THE NEW PATENT RULES PUBLISHED AUGUST 21, 2007

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I. INTRODUCTION

Acronyms referred to below.

ESD - Examination Support Document

FAOM - First office Action On the Merits

SRR - Suggested Requirement for Restriction

RCE - Request for Continued Examination

In this paper, the terms "application" and "non- provisional application" refer to either a U.S. non provisional application or a U.S. national stage entry of a PCT application.

On August 21, 2007, the Federal Register published final rules entitled "Changes to Practice to Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications" at 72 FR 46716 et seq. These are rules, which were promulgated by the USPTO, limit patent applicant's rights to obtain substantive protection. This paper reviews the important aspects of those rules and limitations.

II. SUMMARY AND PERSPECTIVE

Under the pre-existing rules, a patent applicant could file an unlimited number of applications claiming priority to an original application, and each continuing application could contain an unlimited number of independent and dependent claims. Under the new rules, an applicant can file no more than two continuations (excluding divisions) of an original application, and no more than two continuations of each original divisional application in which those two continuations of the original divisional application claim the same originally non-elected invention claimed in the original divisional application (the no more than 3 applications rule). Moreover, the applicant is limited to at most one RCE amongst those three applications. In addition, each application is limited to no more than 5 independent claims and a total of 25 claims (5/25 claims limitation rule). In addition, only one pending and non allowed application can be pending at any time having claims to a patentably indistinct invention.

The 5/25 claims limitation in each application or the no more than 3 applications rule may be violated at great expense and risk to the applicant. Violating these rules generally invokes additional requirement and great burdens, such as filing of an ESD or petition and justification for additional application filings.

Moreover, the new rules impose the additional burden on applicants to timely file papers in each subject application identifying all other applications that meet criteria indicating that those other applications may claim inventions that are patentably indistinct from the claims in the subject application.

Failure to follow any of the foregoing rules, or failure to correct such a failure in a relatively short time and non extendable time period, leads to the draconian result of loss of rights.

The details of these rules and when they become effective are discussed below.

III. EFFECTIVE DATES OF THE VARIOUS RULES AND REQUIREMENTS

A. Changes Applicable to Applications that have not had a FAOM as of 11/1/2007 Changes to 37 CFR 1.75, 1.142(c), and 1.265 are effective for all applications that have not had a FAOM as of 11/1/2007. 72 FR 46716.

A FAOM is not expressly defined in the rules. However, by implication from 37 CFR 1.142(a), and by implication of the practice relating to 37 CFR 1.197, it means an office action in which claims are examined for patentability, and it does not mean an office action containing only a requirement, such as a requirement to restrict or elect between inventions and species.

37 CFR 1.75 specifies the 5/25 limits on claims. 1.142(c) authorizes filing of an SRR. 1.265 specifies the requirements for an ESD and the duties of supplementing an ESD in cases where an ESD is required. Thus, the requirements for the 5/25 limits on claims and the need for an ESD in cases that violate the 5/25 rule kicks in for applications that have not have a FAOM by 11/1/2007. That is, for most applications filed in the last couple of years. For these applications (and families of applications claiming patentably indistinguishable claims), applicants may consider pro-actively canceling claims exceeding the 5/25limits, consolidating claims to patentably indistinguishable inventions from multiple applications into one application and filing an ESD in that application, or consolidating claims to arguably patentably distinct inventions and filing a SRR or an SRR and an ESD.

For applications which have had a FAOM prior to 11/1/2007, the 5/25 limits are inapplicable. Therefore, applicants may consider taking no action in such applications in response to these new rules.

