Tafas v. Dudas et al Doc. 127 Att. 5

Note: It would be preferable to use data for each applicant, rather than each filing, in order to evaluate impacts on any applicants that submit more than one patent filing. The data obtained from PALM do not support such an analysis. Consequently, this analysis inherently assumes that each applicant submits patent filings pertaining to one invention within any given year. There is some support for this assumption, at least for smaller applicants, based on comments requesting that applicants continue to be permitted to file divisional applications serially (i.e., as through continuations or continuation-in-parts), rather than in parallel (i.e., by submitting multiple related applications simultaneously), in order to spread out the associated cost burden over time. This assumption likely does not hold for many large firms and it may not hold for some small firms. Nevertheless, it is likely to hold for most of the very smallest entities (e.g., sole proprietorships) that can least afford an incremental burden.

Entities Affected by the Claims Requirements

The claims requirements in the final rule apply to a portion of total initial patent applications filed. In fiscal year 2006, there were 285,324 initial applications. The final rule requirements apply to patent applications with more than five independent claims or more than 25 total claims. However, as 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 (see Section 1).

As a result, this analysis anticipates that the claims requirements, if they had been applied to applications during FY 2006, would have affected only those initial patent applications having more than 15 independent claims or more than 75 total claims. Based on analysis of PALM data on total claims in initial patent applications, approximately 1,105 filings, or 1.0 percent, submitted by small entities and 3,742 filings, or 0.9 percent, submitted by all entities in FY 2006 would incur costs under the claims requirements. These affected applications can be further subdivided, however, into two groups.

Claims Requirements Only. 780 of the small entity initial applications (1.0 percent) affected by the claims requirements, or 2,818 of all initial applications (1.0 percent), have 15 or more independent claims and 75 or more total claims. These initial applications are not affected by the continued examination filing requirements.

⁹ PALM contains data on the number of independent claims and total claims in each application. Based on analysis of this data, a "rule-of-thumb" approximation is one independent claim out of every seven total claims. Assuming this distribution, the typical application will exceed the threshold for total claims more frequently than the threshold for independent claims. The analysis models total claims based on reported independent claims and the rule-of-thumb described above.

 Continued Examination Filing Requirements and Claims Requirements. 325 of the small entity filings (0.3 percent) affected by the claims requirements, or 924 of all filings (0.2 percent), are also are affected by the continued examination filing requirements.

Entities Affected by the Continued Examination Filing Requirements Only

The final rule requirements related to continued examination filings apply to applications or chains of continued examination filings that include more than two continuing applications (continuation or continuation-in-part applications), and more than a single request for continued examination in any one of these three applications (the initial or two continuing applications). Note that these are not the same as initial applications, as discussed in Section 1. For example, while there were 285,324 initial applications in FY 2006, there were 408,396 total filings. A portion of these total filings would be affected by the final rule's continued examination filing requirements.

To estimate the affected entities, this analysis assumes that all applicants filing their third, fourth, fifth, or greater continuing application and continuation-in-part application will be affected by the continued examination filing requirements. Exhibit 3-1 shows a box

Exhibit 3-1
Applications Affected by the Continued Examination Filing Requirements,
Out of all Applications

APPLICATION PROSECUTION	Out of all Application NUMB INDEPENDE TOTAL CLAIMS IN	ER OF NT CLAIMS/
STAGE	TOTAL CLAIMS IN	FIRE ALL DICATION
Initial Application	< 15 IC / < 75 TC	> 15 IC / > 75 TC
First CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Second CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Third CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Fourth CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Fifth CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Sixth CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Seventh CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Eighth CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Ninth CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Tenth+ CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC

around the affected applications. The double-lined box surrounds applications affected by the continued examination filing requirements. Those applications in the center column are affected only by these requirements, whereas those in the right column also are affected by the claims requirements.¹⁰

In addition to the applications identified in Exhibit 3-1, this analysis also considers FY 2006 RCE filings to determine those RCE filings that trigger the continued examination filing requirements under the final rule.

Based on analysis of PALM data, approximately 3,300 filings, or 3.0 percent, submitted by small entities and 11,326 filings, or 2.8 percent, submitted by all entities in FY 2006 would incur costs under the continued examination filing requirements. These affected filings can be further subdivided, however, into two groups.

- Continued Examination Filing Requirements Only. 2,995 of the small entity filings (2.7 percent) affected by the continued examination filing requirements, or 10,402 of all filings (2.6 percent), have 15 or fewer independent claims and 75 or fewer total claims. These filings are not affected by the claims requirements.
- Continued Examination Filing Requirements and Claims Requirements. 325 of the small entity filings (0.3 percent) affected by the continued examination filing requirements, or 924 of all filings (0.2 percent), have more than 15 independent claims or more than 75 total claims. These filings also are affected by the claims requirements.

Summary of Small Entities Affected by the Final Rule

Exhibit 3-2 summarizes the results described above.

Exhibit 3-2
Summary of Affected Small Entities

		Entity Data		All I	Entity Data	Set
	Total in Universe	Number Affected	Percent Affected	Total in Universe	Number Affected	Percent Affected
Only Claims Requirements	79,050	780	1.0%	285,324	2,818	1.0%
Only Continued Examination Filing Requirements	111,178	2,995	2.7%	408,396	10,402	2.5%
Both	111,178	325	0.3%	408,396	924	0.2%

The methodology used to quantify the applications represented in the exhibit results in significant double-counting of claims. As a result, the analysis will overstate the number of applications affected simultaneously by both the claims requirements and the continued examination filing requirements.

4. Projected Reporting, Recordkeeping, and Other Compliance Requirements

The final rule establishes three compliance requirements that will allow the USPTO to conduct a better and more thorough and reliable examination of patent applications.

- Submittal of an examination support document (ESD) for certain applications;
- Submittal of a petition in support of certain requests for continuing applications or continued examinations;
- Submittal of information related to patentably indistinct claims.

The following subsections discuss these requirements and estimate the associated burden on applicants that must comply with them.

To develop the estimates for the incremental costs resulting from the requirements of the final rule, the analysis uses the following information and data sources:

- Activities resulting in costs were identified based on a review of the draft final rule (provided by the USPTO), the proposed rules, and on discussions with USPTO staff.¹¹
- USPTO fees charged of patent applicants and patent holders were taken from the USPTO's fee schedule.¹²
- The costs associated with baseline patent application preparation were taken from an American Intellectual Property Law Association (AIPLA) report entitled Report of the Economic Survey 2005.¹³
- Finally, USPTO staff provided estimated unit costs for a variety of factors, as noted in Appendix A.

All costs are calculated in 2006 dollars. The analysis applies a legal services labor rate of \$233 per hour¹⁴ (a composite of attorney and paralegal wage rates), and conservatively assume the applicant's labor rate is \$150 per hour. The resulting costs are summarized in Section 5.2.

¹¹ Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 FR 48 (Jan. 3, 2006); Changes to Practice for the Examination of Claims in Patent Applications, 71 FR 61 (Jan. 3, 2006)

http://www.uspto.gov/web/offices/ac/qs/ope/fee2007february01.htm.

¹³ AIPLA. Report of the Economic Survey 2005. Arlington, VA. September 2005.

This labor rate is a blended composite wage based on data from the AIPLA report entitled Report of the Economic Survey 2005. The analysis updated the 2004 composite wage rate to 2006 dollars based on the Consumer Price Index.

4.1 Examination Support Document

Under the final rule, patent applicants will be required to submit an ESD if the application contains more than five independent claims or more than 25 total claims. The final rule states that the ESD must contain the following six elements (Section 1.261(a)(1)-(6) of the final rule):

- (1) A statement that a preexamination search was conducted, including an identification of the field of search by United States class and subclass and the date of the search, where applicable, and, for database searches, the search logic or chemical structure or sequence used as a query, the name of the file or files searched and the database service, and the date of the search;
- (2) An information disclosure statement in compliance with § 1.98 citing the reference or references deemed most closely related to the subject matter of each of the claims (whether in independent or dependent form);
- (3) For each reference cited, an identification of all the limitations of each of the claims (whether in independent or dependent form) that are disclosed by the reference:
- (4) A detailed explanation of how each of the claims (whether in independent or dependent form) is patentable over the references cited with the particularity required by § 1.111(b) and (c);
- (5) A concise statement of the utility of the invention as defined in each of the independent claims; and
- (6) A showing of where each limitation of each of the claims (whether in independent or dependent form) finds support under the first paragraph of 35 U.S.C. 112 in the written description of the specification. If the application claims the benefit of one or more applications under title 35, United States Code, the showing must also include where each limitation of each of the claims finds support under the first paragraph of 35 U.S.C. 112 in each such application in which such support exists.

Patent applicants with applications that exceed the independent or total claims thresholds will incur costs to prepare and submit the ESD.

To estimate the cost of the ESD, the analysis considers each of the six elements in the ESD.

The first element of the ESD requires the applicant to conduct a patent search. Although applicants currently are not required to conduct a patent search, most patent applicants (55 percent) conduct one as part of the application process. According to AIPLA estimates, the cost of a patent search ranges from approximately \$1,000 for a relatively simple patent application up to approximately \$2,500 for a relatively complex patent application.

Under the final rule, applicants that must prepare an ESD will have an incentive to complete the patent search prior to completion of their applications and ESDs. The reason for this is that doing so will reduce their costs for completing other portions of the

ESD (due to the heightened familiarity they will have with the patent search relative to the application). Given this incentive, it would be reasonable to assume that all applicants required to prepare an ESD (including conducting a patent search) would choose to complete the patent search prior to completing their application. Such an assumption would allow the analysis to account for lower ESD preparation costs than apply in cases where the patent search is not conducted until after the application is completed. Nevertheless, as a conservatism, the analysis assumes that only 50 percent of applicants in this situation will conduct the patent search prior to completing the application. The remaining 50 percent of applicants facing ESD requirements are assumed to complete the application first, even though doing so leads to higher ESD preparation costs.

Exhibit 4-1 presents the time estimates for each element of the ESD, assuming the applicant has/hasn't completed the patent search prior to completing the application.

Exhibit 4-1

Examination Support Document Time/Cost Estimates

		Estimate Assuming	Estimate Assuming
ESD		Patent Search is	Patent Search is
Element	Cost Basis	Conducted Prior to	Conducted After
Biomoni		Application	Application
Element 1	Application-based	\$1,000 - \$2,500	\$1,000 - \$2,500
Element 2	Application-based	1 hour	1 hour
	First two independent claims	30 minutes each	40 minutes each
Element 3*	Remaining independent claims	10 minutes each	10 minutes each
	First 10 dependent claims	10 minutes each	10 minutes each
	Remaining dependent claims	5 minutes each	5 minutes each
	Independent claims	10 minutes each	15 minutes each
Element 4	Dependent claims	No additional time needed	No additional time needed
Element 5	Application-based	30 minutes	30 minutes
	First two independent claims	20 minutes each	20 minutes each
Element 6	Remaining independent claims	10 minutes each	10 minutes each
	Dependent claims	5 minutes each	5 minutes each

^{*} To mitigate the final rule's cost impact on small entities, the USPTO will not require small entities, as defined in 13 CFR 121.802, to complete Element 3 of the ESD.

This analysis assumes that the cost associated with three of the ESD elements is "application-based." Specifically, for elements 1, 2, and 5 of the ESD, applicants will incur a flat cost. Conversely, the cost incurred by applicants to complete elements 3, 4, and 6 of the ESD will vary depending on the number of independent and dependent claims in an application. To reduce the final rule's cost impact on small entities, however, the final rule does not require small entities to complete Element 3.

Exhibit 4-2 summarizes the resulting estimates of incremental ESD costs for affected small entities.

- Assuming a patent search is conducted before the patent application is completed, this analysis estimates that the incremental cost associated with the ESD ranges from \$2,563 to \$10,136.
- Assuming a patent search is conducted after the patent application is completed, this analysis estimates that the incremental cost associated with the ESD ranges from \$5,170 to \$13,121.

Exhibit 4-2
Summary of Small Entity Incremental Costs Associated with the ESD

Saminary of Smail Littly more mental Cools rase	Incremental Cost
For applicants that already conduct a patent search in the baseline	\$2,563-\$10,136*
For applicants that do not conduct a patent search in the baseline	\$5,170-\$13,121*

^{*} Cost of preparing an Examination Support Document varies depending on the number of claims in the application. Range shown covers up to 50 independent claims or 350 total claims. The analysis does not assume a range of costs per application, but instead applies the specific cost appropriate to the number of claims in each application.

4.2 Petition for Continuing Applications or Continued Examinations

The final rule also sets a reporting requirement related to continued examination filings. According to the final rule, an application or chain of continued examination filings may include no more than two continuing applications (continuation or continuation-in-part applications), and no more than a single request for continued examination in any one of these three applications (the initial or two continuing applications), without a petition showing why the amendment, argument, or evidence presented could not have been previously submitted. Based on a USPTO staff estimate, this analysis estimates that the petition required under the final rule will cost applicants \$1,000 to complete. 15

In the OMB Paperwork Burden Analysis for the proposed continued examination filings rule, the USPTO estimated the cost of the petition to be \$572. As a conservatism, this analysis assumes the cost of the petition will be higher (\$1,000).

