Exhibit 21

Declaration of Richard B. Belzer, Ph.D.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA

Alexandria Division

TRIANTAFYLLOS TAFAS, Plaintiff, - against - JON. W. DUDAS, et al., et al., Defendants.	1:07cv846 JCC/TRJ Judge Cacheris

CONSOLIDATED WITH

SMITHKLINE BEECHAM CORPORATION, et al.), Plaintiff, - against - JON. W. DUDAS, et al., et al., Defendants.	1:07cv1008 (JCC/TRJ)

DECLARATION OF RICHARD B. BELZER, PH.D.

ACADEMIC AND PROFESIONAL QUALIFICATIONS

1. I have four earned academic degrees: a Bachelor of Science in agricultural economics from the University of California at Davis (1979), a Master of Science in agricultural economics from the University of California at Davis (1980), a Master in Public Policy from the

John F. Kennedy School of Government at Harvard University (1982), and a doctorate in public policy from Harvard University (1989).

2. From November 1988 until September 1998, I was employed as an Economist (a career civil service position) in the Office of Information and Regulatory Affairs (OIRA), in the Office of Management and Budget (OMB). My principal responsibility was to review "major" and "economically significant" draft regulations prior to their publication or promulgation by a federal Executive branch department or agency. The terms "major" and "economically significant" come from Executive Orders 12,291 § 1(b) and 12,866 § 3(f)(1), respectively, and generally encompass the subset of draft regulations likely to have effects exceeding $100 million in any one year, or novel policy implications. I reviewed draft regulations from the Departments of Agriculture, Commerce, Energy, Health and Human Services, Housing and Urban Development, Interior, Labor, and Transportation; and the Environmental Protection Agency. I did not review a draft regulation submitted by the U.S. Patent and Trademark Office (PTO). In addition, I was responsible for managing certain major issues affecting multiple departments and agencies, contributing to OMB guidance (such as its guidance on methods of Regulatory Impact Analysis), reviewing draft reports to Congress on various issues, reviewing Administration testimony related to various statutory and regulatory matters, coordinating across Executive branch agencies and resolving interagency disputes, and helping establish the system of annual reporting to Congress on the benefits and costs of federal regulation, which was first required by law in 1998.

3. During my tenure at OMB, I earned Divisional Awards for superior performance in 1991 and 1992, and a Special Achievement Award for superior performance in 1990. I was the principal author of the final draft of OMB's first guidance on Regulatory Impact Analysis,

published first in 1990. This guidance was published as Appendix V in each edition of the *Regulatory Program of the United States Government* from 1990 through 1992. (The *Regulatory Program* was discontinued in 1993 when Executive Order 12,498 was revoked.) I also was the author of an OMB white paper on risk assessment that was published by OMB in the *Regulatory Program.*

4. In 1995, I was appointed Fellow of the Cecil and Ida Green Center for the Study of Science and Society, at the University of Texas (Dallas).

5. From 1998-2001, I was Visiting Professor of Public Policy at Washington University in St. Louis and Regulatory Program Manager for the Center for the Study of American Business (now the Weidenbaum Center). Since 2001, I have been President of Regulatory Checkbook, a nonpartisan and nonprofit research organization established under IRC § 501(c)(3). Since 2006, I have been Managing Editor of Neutral Source, publisher of a blog on regulatory economics, science and policy matters, including information quality and peer review (see http://neutralsource.org/). Like Regulatory Checkbook, Neutral Source is a nonpartisan and nonprofit organization under IRC § 501(c)(3). Neither Regulatory Checkbook nor Neutral Source engages in any lobbying activity whatsoever. Since leaving OMB, I have gained an additional nine years' experience in regulatory policy, science, and economics.

6. I have become an expert in the 2000 Information Quality Act (IQA), OMB's government-wide implementing guidance, and the specific implementing guidance of several agencies, which are discussed further in ¶ 26-29. In my capacity as President of Regulatory Checkbook, I have provided multiple public comments to OMB and other agencies on various aspects of information quality and the Guidelines, and delivered multiple invited public

presentations. Regulatory Checkbook is currently engaged in multi-year study of agency compliance with the procedural and substantive provisions of the IQA and relevant guidance. In a private consulting capacity, I have advised clients concerning whether issues of concern to them are appropriate candidates for administrative requests for correction. In some cases, I have prepared requests for correction on their behalf or assisted them in the preparation of their own petitions.

7. I am a member of several professional societies including the American Economic Association (AEA) and the Society for Risk Analysis (SRA). In 1998 and 1990, I was elected Treasurer of SRA and served on its Executive Committee from 1998 through 2003. In 2003, I was presented with the SRA's Outstanding Service Award, and I continue to serve on several of its standing committees.

