

$13,000, to a range from three to ten times that amount for more difficult cases, with an average being around triple the PTO's upper-end estimate.

30. With specific reference to the "patentability justification" requirements in the proposed IDS rule, I have observed some differences as compared to the ESD requirements. Nevertheless, in both, the bulk of the costs arise from a comparison of each reference to each claim. In addition, a practitioner would have to explain references and identify pertinent parts, for each reference. Therefore, the cost of a "patentability justification" document involves estimating a per-reference cost and adding an extra cost per claim.

31. In my view, the per-claim amount varies, with the first independent claim being more expensive than dependent claims, and second independent claims being of intermediate expense (because the work for the other claims sometimes will help performing the work for the second independent claim).

32. Once a per-reference cost is estimated, an overall cost estimate can be assembled for a particular application by multiplying the per-reference cost by the number of references.

33. In my opinion, for the 15% of applications to which the proposed IDS rule would apply, the average number of references cited is approximately 30 (and that is a conservatively low number), because some (smaller) fraction of applications within the group cite very large number of references, which brings up the average. I have, for example, personally cited literally hundreds of references to the PTO in certain applications, particularly those related to other applications (whether or not parents) or to other patents in litigation. From visual inspection (I did not calculate the precise figure), the 11 applications in my small sample that exceeded 20 citations likely averaged approximately 40 citations per application, which supports my view that the figure, 30, that I have assumed is conservatively low.

34. In my opinion, I estimate that the costs in actual client billings from the work required to evaluate the average reference and compare it to the claims are:

a. Per-reference (summarizing and identifying pertinent parts): $200

b. Per-first-independent claim (written comparison to reference, element-by-element, for all elements): $150

c. Per-extra-independent claim (same): $100

d. Per-dependent claim (same): $20

35. I do not believe that my estimates depend greatly on the billing rates assumed to apply. If a less-skilled or less-experienced practitioner is used, the number of hours would be correspondingly higher than if a more-advanced practitioner is used, plus a certain amount of oversight and review would be done by a more senior person (and such is quite reasonable to do).

36. In building these estimates, I have thought through the number of hours and actual billing rates available in actual practitioners, which might be applied

assuming that the work is done by various types of practitioners (agents, attorneys, big and small firms, etc.). With respect to billing rates, I am knowledgeable of hourly charges by patent-prosecution practitioners, from the most expensive, who are likely partners in large firms located in big cities, who charge up to about $600/hour, to the least expensive, who are new and less experienced patent agents in solo practice or associate attorneys at smaller law firms, who charge about $100-150/hour.

37. I based those estimates on my experience in performing analogous analyses in a number of contexts. For example, a "patentability justification" document bears some similarity to the work required to prepare claim charts to support a request for *ex parte* reexamination of a patent based on a single reference, for which practitioners regularly would charge several to tens of thousands dollars. There are also similar tasks performed in litigation contexts, for which practitioners regularly charge many tens of thousands of dollars. I believe that the prices quoted above fairly represent averages across charges that might be imposed by a number of types of practitioners in different settings.

38. In calculating these estimates, I have thought through the work that would be required to do a competent job. I have not assumed that any practitioner would reduce the costs by doing a shoddy job, which is less than what one would expect. In actual practice, such as if a survey is taken, a certain amount of practitioners might report prices that were lower than I believe would be appropriate for strategic reasons, such as to earn the business. In view of the risk of accusation of inequitable conduct and the serious consequences for practitioner and patentee alike, I have assumed that instances of low-quality work or lower-than-market quotes would be few and far between and discounted them. If such cases existed, however, the lower cost in preparing lower-quality "patentability justification" documents would be far outweighed by the extra costs in litigating such matters and in reduced value of patent rights on the part of the patentee.

39. In considering the amount of work that is involved, I believe that it is important to recognize that the job of a patent practitioner in preparing a "patentability justification" document is far more difficult and time-consuming than the time that a PTO examiner would need to review and examine the application in light of the group of references. Even though both of those parties must study the same set of references and compare their teachings to each claim, the PTO examiner has the luxury, not available to the practitioner under the proposed IDS rule, of being able to review and discard marginally relevant references quite quickly, without writing any document explaining the reasons or doing any detailed analysis.

40. An examiner can, for example, begin reading a reference but switch to skimming mode upon recognizing the general teachings, and return to it only if it seems pertinent to filling in a "hole" by teaching a feature not in other references. As another example, an examiner can notice a particular disclosure of a certain element in an individual claim but discount it by reaching the conclusion that the reference does not readily combine with the primary references used in a rejection being planned.

41. By contrast, a practitioner operating under the proposed rules must study, discuss, and compare *each and every* reference with *each and every* claim, even after it became apparent that the reference could not support any reasonable rejection for any reason like those illustrated in the examples above. Moreover, the practitioner cannot safely describe the reference in general or imprecise terms, like an examiner can, because of the risk of being accused of inequitable conduct in later litigation. There are well-established mechanisms for correcting errors by an examiner, and an examiner's erroneous statements will not bind the PTO generally. In contrast, every written statement by a practitioner will be binding on the patentee and will be carefully scrutinized by opposing counsel in any future litigation or licensing transaction; therefore such statements must be considered and drafted with *great* care. An applicant's representative thus will take far longer (many times longer) to do a task that, at first glance, might seem roughly equivalent to a task done by an examiner.

42. In addition, examiners specialize in narrow areas to which they are assigned, and they grow to have intimate knowledge of references in that area. By contrast, practitioners nearly always file and pursue applications across a much wider range of subjects, thus they are far less likely to have background or prior knowledge of the references that they are discussing in any given case, and they usually have less intimate knowledge of the technology. It should be unsurprising, therefore, that practitioners will need to spend much more time to review and synopsize references or compare them to each claim and claim element, as compared to examiners.

43. The PTO's consultant who sought to estimate practitioner costs for ESDs did not report speaking with or gathering information from any practitioners, much less taking any valid and reliable sample of practitioners who have studied the nature of the tasks they would be required to perform under the proposed IDS rule. Instead, the consultant may have discussed the time required to review and synopsize references with selected PTO managers or examiners and developed estimates of the time and cost required by using their answers. Any approach that does not investigate or take into account the realities facing practitioners and applicants, ignores the real-world, current market for patent agent and attorney services, and instead relies on information or time estimates from the PTO, even if from PTO examiners and even if they have law degrees, would yield an inherently biased cost estimates, because of the differences between examiner and practitioner time needed to perform tasks, as explained above.