4.3 Information Related to Patentably Indistinct Claims

The final rule also contains a reporting requirement to address patentably indistinct claims. This requirement applies to applicants with pending applications or patents that (1) have an effective filing date within two months of the filing date of the pending application; and (2) name at least one inventor in common with the pending application. Under the final rule, the applicant must name these other commonly-owned applications or patents and must file a terminal disclaimer or explain how the applications (or application and patent) contain only patentably distinct claims if they have the same effective filing date and contain substantial overlapping disclosure.

The analysis estimates that there will be no costs associated with the indistinct claims portion of the rule. The intention of the provision is to close a loophole that might otherwise open after the ESD provisions are promulgated. That is, to avoid preparing an ESD, an applicant might otherwise be able to divide his or her claims among two simultaneous applications ("parallel prosecution"). The indistinct claims provision would prevent this by forcing applicants to justify the indistinct claims in the applications, submit a terminal disclaimer (the costs of which are associated with existing rules) or, more likely, abandoning one of the applications and adding its claims to the other application. USPTO staff believe it would not be possible to successfully justify the dual applications in this case. The applicant, too, would realize this and therefore would not submit such applications. Thus, given that the final rule would establish these rules in advance, the effect of the indistinct claims provision would be to prevent the dual application scenario from being used as a means of avoiding the ESD requirement.

Applicants currently file dual applications for reasons other than avoiding the prospective ESD requirement. This final rule would not generate incremental costs in this situation because 37 CFR 1.78(b) currently provides that applicants can be required to eliminate patentably indistinct claims from all but one application and the double patenting doctrine requires a terminal disclaimer if the patentably indistinct claims are not eliminated from all but one application.

5. Impacts Assessment

To comply with the Regulatory Flexibility Act, agencies must determine whether proposed actions will have a significant economic impact on a substantial number of small entities. If the action will not have a significant impact on a substantial number of small entities, then the agency may certify that this is the case instead of preparing a regulatory flexibility analysis, as would otherwise be required under the Act.

This section considers whether the costs of the rule will lead to a significant economic impact on a substantial number of small entities. Section 5.1 describes the methodology used in this assessment. Section 5.2 presents the results of the analysis. Finally, Section 5.3 draws conclusions regarding whether certification is appropriate.

5.1 Methodology

To assess whether the costs of the rule will lead to a significant economic impact on a substantial number of small entities, this analysis proceeds in four general steps.

- (1) Select an appropriate indicator for measuring impacts;
- (2) Estimate the incremental compliance costs of the final rule;
- (3) Quantify the impacts and the number of entities impacted; and
- (4) Evaluate the impacts.

Each of these steps is described below.

5.1.1 Selection of Impact Measure

The analysis evaluates impacts based on the ratio of annualized incremental cost as a percent of total revenue. This measure was selected after evaluating the following six candidate measures:

- Incremental Cost. This measure considers the increase in cost (present value) to a given entity resulting from the rule. The incremental cost is equivalent to the cost of obtaining a patent under the new rule minus the cost of obtaining a patent under the current rules. While intuitively simple, this measure does not address the significance of the cost relative to any characteristic (e.g., size) of the small entity that incurs the cost. Therefore, incremental cost is used in this analysis only as an intermediate result.
- Annualized Incremental Cost. This measure calculates what the annual incremental cost of the rule would be if the incremental cost (as described above) were financed and paid off in annual installments. This measure can be useful in situations where it is reasonable to allocate costs over a multi-year period. Spreading costs over time is generally appropriate for capital investments (e.g., equipment) that will contribute to income over an extended period. In the case of patents, for example, it is reasonable to allocate the cost of obtaining a patent over the 20-year life of the resulting patent, because the patent holder retains exclusive rights over the patent during that time. In fact, generally accepted accounting principles (GAAP) for amortizing patents require patents to be amortized over the life of the patent. Nevertheless, this measure by itself does not address the significance of the cost relative to the entity that incurs it. Therefore, annualized incremental cost is used in this analysis only as an intermediate result.
- Percent Increase in Costs. This measure calculates the incremental cost as a
 percentage increase relative to the "baseline" costs, which are the costs applicable
 in the absence of the rule. The percent increase in costs can be useful,

¹⁶ See, for example, Statement of Accounting Standards No. 142, Goodwill and Other Intangible Assets, Financial Accounting Standards Board, June 2001.

particularly when percentage increases are small. However, this measure does not address the significance of the cost relative to the entity that incurs the cost. For example, even if a rule leads to a 100 percent increase in costs, that increase might not be significant to an entity if the original cost is sufficiently small. In addition, estimating the "baseline" cost of preparing a patent application is difficult due to the difference between applications with respect to the complexity of the invention, the state of prior art, and the skills and experience of the applicant.

- Cost as a Percent of the Expected Value of the Patent. This measure considers the incremental cost as a fraction of the expected value of the patent. In theory, this measure should be very useful in evaluating whether impacts are likely to be significant. In practice, however, this approach presents significant challenges. For example, it would not be possible to identify the expected value of individual patent applications, which would be ideal from a theoretical standpoint. Instead, it would be necessary to apply one or more average values and make related assumptions. This study evaluated the literature to find information on the value of patent applications and identified estimates ranging from \$220,000 to \$1.3 million. These finding do not appear sufficiently robust to support use of this measure for the present purposes (see Appendix B for further discussion). Finally, this measure would not recognize other types of value that patents and patent applications can provide to applicants (e.g., by providing enhanced competitive protection to existing business lines).
- Incremental Cost as a Percent of Revenue, and Annualized Incremental Cost as a Percent of Revenue. These measures consider cost as a percentage of an entity's total revenue - a common measure of an entity's size - and are common screening measures for evaluating whether costs are significant. All else equal, costs that are small relative to a firm's size are less significant than costs that are larger. Although other factors also influence whether a given cost is significant to an entity, such as the entity's profitability and its ability to "pass through" costs to its customers, these two ratios both are useful screening measures that are applicable to most types of entities.
- Incremental Cost as a Percent of Profits. Incremental cost relative to profits is often considered a useful measure of impacts because profit represents "net" revenue after all expenses have been paid. This measure raises some unique issues, however, including the "adequacy" of any given return on equity, the effect of tax incentives on small entities, and whether a cost should be considered "more significant" to firms that are managed poorly as opposed to firms that are managed more effectively. From a more mechanical perspective, profits data are relatively difficult to obtain, particularly when affected entities span numerous industries, as is the case with patent applicants.

This study focuses on annualized incremental cost as a percent of revenue for several reasons: (1) it considers costs on an annualized basis, which is consistent with the

generally accepted recognition that a patent is an asset conveying a multiyear earning potential; (2) it evaluates impacts relative to revenue, which is a useful and relevant measure of the size of an entity; (3) it can be applied readily across many industries and entity types; (4) data availability typically is not an impediment to analysis; and (5) most people understand it without difficulty.

5.1.2 Estimation of Incremental Compliance Costs

The analysis estimates incremental costs resulting from the requirements of the final rule using the information and sources described in Section 4 and Appendix A. These sources include USPTO staff, AIPLA, and the USPTO fee schedules.

The resulting costs are summarized in Section 5.2. The incremental costs are annualized over a period of 20 years (to coincide with the life of the patent) using an interest rate of seven percent.

5.1.3 Quantify Impacts and Number of Entities Impacted

In the next step, the analysis quantifies the impacts of the final rule and the number of entities impacted at the identified thresholds (described in Section 5.1.4). Impacts are based on incremental costs calculated as described in Section 5.1.2. As noted previously, some costs (those associated with the claims requirements) are a function of the number of claims contained in an application. Therefore, the analysis appropriately models different incremental costs and impacts for filings having different numbers of included claims. All estimates of the number or percentage of affected entities and the distribution of applications by number of claims are based on data from PALM for fiscal year 2006.

5.1.4 Evaluate the Rule's Economic Impacts

In the last step, the quantitative results are screened to determine whether the rule is likely to have a significant impact on a substantial number of small entities.

Significant Impact Criteria

To evaluate significant impact, the study considers the ratio of Annualized Incremental Cost as a Percent of Revenue, as described earlier. Impacts are evaluated relative to two screening thresholds:

 Entities at or above a threshold value of three percent are presumed to face significant impacts unless additional analysis of these entities indicates this will

For applications affected only by the claims requirements, PALM provided data on the number of claims for each application. The analysis conservatively assumes that the filings (other than RCEs) affected by both the claims requirements and by the continued examination filing requirements are those non-initial applications shown by the PALM data as having the most claims. For RCEs, the analysis assumes the same distribution by number of claims as PALM shows for non-initial applications.

not be the case. Note that a three percent threshold is equivalent to determining whether an entity has annual revenue of at least 33.3 times the annualized incremental cost.

Entities at or above a threshold value of *one percent* are presumed to face more moderate impacts that qualify as significant if collectively incurred by a *substantial number* of small entities, as discussed below. Note that a one percent threshold is equivalent to determining whether an entity has annual revenue of at least 100 times the annualized incremental cost.

Because the rule's incremental costs are relatively small, the analysis proceeds by considering how much annual revenue an affected entity - large or small -would have to earn in order to avoid these impacts. To the extent that these minimum levels are below the levels needed to run even the smallest business, then the analysis can conclude that the rule will not result in significant impacts. For purposes of analyzing this rulemaking, the smallest business is modeled as a sole proprietorship owned by a creative and/or technical individual who currently is capable of paying for or financing all necessary patent filing costs and maintenance fees (under current rules) associated with an application of a type that would be affected by the final rule. These filing and maintenance fees can vary by filing, but this study estimates that they range from \$19,940 to \$49,155 for filings that would be affected by the final rule. This study assumes that the minimum annual revenue that would support an individual's living expenses, as well as his/her patent filing and maintenance costs, is \$75,000.18 Therefore, the smallest business in the analysis would exceed the three percent threshold at annualized incremental costs of \$2,250 or higher, and it would exceed the one percent threshold at annualized incremental costs of \$750 or higher. Businesses that earn higher revenue would exceed these thresholds only at proportionately higher incremental costs.

Note that the above thresholds are intended to serve as screening-level indicators and may be overly sensitive for purposes of identifying economic impacts. For example, to the extent that affected entities may earn higher future revenue due to the commercialization of the patent, impacts based on current revenue levels will be overstated. Additional analysis would be needed to definitively determine whether entities exceeding this threshold are likely to incur significant impacts as a result of the rule.

Substantial Number Criteria

The key objective of this analysis is to determine whether the USPTO's final rule will result in a significant economic impact on a *substantial number* of small entities. The concept of a "substantial number" is necessarily relative, however. For purposes of analyzing this rulemaking, it is reasonable to consider it relative to the total number of

Revenue of \$75,000 is higher than the U.S. median income (which is slightly less than \$50,000), but it seems reasonable in light of the creative/technical abilities of an individual seeking a patent, as well as his/her current ability to fund the development and processing of the patent application (under existing regulations) as well as the required maintenance fees.

small entities that apply for patents. The USPTO's PALM system indicates that, in FY 2006, there were a total of 111,178 patent filings submitted by entities claiming smallentity status.

Most of these small entities, however, will not incur costs under the final rule. Of those that are affected, some might face potentially significant impacts. This analysis assumes that a "substantial number" of small entities exists if the number if entities impacted at a given impact threshold (e.g., three percent of revenue) constitutes at least 20 percent of all small entities that apply for patents. The analysis considered developing a numerical threshold (e.g., 2,500) as another criterion for determining "substantial number," but did not do so for two reasons. First, it was clear that the final rule would not affect enough small entities to exceed any of the numbers that would have been considered. Second, given that the number of patent filings the USPTO receives increases by 7 to 8 percent per year when the economy is good, selection of a number that would be appropriate for this year's rulemaking likely would be inappropriate in the near future.

Assumptions and Uncertainties

The analysis relies on several data sources as documented throughout this report. In addition, two assumptions are worth noting.

First, due to data limitations, the analysis considered patent filings rather than applicants. To the extent that applicants might have more than one application in process at a time, this will tend to understate impacts. Although the assumption certainly does not hold true for many large firms, these firms have sufficient revenue to avoid significant impacts under the final rule. The assumption is much more reasonable, however, for the smallest firms, such as the sole proprietorship described above, which might face significant impacts under the rule. See additional discussion in Section 3.2.2.

Second, the analysis of the continued examination filing requirements assumes, as also discussed in Section 3.2.2, that most applicants who would have triggered the final rule's claims requirements based on the applications they submitted in FY 2006 will not trigger those requirements once the rule is promulgated. Instead, these applicants will choose to submit an initial application with fewer claims (to avoid having to prepare an ESD) and then will take advantage of the various steps in USPTO's patent application review process to add additional claims. The final rulemaking contains a description of how these applicants can prosecute their applications in this manner to avoid triggering the ESD requirement.