FACTS TO WHICH I CAN ATTEST FROM GENERAL KNOWLEDGE AND PROFESSIONAL EXPERTISE

8. The Office of Management and Budget (OMB) is the staff office within the Executive Office of the President responsible for preparing the President's budget and overseeing the Executive Branch. The Office of Information and Regulatory Affairs (OIRA) is a statutory office within OMB that was created in 1980 by the Paperwork Reduction Act (44 U.S.C. 3501 et seq., as amended). Since it formally opened for business in 1981, OIRA also has been responsible for implementing presidential Executive Orders related to, among other things, the centralized review of draft proposed and draft final regulations prior to their publication for public comment or promulgation. This review process has been governed primarily by Executive Orders 12,291 (1981 -- 1993), 12,498 (1985 – 1993), and 12,866 (1993 to date). Executive Order 12,866 has been amended twice since my departure from OIRA, in 2002 (Executive Order

13,258) and in 2007 (Executive Order 13,422). These amendments do not impinge on any matter directly related to the subject of this Declaration.

9. Executive Orders 12,291 and 12,866 have required agencies to perform limited f regulatory analysis for "non-major" and "significant" regulatory actions, respectively. For example, EO 12,866 § 6(a)(3)(B)(ii) says agencies "shall provide to OIRA" … "*an assessment of the potential costs and benefits of the regulatory action*, including, an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions" (emphasis added).

10. Executive Order 12,866 also guides agency decision-making "to the extent permitted by law," which is understood to mean where neither Congress nor the President has clearly specified a different decision-making rule. For example, EO 12,866 § 1(b)(6) says: "Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, *propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs"* (emphasis added).

11. Executive Order 12,866 also regulates the nature and quality of information agencies may use in support of regulatory actions. For example, EO 12,866 §1(b)(7) says: "Each agency shall base its decisions on the *best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation*" (emphasis added).

12. Executive Order 12,866 § 2(a) says that the agencies are responsible for complying with its major provisions, including the generation and disclosure of adequate information for decision-making: "*Because Federal agencies are the repositories of significant substantive expertise and experience, they are responsible* for developing regulations and assuring that the regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order" (emphasis added). The agencies, not OMB, are presumed both to have superior expertise in the substantive aspects of their regulatory programs.

13. Executive Order 12,866 § 6(a)(3)(A) provides that the OIRA professional staff generally must rely on the authoring agency for information sufficient to perform its review. Where they believe that body of information to be insufficient, OIRA professional staff often ask the authoring agency for additional supporting information that may or may not be included in the administrative record. In addition, OIRA professional staff can supplement their knowledge by obtaining any manner of publicly available information, and nonpublic information from other federal agencies. However, Executive Order § 6(b)(3(A) generally denies OIRA professional staff the ability to consult with nonfederal parties who either have relevant expertise interests in the regulation under. To the extent that fact-checking claims made by an agency requires such external consultation. OIRA professional staff are not permitted to do so. During my tenure in OIRA, it was a common experience for an agency to complain when I asked for more information, to withhold crucial information from me until I asked just the "right" questions, or to withhold crucial information even if my questions were precisely on target.

14. Executive Order 12,866 § 10 states that the agencies, not OMB, make final decisions concerning the details of the regulations they promulgate: "Nothing in this order shall be construed as displacing the agencies' authority or responsibilities, as authorized by law."

15. Executive Order 12,866 § 11 explicitly states that its provisions are not directly subject to judicial review: "Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person."

16. Executive Order 12,866 § 6(b)(1) limits OIRA review to those draft rules designated as "significant," for which "economically significant" is a subset. OIRA does not review draft rules designated as "not significant": "OIRA may review only actions identified by the agency or by OMB as significant regulatory actions under subsection (a)(3)(A) of this section."

17. Data retained by the General Services Administration (GSA) show that during the 12-1/2 year period in which Executive Order 12,291 was in force, OIRA performed 29,769 regulatory reviews (an average of about 2,400 per year), including 1,051 "major" rules (an average of about 85 per year). During the 14-1/3 year period in which Executive Order 12,866 has been in force, OIRA performed 9,113 regulatory reviews (an average of about 640 per year), including 1,275 "economically significant" rules (an average of about 90 per year). The difference in the average total number of reviews reflects the fact that under EO 12,866, agencies do not submit for OIRA review draft regulations deemed to be "not significant." The similarity in the average annual number of "major" and "economically significant" rules reflects the similarity of the terms "major" and "economically significant." See http://www.reginfo.gov/public/do/eoHistoricReport.

18. Data retained by GSA show that OIRA reviewed 124 draft regulations (an average of about 10 per year) submitted by PTO for review under Executive Order 12,291. Under Executive Order 12,866, OIRA has reviewed 36 draft regulations from PTO (an average of less than 3 per year. See http://www.reginfo.gov/public/do/eoAdvancedSearch. GSA data indicate that none of these draft rules were designated as "major" or "economically significant."

