

EXHIBIT 1

PART 3

as a continuation application. That is, as discussed previously, applicant may file a "voluntary" divisional application as a continuation application in compliance with § 1.78(d)(1)(i) when the prior-filed application was not subject to a requirement for restriction. Specifically, under § 1.78(d)(1)(i), applicant may file two continuing applications of an initial application without a petition and showing and then may file a third or subsequent continuation with a petition and showing under § 1.78(d)(1)(vi). Accordingly, this final rule is not a major divergence from the "voluntary" divisional practice available in other countries.

Moreover, under the PCT and the Paris Convention, the determination of the conditions and effect of internal (domestic) priority claims is a matter for the authority concerned. See, e.g., PCT Article 8(2)(b) and Article 4(G)(2) of the Paris Convention. Efforts in recent years to harmonize substantive patent law have not focused on achieving harmonization on domestic priority. (See <http://www.wipo.int/patent/law/en/harmonization.htm> for further information).

Comment 8: Several comments suggested that eliminating "voluntary" divisional applications violates Article 4G(2) of the Paris Convention.

Response: Section 1.78(d) as adopted in this final rule does not eliminate what has traditionally been referred to as a "voluntary" divisional application. The second sentence of Article 4G(2) of the Paris Convention provides that each country "shall have the right to determine the conditions under which such division shall be authorized." As discussed previously, a "voluntary" divisional application would not meet the definition of divisional application set forth in § 1.78(a)(2), but would instead be a continuation application as defined in § 1.78(a)(3). If the prior-filed application is not subject to a requirement for restriction, the applicant may file a "voluntary" divisional application as a continuation application under the conditions set forth in § 1.78(d)(1)(i). Such a definition is consistent with 35 U.S.C. 121. Furthermore, if the prior-filed application is subject to a requirement for restriction, § 1.78(d)(1)(ii) provides that an applicant may file an "involuntary" divisional application directed to a non-elected invention that has not been examined. Therefore, § 1.78(d) is consistent with Article 4G(2) of the Paris Convention.

Comment 9: One comment suggested amending proposed § 1.78(d)(1)(ii) to define a divisional application as an

application that only includes claims that were non-elected in the prior-filed application to prevent new claims from being filed in the divisional application, thus further increasing the numbers of claims that examiners have to examine.

Response: Such a requirement is unnecessary because applicant may amend the non-elected claims that have been filed in the divisional application during the course of prosecution of the divisional applications as the prior art is developed and/or to correct formal matters. Section § 1.78(d)(1)(ii) as adopted in this final rule permits an applicant to file a divisional application directed to a non-elected invention that has not been examined that was subject to a requirement for restriction in the prior-filed application. Therefore, applicant may present claims in the divisional application that are different than the claims in the prior-filed application if the claims in the divisional application are directed to the subject matter of the non-elected invention.

Comment 10: One comment expressed concern that the Office may pressure examiners to limit the issuance of restrictions in order to reduce the number of applications to be examined, thus artificially making it look like the pendency rate has gone down. The comment requested that the Office implement a policy mandating examiners to issue restrictions when requested by the applicant, except in cases where it is clear that such restrictions are not proper.

Response: Restriction practice is set forth in Chapter 800 of the MPEP. As discussed previously, the applicant may suggest a requirement for restriction under § 1.142(c) if the applicant believes that two or more independent and distinct inventions are claimed in the application. The examiner may accept or refuse the suggested restriction requirement. Alternatively, the examiner may issue a different restriction. See the discussion of § 1.142(c). Either way, it remains important from the standpoint of the public interest that no requirements for restriction are made that might result in the issuance of two patents for the same invention. See MPEP § 803.01.

Comment 11: One comment questioned the status of a divisional application if the restriction requirement is withdrawn after filing of the divisional application.

Response: If a restriction requirement is made and the applicant cancels the non-elected claims (and any generic claims or other types of linking claims if present) in the prior-filed application and files a divisional application, the

restriction requirement will not be withdrawn. Also, as discussed previously, applicants cannot rely upon a requirement for restriction to avoid the requirement for an examination support document where: (1) The applicant traverses the requirement for restriction; (2) the requirement for restriction may be conditional, such as a requirement for election of species in an application that contains a claim that is generic to all of the claimed species (see MPEP § 809), or a requirement for restriction in an application that contains a linking claim (e.g., a subcombination claim linking plural combinations); or (3) the applicant plans to request rejoinder of the claims to the non-elected invention (see MPEP § 821.04 *et seq.*). Under §§ 1.78(a)(2) and 1.78(d)(1)(ii), the prior-filed application to which a divisional application claims the benefit must be 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 and the invention claimed in the divisional application must not have been elected for examination and must not have been examined in any prior-filed application. Thus, a divisional application will be improper when the claims to the non-elected invention have not been cancelled and the requirement for restriction is withdrawn in the prior-filed application (or when the invention claimed in the divisional application has been examined in the prior-filed application). Furthermore, since the claims of the prior-filed application and the divisional application would be drawn to the same invention, both applications may be subject to a double patenting rejection (see MPEP § 821.04) and the provisions of 1.75(b)(4) (determining number of claims for purposes of examination support document threshold when multiple applications contain patentably indistinct claims).