44. Let us assume that the average application among the 15% of applications to which this requirement applies has the number of claims allowed by statute without extra claims fees, namely 3 independent and 20 total claims (meaning 17 dependent claims). That assumption is conservatively low, because obviously many applications pay extra claims fees. The PTO could have, but did not, report the average number of independent or total claims found in the 15% of applications in its sample in which applicants cited more than 20 references. OMB should require PTO to produce and publish that statistic for public comment, because the cost of preparing the "patentability justification" document depends greatly on the number of claims. It would make sense that more references are cited in applications having more claims.

45. Under the conservative assumption that there are only 3 independent and 20 total claims on average in those applications in which applicants cited more than 20 references, the cost of complying with the proposed IDS rule nevertheless would be $200 + $150 + (2x$100) + (17x$20), or a total of $890 per reference. Multiplying by the assumed conservative average of 30 references yields an average cost of $26,700 per application. That figure could be reduced 38% by eliminating the requirement to discuss or cite references with respect to dependent claims, but that reduction, of course, is highly dependent on the average numbers of dependent claims and the array of subjects recited in the set of dependent claims as a whole, and again there is no evidence that the PTO has studied such questions.

46. I have evaluated the result of that per-application calculation on an overall (gestalt) basis, and I believe that the cost is a conservatively low estimate of an average cost of comparing all references to all claims. (The ESD document required by the recently promulgated "Continuation" rule has additional requirements, which would increase that cost quite a bit further, such as requirements to show support in both the application specification and all parent applications.)

47. For example, my estimate above of the average cost to compare a single reference to a first independent claim (including reviewing all subparts and claim elements) is $150, which represents just 15 minutes for a law firm partner billing at $600/hour or one hour for a patent agent or associate billing at $150/hour. In that time, the practitioner must evaluate the reference against all aspects of the claim, which are nearly always numerous (see discussion of one, simplified example below). For another example, my estimated average cost for dependent claims at $20/each assumes that a $600/hour practitioner could work at a rate of 30 dependent claims per hour or that a $150/hour practitioner could work at a rate of 7.5 dependent claims per hour.

48. There will be a wide range of costs to produce "patentability justification" documents across application, with the distribution having a long, thick tail at higher prices. I expect there will be a significant fraction of applications for which my estimate of $890 per reference average cost will be considerably low. Some of the factors that will influence the cost per reference include the length of the reference, the complexity and detail contained in the claim, the clarity of the reference's disclosure, and the complexity of the technology being considered.

49. I notice, by the way, that the proposed IDS rule contains a requirement of updating the "patentability justification" document if the claims change or references are added, so the acts estimated above might not happen all at one time. I have not separately analyzed the impact of that rule by estimating the fraction of applications in which claims are changed sufficiently to require modification of the IDS rule's "patentability justification" document.

50. The PTO is in a better position to produce actual data on foundational questions like the average number of claims, the number of applications that are amended, the percentage of patents that are the subject of litigation, and so forth, through statistical analysis or sampling, but, to my knowledge, PTO has not done so. OMB should require PTO to do actual studies to produce such background facts before

any rules of this sort are approved. For example, the PTO, if it did such a study, would probably find that patents issuing from applications in which more references are cited are more likely to be involved in litigation. A well-conducted study would also probably find that applications in which more references are cited are more likely to have greater numbers of claims than applications citing fewer references.

51. In addition, based on my experience with inequitable-conduct litigation, it is my opinion that, for those applications that result in patents that are litigated, inequitable conduct would be alleged in essentially 100% of cases in which a "patentability justification" document was filed. This is perhaps the easiest estimate that I have made in this declaration. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995) (discussing implications of "the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive"); *Preemption Devices, Inc. v. Minnesota Mining & Mfg'g Co.*, 732 F.2d 903, 907 (Fed. Cir. 1984) (referring to inequitable conduct as "this much-abused and too often last-resort allegation").

52. In every instance I have seen where a practitioner tried to cite the most pertinent references to the PTO, the choice of reference has been challenged and the practitioner has been accused of inequitable conduct, often on the slenderest of grounds. In every instance I have seen where a practitioner made a mistaken statement in an argument to the examiner, or even wrote an ambiguous comment that could be argued as being mistaken, the practitioner has been accused of inequitable conduct. Again, my experience is typical. *See Pfizer, Inc. v. International Rectifier Corp.*, 538 F.2d 180, 186 (8th Cir. 1976) ("A patentee's oversights are easily magnified out of proportion by one accused of infringement")

53. The "patentability justification" document required by the proposed IDS rule would open up vast new fields of opportunity to manufacture charges of inequitable conduct. The proposal would require the document to (a) describe each prior art reference, (b) compare the reference to any element of any claim, and (c) identify the reference's "pertinent part." Any of those parts can lead to charges of inequitable conduct, however unfounded, and it is essentially 100% likely that at least one such charge will be made based on the "patentability justification" document if the application results in a litigated patent.

54. Even though not one of the many dozens of inequitable conduct charges that I have defended against have been affirmed by any court as meritorious, such charges nevertheless were made, and they are enormously expensive and awkward to defend. My experience with unjustified inequitable-conduct charges is hardly atypical. The Federal Circuit has discussed the same concern. *E.g., Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1482 (Fed. Cir. 1998) ("As discussed in *Kingsdown*, the charge of inequitable conduct before the patent office had come to be attached to every patent prosecution, diverting the court from genuine issues and simply spawning satellite litigation"); *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1997) (decrying "the 'plague' of litigation-inspired attacks that fed on the unfamiliarity of decision-makers with the complex procedures of patent examination").

55. I do not believe that the "safe harbor" in the proposed IDS rule is even close to adequate to protect practitioners or patentees. The proposal provides a "safe harbor" only if the practitioner acts in "good faith" and only if the "patentability justification" document's author provides a "reasonable" characterization of the facts. Of course, in all litigated inequitable-conduct charges, by virtue of the standard, the patent-holder can defeat an inequitable-conduct charge anyway if the accused infringer fails to show that the applicant or practitioner *intentionally* committed misconduct by providing *unreasonable* assertions of the true facts with the *bad faith* goal of misleading the PTO. *E.g., Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc) ("the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive") *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003) ("we will not find inequitable conduct on an evidentiary record that is completely devoid of evidence of the patentee's intent to deceive the PTO"). Thus, the "safe harbor" does not provide any safety beyond the inequitable-conduct standards themselves; it will neither reduce the odds of inequitable-conduct allegations being lodged nor reduce the cost of defeating those allegations.