19. The preparation of a Regulatory Impact Analysis always has been required for "major" or "economically significant" draft proposed or draft final regulations. See Executive Order 12,291 § 3 and Executive Order 12,866 § 6(a)(3)(C). Because similar analytic provisions have been in place since 1981, the performance of a Regulatory Impact Analysis in support of "major" or "economically significant" regulatory actions is standard practice in the Executive branch. On at least two occasions, OIRA has revised its 1990 guidance concerning the preparation of Regulatory Impact Analysis. The current version is published as OMB Circular A-4. See http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf. In my professional judgment, OMB Circular A-4 differs only slightly from the 1990 document that I authored (see ¶ 3), and not at all with respect to elementary analytic methods.

20. During my tenure in OIRA, the Office employed about 30 professional staff members who performed regulatory review, including as many as three professional Economists. Whereas the vast majority of professional staff members were Desk Officers assigned to cover the panoply of regulatory activities undertaken by specific agencies or offices within agencies (including the management of paperwork burdens), the Economists were primarily responsible for reviewing "major" or "economically significant" draft regulations and performing other cross-cutting duties.

21. During my tenure in OIRA, I often observed agencies attempt to split draft regulations into smaller parts so as to avoid exceeding the $100 million threshold for a "major" or "economically significant" regulation, presumably in hopes of avoiding the requirements to prepare a Regulatory Impact Analysis. It was my regular practice to combine such regulations for review purposes and treat the divided parts as major or economically significant for purposes of regulatory review, and seek from the submitting agency a competently performed Regulatory Impact Analysis.

22. During my tenure in OIRA, the number of draft regulations submitted, including draft major or economically significant regulations, vastly exceeded the staff capacity to perform competent regulatory review. For that reason, the level of scrutiny and attention that draft regulations received was highly variable. Furthermore, professional staff members allocated limited resources in accordance with a triage regime governed largely by the priorities of senior career managers, OIRA's Administrator or Deputy Administrator, and other officials at OMB and the Executive Office of the President. The level of scrutiny also was strongly influenced by the agency's informed and presumptively good-faith initial designation of a regulation as "not significant," "significant," or "economically significant." I am aware of no facts suggesting that these conditions have changed significantly since my departure in 1998.

23. Agencies are required pursuant to the Regulatory Flexibility Act (RFA) to ascertain whether a planned regulatory action may substantially impact a significant number of small entities. For regulations that they determine have such impacts, the RFA requires the preparation of a Regulatory Flexibility Analysis ("Reg Flex Analysis"). The Small Business Administration's Office of Advocacy (SBA-Advocacy) is primarily responsible for matters related to the RFA. Executive Order 12,866 §1(b)(11) directs agencies to craft regulations, and to

consider alternatives, that take account of the different sizes and capabilities of regulated parties. Therefore, it was my practice at OMB to consult with SBA-Advocacy staff and personally review Reg Flex Analyses for clues and insights concerning impacts on small entities.

24. Agencies are generally required pursuant to the Paperwork Reduction Act (PRA) to obtain prior OIRA approval to obtain information from the public, whether respondents are required to provide this information or the provision of information is voluntarily, including information that the public provides in order to obtain a benefit (such as a patent application). Agencies do this by submitting Information Collection Requests (ICRs) to OMB in accordance with procedures set forth in regulation (5 C.F.R. § 1320 *et seq*.). This regulation requires, among other things, that the agency submit a Supporting Statement containing "a specific, objectively supported estimate of burden, which shall include, in the case of an existing collection of information, an evaluation of the burden that has been imposed by such collection" (§ 1320.8(a)(4)).

25. Although responsibility for managing ICRs rests with Desk Officers, during my tenure in OIRA I often reviewed ICR Supporting Statements for clues and insights about the costs of draft proposed and final regulations.

26. In 2000, Congress enacted a statute that is colloquially called the federal Information Quality Act (IQA) or Data Quality Act (Section 515 of Public Law 106-554, Treasury and General Government Appropriations Act for Fiscal Year 2001), which is codified in the Paperwork Reduction Act (44 U.S.C. 3516 note). OMB was directed to issue government-wide guidelines defining essential terms and requiring all covered agencies to issue their own agency-specific guidelines implementing OMB's guidelines, which it did in February 2002 (67

Fed. Reg. 8452). By law these guidelines were to include "administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines." In its government-wide guidelines, OMB also directed agencies to establish new (or modify existing) pre-dissemination review procedures to minimize the number of valid requests for correction that they receive.