IV. CHANGES APPLICABLE TO APPLICATIONS FILED ON OR AFTER 11/1/2007

Changes to 37 CFR 1.78(a), 1.78(d)(1), 1.114, 1.495, and 1.704(c)(ii) are applicable to applications filed on or after 11/1/2007 with one exception, the "one more" exception. The "one more" exception is that an application is not required to comply with 37 CFR 1.78(d)(1) if it is the first application filed after 8/21/2007 that claims priority to a non-provisional application filed prior to 8/21/2007. 72 FR 46717 left column, first full paragraph. 1.78(d)(1) implements the no more than 3 applications rule. Thus, the "one more" exception allows an applicant that already (by August 21, 2007) has filed 3 or more applications linked by priority claims, other than divisional applications, to file one additional such application.

1.78(a) provides the new definitions for continuing applications. 1.78(d)(1) implements the no more than 3 applications rule. 1.114 implements the limitation to no more than one RCE in any 3 applications family. 1.495 contains the presumption that an application is a PCT national stage application if the filing type is ambiguous. 1.704(c)(ii) implements the reduction in patent term adjustment for failure to comply with the either 5/25 claims limitations or ESD requirements when the 5/25 claims limit is exceeded.

Thus, prosecution for an invention disclosed in an applications filed on or after 11/1/2007 is limited to three non divisional applications and one RCE. The exception is that a single additional non divisional application may be filed, regardless of the number of non divisional applications in that family, if all other non divisional applications in the family have filing dates prior to 8/21/2007.

V. CHANGES APPLICABLE TO RCEs FILED ON OR AFTER 11/1/2007

37 CFR 1.114 limit's to one, the number of Requests for Continued Prosecution (RCEs) that can be filed on or after 11/1/2007 in any family of non divisional applications, unless a

petition justifying each additional RCE is filed and granted.

VI. MISCELLANEOUS RULES CHANGES APPLICABLE TO NON PROVISIONAL APPLICATIONS PENDING ON OR AFTER 11/1/2007

Changes to 37 CFR 1.17 (fees); 1.26 (refunds); 1.52 (provisional filed in a foreign language); 1.53 (application completion); 1.76 (application data sheet); 1.78 (benefit), except for 1.78(a) and 1.78(d)(1); 1.104 (examination); 1.105 (requirement for information); 1.110 (inventorship); 1.136 (extensions of time); 1.142(a) (restriction); and 1.145 (constructive election) are applicable to all non provisional applications pending on and after 11/1/2007.

VII. TIME LIMITS FOR COMPLYING WITH 37 CFR 1.78(F)(1) AND (2) FOR EACH PENDING APPLICATION FILED BEFORE 11/1/2007

37 CFR 1.78(f)(1) and (2) must be complied with in each pending non provisional application filed prior to 11/1/2007 by the later of 2/1/2008 and the time limits specified in 37 CFR 1.78(f)(1)(ii) and (f)(2)(iii), unless the application is allowed prior to the time limit. 37 CFR 1.78(f)(1) specifies the requirements to file a paper identifying closely related applications. 37 CFR 1.78(f)(1) specifies the consequences and requirements when two closely related applications meet criteria raising a presumption that they claim patentably indistinct subject matter; rebut the presumption or file a terminal disclaimer and explanation.

Thus, 1.78(f)(1) requires applicants to file a paper in each application that is pending and not allowed by about 2/1/2008 listing the criteria specified therein. In addition, applicants should pro actively rectify applications which meet the 1.78(f)(1) criteria and claim patentably indistinct subject matter from one another by considering placing claims to patentable distinct inventions in a single application, and consider either limiting to 5/25 the claims in such an application or filing an ESD in that application.

VIII. RULE BY RULE REVIEW OF THE NEW RULES A. THE 5/25 CLAIMS LIMITATIONS RULE

37 CFR 1.75 is amended to define the limitations on the number of claims in an application, and to define how the number of claims in an application is determined.

