

EXHIBIT 10
Part 1 of 4

**CERTIFICATION ANALYSIS UNDER
THE REGULATORY FLEXIBILITY ACT**

**Changes to Practice for Continued Examination Filings,
Patent Applications Containing Patentably Indistinct Claims, and
Examination of Claims in Patent Applications**

**Prepared for:
United States Patent and Trademark Office**

**Prepared by:
ICF International**



June 29, 2007

TABLE OF CONTENTS

Abbreviations and Acronyms ii

Executive Summary 1

1. Need for and Objectives of the Rule 3

 1.1 Background 3

 1.2 The Proposed Rule and Certification 5

 1.3 Summary of the Final Rule 6

2. Significant Issues Raised by Public Comments 8

3. Description and Estimate of the Number of Affected Small Entities 9

 3.1 Industries Affected by the Rule 9

 3.2 Small Entities 10

4. Projected Reporting, Recordkeeping, and Other Compliance Requirements 15

 4.1 Examination Support Document 16

 4.2 Petition for Continuing Applications or Continued Examinations 18

 4.3 Information Related to Patentably Indistinct Claims 19

5. Impacts Assessment 19

 5.1 Methodology 20

 5.2 Results 24

 5.3 Conclusion 28

6. Duplicative, Overlapping, and Conflicting Rules 28

7. Significant Alternatives Considered and Steps Taken to Minimize Impacts on Small Entities 29

 7.1 Alternatives Adopted by USPTO 29

 7.2 Alternatives Considered But Not Adopted 30

Appendix A: Input Cost Estimates 32

Appendix B: Estimating the Value of Patent Applications 33

Abbreviations and Acronyms

AIPLA	American Intellectual Property Law Association
CFR	Code of Federal Regulations
ESD	Examination Support Document
FY	Fiscal Year
FR	Federal Register
NAICS	North American Industry Classification System
PALM	Patent Application Location and Monitoring
PCT	Patent Cooperation Treaty
RCE	Request for Continued Examination
SBA	Small Business Administration
SRR	Suggested Restriction Requirement
USC	United States Code
USPTO	United States Patent and Trademark Office

Executive Summary

The United States Patent and Trademark Office (USPTO) is revising the rules of practice in patent cases relating to continuing applications and requests for continued examination (together referred to as “continued examination filings”), and for the examination of claims in patent applications.

The final rule is intended to ensure that continued examination filings are used efficiently to move applications forward. In addition, the final rule requires applicants with a large number of claims to share the burden of examining the application by submitting an examination support document covering all of the claims in the application (whether in independent or dependent form). The USPTO expects that the changes to the rules of practice in this final rule will lead to more focused and efficient examination, improve the quality of issued patents, result in patents that issue faster, and give the public earlier notice of just what patentees claim and address the growing practice of filing (by a common applicant or assignee) of multiple applications containing patentably indistinct claims.

In response to comments addressing the proposed rules that were critical of the USPTO’s decision to certify the new rules as not having a significant economic impact on a substantial number of small entities, the USPTO has revised its certification analysis to more precisely estimate the final rule’s impact on small entities. In this report, the USPTO describes its revised methodology and the results of the certification analysis.

To evaluate significant impact, the study considers the ratio of Annualized Incremental Cost as a Percent of Revenue. 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 on these entities indicates this will not be the case.
- 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.

For purposes of analyzing this rulemaking, the smallest business is modeled as a sole proprietor who currently is capable of paying for or financing all necessary patent application costs and maintenance fees (under current rules) associated with an application of a type 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 application and maintenance costs, is \$75,000.

The analysis assumes that a “substantial number” of small entities exists if the number of entities impacted at a given impact threshold (e.g., three percent) constitutes more than 20 percent of all small entities that apply for patents.

This analysis estimates that the final rule will result in incremental costs that range from \$872 to \$13,993 per application (present value).¹ 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 – about 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.

¹ Current patent filing and maintenance costs for applicants that would be affected by the final rule are estimated at between \$19,940 and \$49,155.

1. Need for and Objectives of the Rule

The United States Patent and Trademark Office (USPTO) is revising the rules of practice in patent cases relating to continuing applications and requests for continued examination (together referred to as “continued examination filings”), and for the examination of claims in patent applications. This section of the report provides background information and briefly discusses the need for and objectives of the rule. Following some initial background information in Section 1.1 regarding how the patent application process currently works, and in Section 1.2 regarding USPTO’s proposed rules and small entity certifications, Section 1.3 briefly describes the final rule revisions and the objectives they are designed to meet. These changes will allow the USPTO to conduct a better and more thorough and reliable examination of patent applications.