56. Indeed, the "safe harbor" will increase the cost of inequitable-conduct litigation and even encourage inequitable-conduct charges to be brought in even more instances. As the law stands today, some cases hold that it is impossible to demonstrate intent to deceive the PTO by making a statement about a reference that is in front of the PTO examiner. If the PTO examiner can look at the reference for himself or herself, then what the applicant says is considered mere argument that cannot rise to the level of inequitable conduct. *E.g., Beckman Instruments, Inc. v. LKB Produkter, AB*, 5 U.S.P.Q.2d 1462, 1464 (D. Md. 1987) ("The patent examiner was capable of independently evaluating the material before him, and Beckman's representations as to how to interpret that material cannot be the basis for a finding of inequitable conduct") (citations omitted). With the PTO's proposed IDS rule implying that the examiners cannot be bothered to actually review the references and instead will tend to rely on applicant's attorneys' statements in "patentability justification" documents filed under the proposed IDS rule, the courts may well dismiss charges of inequitable conduct less frequently than today based on assertions that references have been misdescribed.

57. Thus, the cost from this part of the proposed IDS rule must add to the cost arising from practitioner fees, estimated above, an extra allocation arising from the cost, if the application results in a litigated patent, in defending the resulting extra inequitable-conduct charges arising from the practitioners' descriptions of references. I have estimated that cost as well.

58. The number of patent lawsuits filed every year in the U.S. is a bit under 3,000, which is roughly one percent of yearly patent applications from several years ago (using a time lag accounts for the time needed to get a patent, for allegedly infringing activity to occur, and for a suit to be brought as a remedy). One academic study found that 1.2%-2.4% of all issued patents are eventually litigated, depending on field. Lanjouw et al., "An Empirical Analysis of the Enforcement of Patent Rights in the

United States," (Feb. 2002) at 2. Further, evidence shows that litigated patents have "significantly more" citations than non-litigated patents, even when limiting to applicant-provided citations. Allison, et al., "Valuable Patents," 92 Geo. L.R. 435, 454 (2003) (the average litigated patent cites 35 total references, while the average non-litigated patent cites 15 total references). It seems clear, conversely, that the 15% of applications that have citations to more than 20 references are far more likely to be litigated than the average application (although the academic article did not provide information necessary to determine how much, the underlying data in the study would reveal that information). Assuming the likelihood is double, which is a conservatively low estimate in my opinion, and using the middle of the range given by the other study, rounded down, there is about a 3% risk that a particular application to which this proposed IDS rule would apply will end up in litigation.

59. The average cost of defending inequitable-conduct charges arising from practitioner description of references and comparison to claims, in my experience and opinion, would be about $250,000 per patent. I have defended against charges of inequitable conduct arising from statements made to the PTO by practitioners describing references or making other arguments about what is disclosed or not disclosed in the art. Such litigations have often run into the millions of dollars to fight, but many are settled before significant proceedings occur, so an average of $250,000 per patent is a conservatively low estimate.

60. Even in those instances in which lawsuits are settled early, the fact that inequitable-conduct charges have been leveled typically leads to a reduction in the potential settlement value, and a reduction in asset value in any non-litigation licensing or patent-sale transaction. I have not estimated the impact of that factor in my calculations, but it is another cost of the regulation and one that supports my opinion that my estimate of costs from extra inequitable-conduct charges is probably lower than the true cost of the regulation.

61. It would be sophistry to argue that litigation cost can be avoided merely by not committing inequitable conduct. Inequitable-conduct charges in patent cases are frequently and easily made but notoriously complex and expensive to rebut and hard to dismiss without extended proceedings in litigation, yet they are rarely meritorious. *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) ("The habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds …. They get anywhere with the accusation in but a small percentage of the cases …."). Thus, the mere fact that such charges are made costs considerable money, and the more charges that are made, the more it will cost to gain their dismissal, which is what happens in the overwhelming majority of instances. It is very easy to make a charge of inequitable conduct, and no practitioner, however careful, can avoid any possibility of such charges.

62. Accordingly, the average cost per application from extra inequitable-conduct allegations arising from the description of references adds another $7,500 cost per application, based on a 3% likelihood of having the submission filed under the

proposed IDS rule result in additional inequitable-conduct charges being made in a subsequent litigation multiplied by an average cost of $250,000 to defend against such charges. This ignores entirely the cost imposed on the accused infringer, who chose to bring an unfounded or unsupportable inequitable-conduct charge, or the court.

63. Adding estimated extra litigation costs to estimated extra practitioner fees yields an estimated average cost of this part of the proposed IDS rule of $34,200 per application.

64. Multiplying calculated per-application cost by the half-million patents to which the proposed IDS rule will apply over the next five years yields a five-year cost, in direct extra practitioner fees, of $17 billion, or *over $3.4 billion per year, from this part of the rule* alone.

65. I have done a bit of sensitivity analysis on my calculations. Even if I have overestimated the cost per application and the costs associated with litigation by a factor of five (which would bring my estimates more in line with what the PTO estimates for the ESD documents), the cost of this part of the proposed IDS rule, per application to which it applies, would still be nearly $7,000, and the total cost of this part of the regulation would still run nearly $700 million dollars per year.

66. The PTO may seek to justify a lower cost from the proposed IDS rule by arguing that practitioners will respond to the rule by citing fewer references, such that the fraction of applications having as many as 20 references will fall. In my opinion, this effect, if it occurs at all, will not materially reduce costs of this part of the proposed IDS rule, for several reasons. However, I have estimated that impact quantitatively too.

67. First, it is extremely risky for practitioners to fail to cite known references to the PTO, for the reasons stated elsewhere in this declaration relating to inequitable-conduct charges during litigation. Inequitable-conduct charges are serious matters – indeed, they call into question the reputation and livelihood of the patent practitioner. Moreover, the PTO's proposal would maintain its pre-existing disclosure rule, 37 C.F.R. §1.56, which *requires* practitioners to disclose references that are "material" and non-cumulative (*i.e.*, not redundant), and practitioners can be disbarred for failing to comply with existing Rule 56. Hence, it is not possible for an applicant or practitioner simply to decide to select the "best" 20 references, if there are a greater number of references known to him or her that the PTO's existing Rule 56 mandates be disclosed. Accordingly, I am not optimistic that practitioners will cite fewer references in most cases. Certainly, reducing the number of references by citing only a subset of known references would simply shift the basis of the litigation inequitable-conduct charges from what is said in the "patentability justification" document to the choice of references cited to the Office, and the overall cost would not decrease.

68. Second, the proposed IDS rule applies retroactively to pending applications and provides no opportunity for an applicant to withdraw references from previously filed IDS statements, including those filed before the proposed IDS rule took effect or was even proposed. An applicant can avoid having more than 20 references by abandoning an application having more than 20 references in favor of a continuation

application, and not citing the references from the parent in the continuation, but that approach would "burn" the "one free continuation" allowed by the PTO's "Continuation" rules. Thus, for *pending* applications, there is no effective opportunity to select the best references and provide them to the examiner, which the PTO says is the intent of the proposed IDS rule.