For example, where claims directed to a product and to a process of making and/or using the product are presented in the same application and subject to a requirement for restriction, the applicant may request rejoinder of the non-elected process claims that depend from or otherwise require all the limitations of an allowable product claim. See MPEP § 821.04(b). Upon rejoinder of claims to a non-elected process invention, the requirement for restriction between the elected product and non-elected process invention is withdrawn. Thus, the rejoinder of non-elected process claims after allowance of the elected product claims may result in a prior or subsequently filed

“divisional” application not being a proper divisional application under §§ 1.78(a)(2) and 1.78(d)(1)(ii) because the prior-filed application is no longer subject to a requirement for restriction. Applicant may avoid this problem by canceling the non-elected process claims and claiming them in a divisional application before rejoinder occurs. In such a situation, because the non-elected claims have been cancelled, the restriction requirement cannot be withdrawn. This will preserve applicant’s rights under 35 U.S.C. 121 and § 1.78(d)(1)(ii).

If the applicant chooses to retain the non-elected claims and files a divisional application claiming the non-elected invention and then the restriction requirement is withdrawn in the prior-filed application, the benefit claim under § 1.78(d)(1)(ii) in the later-filed divisional application would no longer be proper. Thus, the later-filed application would not be entitled to the benefit of the prior-filed application. If applicant still desires to maintain the later-filed application, applicant must delete or correct the benefit claim to indicate that the application is a continuation application if the requirements set forth in § 1.78(d)(1)(i) can be met. If applicant no longer wants to maintain the later-filed application, applicant may abandon the application before the examination has been made of the application and may request a refund of any previously paid search and excess claims fees.

Comment 12: A number of comments suggested that limiting continuation-in-part applications was unnecessary. The comments explained that concerns associated with continually reopening prosecution do not apply to continuation-in-part applications, which are usually filed as a result of the inventor having developed a significant improvement in the invention. One comment stated that limiting continuation-in-part applications will not reduce application filings, but rather will simply cause applicants to file the application as a new application without a benefit claim because the claims of the continuation-in-part application are usually directed to the new subject matter and thus not entitled to benefit of the parent filing date. Several comments suggested that continuation-in-part applications are necessary for adequate protection of improvements to the invention and that these improvements often become the key feature of an invention that leads to its success. One comment, however, suggested that continuation-in-part practice be terminated, because with the twenty-year patent term, there is no

benefit to applicant or to the Office associated with continuing this practice.

Response: Inconsistent rules for continuation applications and continuation-in-part applications would likely lead to confusion and create the potential for abuse. First, there is no reason to treat continuation applications different from continuation-in-part applications where both fall under § 1.78 and are contemplated by 35 U.S.C. 120. Second, there is no reason why the Office should maintain the ability to file an unlimited string of continuation-in-part applications without justification while proceeding with a change to § 1.78 to require a justification for any third or subsequent continuation application. Third, if applicants could file continuation-in-part applications without restriction, then they could be used as a tool to circumvent this final rule. Thus, the Office considers it appropriate to require a justification for any third or subsequent continuing application that is a continuation application or a continuation-in-part application.

The changes in this final rule do not impact applicants’ ability to protect improvements to the invention disclosed in a prior-filed application. Section 1.78(d)(1)(i) allows an applicant to file two continuation-in-part applications of a prior-filed application without a petition and showing. Applicant may also file any third or subsequent continuation-in-part application with a petition and showing. Hence, applicants have ample opportunity to seek protection for improvements.

Furthermore, for the continuation-in-part application to actually receive the benefit of the filing date of the prior-filed application, 35 U.S.C. 120 requires that the subject matter of at least one claim of the continuation-in-part application must be disclosed in the prior-filed application in the manner provided by 35 U.S.C. 112, ¶ 1. See *Studiengesellschaft Kohle m.b.H.*, 112 F.3d at 1564–65, 42 U.S.P.Q.2d at 1677–78. The term of any patent resulting from the continuation-in-part application will be measured under 35 U.S.C. 154(a)(2) from the filing date of the prior-filed application, even if the continuation-in-part application never receives any benefit from the prior-filed application. See *Abbott Labs.*, 104 F.3d at 1309, 41 U.S.P.Q.2d at 1537. To maximize the term of any resulting patent, applicant should file the application containing only claims directed to the improvements without claiming the benefit of the prior-filed application rather than a continuation-in-part application.