5.2 Results

The presentation of results is organized in three parts: (1) costs; (2) number of small entities affected by the rule; (3) magnitude of impacts; and (4) unquantified benefits. This analysis estimates that incremental costs will range from \$872 to \$13,993.¹⁹ Incurring the lowest of these incremental costs are those applicants affected only by the continued examination filing requirements. Applicants incurring incremental costs at the highest end of the range are those having the following three characteristics: (1) they are affected by the claims requirements and have the greatest number of claims (e.g., 350 total claims); (2) they did not choose to conduct a patent search in the baseline; and (3) they also are affected by the continued examination filing requirements. Most applicants will fall between the extremes, as they will be affected by the claims requirements but will have more typical (lower) numbers of claims. Exhibit 5-1 summarizes the cost results, which are discussed in greater detail in Section 4.

Exhibit 5-1
Summary of Incremental Costs and Annualized Incremental Costs

Summary of motornormal econo	Incremental Cost	Annualized Incremental Cost
Continued Examination Filing Requirements Only	\$872	\$82
Claims Requirements Only, for applicants that already conduct a patent search in the baseline	\$2,563-\$10,136*	\$242-\$957*
Claims Requirements Only, for applicants that do not conduct a patent search in the baseline	\$5,170-\$13,121*	\$488-\$1,239*
Both, for applicants that already conduct a patent search in the baseline	\$3,435-\$11,007*	\$324-\$1,039*
Both, for applicants that do not conduct a patent search in the baseline	\$6,042-\$13,993*	\$570-\$1,321*

^{*} Cost of preparing an Examination Support Document varies depending on the number of claims in the application. Range shown covers up to 50 independent claims or 350 total claims. The analysis does not assume a range of costs per application, but instead applies the specific cost appropriate to the number of claims in each application.

5.2.2 Number Affected by the Rule

Exhibit 5-2 summarizes the total number of filings that will incur any incremental cost due to the claims requirements, the continued examination filing requirements, or both. In each case, the number is less than two percent of filings. Looking at the rule as a whole, only approximately 3.69 percent of small entity filings are expected to incur any impacts under the final rule. Under the sensitivity analysis, in which all entities would be considered small entities, this percentage falls to approximately 3.46 percent.

¹⁹ Current patent filing and maintenance costs for applications that would be affected by the final rule are estimated at between \$19,940 and \$49,155.

Exhibit 5-2
Number and Percent of Entity Filings Affected by Final Rule Requirements

Number and Percent of En	Sma	Il Entities	All	Entities*
	Number	Percent	Number	Percent
Continued Examination Filing Requirements Only	2,995	2.69% (of small entity filings)	10,402	2.55% (of all filings)
Claims Requirements Only, for applicants that already conduct a patent search in the baseline	429	0.54% (of small entity initial applications)	1,550	0.54% (of all initial applications)
Claims Requirements Only, for applicants that do not conduct a patent search in the baseline	351	0.44% (of small entity initial applications)	1,268	0.44% (of all initial applications)
Both, for applicants that already conduct a patent search in the baseline	179	0.16% (of small entity filings)	508	0.12% (of all filings)
Both, for applicants that do not conduct a patent search in the baseline	146	0.13% (of small entity filings)	416	0.10% (of all filings)
Total for Final Rule**	4,100	3.69% (of small entity filings)	14,144	3.46% (of all filings)

^{*}Some stakeholder have stated that the USPTO's PALM system understates the number of small entities submitting patent filings. Therefore, as described in Section 3.2, this study evaluates the bounding case of *All Entities* as a sensitivity analysis.

5.2.3 Magnitude of Impacts

Of the 3.69 percent of small entity filings that will incur any impacts under the final rule, very few – an estimated 54, or less than 0.05 percent – may exceed the minimal screening threshold of one percent, as shown in Exhibit 5-3. Moreover, no small entities applicants are expected to incur impacts at the more significant threshold of three percent, as shown in Exhibit 5-4. Under the sensitivity analysis, in which all entities would be considered small entities, an estimated 157 entities, or about 0.04 percent, may exceed the one percent threshold, and none would exceed the three percent threshold.

^{**} Percentages may not add due to rounding.

Exhibit 5-3

Number and Percent of Entity Filings Exceeding the 1 Percent Threshold for Annualized

Incremental Cost as a Percent of Total Revenue

Incremental		Il Entition	A IL F	Entities*
		II Entities		Percent
	Number	Percent	Number	
Continued Examination Filing	0	0% (of all	0	0% (of all
Requirements Only	V I	filings)		filings)
Claims Requirements Only, for		0.01% (of all		0.01% (of all
applicants that already conduct	9 '	initial	24	initial
a patent search in the baseline	Ţ	applications)		applications)
Claims Requirements Only, for		0.02% (of all		0.02% (of all
applicants that do not conduct a	23	initial	76	initial
	20	applications)		applications)
patent search in the baseline		applications/		······································
Both, for applicants that already		0.00% (of all	7	0.00% (of all
conduct a patent search in the	3	filings)		filings)
baseline				
Both, for applicants that do not	***************************************	0.02% (of all		0.01% (of all
conduct a patent search in the	19	filings)	50	filings)
baseline		inings)		
		0.05% (of all	157	0.04% (of all
Total for Final Rule **	54	filings)	13/	filings)

^{*}Some stakeholder have stated that the USPTO's PALM system understates the number of small entities submitting patent filings. Therefore, as described in Section 3.2; this study evaluates the bounding case of *All Entities* as a sensitivity analysis.

Exhibit 5-4
Number and Percent of Entity Filings Exceeding the 3 Percent Threshold for Annualized
Incremental Cost as a Percent of Total Revenue

	Small 1	Entities	All En	All Entities*	
	Number	Percent	Number	Percent	
Continued Examination Filing Requirements	0	0%	Ó	0%	
Claims Requirements, for applicants that already conduct a patent search in the baseline	0	0%	0	0%	
Claims Requirements, for applicants that do not conduct a patent search in the baseline	0	0%	0	0%	
Both, for applicants that already conduct a patent search in the baseline	0	0%	0	0%	
Both, for applicants that do not conduct a patent search in the baseline	0	0%	0	0%	
Total for Final Rule**	0	0%	0	0%	

^{*}Some stakeholder have stated that the USPTO's PALM system understates the number of small entities submitting patent filings. Therefore, as described in Section 3.2, this study evaluates the bounding case of All Entities as a sensitivity analysis.

^{**}Totals may not add due to rounding.

5.2.4 Unquantified Benefits

Partially offsetting the minor impacts of the rulemaking are certain unquantified benefits. The most significant benefit that will accrue to affected small entities seeking patents (and to larger patent applicants) will be the reduction in time required to complete the patent process. As described in Section 1.3, a reduction in processing time is one of the USPTO's key objectives for the rule. A second benefit that will accrue to small entities seeking patents (along with larger patent applicants) may be a reduction in patent fees relative to what those fees might rise to in the absence of the rule. By allowing patent examiners to more efficiently complete their examination of the most time-consuming patents, the rule should reduce the growth in the fee-recoverable cost base. Finally, PTO also expects the rule to contribute to higher-quality patents in many cases. This benefit accrues to society as a whole (including small entities) and might result in various efficiencies as well as a decrease in patent litigation.

5.3 Conclusion

This analysis estimates that the final rule will result in incremental costs that range from \$872 to \$13,993 per application (present value). Based on the methodology and data described in this report, the resulting analysis indicates that no patent applicants will incur significant impacts (defined as annualized incremental costs in excess of three percent of revenue) due to the final rule. Although some applicants will exceed the lower screening threshold of one percent, the number of small entities in this category is estimated at only 54, or about 0.05 percent of all small entity applicants. Even using data for all applicants as a sensitivity analysis, only 157 small entity applicants fall into this category – 0.04 percent of all applicants. These figures do not meet the criterion for a "substantial number" of small entities. Therefore, this analysis concludes that USPTO's final rule will not result in significant economic impacts on a substantial number of small entities.

6. Duplicative, Overlapping, and Conflicting Rules

The USPTO is the sole U.S. government agency responsible for administering the patent system and granting patents. Therefore, no other federal, state, or local entity shares jurisdiction over the United States' patent system.

Other countries, however, have their own patent laws, and an entity desiring a patent in a particular country must make an application for patent in that country, in accordance with the applicable law. Although the potential for overlap exists internationally, this cannot be avoided except by treaty (such as the Paris Convention for the Protection of Industrial Property, or the Patent Cooperation Treaty (PCT)).

²⁰ Current patent filing and maintenance costs are estimated at between \$19,940 and \$49,155 for filings that would be affected by the final rule.

Nevertheless, the USPTO believes that there are no other duplicative or overlapping rules. Some public comments submitted in response to the notices of proposed rulemaking argued that the proposed rules conflict with provisions of the Paris Convention and/or the PCT. The final rulemaking explains why there are no conflicts with either the Paris Convention or the PCT.

Significant Alternatives Considered and Steps 7. Taken to Minimize Impacts on Small Entities

In response to some of the comments received, USPTO considered a variety of alternatives to minimize the impacts on small entities. Section 7.1 describes the alternatives that were adopted as part of the final rule. Section 7.2 discusses other alternatives that were considered but not adopted.

Alternatives Adopted by USPTO

The USPTO implemented five alternatives in the final rule to minimize the impact on small entities. The first two alternatives relate to the claims requirements and the remaining three relate to the continued examination filing requirements. In the final rule, the USPTO changed the ESD requirement threshold from more than ten representative claims in an application (proposed rule) to more than five independent claims or more than 25 total claims in an application (final rule). This change reduces the number of small entities affected by the final rule.

In addition, under the final rule, the USPTO will not require small entities, as defined in 13 CFR 121.802, to include in their ESDs one of the elements that would have been required under the proposed claims rule. Specifically, the final rule will not require small entities (but will require large entities) to identify, for each reference cited, all the limitations of each of the claims (whether independent or dependent) that are disclosed by the references. The USPTO considers this element of the ESD to be the most challenging for patent applicants. As a result of this change, the costs associated with the final rule will be greatly reduced for small entities.

The third alternative adopted in the final rule changes the continued examination filing petition threshold from one continuation application, continuation-in-part application, or RCE (proposed rule) to two continuing applications (continuation or continuation-in-part applications), and no more than a single RCE in any one of the initial or two continuing applications (final rule). This change also reduces the number of small entities affected by the final rule.

As mentioned in Section 3.2.2, some comments requested that applicants continue to be permitted to file divisional applications serially (i.e., in the manner of continuations or continuation-in-parts), rather than in parallel (i.e., by submitting multiple related applications simultaneously), in order to spread out the associated cost burden over time.

In response, the final rule modifies the time period within which any divisional application must be filed. An applicant may currently and under the final rule file a divisional application to each non-elected invention if the USPTO issues a requirement that an application containing claims to multiple inventions be restricted to a single invention (a restriction requirement). The USPTO changed the divisional filing period requirement from during pendency of initial application (proposed rule) to during the pendency of the initial application or its two continuing applications (final rule). As a result, the costs incurred by affected entities will be spread over a longer time period, which will ease the cost burden on these entities.

The final alternative the USPTO implemented in the final rule changes the application of the continued examination filing provisions from any continued examination filing (any continuation, continuation-in-part, or RCE) filed on or after the effective date (proposed rule) to at least "one more" continuation or continuation-in-part application after the effective date, regardless of the number of previous continued examination filings (final rule).

Alternatives Considered But Not Adopted 7.2

The USPTO considered changing the proposed claims requirements to instead provide expedited examination to applications containing less than a set number of claims. The USPTO currently has an accelerated examination program for applicants who limit the number of claims in their applications (to no more than three independent claims and no more than twenty total claims) and who also provide an ESD. Therefore, the USPTO did not pursue this alternative in the final rule.

In addition, the USPTO considered another alternative to the proposed claims requirements. To minimize the impact on small entities, the USPTO considered not applying the ESD requirement to pending applications that have not yet been examined (the backfile). However, the final rule's ESD applicability threshold (i.e., applications having more than five independent claims or more than twenty-five total claims) means that most small entity applicants will not be impacted by the final rule or the decision to apply the final rule to the backfile. Given the current backlog of over 700,000 unexamined applications, a decision to not apply the changes to the backfile would mean that it would be calendar year 2010 before the USPTO would see any benefit from the change, and that the USPTO (and applicants) would be in a transition state until late calendar year 2011.

The USPTO also considered a change that affected both the claims and continued examination filing requirements. The alternative would have imposed additional fees for continued examination filings and/or a graduated excess claims fee schedule. Currently, patent application and excess claims fees are set by statute (35 U.S.C. 41(a)). In 2002, the USPTO proposed a patent fee structure that included a graduated excess claims fees schedule and additional fees for continued examination filings. The USPTO was unable to garner sufficient support from patent user groups for a patent fee structure including a

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graduated excess claims fees schedule or any additional fees for continued examination filings. Therefore, the USPTO did not adopt the alternative.