69. Third, even if some practitioners react by deciding to reduce the number of citations to less than 20 by selecting the most pertinent references, there is a cost of doing the selection. I believe that making such a selection would cost about half of the cost of providing the report required by this part of the proposed IDS rule, because a similar kind of analysis must be done simply to decide which references to cite. The savings mostly would arise because practitioner would not need to *write up* the results of the analysis for submission to PTO, but the analysis is essentially the same.

70. To illustrate the difficulty in selecting which references should be cited from among a pool of greater than 20 references available, consider a typical independent claim having a number of parts labeled (a)-(x). Usually, the subparts of a claim do not have only a single element, even in a mechanical invention, because the language of the claim will contain a number of adjectives or features necessary to that part of the claimed invention.

71. For example, one patent (chosen arbitrarily for illustrative purposes) issuing last week to an Arizona-based inventor (with whom I have no connection) is U.S. patent 7,275,998, entitled "Portable collapsible golf swing guide apparatus." Claim 1 of that sample patent contains 10 subparts, nine subparts labeled (a)-(h) and a tenth in a "wherein" clause that follows part (h).

72. Part (b), for example, recites: "a lockable sliding collar slidingly positioned on an upper portion of the columnar member." Thus, although part (b) is a collar, the claim element further requires that the collar in question be: (i) lockable, (ii) sliding, (iii) positioned on the columnar member (which is a different element, part (a)), and (iv) positioned on "an upper portion" of the columnar member. Similar sub-requirements are found with respect to each of the other 9 subparts of this patent, many of which are much longer than part (b) quoted, and such is typical with essentially all patents.

73. Let us also consider only one dependent claim that is related to part (b), claim 5 of the patent, which adds the element specifying, "wherein the sliding collar is lockably secured on the lower columnar member with a thumb screw." For ease of discussion, let us label the features of the collar of part (b) of our example claim as B1-B4, with the additional feature found in the dependent claim 5 as B5.

74. Continuing the illustration, suppose that a first prior art reference known to the practitioner discloses a design that has a number of the claim elements, including parts A-E of the claim, part G and H of the claim, and with respect to part B, it discloses a collar that has features B1, B3, and B4, but not B2 or B5. Suppose a second known prior art reference has a similar combination, but it discloses a slightly different collar, which is sliding (B2), and lacks parts G and H of the claimed invention. So, a practitioner must decide if the second reference, disclosing A, B1, B2, B3, B4, C, D, and E

is merely cumulative of a first reference that discloses A, B1, B3, B4, C, D, E, G, and H? "Cumulative" references are those that "teach[] no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO," *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1574-75 (Fed. Cir. 1997), and neither the PTO's existing "duty of disclosure" rule, 37 C.F.R. §1.56, nor inequitable-conduct law requires citation of cumulative references, *Upjohn Co. v. Mova Pharmaceutical Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000) ("a reference need not be provided to the examiner if it is merely cumulative to or less material than other references before the examiner"). Does the answer depend on whether other references also disclose B2 as part of other combinations, or whether B2 is known by itself? Practitioners must make those kinds of decisions when narrowing the references to 20 or below.

75. Hypothetically, suppose an applicant had two references that could be used as supporting references for examination of claim 5, so both of them disclose B5. However, one of the two has the combination A, B1, B3, B4, and B5 (*i.e.*, a lockable collar positioned on an upper portion of a columnar member, but which is not slidable, with the thumb screw of claim 5), whereas the second references discloses A, B1, B2, B3, and B5 (*i.e.*, a lockable, sliding collar positioned on the columnar member but not on the upper portion, also with the thumb screw of claim 5).

76. The PTO's Notice of Proposed Rulemaking suggest that PTO management would like applicants to cite fewer, more targeted references, to save examiner time. Thus, in this hypothetical, it seems that the PTO would prefer applicants to cite only one of the two supporting references disclosing the thumb screw feature and conclude that the second "thumb screw lock" reference was merely cumulative. However, such an approach is highly likely to cause a litigation challenge that the uncited reference was in fact not cumulative, whichever reference the practitioner selects.

77. If the practitioner chooses the first supporting reference to disclose, it will be argued that the second was not cumulative because it disclosed the thumb screw *in the context of a slidable collar*. If the practitioner selects the second supporting reference instead, it will be argued that the first was not cumulative because it disclosed the thumb screw in the context of a collar *located on the upper portion of the column*. Such arguments can be made, essentially always, using reasoning of this sort, because virtually no reference has *precisely* the same feature combination as another reference.

78. Although the proposed IDS rule contains a (supposed) "safe harbor" provision intended to reduce the risk of inequitable-conduct charges, that provision only covers statements made under proposed 37 C.F.R. § 1.98(a)(3). The PTO does not even attempt to create a "safe harbor" for the exercise of reasonable judgment in selecting which prior art references to <u>not</u> disclose, should a practitioner wish to select no more than 20 references to avoid the expense of the full report. Accordingly, it seems unlikely that practitioners can avoid the cost of the proposed IDS rule in many cases where more than 20 references are known, even if the practitioner honestly believes that some of those known references are cumulative of others.

79. Non-disclosure is far and away the most common class of "inequitable conduct" allegation raised in litigation. By limiting the ability of applicants to provide

material information to the PTO, the PTO makes it far more difficult for applicants to establish on the record their exercise of reasonable judgment, candor or good faith, and far more likely that "inequitable conduct" allegations will have to be litigated.

80. Aside from the risks from inequitable-conduct charges from making the selection, it is quite clear that, if an applicant wishes to select references from a set of known references that is larger than 20, and even if such a selection is possible, the selection must be done very carefully. Accordingly, it will take considerable time and attention to avoid violating the existing "duty of disclosure" rule (37 C.F.R. § 1.56) as well as to reduce the probability of a successful inequitable-conduct attack.

81. In view of such considerations, it is impossible to predict how many applications will be filed with no more than 20 references under the proposed IDS rule, if promulgated. However, if the IDS rule is wildly successful, such that ***half*** of the new applications now being filed with more than 20 references were to start being filed with fewer than 20 references, then the 15% rate would drop to 7.5% for the 2.875 million new applications and remain at 15% for the 700,000 pending applications, which would reduce the number of applications in which the full report would remain required from above a half million to around 320,000.