27. PTO issued its agency-specific guidelines on or before the October 1, 2002, deadline set by law (http://www.uspto.gov/web/offices/ac/ ido/infoqualityguide.html). PTO's guidelines use definitions of "quality," "objectivity," "utility," and "integrity" that are materially equivalent to the government-wide definitions established by OMB. "Objectivity" requires that information be "accurate, reliable, and unbiased," and "presented in an accurate, clear, complete, and unbiased manner." Data and analyses must be transparent and "reproducible" by competent third parties, exemplified by PTO's strong commitment to full public disclosure: "Reproducibility" of these analytic results does include "especially rigorous robustness checks" and *when asked the USPTO does provide disclosure of the data sources that have been used and the specific quantitative methods and assumptions (if any) that have been employed* (emphasis added). "Utility" is defined by reference to "the usefulness of the information to its intended users, including the public. In assessing the usefulness of information that the agency disseminates to the public, the agency considers the uses of the information not only from its own perspective but also from the perspective of the public" See PTO Information Quality Guidelines §§ IV and VII).

28. The Information Quality Act and its implementing guidelines apply to information to disseminated by PTO in support of regulatory actions. "Information" is defined as

"any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms." Information is "influential" if "the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." Information is disseminated when it is an "agency initiated or sponsored distribution of information to the public." Data, analyses, statistics, and similar "representation[s] of knowledge" that PTO made public in support of the proposed or final rule is information covered by the Information Quality Act and subject to the standards and criteria of OMB's and PTO's implementing guidelines. This includes information as part of an agency's regulatory development (such as Notices of Proposed Rulemaking and Final Rules), information disseminated to inform public comment or as part of an agency's public communication strategy (such as the "Town Hall" slides referenced in ¶ 32), and information disseminated in support of Information Collection Requests under the Paperwork Reduction Act. See OMB Information Quality Guidelines, § V.5-8 (67 Fed. Reg. 8460) and PTO Information Quality Guidelines at http://www1.uspto.gov/web/offices/ac/ido/infoqualityguide.html.

29. Federal agencies have now had more than five years' experience with information quality standards, pre-dissemination review procedures, and administrative processes whereby affected persons can obtain the correction of information that does not adhere to these standards.

30. The preambles to each of the regulatory actions listed in ¶ 31, the information listed in ¶ 32 that PTO publicly disseminated, PTO's ICR Supporting Statements (¶ 33), and PTO's Reg Flex Analysis (¶ 35) all contain "representations of knowledge such as facts or data" (¶¶ 26-28) which are covered by the Information Quality Act and OMB's and PTO's implementing guidelines, in addition to policy judgments which are not.

THE SCOPE OF MY REVIEW FOR THE PURPOSE OF THIS DECLARATION

31. I have reviewed several proposed and final regulations published by the U.S. Patent and Trademark Office (PTO), including: (a) proposed rule "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims," RIN 0651-AB93 ("Proposed Continuations Limit Rule," 71 Fed. Reg. 48 [January 3, 2006]); (b) proposed rule "Changes to Practice for the Examination of Claims in Patent Applications," RIN 0651-AB94 ("Proposed Claims Limit Rule," 71 Fed. Reg. 61 [January 3, 2006]) (c) proposed rule "Changes to Information Disclosure Statement Requirements and Other Related Matters," RIN 0651-AB95 ("Proposed IDS Rule," 71 Fed. Reg. 38808 [July 10, 2006]); and (d) final rule "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications", RIN 0651-AB93 and –AB94 combined ("Final Continuations and Claims Limits Rule," 72 Fed. Reg. 46716 [Aug. 21, 2007]). In my review I have focused on the analytical components related to Executive Order 12,866, the Regulatory Flexibility Act, the Paperwork Reduction Act, and the Information Quality Act.

32. I have reviewed the documents provided by PTO in response to Freedom of Information Act (FOIA) request 06-359 of September 2006, the PTO's reply of October 12, 2006, and the substantially-identical information that the PTO made available on its web page directed to the rules, as that page existed at the end of the notice and comment period.[1] Based on the plain text of the FOIA request and PTO's reply, I infer that these documents (plus the Federal Register notices and public comments) comprise the entire administrative record for the Final

[1] http://web.archive.org/web/20060427110838/http:/www.uspto.gov/web/offices/pac/dapp/opla/presentation/focuspp.html, which archives the page http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/focuspp.html as of April 27, 2006.

Continuations and Claims Limits Rule as of the close of the notice and comment period, that there is no information disclosed in PTO's response to the FOIA request that the Office had not already made public, and that these materials provide the entire information database for public comment.

33. With regard to the Information Quality Act, I have carefully studied both OMB's government-wide and PTO's agency-specific implementing guidelines.

34. I have reviewed two PTO submissions for OMB approval of ICR 0651-0031, the ICR package in which items related to the specific regulations identified in ¶ 32 are located, dated December 22, 2005, and September 26, 2007. PTO attached its Information Quality Guidelines to the September 2007 Supporting Statement.

35. I have reviewed the PTO's "Certification Analysis Under the Regulatory Flexibility Act, Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications," Prepared for: United States Patent and Trademark Office by ICF International (June 29, 2007) ("Reg Flex Analysis").

THE PTO'S ADHERENCE TO PROCEDURES SET FORTH IN EXECUTIVE ORDER 12,866.

