

**EXHIBIT 10**  
**Part 2 of 4**

## 2. Significant Issues Raised by Public Comments

In response to the proposed rulemakings, the USPTO received 342 comments on the continuing application requirements, and 198 comments on the claims requirements. This section summarizes only the comments addressing the USPTO's certification of the proposed rules under the Regulatory Flexibility Act.

A number of comments generally asserted that the USPTO did not comply with the requirements of the Regulatory Flexibility Act in certifying that the changes in the proposed rulemakings will not have a significant economic impact on a substantial number of small entities. The comments stated that:

- (1) the definition of small entities used by the USPTO in its certification of the proposed rules is designed 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;
- (2) the USPTO's certification did not adequately address the impact of the proposed rules on small entities, and the USPTO 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 proposed § 1.78(d)(1)(iv) and § 1.114(f), and supplying an examination support document in compliance with proposed § 1.261, and would hinder the abilities of small entities to enhance their applications and protect their inventions;
- (4) the USPTO should prepare an initial Regulatory Flexibility Analysis and republish the proposed rules before issuing any final rule to enable the USPTO 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 USPTO's compliance with the Regulatory Flexibility Act;
- (5) the USPTO 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);
- (6) the rule changes would be invalid and vulnerable to challenges under 5 U.S.C. 611 if the USPTO fails to comply with the requirements of the Regulatory Flexibility Act;
- (7) the USPTO should exempt small entities from complying with the proposed rules to avoid further scrutiny under the Regulatory Flexibility Act; and

(8) 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.

In response to the comments that were critical of the USPTO's decision to certify, the USPTO has established a business size standard for purposes of conducting analyses or making certifications under the Regulatory Flexibility Act for patent-related regulations (see *71 Federal Register 67109*, November 20, 2006). The USPTO also has revised its certification analysis to more precisely estimate the final rule's impact on small business entities. In this report, the USPTO describes its revised methodology and results of the certification analysis.

In addition, in response to public comments on the proposed rules, including those comments described above, the USPTO revised the continued examination filing requirements in the final rule. Under the proposed rule, the USPTO would have required applicants to file a petition with the second continuation, continuation-in-part, or RCE. The final rule allows two continuations and an RCE without a petition. This relaxation in rule language will reduce the number of affected small entities.

In addition, the USPTO changed the final rule requirements to exempt small businesses, as defined in 13 CFR 121.802, from one of the requirements in the ESD. Under the final rule, the USPTO will not require these small 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, the costs associated with the final rule will be reduced considerably for small entities.

### **3. Description and Estimate of the Number of Affected Small Entities**

To identify the small entities affected by the final rule, this analysis first considers, in Section 3.1, the industries affected by the rule. Section 3.2 then focuses on the definition of small entity that this analysis uses and also estimates the number of small entities affected by the final rule.

#### **3.1 Industries Affected by the Rule**

Patents are intended to spur research and innovation. Because research and innovation can occur in any industry, the universe of potential patent applicants includes all industries. Certain industries tend to account for relatively larger shares of patent filings over certain time periods, but the industries that comprise this group can shift over time. Moreover, the span of industrial fields that generate patent filings is quite broad, as suggested by the USPTO's organization of some of its patent filing review activities around the following seven broad "technology centers":

- Biotechnology and Organic fields
- Chemical and Materials Engineering fields
- Computer Architecture Software and Information Security
- Communications
- Semiconductors, Electrical and Optical Systems and Components
- Transportation, Electronic Commerce, Construction, Agriculture, Licensing and Review
- Mechanical Engineering, Manufacturing and Products

The USPTO does not collect or maintain statistical data on how many patents or patent filings fall within a given industry. This analysis assumes that patent applicants are spread across all industries and that all industries will be equally impacted by the rule.<sup>5</sup>

### **3.2 Small Entities**

#### **3.2.1 Definition of "Small Entity"**

The Small Business Administration (SBA) small business size standards applicable to most analyses conducted to comply with the Regulatory Flexibility Act are set forth in 13 CFR 121.201. These regulations generally define small businesses as those with fewer than a maximum number of employees or less than a specified level of annual receipts for the entity's industrial sector or North American Industry Classification System (NAICS) code.