Comment 13: Several comments suggested that, if the prior-filed application is abandoned in favor of a continuation-in-part application before examination of the prior-filed application, or is filed within a short time of the prior-filed application, the limits on continuing applications should not include such continuation-in-part applications. Several comments explained that in rapidly advancing sciences, continuation-in-part applications are often filed while abandoning the prior application in the chain before an examination of the merits. Thus, a continuation-in-part application is often the first in a series to be examined as an initial application. At a minimum, the rules should be modified to exclude from counting prior-filed applications that are abandoned before issuance of a first action on the merits.

Response: Section 1.78(d)(1)(v) as adopted in this final rule addresses the situation in which an applicant files a continuation (or continuation-in-part) application to correct informalities rather than completing an application for examination under § 1.53. Under § 1.78(d)(1)(v), if the prior-filed application is abandoned due to the failure to timely reply to an Office notice issued under § 1.53(f), the applicant may file “one more” continuation application (or continuation-in-part application) without there being a requirement for a petition and showing under § 1.78(d)(1)(vi). Specifically, § 1.78(d)(1)(v) provides that a continuation application or continuation-in-part application is permitted if the following conditions are met: (1) The application claims benefit under 35 U.S.C. 120 or 365(c) of a prior-filed nonprovisional application filed under 35 U.S.C. 111(a), and the prior-filed nonprovisional application became abandoned due to the failure to timely reply to an Office notice issued under § 1.53(f) and does not claim the benefit of any other nonprovisional application or international application designating the United States of America; (2) the application is a continuation application as defined in § 1.78(a)(3) or a continuation-in-part application as defined in § 1.78(a)(4) that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than three prior-filed applications; and (3) any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than two other nonprovisional applications. This does not include any divisional

application that satisfies the conditions set forth in § 1.78(d)(1)(ii) or continuation application that claims the benefit of such divisional application and satisfies the conditions set forth in § 1.78(d)(1)(iii).

For example, applicant may file a third continuation (or continuation-in-part) application claiming the benefit of an intervening (second) continuation (or continuation-in-part) application, a first continuation (or continuation-in-part) application, and a prior-filed application without a petition under § 1.78(d)(1)(vi), if the prior-filed application became abandoned due to the failure to timely reply to a Notice to File Missing Parts mailed by the Office of Initial Patent Examination and does not claim the benefit of any other application. The prior-filed application, however, must be entitled to a filing date and have paid therein the basic filing fee within the pendency of the application. See § 1.78(d)(2).

Comment 14: One comment suggested that the rule changes encourage applicants to file two applications, *i.e.*, a continuation-in-part application and a divisional application, rather than a single continuation-in-part application, where the non-elected invention is further developed. The comment stated that this is inefficient for both the Office and applicants.

Response: The Office appreciates that the changes being adopted in this final rule do provide some incentive for applicants who seek only to maximize the number of continuing applications and requests for continued examination permitted without any justification to file both a continuation-in-part application and a divisional application in this situation. However, applicants seeking to maximize the number of continued examination filings are not likely to file only a single continuation-in-part application in this situation under either the former practice or the change to continuing application practice being adopted in this final rule. Furthermore, this final rule permits applicant to file two continuation or continuation-in-part applications plus one request for continued examination in an application family, without any justification. And, this final rule permits applicant to file two continuation applications plus one request for continued examination in the divisional application family, without any justification.

Comment 15: One comment suggested that continuation-in-part applications are an important tool for correcting errors in the initial application (*e.g.*, correction of test data) and this should be encouraged, rather than discouraged.

Response: The Office is neither encouraging nor discouraging the filing of continuation-in-part applications. Rather, this final rule treats continuation-in-part applications roughly the same as continuation applications. That is, applicant is permitted to file two continuation or continuation-in-part applications of an initial application without a petition and showing. Applicant is also permitted to file a third or subsequent continuation or continuation-in-part application with a petition and showing. See § 1.78(d)(1)(i). The only notable difference between the two, apart from their definitions, is that an applicant may file only a continuation application of a divisional application and not a continuation-in-part application of a divisional application. See § 1.78(d)(1)(iii). Nevertheless, applicants may use continuation-in-part applications to correct initial applications under this final rule to the extent they were used for this purpose before this final rule. Furthermore, as previously discussed, § 1.78(d)(1)(v) as adopted in this final rule provides that if an applicant files a continuation (or continuation-in-part) application to correct informalities rather than completing an application for examination under § 1.53, the applicant may file "one more" continuation application (or continuation-in-part application) without there being a requirement for a petition and showing under § 1.78(d)(1)(vi). See § 1.78(d)(1)(v).