37 CFR 1.75 is amended so that 1.75(b) defines dependent claims to be claims that "incorporate by reference all limitations of the ... claim to which such dependent claim refers" and that "specify a further limitation." 1.75(b)(2) expressly states that a claim that "refers to another claim but does not incorporate by reference all of the limitations of the claim to which such claim refers will be treated as an independent claim" for purposes of fee calculations and compliance with the 5/25 rule. 1.75(b)(2) specifies that a claim that refers to another claim in a different statutory class of invention will be treated as an independent claim for purposes of fee calculations and compliance with the 5/25 claim limits. (35 USC 101 specifies that the statutory classes of invention are "process, machine, manufacture, or composition of matter.")

Note - The comments to the new rules specify at 72 FR 46724 that the requirement that a dependent claim "incorporate by reference" limitations of the claim from which it depends is based upon the decision in <u>Pfizer, Inc. v. Ranbaxy Laboratories Limited</u>, F.3d 1284; 2006 U.S. App. LEXIS 19416; 79 USPQ2d 1583 (Fed. Cir. August 2, 2006), that a claim such as "A salt of the acid of claim 1" are invalid because a salt is not a further limitation to an acid.¹ Thus, this is apparently not a new requirement as to form; dependent claims most likely need not be amended

to expressly recite that they "incorporate by reference" the limitations of the claim from which they depend. However, an express incorporation by reference recitation would not be bad practice.

37 CFR 1.75 is amended so that 37 CFR 1.75(b)(1) requires the filing of an ESD before a FAOM if the application exceeds the 5/25 claim limits at the time of FAOM, and prohibits adding more than 5/25 claims in an application in which an ESD was not filed prior to the mailing of a FAOM.

37 CFR 1.75 is amended so that 37 CFR 1.75(b)(4) and (5) indicate that all claims pending in all other applications having at least one claim that is patentably indistinct with any claim in the subject application, except for withdrawn claims, will be counted in determining compliance in the subject application with the 5/25 claim limits, if those applications are owned by or subject to assignment to the same legal entity. However, 72 FR 46726, left column, and USPTO power point slide presentation of August 24, 2007, slide 69 state that the Office will consider an application no longer pending for purposes of 37 CFR 1.75(b)(4) if the application is allowed abandoned, or on appeal to the courts.

37 CFR 1.75 is amended so that 37 CFR 1.75(c) specifies that each multiply dependent claim and claim depending from a multiply dependent claim is counted as the number of claims from which the multiply dependent claim refers for purposes of the 5/25 claim limits and claim fees.

37 CFR 1.75 is amended so that 37 CFR 1.75(b)(3) specifies the consequence of inadvertent non-compliance with 1.75(b)(1) and (4)(5/25 limits in each application and for applications having patentably indistinct claims) by mailing a notice setting a 2 month non extendable time limit to comply with the requirements.

37 CFR 1.142 is amended so that 37 CFR 1.142(c) provides that an applicant has the right to file a Suggested Requirement for Restriction (SRR) and an election without traverse to an invention associated with claims not exceeding the 5/25 claim limits, prior to a FAOM, a requirement to restrict, or a requirement to comply with unity of invention under PCT rule 13.

B. THE NO MORE THAN 3 APPLICATIONS RULE

New 37 CFR 1.78(d) specifies the no more than three applications rule. However, all of the changes to rule 1.78 appear below since several of those changes are relevant to 1.78(d).

37 CFR 1.78 is amended so that 1.78(a)(1) expressly defines a "continuing application" to be an application that claims the benefit of a prior filed application under 35 USC 120, 121, or 365(c)(which means benefit of a prior filed U.S. or PCT application). Since the rule references 35 USC 121, "continuing application" includes division applications. 1.78(a)(1) also specifies that a claim in an application under 35 USC 119(a)(to a foreign application), 119(e)(to a provisional application), or 365(a) or (b) (to *foreign priority* of a PCT application) does not make that application a continuing application.

37 CFR 1.78 is amended so that 1.78(a)(2) expressly defines a "divisional application" as an application that discloses and claims only an invention disclosed and claimed in a prior application that was "disclosed and claimed in the prior-filed application, but were subject to a requirement to comply with the 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, and were not elected for examination and were not examined in any prior filed application."