36. PTO submitted to OMB for review the Proposed Continuations Limit Rule on July 13, 2005. OMB concluded its review on October 11, 2005. PTO published the proposed rule on January 3, 2006. See http://www.reginfo.gov/public/do/eoDetails?rrid=112040.

37. PTO submitted to OMB for review the Proposed Claims Limit Rule on July 15, 2005. OMB concluded its review on October 11, 2005. PTO published the proposed rule on January 3, 2006. See http://www.reginfo.gov/public/do/eoDetails?rrid=112055.

38. PTO submitted to OMB for review the Proposed IDS rule on January 3, 2006. OMB concluded its review on March 29, 2006. PTO published the proposed rule on July 10, 2006. See http://www.reginfo.gov/public/do/eoDetails?rrid=112647.

39. PTO submitted to OMB for review the Final Continuations Limit Rule and the Final Claims Limit Rule on April 10, 2007. OMB concluded its reviews on July 10, 2007. See http://www.reginfo.gov/public/do/eoDetails?rrid=114345. PTO published both rules as the combined Final Continuations and Claims Limits Rule on August 21, 2007.

40. PTO designated as "significant" under Executive Order 12,866 the Proposed Continuations Limit Rule (71 Fed. Reg. 57), the Proposed Claims Limit Rule (71 Fed. Reg. 66), and the Final Continuations and Claims Limits Rule (72 Fed. Reg. 46834), but did not designate any of them as "economically significant." Assuming good-faith interpretation of the plain language of Executive Order 12,866, PTO concluded that these rules were not likely to have effects exceeding $100 million in any one year, or have novel policy implications (see ¶ 2). PTO designated as "not significant" under Executive Order 12,866 the Proposed IDS Rule (71 Fed. Reg. 38819). This designation is restricted to regulatory actions too insignificant to warrant OMB review (although such a review in fact occurred; see ¶ 38). At an October 18, 2007 meeting I attended at OMB to discuss the draft Final IDS Rule, which was then under review at

OMB,[2] Mr. Robert Bahr, Senior Patent Counsel in the Office of the Deputy Commissioner for Patent Examination Policy, stated that this was a typographical error. I asked Mr. Bahr if PTO had published a correction in the Federal Register at any time during more than 15 months that had elapsed, and Mr. Bahr acknowledged that the Office had not done so. I suggested to Mr. Bahr that PTO's failure to publish a correction misled the public about the magnitude of the proposed rule's likely consequences. Mr. Bahr declined to respond.

41. In the Supporting Statements for ICR 0651-0031 dated December 22, 2005, PTO estimated that the Proposed Continuations Limits Rule and the Proposed Claims Limit Rule would increase paperwork burden by 75,200 hours (p. 14). Using an hourly rate of $286, the value used by PTO included in the Supporting Statement, the total cost of incremental paperwork burden attributable to these rules was $22 million. In its September 2007 ICR submission, PTO stated that in March 2006 OMB approved an increase in 196,800 burden hours "based on public comments received in response to the proposed rulemakings and further study" (p. 24), for a total of 272,000 burden hours. Using the hourly rate of $304 in its September 2007 Supporting Statement, these paperwork burdens entail private sector costs exceeding $83 million per year.

42. The December 2005 Supporting Statement included no estimates of paperwork burden for the Proposed IDS Rule. The September 2007 Supporting Statements states that in July 2006 OMB approved an increase in 714,850 burden hours due to the Proposed IDS Rule (p. 24). Using PTO's assumed hourly rate of approximately $304, these paperwork burdens entail private sector costs exceeding $217 million.

[2] Written materials from this meeting are memorialized on OMB's web site at http://www.whitehouse.gov/omb/oira/0651/meetings/663.html

43. The September 2007 Supporting Statement states: "The Information Quality Guidelines from Section 515 of Public Law 106-554, Treasury and General Government Appropriations Act for Fiscal Year 2001 [i.e., the Information Quality Act], apply to this information collection and comply with all applicable information quality guidelines, i.e., OMB and specific operating unit guidelines." The syntax of this statement is circular, but I understand it to mean that PTO (a) acknowledges that its estimates of respondent burden are influential information covered by the Information Quality Act; (b) agrees that its burden estimates must satisfy applicable standards for quality, utility, integrity and objectivity, and be transparent and reproducible; and (c) intends and believes that its burden estimates in fact satisfy these standards.

PROFESSIONAL JUDGMENTS AND INFERENCES BASED ON MY TRAINING, EXPERTISE AND EXPERIENCE WITH RESPECT TO EXECUTIVE ORDER 12,866

44. In my professional judgment based on my ten years' specific experience as an Economist reviewing draft regulations for OIRA, it is highly unlikely that PTO's designation of the Proposed IDS Rule as "not significant," discussed in ¶ 40, was actually a typographical error. Draft Federal Register documents are subjected to multiple layers of internal agency review, including review by agency attorneys. PTO has over 25 years' experience with the OMB review process, and designated this proposed rule "significant" when the Office submitted it for OMB review.