Comment 16: One comment suggested that the Office should require applicants to certify that no 35 U.S.C. 102(b) bar applies for continuation-in-part applications filed more than twelve months from the earliest claimed date.

Response: Under § 1.56, applicant has a duty to disclose to the Office all information known to applicant to be material to patentability including any prior art under 35 U.S.C. 102(b). This includes a reference with a publication date more than one year prior to the filing date of the continuation-in-part application if at least one claim in the continuation-in-part application is drawn to the subject matter not disclosed in the prior-filed application. Applicant is required to file a newly executed oath or declaration under § 1.63 upon the filing of a continuation-in-part application. See § 1.63(e). The oath or declaration under § 1.63 must include a statement that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in § 1.56. See § 1.63(b)(3).

Comment 17: One comment argued that requiring applicant to identify whether the claims are supported by the specification before the examination is unfair and unreasonable because it is a legal issue that should be determined during the prosecution. Another comment suggested that the Office should, at most, require applicant to identify the differences between the continuation-in-part application and the prior-filed application. Another comment suggested that when a continuation-in-part application is filed, the Office should require the applicant to discuss whether the new matter added to the specification is inventive or based on ordinary skill. One comment, however, supported the requirement for a continuation-in-part applicant to identify which claims are disclosed in the prior-filed application and thus are entitled to the earlier filing date.

Response: Applicants are in the best position to identify the effective filing date of their claims. Thus, § 1.78(d)(3) provides that if an application is identified as a continuation-in-part application, the applicant must identify the claim or claims for which the subject matter is disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application. Any claim that is not so identified will be treated as only being entitled to the actual filing date of the continuation-in-part application, and subjected to prior art based on the actual filing date of the continuation-in-part application.

Whether any "new matter" is inventive or based on ordinary skill is not determinative of whether the claims of the continuation-in-part application are entitled to the filing date of the prior-filed application. The test is whether the original disclosure of the prior-filed application provides adequate support and enablement for the claimed subject matter of the continuation-in-part application in compliance with the requirement of 35 U.S.C. 112, ¶ 1. See MPEP § 201.11, I, Disclosure Requirement.

Comment 18: A number of comments suggested that the rule changes effectively eliminate the use of "bypass" continuing applications (*i.e.*, an application filed under 35 U.S.C. 111(a) that claims benefit under 35 U.S.C. 120 or 365(c) of the filing date of an earlier international application that did not enter the national stage under 35 U.S.C. 371). The comments argued that a bypass continuing application would be counted as a continuing application whereas a national stage submission under 35 U.S.C. 371 would not. The comments indicated that there are

important reasons for filing bypass applications and suggested that it is unfair to treat bypass applications differently than national stage applications because in both applications the examiner will be examining the claims for compliance with U.S. national law for the first time. Consequently, a number of comments recommended that the international application should not be counted toward the threshold for filing continuing applications unless the international application enters the U.S. national stage, while other comments recommended that the bypass application should not be counted.

Response: The Office notes the concerns expressed in the public comment regarding the proposed changes to § 1.78(d)(1). The Office has modified proposed § 1.78(d)(1) in this final rule to provide for certain "bypass" continuing applications. Under § 1.78(d)(1)(iv), if a Demand has not been filed and the basic national fee has not been paid in the international application, and the international application does not claim the benefit of any other nonprovisional application or international application designating the United States of America, the applicant may file "one more" continuation application (or continuation-in-part application) of such international application without there being a requirement for a petition and showing under § 1.78(d)(1)(vi). Specifically, § 1.78(d)(1)(iv) provides that a continuation application or continuation-in-part application is permitted if the following conditions are met: (1) The application claims benefit under 35 U.S.C. 120 or 365(c) of a prior-filed international application designating the United States of America, and a Demand has not been filed and the basic national fee (§ 1.492(a)) has not been paid in the prior-filed international application and the prior-filed international application does not claim the benefit of any other nonprovisional application or international application designating the United States of America; (2) the application is either a continuation application as defined in § 1.78(a)(3) or a continuation-in-part application as defined in § 1.78(a)(4) that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than three (rather than two) prior-filed applications; and (3) any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than two (rather than one) other nonprovisional applications. This does

not include any divisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii) or continuation application that claims the benefit of such divisional application and satisfies the conditions set forth in § 1.78(d)(1)(iii).

For example, applicant may file a third continuation application claiming the benefit of an intervening (second) continuation (or continuation-in-part) application, the first "bypass" continuation (or continuation-in-part) application, and the prior-filed international application without a petition under § 1.78(d)(1)(vi), if a Demand has not been filed and the basic national fee has not been paid in the international application, and the international application does not claim the benefit of any other nonprovisional application or international application designating the United States of America.