37 CFR 1.78 is amended so that 1.178(a)(3) defines a "continuation application" to mean

a continuing application that discloses and claims only inventions that were disclosed in the prior-filed application. Note: The definition of a "continuation application" appears to include applications that are also divisional applications.

37 CFR 1.78 is amended so that 37 CFR 1.78(a)(4) expressly defines a "continuation-inpart application" to mean a continuing application that discloses subject matter that was not disclosed in the prior-filed application.

37 CFR 1.78 is amended so that 37 CFR 1.78(b) provides the requirements for obtaining benefit in a non-provisional application to a prior filed provisional application. These provisions are generally the same as those in old rule 37 CFR 1.78(a)(4). However, 1.78(b)(1) expressly adds the requirement that the prior filed provisional application must have been filed within 12 months of the date of filing of the non-provisional application, subject to the exceptions specified in 35 USC 21 and 37 CFR 1.7(a). These exceptions are that, when the 12 month date falls on a Saturday, Sunday, or Federal Holiday in the District of Columbia, the 12 month period is de jure extended to the next secular or business day.

37 CFR 1.78 is amended so that 37 CFR 1.78(c) provides the requirements for obtaining benefit in a non-provisional application to a prior filed provisional application in which the claim for that benefit was unintentionally delayed. 1.78(c) provides the same requirements for obtaining benefit in a non-provisional application to a prior filed provisional application in which the claim for that benefit was unintentionally delayed as in old rule 1.78(a)(6).

37 CFR 1.78 is amended so that 37 CFR 1.78(d) provides limitations on to the right to claim benefit to a prior filed applications. 1.78(d)(1) specifies that the right to benefit is limited to non provisional applications that satisfy one of the sets of criteria specified in 1.78(d)(1)(i) - (vi). Generally, these requirements limit an applicant to prosecuting three applications for claims that are not subject to a requirement for election or restriction.

37 CFR 1.78(d)(1)(i) limit's the number of continuation and continuation-in-part benefit claims in non provisional applications.

Specifically, 1.78(d)(1)(i)(A) limit's the number of continuation and continuation-in-part benefit claims in an application, to two. 1.78(d)(1)(i)(B) limits the number of applications that can claim continuation and continuation-in-part benefit from a non provisional application, to two, excluding from that limitation any: divisional applications ((d)(1)(ii)); continuations of divisional applications limited to the inventions claimed in the earlier divisional application ((d)(1)(iii)); and PCT applications in which no demand is filed and no basic US national stage fee (1.492(a) fee) is paid ((d)(1)(iv)). Thus, 1.78(d)(1)(i) limits an applicant to prosecuting no more than three applications in a family of applications related by priority claims, other than division applications.

37 CFR 1.78(d)(1)(ii) pertains to limits on rights to benefit claims in applications to inventions withdrawn and not examined in a prior application, that is, limits on the rights to benefit claims in divisional applications. 37 CFR 1.78(d)(1)(ii)(A) limit's the number of divisional applications to an original divisional application, and the limited additional divisional applications authorized by 1.78(d)(1)(iii) and (iv).

37 CFR 1.78(d)(1)(iii) provides for two additional divisional applications for the same invention. Specifically, 37 CFR 1.78(d)(1)(iii)(A)- (C) limit's the additional divisional applications to a first continuation of the original divisional application and a second continuation of the first continuation, so long as the first and second continuations have claims directed only the invention or inventions disclosed and claimed in the divisional application.

Moreover, 1.78(d)(1)(iii)(D) limit's the number of non provisional applications that claim benefit to the original divisional, to two, excluding from that limitation any: (1) further divisional applications to inventions not elected, withdrawn, and not examined in any prior filed application in the benefit chain and (2) any claim in the non provisional application(s) to benefit under 35 USC 120 or 365(c) to a PCT application in which no Demand is filed and no basic US national fee (1.492(a) fee) is paid.