45. In each of the proposed and final rules listed in ¶ 31, the preamble does not include any useful data, estimates, analysis, or other information concerning the rule's likely societal costs and benefits. The preamble makes claims about the proposed or final rule's effects on pendency (i.e., backlog), processing efficiency, or patent quality that are not accompanied by informative data, estimates or analysis.

46. With respect to the Proposed Continuations Limits Rule, the Proposed Claims Limits Rule, and the Final Continuations and Claims Limits Rule, the documents listed in ¶ 32 do not illuminate in any significant respect the likely social costs and benefits these proposed or final rules. If I had been the OIRA professional staff member responsible for reviewing these rules under Executive Order 12,866, and the documents listed in ¶ 32 documents had been provided to me as their analytical basis, they would have had negligible value to me.

47. Taking at face value PTO's estimate that *paperwork burden alone* exceeds $80 million per year in costs (see ¶ 41), the Proposed Continuations Limit Rule, the Proposed Claims Limit Rule, and the Final Continuations and Claims Limits Rule almost certainly met the objective, quantitative test for being "economically significant" regulatory actions under Executive Order 12,866 § 3(f)(1). It is highly unlikely that a package of proposed regulations with over $80 million in paperwork burden would did not have total effects exceeding $100 million. These rules were submitted twice as a package to OMB, and based on their common dates for submission to and review by OMB (¶¶ 36, 36, and 39), they were reviewed by OMB as a package and should have been designation as "economically significant" as a package. At the time OMB performed its EO 12,866 review of the two proposed rules (July – October 2005; see ¶¶ 36-37), however, PTO had not yet publicly acknowledged its initial estimate of paperwork burdens totaling $22 million (December 2005 ICR Supporting Statement at p. 14). PTO acknowledged the $80+ million burden estimate three months after OMB had concluded its review (September 2007 ICR Supporting Statement at p. 24).

48. Taking at face value PTO's estimate that *paperwork burden alone* exceeds $214 million per year in costs (see ¶ 42), the Proposed IDS Rule easily met the objective, quantitative test for being "economically significant" regulatory actions under Executive Order 12,866

§ 3(f)(1). At the time OMB performed its review of the Proposed IDS Rule (January – March 2006; see ¶ 38), PTO had not publicly acknowledged any additional paperwork burdens (December 2005 ICR Supporting Statement). PTO only acknowledged these burdens three months after OMB concluded its review (September 2007 ICR Supporting Statement at p. 24).

49. As noted in ¶ 19, agencies are required to prepare Regulatory Impact Analyses for "economically significant" regulatory actions. The documents listed in ¶ 32 do not comprise, and are in no way commensurate with or equivalent to, the Regulatory Impact Analysis that PTO was required to prepare for an economically significant draft regulation. In particular, they do not provide: (a) an assessment of reasonably anticipated societal benefits accruing from the proposed regulations (required by Executive Order 12,866 § 6(a)(3)(C)(i)); (b) an assessment of reasonably anticipated societal costs imposed by the proposed regulations (required by Executive Order 12,866 § 6(a)(3)(C)(ii)); or (c) an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the proposed regulations (required by Executive Order 12,866 § 6(a)(3)(C)(iii)).

50. Based on two decades of experience performing and reviewing regulatory analysis, including ten years as an OMB economist with the specific duties of performing EO 12,866 reviews, I can state with certainty that if all the analytic information I had been provided was the information identified in ¶¶ 31-34, I would not have been able to perform a competent review of the Proposed Continuations Limit Rule and Proposed Claims Limit Rule.

51. Based on two decades of experience performing and reviewing regulatory analysis, including ten years as an OMB Economist with the specific duties of performing Executive Order 12,866 reviews and overseeing agency compliance with EO 12,866 and its

predecessor, *I can state with certainty* that if all the analytic information I had been provided was the information identified in ¶¶ 31-34, I would not have been able to perform a competent review of the Final Continuations and Claims Limits Rules.

52. Based on two decades of experience performing and reviewing regulatory analysis, including ten years as an OMB economist with the specific duties of performing Executive Order 12,866 reviews and overseeing agency compliance with EO 12,866 and its predecessor, and having reviewed the materials in ¶¶ 31-34, I have a *very high level of confidence approaching certainty* that the following inferences regarding EO 12,866 are true: (a) PTO knew or should have known that the regulatory actions listed in ¶ 31 were economically significant under EO 12,866; (b) PTO knew or should have known that economically significant regulatory actions must be accompanied by a Regulatory Impact Analysis; (c) PTO knew or should have known that the administrative purpose of these analytic requirements was to ensure that both decision-makers and the public were adequately informed about the likely and plausible effects of regulation; (d) PTO knew or should have known that the information it was disseminating in support of these regulatory actions did not constitute a credible effort at performing a Regulatory Impact Analysis; (e) PTO knew or should have known that these regulatory actions could not be reconciled with the regulatory philosophy and principles set forth in Executive Order 12,866 § 1 based on the data and analysis it decided to publicly disclose; (f) PTO knew or should have known that its certifications of no significant impact on substantial numbers of small entities were not analytically defensible; and (g) PTO withheld from OMB information crucial for estimating, within even an order of magnitude, the likely costs of the regulatory actions listed in ¶ 31; and (h) because it lacked crucial information, OMB was unable to perform a credible review of any of the regulatory actions listed in ¶ 31.