82. Thus, in two thirds of the half million applications, applicants would bear the full costs of filing the required report, and in the remaining third of half million applications, applicants would bear half of that cost, to select the correct 20 references. That effect would reduce the overall total cost by about one sixth, and the total cost of this part of the proposed IDS rule would drop from $3.4 billion per year to five sixths of that figure, or ***about $2.8 billion per year***. Again, if I have overestimated by a factor of five, the overall cost would still approach $600 million per year.

83. Further, the PTO may argue that its examiners' time should be reduced somewhat by virtue of this proposed IDS rule and that such an effect should offset the public burden. I am unaware of how much time examiners take reviewing large IDS's. The PTO should be obligated to produce such estimates for comment by the public.

84. In any event, I cannot imagine that the PTO's cost savings from any reduction in the number of applications with large numbers of IDS filings would exceed even a small fraction of the cost of the regulation estimated above.

85. It is also possible that some practitioners might respond to the proposed IDS rule by adopting a "head in the sand" approach and failing to search for or find possibly pertinent references, to avoid the risk of filing reports of this nature. To the extent that this occurs, there would be extra costs as well. Such costs include the extra cost arising from the examiners needing to search for references without applicant searches, extra costs to the public from some patents issuing unjustifiably because less searching was done, and extra costs on applicants arising from unprotected inventions (temporarily or permanently) or wasted application fees because applications were written without adequate investigation of prior art to focus them on the true inventive aspects. Those costs are harder to estimate, but reactions of that nature are likely even more costly than complying with the proposed IDS rule or selecting the best references.

ADDITIONAL EXPLANATION OF FOREIGN-LANGUAGE OR MODERATELY LONG REFERENCES

86. Aside from the requirement of preparing detailed comparisons of every reference to every claim, which would be required in about 15% or more of the applications filed, apparently the proposed regulation contains additional provisions that would impose lesser but still significant costs. Specifically, the proposed IDS rule would require applicants to provide more information specific to *certain* references. The references for which information would be required are (with minimal exceptions that do not change my analysis): (a) references having more than 25 pages, and (b) references in a foreign language. The information required in those cases includes an explanation of the particular reference and a comparison to the claims.

87. I have estimated the additional cost of this part of the regulation as well. First, it is necessary to estimate the fraction of references cited that exceed 25 pages and the fraction of references cited that are in a foreign language. Again, the PTO ought to have, but apparently has not, disclosed such data.

88. In my sample of 25 patents issuing last week, I found 14 patents that had 20 or fewer applicant citations. I checked the length and language of each reference cited in those 14 applications. The following table shows the results of my sample:

#	*Total # references*	*# foreign language references*	*# English references > 25 pages*
1	14	4	1
2	7	0	2
3	19	0	4
4	7	0	2
5	16	0	2
6	14	6	2
7	2	0	0
8	3	0	0
9	12	2	3
10	13	1	2
11	12	1	1
12	12	3	0
13	20	3	1
14	1	0	0
Sum	*152*	*20*	*20*
%	*100%*	*13%*	*13%*
Avg.	*11*	*1.4*	*1.4*

89. From my data set, I estimate that the PTO's requirement to provide explanations for any foreign-language or moderately long (over 25 pages) reference would require applicants to file papers in the substantial plurality of applications in which 20 or fewer references were cited. Indeed, in my sample, only three of the 14 patents would have been exempt from compliance with this IDS rule, or about 15%. Thus, the proposed IDS rule would apply to about 85% of the applications in this class.

90. Combining that fact with the PTO's estimate that about 15% of all applications would require complete explanations, because they have more than 20 references, the overwhelming impact of this IDS rule can be seen. This part of the proposed IDS rule would apply, then, to about 85% of the 85% of all applications to which the first part of the proposed IDS rule discussed above did not apply. That means that this part of the proposed IDS rule would impact *nearly three quarters of all patent applications* (72%).

91. The second observation from my sample is that the proposed IDS rule would require applications to provide explanations for over a *quarter* of all *references* cited, even in those applications that did not require complete "patentability justification" documents. About half of the references needing explanation would be foreign-language references, and the rest would be those that were moderately lengthy.

92. I observed that all 20 of the references that exceeded 25 pages fell into the following categories: (a) U.S. patents; (b) U.S. patent publications; (c) publications of international applications filed under the Patent Cooperation Treaty; and (c) publications of the European Patent Office. None of the references exceeding 25 pages were books, scientific articles, or the like – applicants cited such materials in some of the applications, but they were always, in my sample, cited in such a way that specific pages, and fewer than 25, were identified.

93. The main reason why the U.S. patents and publications that exceeded 25 pages were that long was simply that some patents have a large number of drawings pages. The PTO's proposed IDS rule seems to have been written with the purpose of having applicants point out specific parts of lengthy *textual* references. That rationale does not seem to apply to U.S. patents and publications that exceed 25 pages merely because they contain many drawings and do not have lengthy textual descriptions.

94. Nearly all of the other references exceeding 25 pages were PCT application publications. In some instances, references of this type exceeded that threshold because of the drawings sheets, like the U.S. patents and publications. In addition, however, WIPO (the United Nations entity that oversees the Patent Cooperation Treaty) publishes patent application documents as direct photocopies of the documents filed by applicants, typically double-spaced, as opposed to the 10-point typeset form of U.S. patents, which are far more compact. It should be hardly surprising that PCT publications would *regularly* exceed 25 pages, and it makes little sense, and provides examiners with little benefit, to have the applicants explain such references. Yet such is the proposed IDS rule.

95. Turning to the estimated cost of complying with this part of the proposed IDS rule, the rule requires the same kind of information as discussed in the first section above, except limited to those references that are either in a foreign language or have more than 25 pages.

96. The data set from my sample shows that the average application that falls within the 85% of applications that are not subject to the proposed IDS rule requiring discussion of all references (discussed in the first part of this statement) will require

explanation of about three references. As explained above, I had estimated that the reports in the remaining 15% of applications would need to explain about 30 references on average. Thus, an average report of the sort needed to comply with this part of the rule will be about one tenth as expensive as the report discussed above.

97. I also conservatively assume that the odds of the report on particular longer or foreign language references being the subject of inequitable-conduct charges, if the application becomes a patent that is litigated, are one in ten. I am fairly sure that this is a low figure, especially because of several famous opinions that have found inequitable conduct arising from foreign-language references, apparently on the theory that, even if the reference is in front of the examiner, the examiner cannot be expected to have the ability to read the foreign language in question.

98. Using those conservative assumptions, in my opinion, the estimated cost for reports under this part of the proposed IDS rule is one tenth that for the reports in the first part of the rule discussed above, which equates to about $3,420 per application. If any of the assumptions turn out to have been too conservative, as I suspect is the case, the average cost would be higher.