35 CFR 1.78(d)(1)(iv) limit's the number of applications an applicant can prosecute that claim priority to a PCT application in which no Demand is filed and no basic US national fee (1.492(a) fee) is paid and in which there is no claim to a prior non provisional or PCT application designating the U.S. In these circumstances, 35 CFR 1.78(d)(1)(iv) limit's the applicant to prosecuting no more than three applications claiming priority to the PCT application, excluding divisions

35 CFR 1.78(d)(1)(v) limit's the number of applications an applicant can prosecute, excluding divisions, that can claim priority to an incomplete U.S. national application, to three.

37 CFR 1.78(d)(1)(vi) allows the applicant to file an application that does not satisfy any of (d)(1)(i) to (v) for a continuing application filed for the purpose of obtaining consideration of an amendment, argument, or evidence that could not have been submitted in during the prosecution of the prior filed application. In order to obtain this consideration, a petition must be timely filed in such an application showing that the amendment, argument, or evidence that could not have been submitted in during the prosecution of the prior filed application. The petition must be filed within 4 months of the national stage entry or application filing date.

37 CFR 1.78(d)(2) requires continuity of inventorship.

37 CFR 1.78(d)(3) - (5) specify substantially the same requirements to the format and timing of making a benefit claim to prior filed U.S. and PCT applications as in old rule 1.78(a).

37 CFR 1.78(d)(6) now requires that cross references to applications for which benefit is not claimed must be in a paragraph separate from the paragraph which contains the benefit claims under 35 USC 119(e), 120,12, and 365(c) required by 119(e) and 120. Thus, references to foreign priority claims for example may not be in the same paragraph as references to domestic priority claims.

37 CFR 1.78 is amended so that 37 CFR 1.78(e) contains the provisions for obtaining benefit to a prior filed non provisional application when the benefit claim is unintentionally delayed. 1.78(e) provides the same requirements for obtaining benefit in a non-provisional application to a prior filed non provisional application in which the claim for that benefit was unintentionally delayed as in old rule 1.78(a)(3).

37 CFR 1.78 is amended so that 37 CFR 1.78(f) requires the applicant of each subject non provisional application that has not been allowed to identify in a paper in the subject non provisional application all other closely related applications, as defined by certain criteria. Specifically, 37 CFR 1.78(f)(1) requires the applicant to file a paper in the subject non provisional application that identifies by application number and patent number, each pending non provisional application and each patent that:

- (1) has any priority date (including non provisional, provisional, foreign, and PCT claimed priority dates) within 2 months of any priority date (including non provisional, provisional, foreign, and PCT claimed priority dates) claimed by the subject application;
 - (2) names at least one inventor in comment with the subject application; and
 - (3) is owned by or subject to an obligation to assign to the same entity as the subject

application.

- 37 CFR 1.78(f)(1) further requires that the foregoing paper be filed within the later of:
- (1) 4 months from the actual filing date of the subject application,
- (2) 4 month from the date of commencement of national stage proceedings in the subject application;
- (3) 4 months from the date of an express request for national stage processing in the subject application; or
- (4) 2 months from the mailing date of an initial filing receipt in any other application that is closely related to the subject application.
- 37 CFR 1.78(f)(2)(i) specifies that a rebuttable presumption exists that the subject application and another application contain patentably indistinct claims if the two applications have:
 - (1) a common priority date;
- (2) a common inventor, are owned by or subject to an obligation to assign to the same entity; and
- (3) the other application has 112 first paragraph support for any claim in the subject application.
- 37 CFR 1.78(f)(2)(ii) specifies that, if such a rebuttable presumption exists and the subject application is not allowed, the applicant must promptly either rebut the presumption or submit a terminal disclaimer in the subject application and explain why there is another application pending containing patentably indistinct claims.
- 37 CFR 1.78(f)(iii) specifies that the rebuttal or terminal disclaimer and explanation must be filed by the later of:
 - (1) 4 months from the date of filing of the subject application;
- (2) 4 months from date of national stage proceedings or express request for national stage proceedings in the subject application;
- (3) the date on which a claim that is not patentably distinct is presented in one of the other applications; or
 - (4) 2 months from the mail date of an initial filing receipt in the other application.
- 37 CFR 1.78(f)(3) notes that the Office may require cancellation of claims to patentably indistinct claims from more than one application. This provision is substantively identical to the provisions in old rule 1.78(b).