The final alternative the USPTO considered but did not adopt addressed the continued examination filing requirements. The change would have expanded the deferral of examination provisions to allow a longer deferral of examination. The USPTO currently has a provision (37 CFR 1.103(d)) under which an applicant may request deferral of examination for up to three years from the earliest filing date for which a benefit is claimed. The USPTO continues to study whether changes (e.g., an increased deferral period, third party request for examination, and patent term adjustment) to the deferral of examination procedure would be appropriate, but notes that patent user groups have historically not favored increases in the deferral of examination. Therefore, the final rule does not contain this alternative.

Appendix A: Input Cost Estimates

		A THE RESIDENCE OF THE PROPERTY OF THE PROPERT
Cost elements	Estimate	Description/Source
Patentability search - Simple	\$1,000	AIPLA Report 2005, Table Q39o, 25th percentile, All Individuals
Patentability search - Complex	\$2,500	AIPLA Report 2005, Table Q39o, 75th percentile, All Individuals
Applicant's time, prepare and attend client interview - Simple	\$450	3 hours @ \$150 (range from 3-21 hours)
	مي مي	48 hours @ \$150 (range from 3-21 hours)
Applicant's time, prepare and attend circuit interview - complex	44,400	10 Hours (20 4 100 (10119 C 11011 C 2) (1001)
Attorney's fee for patent application - Simple	\$7,000	AIPLA Report 2005, Table Q39e, 25th percentile, All Individuals
Attorney's fee for patent application - Complex	\$15,000	AIPLA Report 2005, Table Q39c, 75th percentile, All Individuals
Application Filing Fee (Initial/Cont/CIP) (USPTO)	\$500	USPTO FY2006 Fees
Excess independent claims fee (USPTO)**	\$1,300	USPTO FY2006 Fees
Excess total claims fee (USPTO)**	\$1,400	USPTO FY2006 Fees
Response to First Office Action - Simple	\$1,000	AIPLA Report 2005, Table Q39f, 25th percentile, All Individuals
Response to First Office Action - Complex	\$4,500	AIPLA Report 2005, Table Q399, 75th percentile, All Individuals
Prenare CIP annication, lawver's fees	\$3,500	USPTO staff estimate, September 12, 2006
Response to Final Office Action - Simple	\$1,000	AIPLA Report 2005, Table Q39f, 25th percentile, All Individuals
Response to Final Office Action - Complex	\$4,500	AIPLA Report 2005, Table Q39g, 75th percentile, All Individuals
Issue Fee (USPTO)	\$700	USPTO FY2006 Fees
l awver fee to pay an Issue Fee - Simple	\$350	AIPLA Report 2005, Table Q39I, 25th percentile, All Individuals
Lawyer fee to pay an issue Fee - Complex	\$1,000	AIPLA Report 2005, Table Q39I, 75th percentile, All Individuals
First Maintenance Fee (USPTO)	\$450	USPTO FY2006 Fees
Second Maintenance Fee (USPTO)	\$1,150	USPTO FY2006 Fees
Third Maintenance Fee (USPTO)	\$1,900	USPTO FY2006 Fees
Lawver fee to pay Maintenance Fees - Simple	\$150	AIPLA Report 2005, Table Q39n, 25th percentile, All Individuals
Lawyer fee to pay Maintenance Fees - Complex	\$300	AIPLA Report 2005, Table Q39n, 75th percentile, All Individuals
1	\$385	USPTO FY2006 Fees
Petition Fee	\$400	USPTO FY2006 Fees
Petition Preparation	\$1,000	USPTO staff estimate, September 11, 2006

**Estimates of incremental costs are calculated based on the number of claims contained in each application. Estimated baseline costs, however, conservatively assume the application has 76 total claims and 16 independent claims, and therefore may understate the baseline costs.

Appendix B: Estimating the Value of Patent Applications

One way to measure the incremental cost of the proposed rule is to express the cost as a percentage of the expected value derived from the patent over its lifetime. Economists have been studying the expected lifetime market value of patents in order to measure the impact of technological innovation on the macro-economy. For reasons discussed below, however, estimates of patent value show significant variation among various studies and approaches.

One measure of the expected value is derived from estimating the total income from patented ideas. Eaton and Kortum (1995) estimated the value of all patented ideas in the U.S. to be about \$197 billion in 1998. According to USPTO data, there were 84,272 patents granted in 1988 in the U.S. whereas the total number of patent applications in that year was 151,491. Thus, based on the income earned from patented ideas, the average value of a patent in 1988 was about \$2.3 million per patent granted, and about \$1.3 million per patent application.

Because of the hazard of imitation in some of the developing countries, economists estimating the worldwide value for patents (as opposed to in the domestic country only) find the average expected value to be significantly lower. For example, McCalman (2005) analyzed the worldwide value of patent applications filed by U.S. inventors in the same year as above, and estimated it to be about \$163,700 per application in 1988.

Perhaps the most realistic measure of the market value of patents is provided by Hall, et al (2000). They matched USPTO's patent database to publicly traded firm-level data from Compustat to estimate the market value of patents. Using data from 1976 – 1992, they found the marginal shadow value of a patent to be \$370,000. Drawing on USPTO data for this period, the ratio of patents granted to total applications was 59 percent. Therefore, the marginal shadow value of patent per application in this period was about \$220,000.

This discussion illustrates the wide variation in the economics literature on lifetime patent values. One reason for such differences is whether the value of the patent is estimated for the U.S. only or for values accruing to patents around the world. Moreover, as Griliches, Hall, and Pakes (1987) point out, the distribution of the patent values is known to be extremely skewed with a few patents being very valuable, and many worth almost nothing. Any exercise in estimating the future value of patents or patent applications is, therefore, fraught with uncertainty and likely to produce extremely noisy measures.

References:

Eaton, J, S. Kortum. 1995. "Trade in Ideas: Patenting and Productivity in the OECD." National Bureau of Economic Research Working Paper Series, No. 5049.

Griliches, Z, A. Pakes, and B. Hall. 1987. "The Value of Patents as Indicators

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of Inventive Activity," in Dasgupta, Partha, and Paul Stoneman (eds.), Economic Policy and Technological Performance. Cambridge, England: Cambridge University Press, 97-124.

Hall, B, A Jaffe, M Trajtenberg. 2000. "Market Value and Patent Citations: A First Look." Institute of Business and Economic Research, University of California, Berkeley. Working Paper E00'277.

McCalman, P. 2005. "Who Enjoys 'TRIPS' Abroad? An Empirical Analysis of Intellectual Property Rights in the Uruguay Round." Canadian Journal of Economics: 574-603.

Projected Reporting, Recordkeeping, and Other 4. **Compliance Requirements**

The final rule establishes three compliance requirements that will allow the USPTO to conduct a better and more thorough and reliable examination of patent applications.

- Submittal of an examination support document (ESD) for certain applications;
- Submittal of a petition in support of certain requests for continuing applications or continued examinations;
- Submittal of information related to patentably indistinct claims.

The following subsections discuss these requirements and estimate the associated burden on applicants that must comply with them.

To develop the estimates for the incremental costs resulting from the requirements of the final rule, the analysis uses the following information and data sources:

- Activities resulting in costs were identified based on a review of the draft final rule (provided by the USPTO), the proposed rules, and on discussions with USPTO staff.11
- USPTO fees charged of patent applicants and patent holders were taken from the USPTO's fee schedule.1
- The costs associated with baseline patent application preparation were taken from an American Intellectual Property Law Association (AIPLA) report entitled Report of the Economic Survey 2005. 13
- Finally, USPTO staff provided estimated unit costs for a variety of factors, as noted in Appendix A.

All costs are calculated in 2006 dollars. The analysis applies a legal services labor rate of \$233 per hour¹⁴ (a composite of attorney and paralegal wage rates), and conservatively assume the applicant's labor rate is \$150 per hour. The resulting costs are summarized in Section 5.2.

¹¹ Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 FR 48 (Jan. 3, 2006); Changes to Practice for the Examination of Claims in Patent Applications, 71 FR 61 (Jan. 3, 2006)

http://www.uspto.gov/web/offices/ac/qs/ope/fee2007february01.htm.

¹³ AIPLA. Report of the Economic Survey 2005. Arlington, VA. September 2005.

¹⁴ This labor rate is a blended composite wage based on data from the AIPLA report entitled Report of the Economic Survey 2005. The analysis updated the 2004 composite wage rate to 2006 dollars based on the Consumer Price Index.

Examination Support Document 4.1

Under the final rule, patent applicants will be required to submit an ESD if the application contains more than five independent claims or more than 25 total claims. The final rule states that the ESD must contain the following six elements (Section 1.261(a)(1)-(6) of the final rule):

- (1) A statement that a preexamination search was conducted, including an identification of the field of search by United States class and subclass and the date of the search, where applicable, and, for database searches, the search logic or chemical structure or sequence used as a query, the name of the file or files searched and the database service, and the date of the search;
- (2) An information disclosure statement in compliance with § 1.98 citing the reference or references deemed most closely related to the subject matter of each of the claims (whether in independent or dependent form);
- (3) For each reference cited, an identification of all the limitations of each of the claims (whether in independent or dependent form) that are disclosed by the
- (4) A detailed explanation of how each of the claims (whether in independent or dependent form) is patentable over the references cited with the particularity required by § 1.111(b) and (c);
- (5) A concise statement of the utility of the invention as defined in each of the independent claims; and
- (6) A showing of where each limitation of each of the claims (whether in independent or dependent form) finds support under the first paragraph of 35 U.S.C. 112 in the written description of the specification. If the application claims the benefit of one or more applications under title 35, United States Code, the showing must also include where each limitation of each of the claims finds support under the first paragraph of 35 U.S.C. 112 in each such application in which such support exists.

Patent applicants with applications that exceed the independent or total claims thresholds will incur costs to prepare and submit the ESD.

To estimate the cost of the ESD, the analysis considers each of the six elements in the

The first element of the ESD requires the applicant to conduct a patent search. Although applicants currently are not required to conduct a patent search, most patent applicants (55 percent) conduct one as part of the application process. According to AIPLA estimates, the cost of a patent search ranges from approximately \$1,000 for a relatively simple patent application up to approximately \$2,500 for a relatively complex patent application.

Under the final rule, applicants that must prepare an ESD will have an incentive to complete the patent search prior to completion of their applications and ESDs. The reason for this is that doing so will reduce their costs for completing other portions of the

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ESD (due to the heightened familiarity they will have with the patent search relative to the application). Given this incentive, it would be reasonable to assume that all applicants required to prepare an ESD (including conducting a patent search) would choose to complete the patent search prior to completing their application. Such an assumption would allow the analysis to account for lower ESD preparation costs than apply in cases where the patent search is not conducted until after the application is completed. Nevertheless, as a conservatism, the analysis assumes that only 50 percent of applicants in this situation will conduct the patent search prior to completing the application. The remaining 50 percent of applicants facing ESD requirements are assumed to complete the application first, even though doing so leads to higher ESD preparation costs.

Exhibit 4-1 presents the time estimates for each element of the ESD, assuming the applicant has/hasn't completed the patent search prior to completing the application.

Exhibit 4-1

Examination Support Document Time/Cost Estimates

L'Adminiation bapport s'e		
	Estimate Assuming	Estimate Assuming
Cost Rasis		Patent Search is
Cost Basis	Conducted Prior to	Conducted After
	Application	Application
Application-based	\$1,000 - \$2,500	\$1,000 - \$2,500
	1 hour	1 hour
First two independent claims	30 minutes each	40 minutes each
Remaining independent claims	10 minutes each	10 minutes each
First 10 dependent claims	10 minutes each	10 minutes each
Remaining dependent	5 minutes each	5 minutes each
claims	J innutes each	
Independent claims	10 minutes each	15 minutes each
	No additional time	No additional time
Dependent claims	needed	needed
Application-based	30 minutes	30 minutes
	20 minutes each	20 minutes each
claims	20 minutes caen	20 1111111100 00011
Remaining independent	10 minutes each	10 minutes each
claims		
Dependent claims	5 minutes each	5 minutes each
	Cost Basis Application-based Application-based First two independent claims Remaining independent claims First 10 dependent claims Remaining dependent claims Independent claims Dependent claims Application-based First two independent claims Remaining independent claims Remaining independent	Cost Basis Conducted Prior to Application Application-based \$1,000 - \$2,500 Application-based 1 hour First two independent claims Remaining independent claims First 10 dependent claims Remaining dependent claims Independent claims Independent claims Dependent claims Application-based 30 minutes each No additional time needed Application-based 30 minutes First two independent claims Remaining independent claims Pependent claims Remaining independent claims Remaining independent claims Remaining independent claims Pependent claims To minutes each 10 minutes each 10 minutes each 10 minutes each 5 minutes each 10 minutes each

^{*} To mitigate the final rule's cost impact on small entities, the USPTO will not require small entities, as defined in 13 CFR 121.802, to complete Element 3 of the ESD.