99. Thus, this part of the proposed IDS rule would, in my opinion, impose total costs of about $3,420 per application, averaged across the 85% of all applications that have 20 or fewer cited references and that therefore do not require a report explaining all references. This would impact about 3 million applications over the next five years (including those in the pending backlog), for a total cost to the public of about $10.4 billion, from this factor alone, which exceeds *$2 billion per year*.

100. This part of the proposed IDS rule will result in another category of costs aside from the cost of practitioner time to create and provide the explanations sought by the PTO through this proposed rule. In my opinion, this part of the rule would also require applicants to translate foreign-language references more frequently, to allow for proper compliance with the rule. I am aware that the proposed IDS rule does not explicitly require translations of foreign-language references. To the contrary, the rule as proposed merely requires applicants to provide translations if they are "available."

101. However, the proposed IDS rule requires applicants to identify the portions of foreign-language references deemed relevant to the claims and to summarize such references. To do an *effective* job of complying with those requirements, it is my opinion that a full translation is at least prudent, if not required. To do otherwise heightens the risk of mischaracterizing the reference, with the consequences of rendering the patent unenforceable and leaving the practitioner subject to disciplinary action and with a destroyed reputation.

102. I do not know what percentage of foreign-language references submitted in IDS statements have been translated in full anyway. The PTO should study that question and provide survey evidence. Obviously, this part of the rule would not impose extra expense, on account of this effect, with respect to those references that had already been translated, independent of this rule. However, it seems reasonable to suppose that more translations will result from passage of this rule.

103. Translating the average foreign-language reference costs about $1,000, on average, in my experience. It appears from my sample that approximately 13% of all references cited in IDS statements are foreign-language references, or about 1.4 references per application (obviously more per application in those that exceed 20 references). I conservatively assume that the proposed IDS rule would trigger extra translations at a rate of about one foreign language reference in every other application, resulting in extra per-application cost from this factor of about $500, on average. However, that figure is averaged across all applications, whether or not the full report or a partial report is required. For 3.5 million applications (including those that the PTO expects to be filed over the next five years and those pending), the total cost would be nearly an additional $1.8 billion, or about an *extra $350 million/year*.

104. In sum, in my opinion, the cost from this part of the proposed IDS rule is estimated to be at least ***$2.4 billion per year***.

REQUIREMENTS FOR CITATION OF REFERENCES AFTER FAOM

105. A third category of cost arises from the proposed IDS rule's requirements with respect to citing supplemental references after the examiner first acts by issuing an Office Action. Specifically, the proposal would bar applicants from citing new references without a showing as to how each new reference was not cumulative of any other reference previously cited. That showing would be quite expensive, as it would require comparison of each new reference to each other previously cited reference, and such a comparison must consider whether the new reference was closer to any of the many claim elements found in any of the many claims.

106. The proposal contains an exception for references that were cited in foreign examination reports. However, the rule provides no exception for references cited by a U.S. examiner in a related or unrelated copending application (that is not a parent to which priority is claimed under 35 U.S.C. § 120). Because many (if not most) references that are cited after first action arise from the need to cross-cite references brought to applicant's or owner's attention in a copending U.S. application, the limited nature of the PTO's exception significantly increases the likelihood that a "patentability justification" document will be needed.

107. The PTO has provided no sampling data showing how often references are cited after first action. However, my experience is that it occurs about 50% of the time, with a reasonable estimate of the average number of references for which citation would be sought being five, in those applications in which it happens.

108. If references come to the attention of an applicant or practitioner that might be pertinent to a particular application in which a first action has already been issued, then I estimate it will cost the applicant at least the same $890 per reference estimated in the first part above, plus an additional $300 per reference to compare the new reference to the previous references and explain why the new one is not cumulative. For five new references, the total cost of an average report thus would run about $5,000 to comply with this part of the rule.

109. If a report of this nature is required in half of all applications, this proposed IDS rule imposes about $2,500 per application of extra costs, on average.

110. In addition, the other portions of the proposed IDS rule discussed in previous sections of this report apply as well. So, for the one sixth of applications that are subject to the full report, a supplemental report must be submitted to discuss the new references in the same way as the old. For the rest of the applications, there is presumably a one in four chance that any particular new reference exceeds 25 pages or is in a foreign language, in which case the targeted report must be filed discussing that particular reference. However, the information required by those rules partially overlap the information needed to make an effective showing of non-cumulativeness. I estimate that the extra showings that do not overlap would increase the cost of an average report by 25%, to a total estimated average of $3,000 per application.

111. For 3.5 million applications (including those that the PTO expects to be filed over the next five years and those pending), the total cost from this part of the proposed IDS rule would be about an additional $10.7 billion, or at least about an ***extra $2.1 billion per year***.

112. The PTO is eliminating the fees for filing a late IDS statement. However, I do not believe that the PTO collects much revenue under that fee anyway. The PTO could easily provide such data from its financial accounting database, but it has not done so, to my knowledge. Accordingly, I believe that the offsetting value from elimination of that fee is quite small as to be negligible compared to the costs imposed instead arising from the need to provide the reports discussed here.

113. I have rarely needed to pay the late-IDS fees for my clients, because those fees do not apply if one merely cites the newly found reference within three months of the date they are discovered or brought to the applicant's or practitioner's attention. By contrast, the PTO's proposed new rule of showing non-cumulativeness would be required in all cases, even when an applicant or practitioner only recently learned of new references (with the narrow exception for references cited in a foreign search or examination report). For that reason, the costs from the proposed IDS rule would in no way be relieved significantly through elimination of the relatively rarely paid fee.

TOTAL COST OF THE RULE

114. Adding up the estimates of the costs of the three main parts of the proposed IDS rule (those parts that I believe would impose significant extra costs) results in a total estimated paperwork costs arising from the proposed rule of about ***$7.3 billion per year*** (from paragraphs 82, 104, and 111).

115. This estimate includes direct costs of practitioners' time to produce the required reports and indirect costs from litigation costs and extra translations. It does not account for the substantial added cost from inventions that would have insufficient patent protection, such as because the patentee is discouraged from seeking protection because of the higher-than-previous expense of obtaining the average patent.

116. Nor does this estimate account for the destruction of patent asset value, including reduced licensing or sales value on account of the increased likelihood that a prospective licensee or infringer will raise a non-meritorious but expensive-to-rebut charge of inequitable conduct arising from statements made in the course of the reports required by this rule. Nor does it account for the losses to the U.S. economy arising from the ability of foreign-based competitors to produce competing products or provide competing services to customer in the U.S. because innovation in this country is insufficiently protected.