Comment 19: Several comments questioned whether an international application that designates the United States of America and claims benefit to a prior nonprovisional application would be treated as a second continuation application upon entry into the U.S. national stage if a request for continued examination is filed in the nonprovisional application prior to entering the national stage. Another comment questioned whether a request for continued examination could be filed in a nonprovisional application if a U.S. national stage application claims benefit under 35 U.S.C. 120 or 365(c) to the nonprovisional application. Several comments suggested that if an international application designating the United States of America claims benefit to a prior-filed nonprovisional application, and a request for continued examination is filed in the nonprovisional application, then a petition under § 1.78(d)(1)(vi) would be required, in violation of PCT Rule 51*bis*, in order to perfect entry of the international application into the U.S. national stage. The comments also suggested that any refusal to grant such a petition would violate the PCT because there is no basis in the treaty for refusing national stage perfection on such grounds.

Response: The Office notes the concerns expressed in the public comment regarding the proposed changes to §§ 1.78(d)(1) and 1.114 that would permit an applicant to file only one of the following: A continuation application, a continuation-in-part application, or a request for continued examination, without any justification. The Office has made modifications to these proposed changes such that this

final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Therefore, under this final rule, applicant is permitted to have the national stage of an international application designating the United States of America claim the benefit of a prior-filed nonprovisional application in which a request for continued examination has been filed without a petition and showing. The provisions of § 1.78(d)(1) are independent of the provisions of § 1.114. The filing of a request for continued examination in a nonprovisional application does not preclude a U.S. national stage application from claiming the benefit of the nonprovisional application. Likewise, a U.S. national stage application claiming the benefit under 35 U.S.C. 120 or 365(c) of a nonprovisional application will not preclude an applicant from filing a request for continued examination in the nonprovisional application.

Applicant may also file any additional continuation or continuation-in-part application or request for continued examination with a petition and showing. If an international application that enters the U.S. national stage contains or is amended to contain a specific reference to a prior-filed application that is not permitted by at least one of §§ 1.78(d)(1)(i) through (d)(1)(vi), the Office will refuse to enter, or will delete if present, the specific reference to the prior-filed application. See § 1.78(d)(1). Furthermore, the national stage application will be treated as entitled only to the actual international filing date of the national stage application, and will be subject to prior art based on the actual international filing date.

Refusal to grant a petition under § 1.78(d)(1)(vi) (assuming such a petition is necessary) would not prevent an applicant from completing the requirements for entry into the national phase under 35 U.S.C. 371. The requirements for entry of an international application into the national phase under 35 U.S.C. 371 are set forth in 35 U.S.C. 371(c) and § 1.495. The effect of a refusal to grant any such petition would only be that the national stage application would not be entitled to the benefit of the filing date of the nonprovisional application under 35 U.S.C. 120 and 365(c). Furthermore, the necessity to file a petition under § 1.78(d)(1)(vi) in the national stage application to obtain benefit to the nonprovisional application would not

violate PCT Rule 51*bis*. PCT Rule 51*bis* does not govern the requirements that a designated Office may impose for recognition of domestic benefit claims. Rather, the ability of a designated Office to establish conditions for, and the effect of, domestic benefit claims is expressly provided for in PCT Article 8(2). PCT Article 8(2) states, in pertinent part, that "[w]here, in the international application, the priority of one or more national applications filed in or for a designated State is claimed, or where the priority of an international application having designated only one State is claimed, the conditions for, and the effect of, the priority claim in that State shall be governed by the national law of that State."

Comment 20: Several comments suggested that the rules create an anomaly. The comments argued that if an application is first filed as a nonprovisional application followed by an international application claiming benefit to the nonprovisional application, and a request for continued examination is subsequently filed in the nonprovisional application, then a petition under § 1.78(d)(1)(vi) would be needed when the international application enters the U.S. national phase. The comments, however, further argued that if the application is first filed as a provisional application followed by, one year later, concurrently filed international and nonprovisional applications both claiming benefit to the provisional application, then a petition under § 1.78(d)(1)(vi) would not be needed when the international application enters the U.S. national phase even if a request for continued examination was filed in the nonprovisional application.

Response: The Office has made modifications to the proposed changes to §§ 1.78(d)(1) and 1.114 such that this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Therefore, under this final rule, applicant may enter the U.S. national stage in an international application designating the United States of America claiming the benefit of a prior-filed nonprovisional application in which a request for continued examination has been filed without a petition and showing. As discussed previously, the provisions of § 1.78(d)(1) are independent of the provisions of § 1.114. The filing of a request for continued examination in a nonprovisional application does not preclude a U.S. national stage

application from claiming the benefit of the nonprovisional application.