1.1 Background

To provide context for understanding the need for and objectives of the final rule, this section presents an overview of the current patent application review process. When an inventor wants to establish ownership of an invention by patenting it, s/he prepares and submits a patent application to the USPTO. One of the key elements of a patent application is the statement of “claims.” In the context of a patent or patent application, claims provide the legal description that bounds whatever the inventor is claiming as his or her invention. There are two types of claims: independent and dependent. An independent claim stands by itself as a description of the invention or an aspect of the invention. Dependent claims, in the simplest of terms, reference an independent claim and cannot stand on their own. In some cases, dependent claims may describe ancillary features, (e.g., “bells and whistles”) related to the more fundamental independent claims. In FY 2006, the number of independent claims in patent applications under review by the USPTO ranged from 1 to over 50, and the number of total claims ranged from 1 to over 350. According to USPTO staff, a typical patent application has 20 total claims, while an average patent application has approximately 21 total claims, including approximately 3 independent claims.

According to USPTO staff estimates, over 90 percent of patent applicants use a patent attorney to prepare and prosecute their patent applications. A typical patent application contains many elements, including specifications, claims, and drawings. Most applicants (55 percent) conduct a patent search and include a description of it in the application, although this is not a requirement and many applicants (45 percent) do not conduct a patent search.

The Application Process

Once an applicant submits his or her patent application, a USPTO patent examiner examines the application. Following the initial examination, the USPTO will take an “initial first action” on the application. If the patent examiner’s initial first action is a rejection, then the applicant may file a response to the USPTO’s initial first action. In

general, the applicant's response will modify the application in some respect, including by deleting claims (usually) or adding claims (occasionally). Following this response, the patent examiner will issue his or her final action on the patent application.

If the USPTO does not grant the patent in the final action, the patent applicant may pursue further prosecution of the rejected application. The process that the applicant pursues varies by case, and there is not a "typical" prosecution path through the patent approval system. However, for the purposes of this final rule, this analysis describes one of the application prosecution paths that would trigger the final rule's continued examination filing requirements, which are described in Section 1.3.

Following the USPTO's final action, an applicant may decide to file a continuation application. A continuation is considered a separate application relative to the initial application. However, everything that the inventor claims in the original application is once again claimed in the continuation application, and it should not include any new matter. (If the applicant wishes to add new subject matter, the applicant would instead file a continuation-in-part.) Similar to the initial application, the USPTO takes a first action on the continuation and the applicant will be able to respond to that first action if necessary by deleting or adding claims or making other modifications. Following the applicant's response, the USPTO issues its final action on the first continuation.

If the final action on the continuation is a rejection, the applicant may continue prosecution of his or her application by filing a second continuation application. As described for the first continuation, the USPTO issues a first action, and the patent applicant may submit a response to the first action on the second continuation. Following the applicant's response, the USPTO issues its final action on the second continuation.

The patent applicant may then decide to file a "request for continued examination" (or "RCE"). An RCE is not a separate application; instead it is a request for continued examination of an application (initial, continuation, or continuation-in-part), without requiring the applicant to file a continuing application. Although an RCE is not considered an application, the USPTO responds with a first action, and the applicant may respond to the first action. After this response, the USPTO issues its final action on the RCE.

If the final action on the RCE is a rejection, the applicant may continue prosecution of his or her application by filing a third continuation application, and so on. The baseline (i.e., current) application cost estimated in this study assumes that the USPTO grants the patent after the third continuation and after the applicant pays the USPTO's issue fee.²

Over the 20-year lifespan of the patent, the USPTO requires patent holders to pay three patent maintenance fees. These fees are due 3 ½, 7 ½, and 11 ½ years from the date of the original patent grant.

² Applicants that are issued patents earlier in the process would incur lower costs but would not be affected by the final rule's requirements for continued examination filings.

Patentably Indistinct Claims

USPTO's current rules of practice provide that "Where two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application." (See current Sec. 1.78(b).) Despite this existing rule, the USPTO still receives multiple applications with overlapping disclosures, a common inventor, and the same filing date.

Patent law prevents an inventor from obtaining two patents that cover the same invention or an obvious variation of the same invention. In cases where the patents cover identical inventions, the second patent is considered invalid. If there are obvious variations between the patents, the applicant may file a terminal disclaimer that states that the second patent to issue will expire on the same date as the first patent. This terminal disclaimer eliminates the possibility of an inventor gaining an improper extension of the patent period resulting from the second patent. To prevent double patenting, the patent examiners must closely inspect these applications and require applicants to either file a terminal disclaimer or combine applications that should have been filed as one application.

Need for the Rule

Although the filings affected by this rulemaking (including continued examination filings, applications with large numbers of claims, and applications with indistinct claims) are relatively few in number, they occupy a disproportionate portion of USPTO resources. Therefore, the USPTO spends a disproportional amount of its review time on relatively few applications, which takes away from the review time that the USPTO could otherwise commit to new initial applications. This situation is a significant cause of the backlog of unexamined applications before the USPTO and has created the need for the rule.