What happens if the applicant fails to timely comply with the 1.78(f)(2) requirements? The rule does not specify the result. The rule seems to leave open the possibility that, if the applicant fails to comply, the applicant could contest a resulting requirement or a holding of abandonment. For example, in response to an applicant's failure to comply with 1.78(f)(1) and (2), the USPTO could hold the application as abandoned for failure to comply with the rule, could require cancellation of all claims pursuant to 1.78(f)(3), and could require filing of a terminal disclaimer and explanation pursuant to 1.78(f)(2). It could take any of those actions. In response, the applicant could contest any such requirement on the basis that the failure to comply was excusable and belatedly comply. One way to comply would be to file a rebuttal of the presumption. I do not advocate failing to comply with 1.78. I merely point out the possible consequences.

37 CFR 1.78(g) contains substantial the same content as old rule 1.78(c), which regards the doctrine of election by a common assignee.²

37 CFR 1.78(h) specifies that parties to a joint research agreement are deemed to be the same party for purposes "this section," if the prior art exclusion specified in 35 USC 103(c)(2)(C) due to the joint research agreement is claimed. Rule 1.78 is part of the section of the rules entitled "SPECIFICATION" that begins with rule 1.71 and ends with rule 1.79. Thus, 37 CFR 1.78(h) indicates that an application invoking the joint research exclusions to prior art also invokes the requirements and limitations of new rule 1.78 for applications owned by any party to the joint research agreement.³

C. THE ESD

- 37 CFR 1.265 specifies the requirements for an ESD.
- 37 CFR 1.265(a) specifies that the ESD must:
- (1) include a statement that a search was conducted complying with the requirements of 1.265(b);
 - (2) list the references most closely related to the subject matter of each claim;
- (3) provide a detailed explanation pointing out how each of the independent claims is patentable over the cited references;
- (4) provide a showing where each limitation of each claim finds support in the specification; and
- (5) provide a showing where each limitation of each claim finds support in each priority and benefit application.
- 37 CFR 1.265(b) specifies the requirements for the search for an ESD. 1.265(b) requires the search must involve U.S. patents and patent application publications, foreign patent documents, non-patent literature. The search must be 'directed to the claimed invention' and "encompass all limitations of each of the claims... giving the claims their broadest reasonable interpretation."
- 37 CFR 1.265(c) and (c)(1) specify that the listing of references in the ESD must include a list identifying U.S. patents and patent publications in a separate section, and that the listing must include on each page:
 - (1) the application number of the application to which the ESD is directed;
 - (2) a heading indicating that the list is part of an ESD; and
 - (3) a column having a space for examiner's initials next to each reference citation.
- 37 CFR 1.265(c)(2) specifies that each reference must be cited by providing the following information. For U.S. patents, first named patentee, patent number, and issue date. For U.S. published applications, applicant, patent application publication number, and publication date. For U.S. applications, applicant, application number, and filing date. For foreign patent publications, country or patent office, document number, and publication date. For publications, publisher, author, title, relevant pages, date, place of publication.
- 37 CFR 1.265(c)(3) specifies that the listing of references must be accompanied by a copy of each reference other than U.S. patents and U.S. patent application publications.
- 37 CFR 1.265(c)(3) specifies that any English language translation within the possession, custody, or control of, or readily available to any individual identified in 37 CFR 1.56(c) (which specifies the inventors and every person involved in preparing and prosecuting the application), of any non English language reference must also be submitted.
- 37 CFR 1.265(d) specifies that any IDS filed in an application in which an ESD was required and has been filed must include a supplemental ESD addressing the references in the

manner required in (a)(3) and (a)(4) (identifying all limitations in each claim disclosed in each reference and a detailed explanation why each independent claim is patentable over each reference). However, 1.265(d) contains the exclusion from these requirements if "the information disclosure statement cites only references that are less closely related to the subject matter of one or more claims ... than the references cited in the examination support document listing of references...." The meaning and effect of passage in the foregoing quotation is not clear.