117. Finally, the estimate does not include the costs that will be imposed on the patentee's competitors who seek in good faith to "design around" valid patents. A common strategy for a "design around" is to adopt a technique disclosed in the prior art references appearing in the patent file. If there are fewer references, there will be fewer design-arounds available to competitors, or it will cost more to search for and find the same references, for use in designing-around patents.

118. This is a particularly cumbersome set of rules that the public is being asked to follow. The paperwork requirements are extreme and quite expensive. The PTO's entire strategy is flawed, because (a) it seeks to shift duties from the examiners, who can perform such duties cheaply and without paperwork, to applicants, who are positioned to perform such duties more expensively and who must submit the paperwork only in the most careful fashion, and (b) it places applicants and practitioners in a "Catch-22" situation by, under an existing rule, mandating disclosure of material, known prior art references, while simultaneously, under the proposed new rule, mandating high extra cost and grave risks in instances where there is a duty to disclose many references or references that are relatively lengthy or written other than in English. Also, the requirements would impose much detailed work on applicants that no examiner would ever need to do to perform a proper analysis. Any reduction in cost to, or burden on, the Office is grossly outweighed by the significantly increased cost to the public.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on this 5th day of October, 2007, in [redacted]

[redacted]

PEER REVIEW REPORT #1

Peer Review of Declaration on Anticipated Expenses Associated with Proposed IDS Rules

Peer Reviewer Qualifications

I am a partner in a large intellectual property firm. I have been a practicing intellectual property lawyer in the area of biotechnology since 1988. While my experience includes both prosecution and litigation, my focus over the past several years has been almost exclusively patent prosecution of biotech and pharmaceutical applications.

I read the declaration on anticipated expenses associated with the proposed IDS rule changes. I was impressed with the very thorough analysis provided in the declaration and I agree in large part with the conclusions reached in the declaration. However I believe that the declarant's estimation of the costs associated with the proposed IDS rules are too conservative and are unrealistically low for biotechnology and even most pharmaceutical applications, where I believe (1) that well over 80% of applications filed will involve filing more than 20 references and (2) even those that may be able to cite less than 20 references will include more documents over 25 pages than projected by the declarant.

1. To construct an estimate of the burden for an individual applicant, the affiant says the burden of preparing a "patentability justification document" is similar to the cost of preparing an ESD is similar. If you had to choose, would you say the cost of preparing a "patentability justification document" is:

    a. *Less than the cost of preparing an ESD*?
    b. About the same as the cost of preparing an ESD?
    c. More than the cost of preparing an ESD?

    I think the costs may be similar but I expect the ESD to ultimately cost more because of the search component.

2. The affiant also used several building blocks to estimate the cost of preparing an ESD. If you had to choose, would you say that the values are:

    a. Too low?
    b. About right?
    c. Too high?

    I believe that at least for the biotechnology and possibly the pharmaceutical industry as well, the cost estimates made by the declarant are too low. I believe that the costs will be much higher per application in the biotechnology arts partly due to the complexity of the technology and the references cited, but also because there are many more relevant publications in these arts in general.

3. The affiant identified specific provision in the proposed rule judged to be significant. Based on your knowledge of the proposed rule, did the affiant:

    a. Miss any regulatory provision that you believe may impose a significant burden? If so, please identify it. (You need not supply any estimate of its magnitude, but you can if you feel comfortable doing so.) *No.*

b. Include any element that you believe is actually minor? *No.*
c. Use reasonable judgment? *Yes.*

4. To construct the burden estimate for the rule as a whole, the affiant made certain assumptions about the number of applications affected. The number of applications could be affected by the rule, a dynamic or adaptive effect. For burden estimation purposes, please ignore such dynamic or adaptive effects and assume that the propensity to submit an application is unchanged. With that foundation, would you say that the affiant's estimate of the number of applications affected by proposed rule is:

    a. Too low?
    b. About right?
    c. Too high?

As I stated above, I believe that the estimated number of applications may be low. However, I also believe that the proposed rules disproportionately affect the biotechnology and pharmaceutical industries where more references are required to be cited to comply with duty of disclosure requirements.

I ran a search on the USPTO web site using the claim terms DNA or antibody. Of the first ten patents that came up on the list, nine of them listed more than 20 references.

5. Is there any aspect of the declaration that you consider implausible or unreasonable, based on your experience?

No.

PEER REVIEW REPORT #2

IDS Rule Burden Estimate: Peer Review Charge

The declaration we are asking you to review provides an estimate of the burden that would be imposed by the IDS Rule, as proposed. (The text of the draft final rule is not public.) It is widely known that knowledge of the identity of an author has real, though sometimes subtle, effects on peer reviewers. For that reason, we have redacted the identity of the affiant in accordance with normal "blind" peer review procedures,

We are not asking you to replicate or reproduce the affiant's estimates. We are asking you only to opine, based on your professional experience and judgment, on the reasonableness of the methodology used and the figures provided, and whether you believe them to be biased in either direction. We will not disclose your identity.

Please review the declaration and answer the following questions. A sentence or two on each is sufficient.

1. To construct an estimate of the burden for an individual applicant, the affiant says the burden of preparing a "patentability justification document" is similar to the cost of preparing an ESD is similar. If you had to choose, would you say the cost of preparing a "patentability justification document" is:
    a. Less than the cost of preparing an ESD?
    b. About the same as the cost of preparing an ESD?
    c. More than the cost of preparing an ESD?

    Response: I would probably class the ESD and patentability justification document (PJD) about the same in terms of cost. One thing not mentioned in the affidavit is an estimate of comparing the combination of any references with the claims, only the direct comparison of references to claims. Statements in the ESD or the PJD are going to be made regarding the combination or reasons not to combine as well. The cost of developing these reasoned statements was not addressed and the cost of the defense of inequitable conduct charges based on these statements was not included (although these MAY fall into the same category as arguments against combination made to an Examiner during prosecution).

2. The affiant also used several building blocks to estimate the cost of preparing an ESD. If you had to choose, would you say that the values are:
    a. Too low?
    b. About right?
    c. Too high?

    Response: Building blocks for costs seem appropriately described as conservative. I could argue that they will be higher but these are acceptable for the purpose of this document.

3. The affiant identified specific provision in the proposed rule judged to be significant. Based on your knowledge of the proposed rule, did the affiant:

a. Miss any regulatory provision that you believe may impose a significant burden? If so, please identify it. (You need not supply any estimate of its magnitude, but you can if you feel comfortable doing so.)
b. Include any element that you believe is actually minor?
c. Use reasonable judgment

Response: The affiant used reasonable judgment.