1.2 The Proposed Rule and Certification

The USPTO published two proposed rules in January 2006 (Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 *Federal Register* 48, January 3, 2006); and Changes to Practice for the Examination of Claims in Patent Applications, 71 *Federal Register* 61, January 3, 2006). Under the first proposed rule, which addressed continuing applications, RCEs, and patentably indistinct claims, the USPTO proposed to change the rules of practice to require that: (1) any second or subsequent continued examination filing (continuation or continuation-in-part application or request for continued examination) include a showing as to why the amendment, argument, or evidence could not have been submitted prior to the close of prosecution after a single continuation or continuation-in-part application or request for continued examination; and (2) 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 of

how the claims are patentably distinct, or a terminal disclaimer and explanation of why patentably indistinct claims have been filed in multiple applications.

Under the second proposed rule, which addressed the examination of claims, the USPTO proposed to revise application review practices as follows: (1) the USPTO would conduct an initial examination only of "representative claims," which would have included all of the independent claims and only the dependent claims that the applicant expressly designated for initial examination; and (2) if the number of representative claims is greater than ten, the USPTO would require the applicant to share the burden of examining the application by submitting an examination support document (ESD) to provide certain information regarding all of the representative claims.

In each of the two published notices, the USPTO certified that an initial Regulatory Flexibility Act analysis was not required because the proposed changes would not have a significant economic impact on a substantial number of small entities. In response to this certification, the USPTO received a number of comments, which are discussed in Section 2.

1.3 Summary of the Final Rule

The final rule combines the two proposed rules described above. As a convenience, this analysis distinguishes between the final rule requirements that originated in the first proposed rulemaking (the "continued examination filing requirements") and the final rule requirements that originated in the second proposed rulemaking (the "claims requirements") because many applicants are not affected by both sets of requirements.

Continued Examination Filing Requirements

The USPTO is changing the continued examination practice because each continued examination filing, whether a continuing application or request for continued examination, requires the USPTO to delay taking up a new application and thus contributes to the backlog of unexamined applications before the USPTO. Further, the current practice allows an applicant to generate an unlimited string of continued examination filings from an initial application. In such a string of continued examination filings, the exchange between examiners and applicants becomes less beneficial and suffers from diminishing returns with each continued examination filing.³

Therefore, in the final rule, the USPTO revised the continued examination filing rules so that an applicant may file at most two continuing applications (or two continuation-in-part applications, or one continuation application and one continuation-in-part application) plus a request for continued examination in any one of the initial application or two continuation or continuation-in-part applications, without any showing (referred to as a "petition" in this analysis) as to why the amendment, argument, or evidence could

³ See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 *Federal Register* 48, January 3, 2006.

not have been submitted prior to the close of prosecution after a single continuation or continuation-in-part application or request for continued examination. Any additional continuation application, continuation-in-part application, or request for continued examination, however, would have to be supported by a petition in order to be considered by the USPTO.

The final rule also eases the burden of examining multiple applications that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and common assignee by requiring that all patentably indistinct claims in such applications be submitted in a single application (absent good and sufficient reason).⁴

The current, unrestricted continued examination practice and the filing of multiple applications containing patentably indistinct claims are impairing the USPTO's ability to examine new applications, even without real certainty that these unrestricted practices effectively advance prosecution, improve patent quality, or serve the typical applicant or the public. The final rule is intended to ensure that continued examination filings are used efficiently to move applications forward. The USPTO expects that the changes to the rules of practice in this final rule will: (1) lead to more focused and efficient examination, improve the quality of issued patents, result in patents that issue faster, and give the public earlier notice of just what patentees claim; and (2) address the growing practice of filing (by a common applicant or assignee) of multiple applications containing patentably indistinct claims.

Claims Requirements

In response to the proposed claims rule, the USPTO received a substantial number of comments from the public opposing the "representative claims" examination approach and suggesting that the USPTO simply adopt a strategy based upon whether an application contains more than a given number of independent and total claims. In response to these public comments, the USPTO modified the final rule to make the presentation of more than five independent claims or more than twenty-five total claims (rather than the presentation of more than ten representative claims) the threshold for invoking the examination support document requirement.

The final rule provides that if the number of independent claims is greater than five, or the number of total claims is greater than twenty-five, the applicant must share the burden of examining the application by submitting an examination support document covering all of the claims in the application (whether in independent or dependent form).

The final rule 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 rule. Small entities will not need to identify, for each reference cited, all the limitations of each of the claims (whether independent or dependent) that are disclosed by the references. Large entities, however, will need to include this information in their ESDs.

⁴ The analysis estimates that there will be no incremental costs resulting from this requirement, as discussed in Section 4.