This analysis assumes that the cost associated with three of the ESD elements is "application-based." Specifically, for elements 1, 2, and 5 of the ESD, applicants will incur a flat cost. Conversely, the cost incurred by applicants to complete elements 3, 4, and 6 of the ESD will vary depending on the number of independent and dependent claims in an application. To reduce the final rule's cost impact on small entities, however, the final rule does not require small entities to complete Element 3.

Exhibit 4-2 summarizes the resulting estimates of incremental ESD costs for affected small entities.

- Assuming a patent search is conducted before the patent application is completed, this analysis estimates that the incremental cost associated with the ESD ranges from \$2,563 to \$10,136.
- Assuming a patent search is conducted after the patent application is completed, this analysis estimates that the incremental cost associated with the ESD ranges from \$5,170 to \$13,121.

Exhibit 4-2
Summary of Small Entity Incremental Costs Associated with the ESD

Summary of Small Entity Incremental Costs 713500	Incremental Cost
For applicants that already conduct a patent search in the baseline	\$2,563-\$10,136*
For applicants that do not conduct a patent search in the baseline	\$5,170-\$13,121*

^{*} Cost of preparing an Examination Support Document varies depending on the number of claims in the application. Range shown covers up to 50 independent claims or 350 total claims. The analysis does not assume a range of costs per application, but instead applies the specific cost appropriate to the number of claims in each application.

4.2 Petition for Continuing Applications or Continued Examinations

The final rule also sets a reporting requirement related to continued examination filings. According to the final rule, an application or chain of continued examination filings may include no more than two continuing applications (continuation or continuation-in-part applications), and no more than a single request for continued examination in any one of these three applications (the initial or two continuing applications), without a petition showing why the amendment, argument, or evidence presented could not have been previously submitted. Based on a USPTO staff estimate, this analysis estimates that the petition required under the final rule will cost applicants \$1,000 to complete. 15

¹⁵ In the OMB Paperwork Burden Analysis for the proposed continued examination filings rule, the USPTO estimated the cost of the petition to be \$572. As a conservatism, this analysis assumes the cost of the petition will be higher (\$1,000).

The final rule also contains a reporting requirement to address patentably indistinct claims. This requirement applies to applicants with pending applications or patents that (1) have an effective filing date within two months of the filing date of the pending application; and (2) name at least one inventor in common with the pending application. Under the final rule, the applicant must name these other commonly-owned applications or patents and must file a terminal disclaimer or explain how the applications (or application and patent) contain only patentably distinct claims if they have the same effective filing date and contain substantial overlapping disclosure.

The analysis estimates that there will be no costs associated with the indistinct claims portion of the rule. The intention of the provision is to close a loophole that might otherwise open after the ESD provisions are promulgated. That is, to avoid preparing an ESD, an applicant might otherwise be able to divide his or her claims among two simultaneous applications ("parallel prosecution"). The indistinct claims provision would prevent this by forcing applicants to justify the indistinct claims in the applications, submit a terminal disclaimer (the costs of which are associated with existing rules) or, more likely, abandoning one of the applications and adding its claims to the other application. USPTO staff believe it would not be possible to successfully justify the dual applications in this case. The applicant, too, would realize this and therefore would not submit such applications. Thus, given that the final rule would establish these rules in advance, the effect of the indistinct claims provision would be to prevent the dual application scenario from being used as a means of avoiding the ESD requirement.

Applicants currently file dual applications for reasons other than avoiding the prospective ESD requirement. This final rule would not generate incremental costs in this situation because 37 CFR 1.78(b) currently provides that applicants can be required to eliminate patentably indistinct claims from all but one application and the double patenting doctrine requires a terminal disclaimer if the patentably indistinct claims are not eliminated from all but one application.

5. Impacts Assessment

To comply with the Regulatory Flexibility Act, agencies must determine whether proposed actions will have a significant economic impact on a substantial number of small entities. If the action will not have a significant impact on a substantial number of small entities, then the agency may certify that this is the case instead of preparing a regulatory flexibility analysis, as would otherwise be required under the Act.

This section considers whether the costs of the rule will lead to a significant economic impact on a substantial number of small entities. Section 5.1 describes the methodology used in this assessment. Section 5.2 presents the results of the analysis. Finally, Section 5.3 draws conclusions regarding whether certification is appropriate.

5.1 Methodology

To assess whether the costs of the rule will lead to a significant economic impact on a substantial number of small entities, this analysis proceeds in four general steps.

- (1) Select an appropriate indicator for measuring impacts;
- (2) Estimate the incremental compliance costs of the final rule;
- (3) Quantify the impacts and the number of entities impacted; and
- (4) Evaluate the impacts.

Each of these steps is described below.

5.1.1 Selection of Impact Measure

The analysis evaluates impacts based on the ratio of annualized incremental cost as a percent of total revenue. This measure was selected after evaluating the following six candidate measures:

- Incremental Cost. This measure considers the increase in cost (present value) to a given entity resulting from the rule. The incremental cost is equivalent to the cost of obtaining a patent under the new rule minus the cost of obtaining a patent under the current rules. While intuitively simple, this measure does not address the significance of the cost relative to any characteristic (e.g., size) of the small entity that incurs the cost. Therefore, incremental cost is used in this analysis only as an intermediate result.
- Annualized Incremental Cost. This measure calculates what the annual incremental cost of the rule would be if the incremental cost (as described above) were financed and paid off in annual installments. This measure can be useful in situations where it is reasonable to allocate costs over a multi-year period. Spreading costs over time is generally appropriate for capital investments (e.g., equipment) that will contribute to income over an extended period. In the case of patents, for example, it is reasonable to allocate the cost of obtaining a patent over the 20-year life of the resulting patent, because the patent holder retains exclusive rights over the patent during that time. In fact, generally accepted accounting principles (GAAP) for amortizing patents require patents to be amortized over the life of the patent. Nevertheless, this measure by itself does not address the significance of the cost relative to the entity that incurs it. Therefore, annualized incremental cost is used in this analysis only as an intermediate result.
- Percent Increase in Costs. This measure calculates the incremental cost as a percentage increase relative to the "baseline" costs, which are the costs applicable in the absence of the rule. The percent increase in costs can be useful,

See, for example, Statement of Accounting Standards No. 142, Goodwill and Other Intangible Assets, Financial Accounting Standards Board, June 2001.

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particularly when percentage increases are small. However, this measure does not address the significance of the cost relative to the entity that incurs the cost. For example, even if a rule leads to a 100 percent increase in costs, that increase might not be significant to an entity if the original cost is sufficiently small. In addition, estimating the "baseline" cost of preparing a patent application is difficult due to the difference between applications with respect to the complexity of the invention, the state of prior art, and the skills and experience of the applicant.

- Cost as a Percent of the Expected Value of the Patent. This measure considers the incremental cost as a fraction of the expected value of the patent. In theory, this measure should be very useful in evaluating whether impacts are likely to be significant. In practice, however, this approach presents significant challenges. For example, it would not be possible to identify the expected value of individual patent applications, which would be ideal from a theoretical standpoint. Instead, it would be necessary to apply one or more average values and make related assumptions. This study evaluated the literature to find information on the value of patent applications and identified estimates ranging from \$220,000 to \$1.3 million. These finding do not appear sufficiently robust to support use of this measure for the present purposes (see Appendix B for further discussion). Finally, this measure would not recognize other types of value that patents and patent applications can provide to applicants (e.g., by providing enhanced competitive protection to existing business lines).
- Incremental Cost as a Percent of Revenue, and Annualized Incremental Cost as a Percent of Revenue. These measures consider cost as a percentage of an entity's total revenue - a common measure of an entity's size - and are common screening measures for evaluating whether costs are significant. All else equal, costs that are small relative to a firm's size are less significant than costs that are larger. Although other factors also influence whether a given cost is significant to an entity, such as the entity's profitability and its ability to "pass through" costs to its customers, these two ratios both are useful screening measures that are applicable to most types of entities.
- Incremental Cost as a Percent of Profits. Incremental cost relative to profits is often considered a useful measure of impacts because profit represents "net" revenue after all expenses have been paid. This measure raises some unique issues, however, including the "adequacy" of any given return on equity, the effect of tax incentives on small entities, and whether a cost should be considered "more significant" to firms that are managed poorly as opposed to firms that are managed more effectively. From a more mechanical perspective, profits data are relatively difficult to obtain, particularly when affected entities span numerous industries, as is the case with patent applicants.

This study focuses on annualized incremental cost as a percent of revenue for several reasons: (1) it considers costs on an annualized basis, which is consistent with the

generally accepted recognition that a patent is an asset conveying a multiyear earning potential; (2) it evaluates impacts relative to revenue, which is a useful and relevant measure of the size of an entity; (3) it can be applied readily across many industries and entity types; (4) data availability typically is not an impediment to analysis; and (5) most people understand it without difficulty.

5.1.2 Estimation of Incremental Compliance Costs

The analysis estimates incremental costs resulting from the requirements of the final rule using the information and sources described in Section 4 and Appendix A. These sources include USPTO staff, AIPLA, and the USPTO fee schedules.

The resulting costs are summarized in Section 5.2. The incremental costs are annualized over a period of 20 years (to coincide with the life of the patent) using an interest rate of seven percent.

5.1.3 Quantify Impacts and Number of Entities Impacted

In the next step, the analysis quantifies the impacts of the final rule and the number of entities impacted at the identified thresholds (described in Section 5.1.4). Impacts are based on incremental costs calculated as described in Section 5.1.2. As noted previously, some costs (those associated with the claims requirements) are a function of the number of claims contained in an application. Therefore, the analysis appropriately models different incremental costs and impacts for filings having different numbers of included claims. All estimates of the number or percentage of affected entities and the distribution of applications by number of claims are based on data from PALM for fiscal year 2006.

5.1.4 Evaluate the Rule's Economic Impacts

In the last step, the quantitative results are screened to determine whether the rule is likely to have a significant impact on a substantial number of small entities.

Significant Impact Criteria

To evaluate significant impact, the study considers the ratio of Annualized Incremental Cost as a Percent of Revenue, as described earlier. Impacts are evaluated relative to two screening thresholds:

 Entities at or above a threshold value of three percent are presumed to face significant impacts unless additional analysis of these entities indicates this will

For applications affected only by the claims requirements, PALM provided data on the number of claims for each application. The analysis conservatively assumes that the filings (other than RCEs) affected by both the claims requirements and by the continued examination filing requirements are those non-initial applications shown by the PALM data as having the most claims. For RCEs, the analysis assumes the same distribution by number of claims as PALM shows for non-initial applications.

not be the case. Note that a three percent threshold is equivalent to determining whether an entity has annual revenue of at least 33.3 times the annualized incremental cost.

• Entities at or above a threshold value of *one percent* are presumed to face more moderate impacts that qualify as significant if collectively incurred by a *substantial number* of small entities, as discussed below. Note that a one percent threshold is equivalent to determining whether an entity has annual revenue of at least 100 times the annualized incremental cost.

Because the rule's incremental costs are relatively small, the analysis proceeds by considering how much annual revenue an affected entity - large or small -would have to earn in order to avoid these impacts. To the extent that these minimum levels are below the levels needed to run even the smallest business, then the analysis can conclude that the rule will not result in significant impacts. For purposes of analyzing this rulemaking, the smallest business is modeled as a sole proprietorship owned by a creative and/or technical individual who currently is capable of paying for or financing all necessary patent filing costs and maintenance fees (under current rules) associated with an application of a type that would be affected by the final rule. These filing and maintenance fees can vary by filing, but this study estimates that they range from \$19,940 to \$49,155 for filings that would be affected by the final rule. This study assumes that the minimum annual revenue that would support an individual's living expenses, as well as his/her patent filing and maintenance costs, is \$75,000.18 Therefore, the smallest business in the analysis would exceed the three percent threshold at annualized incremental costs of \$2,250 or higher, and it would exceed the one percent threshold at annualized incremental costs of \$750 or higher. Businesses that earn higher revenue would exceed these thresholds only at proportionately higher incremental costs.

Note that the above thresholds are intended to serve as screening-level indicators and may be overly sensitive for purposes of identifying economic impacts. For example, to the extent that affected entities may earn higher future revenue due to the commercialization of the patent, impacts based on current revenue levels will be overstated. Additional analysis would be needed to definitively determine whether entities exceeding this threshold are likely to incur significant impacts as a result of the rule.

Substantial Number Criteria

The key objective of this analysis is to determine whether the USPTO's final rule will result in a significant economic impact on a *substantial number* of small entities. The concept of a "substantial number" is necessarily relative, however. For purposes of analyzing this rulemaking, it is reasonable to consider it relative to the total number of

Revenue of \$75,000 is higher than the U.S. median income (which is slightly less than \$50,000), but it seems reasonable in light of the creative/technical abilities of an individual seeking a patent, as well as his/her current ability to fund the development and processing of the patent application (under existing regulations) as well as the required maintenance fees.

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small entities that apply for patents. The USPTO's PALM system indicates that, in FY 2006, there were a total of 111,178 patent filings submitted by entities claiming smallentity status.