4. To construct the burden estimate for the rule as a whole, the affiant made certain assumptions about the number of applications affected. The number of applications could be affected by the rule, a dynamic or adaptive effect. For burden estimation purposes, please ignore such dynamic or adaptive effects and assume that the propensity to submit an application is unchanged. With that foundation, would you say that the affiant's estimate of the number of applications affected by proposed rule is:
    a. Too low?
    b. About right?
    c. Too high?

    Response: I have a different experience with regard to the references filed after FAOM in my current practice. However, in a prior position, I did see a lot of cross-pollination of references between related or similar applications within the portfolio of a large corporate client. In my current role, I do not see as much of this in smaller (mid-market, $5 to 50 million annual revenue) clients, so this 50% estimate may be high for some sectors of the corporate world and low in other sectors. Probably very practice specific or client specific.

    Other aspects seem to be reasonably and conservatively estimated.

5. Is there any aspect of the declaration that you consider implausible or unreasonable, based on your experience?

    Response: As stated above, some aspects may be more client or practice specific than presented, but overall I agree with the numbers and the basis for the numbers. My gut level reaction is that the estimates are low. Maybe with several (10+) years of experience practicing under the new rules, we may be more adept at conforming, but the initial costs are likely to be higher than the affiant estimated.

PEER REVIEW REPORT #3

IDS Rule Burden Estimate: Peer Review Charge

The declaration we are asking you to review provides an estimate of the burden that would be imposed by the IDS Rule, as proposed. (The text of the draft final rule is not public.) It is widely known that knowledge of the identity of an author has real, though sometimes subtle, effects on peer reviewers. For that reason, we have redacted the identity of the affiant in accordance with normal "blind" peer review procedures,

We are not asking you to replicate or reproduce the affiant's estimates. We are asking you only to opine, based on your professional experience and judgment, on the reasonableness of the methodology used and the figures provided, and whether you believe them to be biased in either direction. We will not disclose your identity.

Please review the declaration and answer the following questions. A sentence or two on each is sufficient.

1. To construct an estimate of the burden for an individual applicant, the affiant says the burden of preparing a "patentability justification document" is similar to the cost of preparing an ESD is similar. If you had to choose, would you say the cost of preparing a "patentability justification document" is:
    a. Less than the cost of preparing an ESD?
    b. About the same as the cost of preparing an ESD?
    c. More than the cost of preparing an ESD?

First, it should be noted that the Certification analysis relied upon paragraph 28 appears to include a cost of searching (which is wildly low). Such a search is not required for the IDS rule. Second, the ESD has many of the same components, includes a 112 element identification, whereas the patentability justification requires a non-cumulative statement. The non-cumulative statement outlined in paragraph 105 will, during prosecution, be far more expensive than merely identifying the 112 support for the claims since it will, by definition, require a re-review of all prior citations (>20 in number, having >25 pages, being in a non-English language) and a statement of distinction which is in addition to the distinction over the claims. Thus, new prior art will trigger both a claims comparison and a prior art comparison.

2. The affiant also used several building blocks to estimate the cost of preparing an IDS patentability justufication. If you had to choose, would you say that the values are:
    a. Too low?
    b. About right?
    c. Too high?

This would be in line with my experience. Another potential comparison relates to the cost of preparing an amendment, which is similar to a patentability justification and the ESD analysis in some ways. For an easy amendment (i.e., only one 102 rejection), the cost would be close to $1500-1600 (AIPLA Survey 2007). Assuming 20 claims and 3 independent claims, that breaks down to about $80 per claim or $533 per independent claim in order to do comparable work on a single reference. However, amendments involve additional work, thus driving up the per claim/per reference costs. As such, the costs outlined appear in line

with what I would expect where I have 20 references to analyze, and are also consistent with costs used to prepare validity and infringement claim charts.

3. The affiant identified specific provision in the proposed rule judged to be significant. Based on your knowledge of the proposed rule, did the affiant:
    a. Miss any regulatory provision that you believe may impose a significant burden? If so, please identify it. (You need not supply any estimate of its magnitude, but you can if you feel comfortable doing so.)
    b. Include any element that you believe is actually minor?
    c. Use reasonable judgment

4. To construct the burden estimate for the rule as a whole, the affiant made certain assumptions about the number of applications affected. The number of applications could be affected by the rule, a dynamic or adaptive effect. For burden estimation purposes, please ignore such dynamic or adaptive effects and assume that the propensity to submit an application is unchanged. With that foundation, would you say that the affiant's estimate of the number of applications affected by proposed rule is:
    a. Too low?
    b. About right?
    c. Too high?

From my experience, the assumptions are about right (especially since many are based upon the USPTO's low estimate of the number of applications affected).

5. Is there any aspect of the declaration that you consider implausible or unreasonable, based on your experience?

The only question I would have would be in regards to the source of the PCT and foreign applications in the sample at paragraph 88. If those foreign references or PCT applications were from related foreign applications, the IDS rules do not require a patentability justification. Thus, the number of affected of applications having the >25 page references and the foreign references may be lower. However, from my experience, most foreign filed applications (which make up about half of all filings according to the USPTO) will cite foreign prior art *prior* to receiving a foreign office action, making them subject to the patentability justification.

PEER REVIEW REPORT #4

Response to Peer Review Charge

1. I would probably class the ESD and patentability justification doc about the same in terms of cost. One thing not mentioned in the affidavit is an estimate of comparing the combination of any references with the claims, only the direct comparison of refs to claims. Statements in the ESD or the PJD are going to be made regarding the combination or reasons not to combine as well. The cost of developing these reasoned statements was not addressed and the cost of the defense of inequitable conduct charges based on these statements was not included (although these MAY fall into the same category as arguments against combination made to an Examiner during prosecution)
2. Building blocks for costs seem appropriately described as conservative. I could argue that they will be higher but these are acceptable for the purpose of this document.
3. The affiant used reasonable judgment.
4. I have a different experience with regard to the refs filed after FAOM in my current practice but in a prior position, I did see a lot of cross-pollination of refs between related or similar applications within the portfolio of a large corporate client. In my current role, I do not see as much of this in smaller (mid-market, $5 to 50 million annual revenue) clients, so this 50% estimate may be high for some sectors of the corporate world. Probably very practice specific.

   Other aspects seem to be reasonably and conservatively estimated.
5. As stated above, some aspects may be more practice specific than presented, but overall I agree with the numbers and the basis for the numbers. My gut level reaction is that the estimates are low. Maybe with several (10+) years of experience practicing under the new rules, we may be more adept at conforming, but the initial costs are likely to be higher than the affiant estimated.