Note that, in the first described application chain, the international application claims benefit to a nonprovisional application under 35 U.S.C. 120 or 365(c) and therefore is a "continuing application" as defined in § 1.78(a). In the second described application chain, the international application is not a continuing application as it only claims benefit to the provisional application. In any event, § 1.78(d)(1) as adopted in this final rule would not require a petition and showing for the national stage application to claim the benefit of a prior-filed application in which a request for continued examination has been filed.

Comment 21: One comment argued that applicants who first file a nonprovisional application followed by a continuation-in-part application would not be able to designate the United States in any subsequently filed international application without a showing as to why the international application could not have been filed earlier. The comment argued that this violates the PCT.

Response: The Office has made modifications to the proposed changes to § 1.78(d)(1) such that this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Therefore, under this final rule, applicant may file an international application designating the United States of America claiming the benefit of two prior-filed nonprovisional applications without a petition and showing. Applicant may also file any additional continuation or continuation-in-part application or request for continued examination with a petition and showing. The petition procedure under § 1.78(d)(1)(vi) applies only to international applications that have entered the U.S. national stage after compliance with 35 U.S.C. 371. Thus, the rule neither requires nor provides for the submission of such petitions in international applications during the international phase. It is also noted that under PCT Rule 4.9, the designation of all states, including the United States of America, in international applications is automatic upon filing of the PCT request.

Comment 22: Several comments questioned whether the limitation on the examination of claims in nonprovisional applications under § 1.75(b) could be circumvented by first filing an international application with

as many claims as desired and then entering the U.S. national phase after the claims have been searched in the international phase. The comments suggested that the Office should examine all claims in a national stage application that were the subject of a search and written opinion in the international phase, particularly if the United States Patent and Trademark Office was the international searching authority.

Response: The requirements of § 1.75(b) apply to national stage applications under 35 U.S.C. 371 as well as to applications filed under 35 U.S.C. 111(a). Thus, the rule cannot be circumvented by utilizing the PCT route. The fact that more than five independent claims or more than twenty-five total claims may have been searched and even subjected to international preliminary examination in the international phase will not entitle applicants to more than five independent claims or more than twenty-five total claims in the U.S. national phase application without the submission of an examination support document. This is analogous to existing practice under § 1.499, which permits restriction of claims in a national stage application for lack of unity notwithstanding that such claims may have been searched and subject to international preliminary examination in the international phase. Applying § 1.75(b) to national stage applications is appropriate because prior art uncovered during the international search often necessitates the need to make substantial amendments to the claims in the national phase. Additionally, the claims would need to be examined for compliance with all substantive requirements of U.S. national law.

Comment 23: One comment suggested that the rules limiting continuing applications would result in more applicants filing international applications and entering the U.S. national stage in order to avoid onerous restriction requirements. Another comment suggested that the rules limiting the examination of claims might trigger increased usage of the PCT and national stage entry into the U.S.

Response: Applicants are free to choose whichever route they believe is more advantageous for obtaining patent protection in the United States, whether through the PCT or through a direct national filing under 35 U.S.C. 111(a).

Comment 24: A number of comments requested that the Office should notify the applicant in an Office action when a continuing application is not available under any one of the first three conditions in § 1.78(d)(1). A number of

comments stated that the refusal to enter or to delete any references to prior-filed applications that are not permitted under § 1.78(d)(1) would place a heavy burden on the Office.

Response: The changes to §§ 1.78 and 1.114 in this final rule are clearly set forth in this final rule. Applicant and his or her representative have the duty to know the rules of practice when prosecuting an application for patent before the Office. Applicant should not file a continuing application without knowing whether it is proper. The refusal to enter or to delete any references to prior-filed applications that are not permitted under § 1.78(d)(1) would not place any additional burden on the Office.

Comment 25: A number of comments argued that the rule changes would protract the examination process and divert resources from examining functions to administrative tasks. In particular, the comments predicted that the rule changes would increase the number of petitions, including petitions for filing additional continuing applications and requests for continued examination and petitions for supervisory review of Office actions and restriction requirements. Several other comments argued that the delay in prosecution of an application would increase while decisions on petitions under §§ 1.78(d)(1)(vi) and 1.114(g) were debated and reviewed. Several comments questioned whether the Office would be adequately staffed with enough personnel to handle the onslaught of petitions, as well as further review of decisions dismissing the petitions. Several comments also argued that any reduction in backlog would be insignificant given that the Office would grant some of the petitions for additional continuing applications and requests for continued examination. Several comments suggested that the proposed changes to the continued examination practice will force applicants to petition every improper procedural requirement by examiners, including restriction requirements, finality and non-entry of after-final amendments, in order to preserve applicant's rights. One comment stated that applicants are likely to file petitions, such as petitions addressing the prematurity of a final rejection under § 1.181, to save their one "as-matter-of-right" continuation or continuation-in-part application or request for continued examination. Several comments stated that applicants would petition almost all restriction requirements, resulting in an increase in the number of petitions filed. Another comment stated petitions seeking

review of restriction requirements would be filed in order to determine early in the prosecution cycle the number of divisional applications that must be filed to preserve patent rights.