Most of these small entities, however, will not incur costs under the final rule. Of those that are affected, some might face potentially significant impacts. This analysis assumes that a "substantial number" of small entities exists if the number if entities impacted at a given impact threshold (e.g., three percent of revenue) constitutes at least 20 percent of all small entities that apply for patents. The analysis considered developing a numerical threshold (e.g., 2,500) as another criterion for determining "substantial number," but did not do so for two reasons. First, it was clear that the final rule would not affect enough small entities to exceed any of the numbers that would have been considered. Second, given that the number of patent filings the USPTO receives increases by 7 to 8 percent per year when the economy is good, selection of a number that would be appropriate for this year's rulemaking likely would be inappropriate in the near future.

Assumptions and Uncertainties

The analysis relies on several data sources as documented throughout this report. In addition, two assumptions are worth noting.

First, due to data limitations, the analysis considered patent filings rather than applicants. To the extent that applicants might have more than one application in process at a time, this will tend to understate impacts. Although the assumption certainly does not hold true for many large firms, these firms have sufficient revenue to avoid significant impacts under the final rule. The assumption is much more reasonable, however, for the smallest firms, such as the sole proprietorship described above, which might face significant impacts under the rule. See additional discussion in Section 3.2.2.

Second, the analysis of the continued examination filing requirements assumes, as also discussed in Section 3.2.2, that most applicants who would have triggered the final rule's claims requirements based on the applications they submitted in FY 2006 will not trigger those requirements once the rule is promulgated. Instead, these applicants will choose to submit an initial application with fewer claims (to avoid having to prepare an ESD) and then will take advantage of the various steps in USPTO's patent application review process to add additional claims. The final rulemaking contains a description of how these applicants can prosecute their applications in this manner to avoid triggering the ESD requirement.

Results 5.2

The presentation of results is organized in three parts: (1) costs; (2) number of small entities affected by the rule; (3) magnitude of impacts; and (4) unquantified benefits.

5.2.1 Cost Results

This analysis estimates that incremental costs will range from \$872 to \$13,993. 19 Incurring the lowest of these incremental costs are those applicants affected only by the continued examination filing requirements. Applicants incurring incremental costs at the highest end of the range are those having the following three characteristics: (1) they are affected by the claims requirements and have the greatest number of claims (e.g., 350 total claims); (2) they did not choose to conduct a patent search in the baseline; and (3) they also are affected by the continued examination filing requirements. Most applicants will fall between the extremes, as they will be affected by the claims requirements but will have more typical (lower) numbers of claims. Exhibit 5-1 summarizes the cost results, which are discussed in greater detail in Section 4.

> Exhibit 5-1 Summary of Incremental Costs and Annualized Incremental Costs

Summary of merementar cost	Incremental Cost	Annualized Incremental Cost
Continued Examination Filing Requirements Only	\$872	\$82
Claims Requirements Only, for applicants that already conduct a patent search in the baseline	\$2,563-\$10,136*	\$242-\$957*
Claims Requirements Only, for applicants that do not conduct a patent search in the baseline	\$5,170-\$13,121*	\$488-\$1,239*
Both, for applicants that already conduct a patent search in the baseline	\$3,435-\$11,007*	\$324-\$1,039*
Both, for applicants that do not conduct a patent search in the baseline	\$6,042-\$13,993*	\$570-\$1,321*

Cost of preparing an Examination Support Document varies depending on the number of claims in the application. Range shown covers up to 50 independent claims or 350 total claims. The analysis does not assume a range of costs per application, but instead applies the specific cost appropriate to the number of claims in each application.

5.2.2 Number Affected by the Rule

Exhibit 5-2 summarizes the total number of filings that will incur any incremental cost due to the claims requirements, the continued examination filing requirements, or both. In each case, the number is less than two percent of filings. Looking at the rule as a whole, only approximately 3.69 percent of small entity filings are expected to incur any impacts under the final rule. Under the sensitivity analysis, in which all entities would be considered small entities, this percentage falls to approximately 3.46 percent.

Current patent filing and maintenance costs for applications that would be affected by the final rule are estimated at between \$19,940 and \$49,155.

Exhibit 5-2
Number and Percent of Entity Filings Affected by Final Rule Requirements

Number and Percent of Entity Filings Affected by Final Rule Requirements Small Entities All Entities*						
	Small Entities					
	Number	Percent	Number	Percent		
Continued Examination Filing Requirements Only	2,995	2.69% (of small entity filings)	10,402	2.55% (of all filings)		
Claims Requirements Only, for applicants that already conduct a patent search in the baseline	429	0.54% (of small entity initial applications)	1,550	0.54% (of all initial applications)		
Claims Requirements Only, for applicants that do not conduct a patent search in the baseline	351	0.44% (of small entity initial applications)	1,268	0.44% (of all initial applications)		
Both, for applicants that already conduct a patent search in the baseline	179	0.16% (of small entity filings)	508	0.12% (of all filings)		
Both, for applicants that do not conduct a patent search in the baseline	146	0.13% (of small entity filings)	416	0.10% (of all filings)		
Total for Final Rule**	4,100	3.69% (of small entity filings)	14,144	3.46% (of all filings)		

^{*}Some stakeholder have stated that the USPTO's PALM system understates the number of small entities submitting patent filings. Therefore, as described in Section 3.2, this study evaluates the bounding case of All Entities as a sensitivity analysis.

5.2.3 Magnitude of Impacts

Of the 3.69 percent of small entity filings that will incur any impacts under the final rule, very few – an estimated 54, or less than 0.05 percent – may exceed the minimal screening threshold of one percent, as shown in Exhibit 5-3. Moreover, no small entities applicants are expected to incur impacts at the more significant threshold of three percent, as shown in Exhibit 5-4. Under the sensitivity analysis, in which all entities would be considered small entities, an estimated 157 entities, or about 0.04 percent, may exceed the one percent threshold, and none would exceed the three percent threshold.

^{**} Percentages may not add due to rounding.

Exhibit 5-3
Number and Percent of Entity Filings Exceeding the 1 Percent Threshold for Annualized
Incremental Cost as a Percent of Total Revenue

Incremental Cost as a Percent of Total Revenue							
	Small Entities		All E	Entities*			
	Number	Percent	Number	Percent			
Continued Examination Filing Requirements Only	0	0% (of all filings)	0	0% (of all filings)			
Claims Requirements Only, for applicants that already conduct a patent search in the baseline	9	0.01% (of all initial applications)	24	0.01% (of all initial applications)			
Claims Requirements Only, for applicants that do not conduct a patent search in the baseline	23	0.02% (of all initial applications)	76	0.02% (of all initial applications)			
Both, for applicants that already conduct a patent search in the baseline	3	0.00% (of all filings)	7	0.00% (of all filings)			
Both, for applicants that do not conduct a patent search in the baseline	19	0.02% (of all filings)	50	0.01% (of all filings)			
Total for Final Rule **	54	0.05% (of all filings)	157	0.04% (of all filings)			

^{*}Some stakeholder have stated that the USPTO's PALM system understates the number of small entities submitting patent filings. Therefore, as described in Section 3.2, this study evaluates the bounding case of All Entities as a sensitivity analysis.

Exhibit 5-4
Number and Percent of Entity Filings Exceeding the 3 Percent Threshold for Annualized
Incremental Cost as a Percent of Total Revenue

Allor	Small Entities		All Entities*	
	Number	Percent	Number	Percent
Continued Examination Filing Requirements	0	0%	0	0%
Claims Requirements, for applicants that already conduct a patent search in the baseline	0	0%	0	0%
Claims Requirements, for applicants that do not conduct a patent search in the baseline	0	0%	0	0%
Both, for applicants that already conduct a patent search in the baseline	0	0%	0	0%
Both, for applicants that do not conduct a patent search in the baseline	0	0%	0	0%
Total for Final Rule**	0	0%	0	0%

^{*}Some stakeholder have stated that the USPTO's PALM system understates the number of small entities submitting patent filings. Therefore, as described in Section 3.2, this study evaluates the bounding case of All Entities as a sensitivity analysis.

^{**}Totals may not add due to rounding.

5.2.4 Unquantified Benefits

Partially offsetting the minor impacts of the rulemaking are certain unquantified benefits. The most significant benefit that will accrue to affected small entities seeking patents (and to larger patent applicants) will be the reduction in time required to complete the patent process. As described in Section 1.3, a reduction in processing time is one of the USPTO's key objectives for the rule. A second benefit that will accrue to small entities seeking patents (along with larger patent applicants) may be a reduction in patent fees relative to what those fees might rise to in the absence of the rule. By allowing patent examiners to more efficiently complete their examination of the most time-consuming patents, the rule should reduce the growth in the fee-recoverable cost base. Finally, PTO also expects the rule to contribute to higher-quality patents in many cases. This benefit accrues to society as a whole (including small entities) and might result in various efficiencies as well as a decrease in patent litigation.

Conclusion 5.3

This analysis estimates that the final rule will result in incremental costs that range from \$872 to \$13,993 per application (present value).20 Based on the methodology and data described in this report, the resulting analysis indicates that no patent applicants will incur significant impacts (defined as annualized incremental costs in excess of three percent of revenue) due to the final rule. Although some applicants will exceed the lower screening threshold of one percent, the number of small entities in this category is estimated at only 54, or about 0.05 percent of all small entity applicants. Even using data for all applicants as a sensitivity analysis, only 157 small entity applicants fall into this category - 0.04 percent of all applicants. These figures do not meet the criterion for a "substantial number" of small entities. Therefore, this analysis concludes that USPTO's final rule will not result in significant economic impacts on a substantial number of small entities.

Duplicative, Overlapping, and Conflicting Rules 6.

The USPTO is the sole U.S. government agency responsible for administering the patent system and granting patents. Therefore, no other federal, state, or local entity shares jurisdiction over the United States' patent system.

Other countries, however, have their own patent laws, and an entity desiring a patent in a particular country must make an application for patent in that country, in accordance with the applicable law. Although the potential for overlap exists internationally, this cannot be avoided except by treaty (such as the Paris Convention for the Protection of Industrial Property, or the Patent Cooperation Treaty (PCT)).

Current patent filling and maintenance costs are estimated at between \$19,940 and \$49,155 for fillings that would be affected by the final rule.

Nevertheless, the USPTO believes that there are no other duplicative or overlapping rules. Some public comments submitted in response to the notices of proposed rulemaking argued that the proposed rules conflict with provisions of the Paris Convention and/or the PCT. The final rulemaking explains why there are no conflicts with either the Paris Convention or the PCT.

7. Significant Alternatives Considered and Steps Taken to Minimize Impacts on Small Entities

In response to some of the comments received, USPTO considered a variety of alternatives to minimize the impacts on small entities. Section 7.1 describes the alternatives that were adopted as part of the final rule. Section 7.2 discusses other alternatives that were considered but not adopted.

7.1 Alternatives Adopted by USPTO

The USPTO implemented five alternatives in the final rule to minimize the impact on small entities. The first two alternatives relate to the claims requirements and the remaining three relate to the continued examination filing requirements. In the final rule, the USPTO changed the ESD requirement threshold from more than ten representative claims in an application (proposed rule) to more than five independent claims or more than 25 total claims in an application (final rule). This change reduces the number of small entities affected by the final rule.

In addition, under the final rule, the USPTO will not require small entities, as defined in 13 CFR 121.802, to include in their ESDs one of the elements that would have been required under the proposed claims rule. Specifically, the final rule will not require small entities (but will require large entities) to identify, for each reference cited, all the limitations of each of the claims (whether independent or dependent) that are disclosed by the references. The USPTO considers this element of the ESD to be the most challenging for patent applicants. As a result of this change, the costs associated with the final rule will be greatly reduced for small entities.

The third alternative adopted in the final rule changes the continued examination filing petition threshold from one continuation application, continuation-in-part application, or RCE (proposed rule) to two continuing applications (continuation or continuation-in-part applications), and no more than a single RCE in any one of the initial or two continuing applications (final rule). This change also reduces the number of small entities affected by the final rule.

As mentioned in Section 3.2.2, some comments requested that applicants continue to be permitted to file divisional applications serially (i.e., in the manner of continuations or continuation-in-parts), rather than in parallel (i.e., by submitting multiple related applications simultaneously), in order to spread out the associated cost burden over time.

In response, the final rule modifies the time period within which any divisional application must be filed. An applicant may currently and under the final rule file a divisional application to each non-elected invention if the USPTO issues a requirement that an application containing claims to multiple inventions be restricted to a single invention (a restriction requirement). The USPTO changed the divisional filing period requirement from during pendency of initial application (proposed rule) to during the pendency of the initial application or its two continuing applications (final rule). As a result, the costs incurred by affected entities will be spread over a longer time period, which will ease the cost burden on these entities.

The final alternative the USPTO implemented in the final rule changes the application of the continued examination filing provisions from any continued examination filing (any continuation, continuation-in-part, or RCE) filed on or after the effective date (proposed rule) to at least "one more" continuation or continuation-in-part application after the effective date, regardless of the number of previous continued examination filings (final rule).