53. Based on two decades of experience performing and reviewing regulatory analysis, including ten years as an OMB economist with the specific duties of performing EO 12,866 reviews and overseeing agency compliance with EO 12,866 and its predecessor, and having reviewed the materials in ¶¶ 31-34, I have a *very high level of confidence* that the following inferences concerning the Information Quality Act and its implementing Guidelines are true: (a) PTO knew or should have known that the information it publicly disseminated in support of these regulatory actions did not adhere to OMB's or its own Information Quality Act Guidelines; (b) PTO knew or should have known that if the Office complied with the reproducibility requirement in these Guidelines, competent third parties were almost certain to try to show, and were more likely than not to succeed in showing, that the Office's estimates of programmatic effects were inaccurate and biased, and thus not substantively objective.

54. Based on two decades of experience performing and reviewing regulatory analysis, including ten years as an OMB economist with the specific duties of performing Executive Order12,866 reviews and overseeing agency compliance with EO 12,866 and its predecessor, and having reviewed the materials in ¶¶ 31-34, I have a *very high level of confidence* that the following inferences with respect to impacts on small entities are true: (a) PTO knew or should have known that any certification that the Final Continuations and Claims Limits Rule would not have a significant effect on a substantial number of small entities would be analytically invalid and unreliable; (b) PTO determined to certify the absence of substantial impacts on a significant number of small entities prior to commissioning ICF International to prepare the study identified in ¶ 35, upon which the certification depends; and (c) PTO knew or should have known that its characterization of impacts on small entities contained in its ICR submissions (¶ 34) were nonsensical (¶ 60).

PROFESSIONAL JUDGMENTS AND INFERENCES BASED ON MY TRAINING, EXPERTISE AND EXPERIENCE WITH RESPECT TO THE INFORMATION QUALITY ACT

55. In my professional judgment, the information listed in ¶ 31-35 does not adhere to the quintessential IQA procedural requirements for transparency and third-party reproducibility. PTO provided graphs and point-estimate summaries of the results of analyses that it performed but did not publicly disclose. I am unable to reproduce information (i.e.,"representations1 of knowledge such as facts or data") in the preambles concerning the effects of various proposed and final rules on patent application and processing; in the ICR Supporting Statements; or in the Reg Flex Analysis. Because PTO has issued Information Quality Act Guidelines and committed to follow them, and it has had more than five years' experience doing so, it is inconceivable to me that PTO's decision not to adhere to its own reproducibility standard was inadvertent or accidental. In my professional judgment, it is certain that PTO knew that the information it had disseminated was not reproducible by competent third parties. Because affected parties asked for more extensive documentation, which PTO declined to disclose, it is all but certain that PTO intended that its information not be reproducible.

56. In my professional judgment, the information listed in ¶ 31-35 does not adhere to the IQA standard for presentational objectivity for at least three reasons. First, representations of knowledge such as facts or data in the preambles, the analytic information disseminated by PTO in support of the proposed rules, the ICR Supporting Statements, and the Reg Flex Analysis are reported as point estimates without error bounds and with as many as six significant figures. These quantitative statements inherently imply meaningful precision that is not and cannot be supported by the precision of the underlying data. Second, even where graphs and tables are clearly labeled they often incorporate inscrutable, undocumented shorthand. Third,

representations of knowledge such as facts or data concerning the proposed or final rules' effects on PTO itself are not presentationally objective because they do not include, for example, any useful information about the rules' likely effects on patent applicants and patentees, including most notably applicants' adaptive responses, which clearly and significantly impact the PTO endogenously. Because PTO has issued and committed to follow Information Quality Act guidance, and it has had more than five years' experience doing so, it is inconceivable to me that PTO's *decision not to adhere* to its own presentational objectivity standard was inadvertent or accidental. In my professional judgment, it is highly likely that PTO knew or should have known that the information it had disseminated was not presentationally objective.