Response: One of the Office's goals is to focus its limited patent examining resources on the examination of new applications, and thereby increase the effectiveness of Office resources while also reducing the backlog of unexamined patent applications. The requirements for seeking third and subsequent continuing applications will not have an effect on the vast majority of patent applications. The changes being adopted in this final rule, however, will reduce the strain on the Office's patent examining resources, which will allow for a better, more timely examination of new applications.

The Office recognizes the amount and type of resources needed to implement the changes to §§ 1.78 and 1.114 being adopted in this final rule. The authority to decide petitions under §§ 1.78(d)(1)(vi) and 1.114(g) has been delegated to the Deputy Commissioner for Patent Examination Policy (who may further delegate this authority to officials under the Deputy Commissioner for Patent Examination Policy). The Office is planning to provide sufficient staff to handle the projected number of petitions.

The Office provides the procedure under § 1.181 for applicants to seek review of requirements and objections made by the examiner. If applicant finds that a requirement or an objection made in an Office action is procedurally wrong, applicant should request reconsideration or file a petition under § 1.181 to review the requirement or objection. As an example, when applicant challenges the finality of an Office action as being premature, the applicant should focus on whether the Office action met the appropriate standard for finality. The Office will make every effort to decide the petitions in a timely manner. Applicant, however, should not file a continuing application or a request for continued examination in an effort to address improper procedural requirements. Petitions for supervisory review of Office actions and restriction requirements will continue to be decided by supervisory patent examiners or other managers. Therefore, examiners will not be diverted from the examination process by these petitions. Finally, it should be noted that complaints about an Office action that relate to the merits of patentability of the claims must be addressed in an appeal to the BPAL, and not in a petition under § 1.181 for supervisory review, even if the issues may be phrased in

procedural terms. See *Boundy v. U.S. Pat. & Trademark Office*, 73 U.S.P.Q. 2d 1468, 1472 (E.D. Va. 2004).

Comment 26: Several comments stated that any resources saved via implementation of these final rules would be used for other filings necessitated by the changes. Thus the rule changes, according to the comments, would increase the backlog and pendency and add to the administrative cost and burdens of the Office. In particular, a number of comments predicted that the number of applications would increase because applicants would file more of the following: (1) Provisional applications; (2) continuation applications rather than requests for continued examination; (3) reissue applications to perfect or broaden claims; (4) reexamination proceedings to have prior art considered; (5) divisional applications (because applicants are required to file all divisional applications during the pendency of the first application); (6) multiple parallel applications that have similar or the same disclosures; and (7) continuing applications before the effective date.

Response: The Office notes the concerns expressed in the public comment and has attempted to avoid the possibility of increased filings' necessitated by modifying the proposed changes. The Office has made modifications to the proposed changes to §§ 1.78(d)(1) and 1.114 such that this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Also, under this final rule, a divisional application need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. This final rule also permits applicant to file two continuation applications of a divisional application plus a request for continued examination in the divisional application family, without any justification. Therefore, the Office does not expect any significant increase in filings of applications. Specifically, the Office does not expect that the number of divisional applications would increase in response to the changes being adopted in this final rule because applicants should have sufficient time to determine whether to file a divisional application for a non-elected invention following a restriction requirement. Furthermore, an increase in filings of provisional applications will not place additional burden on the Office's patent

examining resources because no examination is provided in provisional applications. The Office does not expect its examining resources to be impacted when applicants file continuation applications rather than requests for continued examination, or when applicants file reissue applications and reexamination proceedings rather than continuing applications.

The changes being adopted in this final rule do not encourage applicants to file multiple applications with patentably indistinct claims. Pursuant to § 1.78(f)(3), the Office may require elimination of the patentably indistinct claims from all but one of the nonprovisional applications. If the patentably indistinct claims are not eliminated from all but one of the applications, the Office will treat each application as having the total of all of the claims (whether in independent or dependent form) for purposes of determining whether an examination support document is required by § 1.75(b). See § 1.75(b)(4). Moreover, when an applicant (or assignee) files multiple applications with the same claimed filing or priority date, a common inventor, and substantial overlapping disclosures, the Office will presume that the applications contain patentably indistinct claims. See § 1.78(f)(2). The applicant must either rebut this presumption or submit the appropriate terminal disclaimers and explain why two or more pending applications containing patentably indistinct claims should be maintained. Once applicant recognizes that having multiple applications that contain patentably indistinct claims is not needed, applicant would abandon the applications or stop filing multiple applications that have patentably indistinct claims.