Alternatives Considered But Not Adopted 7.2

The USPTO considered changing the proposed claims requirements to instead provide expedited examination to applications containing less than a set number of claims. The USPTO currently has an accelerated examination program for applicants who limit the number of claims in their applications (to no more than three independent claims and no more than twenty total claims) and who also provide an ESD. Therefore, the USPTO did not pursue this alternative in the final rule.

In addition, the USPTO considered another alternative to the proposed claims requirements. To minimize the impact on small entities, the USPTO considered not applying the ESD requirement to pending applications that have not yet been examined (the backfile). However, the final rule's ESD applicability threshold (i.e., applications having more than five independent claims or more than twenty-five total claims) means that most small entity applicants will not be impacted by the final rule or the decision to apply the final rule to the backfile. Given the current backlog of over 700,000 unexamined applications, a decision to not apply the changes to the backfile would mean that it would be calendar year 2010 before the USPTO would see any benefit from the change, and that the USPTO (and applicants) would be in a transition state until late calendar year 2011.

The USPTO also considered a change that affected both the claims and continued examination filing requirements. The alternative would have imposed additional fees for continued examination filings and/or a graduated excess claims fee schedule. Currently, patent application and excess claims fees are set by statute (35 U.S.C. 41(a)). In 2002, the USPTO proposed a patent fee structure that included a graduated excess claims fees schedule and additional fees for continued examination filings. The USPTO was unable to garner sufficient support from patent user groups for a patent fee structure including a

Appendix A: Input Cost Estimates

Cost elements	Estimate	Description/Source
Patentabilify search - Simple	\$1,000	AIPLA Report 2005, Table Q39o, 25th percentile, All Individuals
Patentability search - Complex	\$2,500	AIPLA Report 2005, Table Q39o, 75th percentile, All Individuals
Applicant's time, prepare and attend client interview - Simple	\$450	3 hours @ \$150 (range from 3-21 hours)
Applicant's time, prepare and attend client interview - Complex	\$2,400	16 hours @ \$150 (range from 3-21 hours)
Attornev's fee for patent application - Simple	\$7,000	AIPLA Report 2005, Table Q39e, 25th percentile, All Individuals
Afforney's fee for patent application - Complex	\$15,000	AIPLA Report 2005, Table Q39c, 75th percentile, All Individuals
Application Filing Fee (Initial/Cont/CIP) (USPTO)	\$500	USPTO FY2006 Fees
	\$1,300	USPTO FY2006 Fees
Excess total claims fee (USPTO)**	\$1,400	USPTO FY2006 Fees
Response to First Office Action - Simple	\$1,000	AIPLA Report 2005, Table Q39f, 25th percentile, All Individuals
Resnanse to First Office Action - Complex	\$4,500	AIPLA Report 2005, Table Q39g, 75th percentile, All Individuals
Prenare CIP application, lawyer's fees	\$3,500	USPTO staff estimate, September 12, 2006
Response to Final Office Action - Simple	\$1,000	AIPLA Report 2005, Table Q39f, 25th percentile, All Individuals
Response to Final Office Action - Complex	\$4,500	AIPLA Report 2005, Table Q39g, 75th percentile, All Individuals
Issue Fee (USPTO)	\$700	USPTO FY2006 Fees
l awver fee to pay an Issue Fee - Simple	\$350	AIPLA Report 2005, Table Q39I, 25th percentile, All Individuals
Lawyer fee to pay an issue Fee - Complex	\$1,000	AIPLA Report 2005, Table Q39I, 75th percentile, All Individuals
First Maintenance Fee (USPTO)	\$450	USPTO FY2006 Fees
Second Maintenance Fee (USPTO)	\$1,150	USPTO FY2006 Fees
Third Maintenance Fee (USPTO)	\$1,900	USPTO FY2006 Fees
Lawyer fee to pay Maintenance Fees - Simple	\$150	AIPLA Report 2005, Table Q39n, 25th percentile, All Individuals
Lawyer fee to pay Maintenance Fees - Complex	\$300	AIPLA Report 2005, Table Q39n, 75th percentile, All Individuals
RCE Fee (USPTO)	\$395	USPTO FY2006 Fees
Petition Fee	\$400	USPTO FY2006 Fees
Petition Preparation	\$1,000	USPTO staff estimate, September 11, 2006

**Estimates of incremental costs are calculated based on the number of claims contained in each application. Estimated baseline costs, however, conservatively assume the application has 76 total claims and 16 independent claims, and therefore may understate the baseline costs.

Appendix B: Estimating the Value of Patent **Applications**

One way to measure the incremental cost of the proposed rule is to express the cost as a percentage of the expected value derived from the patent over its lifetime. Economists have been studying the expected lifetime market value of patents in order to measure the impact of technological innovation on the macro-economy. For reasons discussed below, however, estimates of patent value show significant variation among various studies and approaches.

One measure of the expected value is derived from estimating the total income from patented ideas. Eaton and Kortum (1995) estimated the value of all patented ideas in the U.S. to be about \$197 billion in 1998. According to USPTO data, there were 84,272 patents granted in 1988 in the U.S. whereas the total number of patent applications in that year was 151,491. Thus, based on the income earned from patented ideas, the average value of a patent in 1988 was about \$2.3 million per patent granted, and about \$1.3 million per patent application.

Because of the hazard of imitation in some of the developing countries, economists estimating the worldwide value for patents (as opposed to in the domestic country only) find the average expected value to be significantly lower. For example, McCalman (2005) analyzed the worldwide value of patent applications filed by U.S. inventors in the same year as above, and estimated it to be about \$163,700 per application in 1988.

Perhaps the most realistic measure of the market value of patents is provided by Hall, et al (2000). They matched USPTO's patent database to publicly traded firm-level data from Compustat to estimate the market value of patents. Using data from 1976 - 1992, they found the marginal shadow value of a patent to be \$370,000. Drawing on USPTO data for this period, the ratio of patents granted to total applications was 59 percent. Therefore, the marginal shadow value of patent per application in this period was about \$220,000.

This discussion illustrates the wide variation in the economics literature on lifetime patent values. One reason for such differences is whether the value of the patent is estimated for the U.S. only or for values accruing to patents around the world. Moreover, as Griliches, Hall, and Pakes (1987) point out, the distribution of the patent values is known to be extremely skewed with a few patents being very valuable, and many worth almost nothing. Any exercise in estimating the future value of patents or patent applications is, therefore, fraught with uncertainty and likely to produce extremely noisy measures.

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UNITED STATES PATENT AND TRADEMARK OFFICE

OFFICE OF THE GENERAL COUNSEL

July 10, 2007

Case 1:07-cv-00846-JCC-TRJ

MEMORANDUM FOR:

Thomas M. Sullivan

Chief Counsel for Advocacy

Small Business Administration

FROM:

William Covey

Deputy General Counsel for General Law

SUBJECT:

Certification Under 605(b) of the

Regulatory Flexibility Act

The Deputy General Counsel for General Law of the United States Patent and Trademark Office certifies to the Chief Counsel for Advocacy of the Small Business Administration that the changes implemented in this final rule, Changes to Practice for Continued Examination Filings, Patent Applications Coontaining Patentably Indistinct Claims, and Examination of Claims in Patent Applications RIN 0651-AB93 and RIN 0651-AB94) will not have a significant economic impact on a substantial number of small entities. As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 (or any other law), neither a regulatory flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) are required. See 5 U.S.C. 603. Nevertheless, the Office published notices of proposed rule making setting forth the factual basis for certification under the Regulatory Flexibility and sought public comment on that certification. See Changes to Practice for the Examination of Claims in Patent Applications, 71 FR at 66, 1302 Off. Gaz. Pat. Office at 1333, and Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 FR at 56-57, 1302 Off. Gaz. Pat. Office at 1325. For the reasons set forth herein, the Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that the changes in this final rule will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

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 as to why the amendment, argument, or evidence 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) any divisional application be the result of a requirement to comply with the

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requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 in the prior-filed application; (3) 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); and (4) multiple applications that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and a common assignee include either an explanation as to how the claims are patentably distinct, or a terminal disclaimer and explanation as to why patentably indistinct claims have been filed in multiple applications.

In response to the Office's certification in the notices of proposed rulemaking, the Small Business Administration Office of Advocacy (SBA-Advocacy) submitted a comment contending that the proposed changes are likely to have a significant economic impact on a substantial number of small entities, including small businesses and small independent inventors. SBA-Advocacy recommended that the Office conduct a supplemental Initial Regulatory Flexibility Analysis before publishing a final rule.

The Office's analysis of the proposed rules indicated that the rules would not have a significant economic impact on a substantial number of small entities. The Office considered all public comments addressing small entities, including those submitted by SBA-Advocacy. In response to these comments, this final rule incorporates a number of revisions designed to further reduce the number of small entities affected by the changes and the impacts on small entities. These changes in this final rule vis-à-vis the proposed rules that reduce small entity impacts are as follows: (1) this final rule adopts an examination support document requirement threshold five independent claims or twentyfive total claims, rather than ten representative claims; (2) this final rule provides that small entities as defined by the Regulatory Flexibility Act are exempt from the requirement that an examination support document must, for each cited reference, include an identification of all the limitations of each of the claims that are disclosed by the reference; (3) this final rule adopts a continued examination filing petition threshold of two continuing applications (continuation or continuation-in-part applications), plus a request for continued examination in any one of the initial or two continuing applications, rather than one continuation application, continuation-in-part application, or request for continued examination; (4) this final rule does not require that a divisional application be filed during pendency of initial application; and (5) this final rule provides for at least "one more" continuation or continuation-in-part application after the effective date, regardless of the number of previous continued examination filings.

In addition, the Office commissioned a detailed analysis of the impacts of this final rule on small entities. The analysis concludes that this final rule is not expected to result in a significant economic impact on a substantial number of small entities. The analysis measured economic impact in terms of annualized incremental cost as a percentage of revenue. The analysis indicated that the incremental cost (not annualized) would be between \$2,563 and \$13,121 for an entity who would be required to file an examination support document, a petition for an additional continued examination filing, or both. The analysis presumed that an economic impact greater than three percent of annualized

incremental cost as a percentage of revenue was a significant impact. The analysis indicated that no small entities fell into this category. The analysis also presumed that an economic impact greater than one percent of annualized incremental cost as a percentage of revenue was a more moderate impact. The analysis indicated that fewer than one percent of small entities fell into this category. The analysis also presumed that a substantial number of small entities are affected if more than twenty percent of small entities are impacted. The analysis indicated that about 1.0 percent of small entities would be affected by the requirement to submit an examination support document, that about 2.7 percent of small entities would be affected by the requirement for submit a petition for an additional continued examination filing, and that about 0.3 percent of small entities would be affected by both the requirement to submit an examination support document and the requirement for submit a petition for an additional continued examination filing. A copy of the report containing this analysis is available on the Office's Web site at www.uspto.gov.

As a result of this analysis, the Office has determined that it is appropriate to make a certification that the changes being adopted in this final rule would not have a significant economic impact on a substantial number of small entities. The Office has revised the final rule requirements, as discussed previously, to further reduce economic impacts on small entities.

SBA-Advocacy commented that while the Office asserts that preparation of the examination support document should cost about \$2,500, small entities contend that completing an examination support document will be more costly, time consuming and restrict their ability to prosecute patents vigorously. SBA-Advocacy also commented that small entity representatives have provided feedback that completion of an examination support document could cost from \$25,000 to \$30,000.

The Claims Proposed Rule referenced a \$2,500 figure covering a patent novelty search, analysis, and opinion, as reported in a 2003 survey conducted by the American Intellectual Property Law Association (AIPLA). The Office agrees with the comments that this figure is probably less than the cost of an examination support document in most situations. Therefore, the Office has further analyzed costs based on the modified examination support document requirements applicable to small entities. The analysis models cost variability based on the number of claims the examination support document must address, and on whether or not a prior art search was conducted when the application was prepared. Based on this analysis, the Office estimates that the examination support document costs for small entities will range from \$2,563 up to \$13,121, although this latter figure assumes the examination support document must address as many as fifty independent claims or three hundred and fifty total claims. Only a small number of small entities, however, will be required to prepare an examination support document, and nearly all of these will incur costs towards the lower end of the range. Thus, the Office does not expect the final rule to result in a significant impact on a substantial number of small entities.

SBA-Advocacy commented that small entity representatives have asserted that, taken together, the two proposed changes would increase the cost of application preparation and hinder the patent prosecution process.

As discussed previously, the Office commissioned a detailed analysis of the impact of the final rule on small entities. The analysis explicitly considered the combined cost of both proposed rules (which have been combined into a single final rule). The analysis concludes that the final rule is **not** expected to result in a significant economic impact on a substantial number of small entities.

SBA-Advocacy commented that small entity representatives have raised concerns that the proposed changes will significantly impact the most valuable and commercially viable patents because those types of patents typically involved a higher number of continuations.