57. The information listed in ¶ 31-35 almost certainly does not adhere to the Information Quality Act standard for substantive objectivity. Practical certainly requires, at a minimum, that PTO "show its work" such that it can be refuted if it is in error, but which PTO has not done. Nevertheless, because PTO's representations of knowledge such as facts or data with respect to the rules' effects on the Office itself do not appear to account for, among other things, adaptive responses by patent applicants and patentees, and adaptive effects are endogenous, these representations are virtually certain to be inaccurate and biased. Because PTO has issued and committed to follow Information Quality Act guidance, and it has had more than five years' experience doing so, it is implausible that PTO's *decision not to adhere* to its own substantive objectivity standard was inadvertent or accidental. In my professional judgment, it is highly likely that PTO knew or should have known that the information it had disseminated was not substantively objective.

58. In my professional judgment, the information listed in ¶ 31-35 does not adhere to the IQA standard for utility. Information that is (or should be) known by an agency not to be

"accurate, reliable, and unbiased," or "presented in an accurate, clear, complete, and unbiased manner," cannot have utility for any legitimate regulatory purpose.

PROFESSIONAL JUDGMENTS AND INFERENCES BASED ON MY TRAINING, EXPERTISE AND EXPERIENCE WITH RESPECT TO ESTIMATING IMPACTS ON SMALL ENTITIES

59. The preambles to the proposed and final rules contain various claims and certifications regarding impacts on small entities (see ¶ 31). In my professional judgment, this information is not useful for gaining a credible perspective on likely impacts.

60. The December 2005 and September 2007 Supporting Statements for ICR 0651-0031 both state in § 5: "No significant impact is placed on small entities. Small entities simply need to identify themselves as such to obtain the benefits of small entity status." The explanation in the second sentence purporting to support the conclusion reached in the first sentence is a non sequitur. The "benefits" of small entity status listed consist solely of reduced filing fees. Elsewhere, however, the Supporting Statements make clear that filing fees are a small fraction of paperwork burden and transactions costs.

61. The most crucial elements of PTO's Reg Flex Analysis rest solely on the "beliefs" of PTO staff. For example, on p. 12 it is stated: "[A]s described in the Federal Register notice accompanying the final rule, USPTO staff believe that once the final rule is adopted, applicants with more than five but less than 15 independent claims, or more than 25 but less than 75 total claims, will choose to prosecute their application in a manner that does not trigger the claims requirements, They will be able to do this under the final rule by submitting an initial application containing up to five independent claims and up to 25 total claims, and then adding a similar number of claims in each of two continuation applications (or two continuation-in-part

applications, or one continuation application and one continuation-in-part application) as permitted without a petition." This "belief" is a "representation[] of knowledge such as facts or data" and thus is covered by the Information Quality Act, and OMB's and PTO's Guidelines. As a practical matter, PTO's "belief" assumes away the very analytic question that the Reg Flex Analysis is by law supposed to address. By relying on this "belief," the Reg Flex Analysis *logically requires* that the claims components of the Final Continuations and Claims Limits Rule *not* have "significant impacts on a substantial number of small entities." However, PTO's "belief" is not supported by any disclosed data, modeling, or regulatory or statistical analysis, and thus it clearly fails applicable Information Quality Act requirements for transparency and reproducibility, presentational and substantive objectivity, and utility. ICF International, the consultant PTO hired to prepare the Reg Flex Analysis, did not address Information Quality Act requirements in its report. Nevertheless, it is significant that ICF International declined to take responsibility for, or attempt to analytically support, PTO's "belief."

62. For the "belief" set forth in ¶ 61 to be plausible, the final rule (which limits applicants to five independent and 25 dependent claims, plus two continuations) is equivalent in all material respects to an different final rule permitting 15 independent and 75 dependent claims with no continuations. Equivalence is necessary because PTO apparently directed ICF International to rely on (undisclosed) statistics for the latter scenario to predict outcomes under the former scenario. For these scenarios to be equivalent, several factual conditions must hold, including the following conditions that economic logic alone, without expertise in patent law or prosecution, is sufficient to divine: (a) the patentable attributes of inventions must serendipitously group into "buckets" such that there is exactly a 5:1 ratio between dependent and independent claims, and packages of 15 independent and 75 dependent claims are divisible

exactly by 3; (b) the shorter patent terms for the first and second continuations must entail no reduction in economic present value; (c) later patent grant dates for the first and second continuations must entail no reduction in economic present value; (d) Patent Law and PTP procedures must be applied consistently both within and across PTO Examiners such that neither the identity of the Examiner nor the timing of a claim affects its patentability; (e) transaction costs must be the same; and (f) at the date of original application, applicants must be clairvoyant about (i) which attributes of their inventions are patentable, (ii) the full domain of relevant prior art, and (iii) future market conditions during the life of the prospective patent.

63. Based on my expertise in economics, it is my professional judgment that the conditions set forth in ¶ 62 cannot hold except under truly extraordinary circumstances. Therefore, PTO's "belief" set forth in ¶ 61 is without analytic merit.

I declare under penalty of perjury pursuant to 18 U.S.C. § 1001 that the foregoing is true and correct.

December 26, 2007