- 37 CFR 1.265(e) specifies the penalties for an ESD deemed to be insufficient respecting the pending claims. Specifically, if the ESD is "deemed to be insufficient", or if the claims are amended such that the "ESD no longer covers" the amended claims, the USPTO will mail a notice providing a non extendable 2 month time limit to correct. The applicant may respond to the notice by either filing a corrected ESD or by amending the claims so that they do not exceed the 5/25 limits. Failure to comply results in abandonment of the application.
- 37 CFR 1.265(f) provides an exclusion to the (a)(3) requirements (to identify all limitations of each claim that are disclosed in each reference) for the following entities:
- (1) any business that has no more than 500 employees and which has not assigned, licensed, and is under no obligation to assign or license to any entity that is not a non profit organization or is does not have more than 500 employees;
- (2) a "not-for-profit enterprise which is independently owned an operated and not dominant in its field"; and
- (3) a "government or a city, county, town, township, village, school district, or special district with a population less than 50,000."

Note that 37 CFR 1.265(f)(1)(ii) contains an apparent error because there is no "non-profit organization" referred to in 37 CFR 1.265(f)(1)(i). It appears that the definition of the "non-profit organization" recited in 37 CFR 1.265(f)(1)(ii) should be by reference therein to in 37 CFR 1.265(f)(2).

IX. MISCELLANEOUS RULES CHANGES

- 37 CFR 1.17 specifies patent applications and reexamination processing fees. 1.17 is amended to provide a \$400 fee for a petition to file an additional continuation application or RCE above the limits, per 1.78(d(1)(iv) for additional continuations and 1.114(g) for additional RCEs.
- 37 CFR 1.26 provides for an exception for refunds requested pursuant to 37 CFR 1.117. 37 CFR 1.117 provides for refund of fees paid for (independent, dependent, and multiply dependent) canceled claims, if an amendment canceling those claims is filed before a FAOM and a request for refund for the fees paid for initially presenting the canceled claims is filed within 2 months of the date on which the claims were canceled.
- 37 CFR 1.52 is amended so that 37 CFR 1.52(d)(2) requires that an English language translation of a non-English language provisional application be filed in the provisional application if a non provisional application claims the benefit of the provisional application.
- 37 CFR 1.53 is only formally amended so that 37 CFR 1.53(b) refers to the new regulatory definitions in 37 CFR 1.78(a)(4) for continuation, division, and continuation-in-part.
- 37 CFR 1.76 is amended so that 37 CFR 1.76(b)(5) no longer requires status information for applications specified in an Application Data Sheet (ADS).