The USPTO, however, recently adopted an alternate size standard as the size standard for the purpose of conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations (see 71 *Federal Register* 67109, November 20, 2006 for a detailed discussion of the USPTO's considerations in establishing this size standard).<sup>6</sup> Unlike the SBA small business size standards set forth in 13 CFR 121.201, this size standard is not industry-specific. Specifically, the USPTO's definition of small business concern for Regulatory Flexibility Act purposes is a business or other concern that: (1) meets the SBA'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,

<sup>5</sup> Although some industries may generate relatively more patent applications than others (as noted above), these industries are not more likely to face significant impacts because the applications are most likely to come either from large entities or from small entities that are able to attract investment capital. The analysis described in this report is not sensitive to this assumption.

<sup>6</sup> This small business size standard previously was established for purposes of identifying the criteria entities must meet to pay reduced patent fees; patent applicants that choose to self-identify themselves on the patent application qualify for reduced patent fees. The USPTO captures this data in the Patent Application Location and Monitoring (PALM) database system, which tracks information on each patent application submitted to USPTO. Some patent applicants contend that applicants do not always self-identify as small entities even though they would qualify for reduced fees by doing so. Assuming this is true, then data from PALM would understate the number of small entity applicants. The analysis specifically considers this possibility, as detailed in Section 3.2.2.

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.

### 3.2.2 Small Entities Affected by the Rule

This analysis estimates the number of small entities using two alternative sets of data taken from the USPTO's Patent Application Location and Monitoring (PALM)<sup>7</sup> database system, which tracks information on each patent application submitted to USPTO:

- (1) Small Entity Data Set. The first data set consists of data for just those FY 2006 filings for which the applicant self-identified as a small entity for purposes of paying reduced patent fees. Some patent applicants, however, contend that applicants do not always self-identify as small entities even though they would qualify for reduced fees by doing so. To the extent that this is true, then this first data set will understate the number of small entity applicants.
- (2) All Entity Data Set. As a sensitivity analysis, the second data set considers data for all FY 2006 filings. The rationale for this data set is drawn from a report issued by the Small Business Administration stating that approximately 99.9 percent of businesses qualify as small entities using a size threshold of 500 employees (i.e., the same threshold that appears in the USPTO alternative definition of small entity).<sup>8</sup> Therefore, the second data set considers data for all FY 2006 filings as an approximation of the 99.9 percent figure. This data set clearly is overly conservative (it implicitly assumes that large entities do not submit any patent filings) and is useful primarily as a bounding case.

Regardless of which data set is used, however, not all entities will be affected by the final rule or will incur impacts. Therefore, this study analyzes each data set to estimate the number of small entities affected by the final rule. Affected small entities fall into one of three categories: (1) filings affected by the claims requirements only; (2) filings affected by the continued examination filing requirements only; and (3) filings affected by both the claims and the continued examination filing requirements.

<sup>7</sup> The number of applications included in this analysis account for only those applications with claims data reported in PALM. The USPTO receives some applications without knowing the number of claims in the application. As a result, the number of applications the USPTO received in FY 2006 may be higher than what is reported in this report.

<sup>8</sup> Small Business Administration Office of Advocacy. *The Small Business Economy For Data Year 2005, A Report to the President*. U.S. Government Printing Office: Washington, DC. December 2006. See page 8.

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,<sup>9</sup> 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.

<sup>9</sup> 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 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 I. 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 STAGE	NUMBER OF INDEPENDENT CLAIMS/ TOTAL CLAIMS IN THE APPLICATION	
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.<sup>10</sup>

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

	Small Entity Data Set			All 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%

<sup>10</sup> 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.