The Office notes that there are studies espousing the position that many commercially valuable patents are the result of a continuing application, or of a second or subsequent continuing application. However, these studies do not support the position that the applicants could not have obtained these commercially valuable patents but for the availability of an unlimited number of continuing applications. That is, these studies do not show that these commercially valuable patents could not have been obtained via two or fewer continuing applications prosecuted with a reasonable amount of foresight and diligence. Thus, these studies do not demonstrate that these commercially valuable patents happen to be the result of a continuing application or of multiple continuing applications for any reason other than simply because the prosecution tactics employed in the applications underlying these patent were based upon the availability of an unlimited number of continuing applications.

The analysis commissioned by the Office specifically considered the claim that the most valuable and commercially viable patents because those types of patents typically involved a higher number of continuations. The Office ultimately rejected the claim that this final rule will preclude applicants from being able to obtain a patent on the most valuable and commercially viable patents due to the speculative nature of the nexus drawn between the availability of an unlimited number of continuing applications and an applicant's ability to obtain these commercially valuable patents.

SBA-Advocacy commented that small entity representatives have indicated that limiting applicants to ten representative claims would make it very difficult to properly identify a potential patent, could create future liability concerns, and would weaken potential patents.

The final rule requirements apply to patent applications with more than five independent claims or more than twenty-five total claims, rather than ten representative claims. As discussed previously, applicants with more than five but less than fifteen independent claims, or more than twenty-five but less than seventy-five total claims, to an invention are able to prosecute their application in a manner that does not trigger the claims or

continuations requirements. Specifically, an applicant may do this by submitting an initial application containing up to five independent claims and up to twenty-five 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) permitted without a petition. Moreover, even for those applications that will require an examination support document, the requirement does not "limit" applicants to any particular number of claims. Applicants may continue to submit as many claims as necessary to appropriately identify their patents, even if doing so required them to prepare and submit an examination support document.

SBA-Advocacy commented that small entity representatives have contended that limiting continuation applications and examinations would inhibit their ability to enhance their applications, significantly increase costs through new fees, and force small entities to seek review through the very expensive appeals process. Small entity representatives thus assert that limiting the number of continuations could severely weaken small entities' ability to protect their patents.

The Office analysis indicates that the continued examination filing requirements adopted in this final rule will not lead to significant cost increases nor will it have a significant economic impact on a substantial number of small entities. The requirements are necessary to ensure that patent applications are of reasonable quality and that applicants pursue their patents in good faith. The excessive use of continued examination filings has been a major factor in the growing backlog of unexamined applications. With respect to having to use the appeals process in place of additional continued examination filings, if an applicant disagrees with the examiner's rejections, the applicant should file an appeal rather than filing a continuation application or a request for continued examination, for reasons discussed in detail in the statement of considerations for the final rule. The Office believes that applicants should have sufficient opportunity to place the application in condition for appeal during the prosecution of the initial application, two continuing applications, and a request for continued examination. An applicant who considers this to be insufficient may file a third or subsequent continuing application or second or subsequent request for continued examination with a petition showing why the amendment, argument, or evidence could not have been previously submitted.

SBA-Advocacy commented that the proposed changes will affect a substantial number of small entities, and that the two proposed changes to the rules reshape the basic rights of any small entity that files a patent application.

The Office agrees that the final rule places new requirements on the current patent application process. However, the Office's analysis indicates that the rule will not have a significant economic impact on a substantial number of small entities. In fact, only a small proportion of small entities will be affected by the changes in this final rule.

SBA-Advocacy commented that small entity representatives have contended that the definition of small entity that the Office uses in its certification is for calculating filing fees and excludes any small entity that has a contractual arrangement involving the

invention with a larger company. SBA-Advocacy commented that small entity representatives have further asserted that small business size standards for RFA purposes do not include this restriction so the number of small businesses affected is likely to be larger than stated in the certification.

The Regulatory Flexibility Act permits an agency head to establish, for purposes of Regulatory Flexibility Act analysis and certification, one or more definitions of "small business concern" that are appropriate to the activities of the agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment. See 5 U.S.C. 601(3) and 13 CFR 121.903(c). Pursuant to this authority, the Office has established the following definition of small business concern for purposes of the Office conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations: A small business concern for Regulatory Flexibility Act purposes for patent-related regulations is a business or other concern that: (1) meets the Small Business Administration's definition of a "business concern or concern" set forth in 13 CFR 121.105; and (2) meets the size standards set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees, namely, an entity: (a) whose number of employees, including affiliates, does not exceed 500 persons; and (b) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under this definition. See Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations, 71 FR 67109, 67112 (Nov. 20, 2006), 1313 Off. Gaz. Pat. Office 60, 63 (Dec. 12, 2006) (notice). Prior to establishing this definition of small business concern for purposes of the Office conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations, the Office consulted with the Small Business Administration Office of Advocacy and published such a definition for public comment. See Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations, 71 FR 38388 (Jul. 6, 2006), 1309 Off. Gaz. Pat. Office 37 (Aug. 1, 2006) (notice). The Small Business Administration small entity size standards set forth in 13 CFR 121.802 excludes any business concern that has assigned, granted, conveyed, or licensed any rights in the invention to an entity which would not qualify for small entity status.

Nevertheless, in analyzing the provisions of the final rule, the Office explicitly considered a sensitivity analysis that assumed all patent applicants qualified as small entities. Even under this sensitivity analysis, this final rule is not expected to result in a significant impact on a substantial number of small entities.

SBA-Advocacy suggested that with respect to the continued examination filing requirements, the Office should increase the number of permissible continuing applications.

The final rule changes the continued examination filing petition threshold from a single continuation application, continuation-in-part application, or request for continued examination as proposed to two continuing applications (continuation or continuation-in-part applications), and a single request for continued examination in any one of the initial or two continuing applications.

SBA-Advocacy suggested that with respect to the continued examination filing requirement, the Office should consider increasing the fees for additional continuation applications.

Currently, patent application and excess claims fees are set by statute (35 U.S.C. 41(a)). In 2002, the Office proposed a patent fee structure that included a graduated excess claims fees schedule and additional fees for continued examination filings. As discussed previously, however, the Office was unable to garner sufficient support from patent user groups for a patent fee structure including a graduated excess claims fees schedule or any additional fees for continued examination filings. Therefore, the Office did not pursue this alternative.

SBA-Advocacy suggested that with respect to the continued examination filing requirement, the Office should defer review of subsequent continuation applications.

The Office considered expanding the deferral of examination provisions to allow a longer deferral of examination. The Office currently has a provision (37 CFR 1.103(d)) under which an applicant may request deferral of examination for up to three years from the earliest filing date for which a benefit is claimed. As discussed previously, the Office is studying whether changes (e.g., the maximum deferral period, third party request for examination, and patent term adjustment) to the deferral of examination procedure would be appropriate.

SBA-Advocacy suggested that with respect to the claims requirements, the Office should expand the number of representative claims included in initial review.

The Office has revised the final rule to change the examination support document threshold from ten representative claims to five independent claims or twenty-five total claims. As discussed previously, however, applicants with more than five but less than fifteen independent claims, or more than twenty-five but less than seventy-five total claims, to an invention are able to prosecute their application in a manner that does not trigger the claims or continuations requirements.

SBA-Advocacy suggested that with respect to the claims requirements, the Office should provide expedited review of applications that contain ten or fewer representative claims. The Office has considered the suggestion to provide expedited examination to applications containing less than a set number of claims. As discussed previously, the Office currently has an accelerated examination program for applicants who limit the number of claims in their applications (to no more than three independent claims and no

more than twenty total claims) and who also provide an accelerated examination support document. Therefore, the Office did not pursue this alternative in the final rule.

SBA-Advocacy suggested that with respect to the claims requirements, the Office should not apply the regulation to the backlog of pending unexamined applications.

The Office has considered not applying the claims requirement to pending applications that have not yet been examined to minimize the impact on small entities. The examination support document threshold being adopted in this final rule (i.e., more than five independent claims or more than twenty-five total claims) means that most small entity applications will not be impacted by the final rule or the decision to apply the final rule to the backlog of unexamined applications. Given the current backlog of over 700,000 unexamined applications, a decision to not apply the changes to the backlog of unexamined applications would mean that it would be calendar year 2010 before the Office would see any benefit from the change, and that the Office (and applicants) would be in a transition state until late calendar year 2011. Therefore, this suggestion was not adopted in the final rule.

The Office also received a number of additional comments from the public generally asserting that the Office did not comply with the requirements of the Regulatory Flexibility Act in certifying that the changes in this rule making will not have a significant economic impact on a substantial number of small entities. The comments stated that: (1) in light of the fact that several large companies support the proposed changes it is questionable whether the rule changes are truly neutral towards small companies and that a bias in favor of large companies and against small entities could be in violation of the Regulatory Flexibility Act; (2) the Office's certification did not adequately address the impact of the proposed rules on small entities, and the Office failed to provide a credible factual basis to justify its certification that the proposed rules would not have a significant economic impact on a substantial number of small entities in compliance with 5 U.S.C. 605(b); (3) the rule changes would have a significant economic impact on a substantial number of small entities seeking patents due to the additional costs associated with preparing an application, establishing the required showing under 37 CFR 1.78(d)(1)(vi) and 1.114(g), and supplying an examination support document in compliance with 37 CFR 1.265, and would hinder the abilities of small entities to enhance their applications and protect their inventions; (4) the definition of small entities used by the Office in its certification of the proposed rules is for the purpose of paying reduced patent fees and excludes any application from a small business that has assigned, granted, conveyed, or licensed any rights in the invention to an entity which would not qualify for small entity status; (5) the Office should prepare an initial Regulatory Flexibility Analysis and republish the proposed rules before issuing any final rule to enable the Office to closely examine the impact on the affected small entities, encourage small entities to comment on additional information provided by the analysis, identify viable regulatory alternatives to the proposed rules, and demonstrate the Office's compliance with the Regulatory Flexibility Act; (6) the Office did not describe any viable alternatives to the proposed rules to provide regulatory relief to small entities as required under 5 U.S.C. 603(c); (7) the rule changes would be invalid and vulnerable to challenges under 5 U.S.C. 611 if the Office fails to comply with the requirements of the Regulatory Flexibility Act; and (8) the Office should exempt small entities from complying with the proposed rules to avoid further scrutiny under the Regulatory Flexibility Act.

The Office has received comments from some large entities that the changes being adopted in this final rule have a bias against large entities, and has received comments from small entities that the changes being adopted in this final rule have a bias in favor of large entities. The changes being adopted in this final rule are neutral towards both small entities and large entities. That several large entities support the changes being adopted in this final rule are more likely indicative of a willingness to take a systemic view of the impact that continuing on the present course without taking more aggressive steps to address patent quality and pendency will have on the patent system.

As discussed previously, the Office commissioned a detailed analysis of the final rule's impacts on small entities. As a result of this analysis, the Office has determined that it is appropriate to make a certification that the changes being adopted in this final rule would not have a significant economic impact on a substantial number of small entities. Therefore, the Office is not required to conduct a Regulatory Flexibility Analysis.

Pursuant to 5 U.S.C. 605(b), the requirements in 5 U.S.C. 603 and 604 for an initial and final Regulatory Flexibility Analysis (including identification of viable regulatory alternatives to the proposed rules) do not apply if the agency head certifies that the changes will not have a significant economic impact on a substantial number of small entities. In accordance with 5 U.S.C. 605(b), the Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that the proposed changes would not have a significant economic impact on a substantial number of small entities.

The Office considers this rule making to be in compliance with the requirements of the Regulatory Flexibility Act. Thus, the possibility of legal action does not warrant a decision to delay proceeding with the changes being adopted in this final rule to allow for preparation of an initial and final Regulatory Flexibility Analysis, or to completely exempt small entities from complying with the changes being adopted in this final rule.

McDowell, Jennifer

From: Barnes, Carrol L. [Carrol.Barnes@sba.gov]

Sent: Friday, June 29, 2007 11:26 AM

To: McDowell, Jennifer
Cc: Johnson, Joseph
Subject: RE: Revised AB93 AB94

Jenny,

I have reviewed the new language and think it looks really good. Thank you for sharing this in advance and Advocacy has no further comments or changes. Also, from a historical standpoint in dealing with agency compliance, I would say this is one of the best responses to Section 3(c) of E.O. 13272 that I have seen.

Have a great weekend!

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----Original Message----
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From: McDowell, Jennifer [mailto:Jennifer.McDowell@USPTO.GOV]

Sent: Friday, June 29, 2007 9:39 AM

To: Barnes, Carrol L.

Subject: FW: Revised AB93 AB94

Carrol

Please find attached the latest version of the claims and continuations final rule.

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> ----Original Message----
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> From: Bahr, Robert

> Sent: Friday, June 29, 2007 8:40 AM
> To: McDowell, Jennifer; Hassan, Shirley

> Subject: Revised AB93 AB94

> > <<AB93&AB94 FR 06-28-2007.pdf>>