- 37 CFR 1.104 is amended only formally, to clarify the scope of the examiner's examination of a patent application.
- 37 CFR 1.105 is amended by adding section 1.105(a)(1)(ix) that expressly authorizes the examiner to require the applicant to specify where, by page and line or paragraph number, 35 USC 112 first paragraph support exists for the invention defined in the claims, (1) in the application, and (2) in any application to which the application being examined claims priority.
- 37 CFR 1.110 is amended to limit the right of the USPTO to require the applicant to specify either of inventive entity of the subject matter defined by each claim or ownership and date of invention information to situations where that information is "necessary for purposes of an Office proceeding."
- 37 CFR 1.136 is amended by revising 1.136(a) (1). 1.136(a)(1) is the rule providing for automatic extensions of time for shortened or non statutory periods for responding to a paper in an application transmitted from the USPTO to the applicant. 1.136(a)(1) is amended to specify that the time periods for complying with a notice requiring compliance with either 1.75(b) (limitations on the number of claims) or 1.265 (requirements for an ESD and its underlying pre-examination search) is not extendable. This section impliedly refers to 1.75(b)(3) and 1.265(e).
- 1.75(b)(3) specifies that the USPTO will issue a notice requiring compliance, within 2 months of the notice, of a violation of the 5/25 limitations on claims and a 2 month period for reply to the notice in situations where the violation "appears to have been inadvertent".
- 1.265(e) specifies that the USPTO will issue a notice requiring compliance with the ESD requirements within a 2 months, if the notice specifies that the ESD or its supporting pre-examination search is insufficient, or if an amendment of the claims is such that the prior ESD no longer covers each claim.
- 37 CFR 1.142(a) is amended by authorizing the examiner to not require restriction when two or more independent and distinct inventions are claimed in a single application. Specifically, this section is revised from "the examiner ... will require the applicant ... to elect" to "the examiner ... may require the applicant ... to elect."
 - 37 CFR 1.145 is amended in two respects.
- First, 1.145 is amended to clarify when an applicant can no longer present claims to independent and distinct inventions as a matter of right in an application. Specifically, 1.145 is amended from stating that, "after an office action on an application: to "after an office action on the merits on an application" the applicant may be required to restrict the claims to the invention previously claimed.
- Second, 1.145 is amended in correspondence to the authority provided to the examiner by the amendment to 37 CFR 1.142(c) to allow the examiner to not restrict when two or more independent and distinct inventions are claimed in a single application. Specifically, 1.145 is amended from stating that "the applicant will be required to restrict" to stating that "the applicant may be required to restrict."
- 37 CFR 1.704 is amended so that 1.704(c)(11) provides for limitation on patent term extensions for failure to comply with the 5/25 claims limitation rule implemented in 1.75(b). Specifically, 1.704(c)(11) reduces patent term adjustment by the number of days as follows. The start date is the day after either an amendment violationg 1.75(b) is filed, or the date of filing or U.S. national stage entry. The end date for the number of days is when:
 - (1) an ESD is filed curing the lack of compliance with 1.75(b);
 - (2) an election is filed in reply to a restriction or election of species requirement under

- rule 1.142(a) in an application violating the 5/25 rule and the election cures the lack of compliance by presenting no more than 5/25 claims for examination;
- (3) an election is filed in response to a requirement to restrict based upon lack of Unity of invention under fule 1.499 in a U.S. national stage entry of a PCT application violating the 5/25 rule and the election cures the lack of compliance by presenting no more than 5/25 claims for examination;
- (4) an amendment restricting claims to the invention originally presented in response to a requirement under 1.146 based upon the doctrine of election by original presentation.
 - (5) a suggested restriction requirement in compliance with 1.142(c) was filed.
- 1. For a discussion of this case see Neifeld, Review and Analysis of <u>Pfizer, Inc. v. Ranbaxy Laboratories Limited</u>, F.3d 1284; 2006 U.S. App. LEXIS 19416; 79 USPQ2d 1583 (Fed. Cir. August 2, 2006), published at http://www.neifeld.com/Pfizer_v_Roxbury.pdf.
- 2. See Neifeld, "Viability of the Hilmer Doctrine", Neifeld, Richard, 81 JPTOS 544 (July 1999), republished at http://www.neifeld.com/hilmer.html, at section III.A, for a discussion of the doctrine of election.
- 3. See Neifeld, "The Changes to the United States Prior Art Law Implemented by PL 108-453 Enacted December 10, 2004" Neifeld, Richard, 87 JPTOS 646, no. 8 (August 2005), republished at http://www.neifeld.com/103c_041123.pdf, for a discussion of the joint research agreement exclusion from prior art.

RAN

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