Comment 27: One comment stated that a requirement for Director's approval to file a second or subsequent continuing application or request for continued examination would create a disincentive for examiners to provide a thorough examination, leaving the burden on the applicant to prosecute the application.

Response: The Office modified the proposed provision that would have limited applicant to one continuation or continuation-in-part application or to one request for continued examination, without any justification. This final rule allows applicant to file two continuation or continuation-in-part applications plus a request for continued examination in an application family, without any justification. What is more, the Office expects that limiting the number of

continuing applications and requests for continued examination that may be filed without justification will encourage both applicants and examiners to engage in a more thorough prosecution and examination earlier in the application process. Examiners are professionals who perform their duties in compliance with patent laws, rules of practice, and patent examining procedures set forth in the MPEP. They are responsible for the quality of their work product. There is no reason why examiners would provide lower quality examination in response to the changes in this final rule. In fact, this final rule is intended to improve the quality of examination by facilitating the examination of applications that contain more than five independent claims or twenty-five total claims via the examination support document.

Comment 28: A number of comments stated that the Office should treat continuing applications the same as new applications and should not limit the available protection because applicants who file continuing applications pay the same filing fees as those who file a new application. One comment argued that continuing applications should not be limited because they claim "new inventions" in that they pursue broader claims, a different invention, or an improvement, and the purpose of patents is to protect inventions, not to facilitate examination. One comment argued that continuation and continuation-in-part applications are legitimate because the statutes that create and authorize "continuation practice" do not distinguish such applications from "new" applications in terms of their importance, nor do they limit the resources that are committed to them.

Response: The former unrestricted continued examination practice was impairing the Office's ability to examine new applications. As a result, the Office is modifying continued examination practice in this final rule to address the backlog of unexamined new applications. Under this final rule, therefore, if the amendments, arguments, or evidence sought to be entered could have been previously submitted in the initial application, two continuing applications, and a request for continued examination, applicants are encouraged to make such submissions early rather than wait to do so in another continuing application or request for continued examination. That way, the examiner would have the information earlier to make the patentability determination. If applicant could not have submitted them earlier, applicant may file a third continuing

application with a petition and showing under § 1.78(d)(1)(vi) or a second request for continued examination with a petition and showing under § 1.114(g).

Comment 29: A number of comments stated that the rule changes would not permit applicants to file even a single continuation or continuation-in-part application, when the applicant filed a request for continued examination in the initial application.

Response: The Office has made modifications to the proposed changes to §§ 1.78(d)(1) and 1.114 such that this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Applicant may also file any additional continuation or continuation-in-part application or request for continued examination with a petition and showing as to why the amendment, argument, or evidence sought to be entered could not have been submitted earlier. The provisions of § 1.78(d)(1) are independent of the provisions of § 1.114. The filing of a request for continued examination in the initial application does not preclude applicant from filing a continuing application of the initial application.

Comment 30: Several comments objected to the Office's proposal that a petition under § 1.78 to accept an unintentionally delayed claim under 35 U.S.C. 120, 121, or 365(c) will not be granted in an application in which a request for continued examination has been filed. One comment argued that applicant would lose substantial rights if the Office dismisses a petition to accept an unintentionally delayed claim filed after a request for continued examination has been filed in the prior-filed application.

Response: The Office has made modifications to the proposed changes to §§ 1.78 and 1.114 such that the provisions of § 1.78(d) as adopted in this final rule are independent of the provisions of § 1.114. Thus, § 1.78(e) as adopted in this final rule does not provide that a petition to accept an unintentionally delayed claim under 35 U.S.C. 120, 121, or 365(c) will not be granted in an application in which a request for continued examination has been filed.

Comment 31: A number of comments stated that the rule changes would not permit applicants to consolidate two applications into a single continuation-in-part application, which is contrary to the goal of reducing the number of applications.

Response: The Office has made modifications to the proposed changes such that this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Therefore, applicant is permitted to file a continuation-in-part application that claims the benefit of two prior-filed applications without a petition and showing under § 1.78(d)(1)(vi). If applicant thinks that a third or subsequent continuation-in-part application is necessary for consolidation purposes, then such applicant may file a petition and showing under § 1.78(d)(1)(vi) to obtain the additional filing.

Comment 32: Several comments argued that applicants need continuing applications and requests for continued examination because the reissue procedure does not give applicants the same flexibility.

Response: Continuing applications and requests for continued examination are not, by statute, available for the same purposes as reissue applications. Continuing applications and requests for continued examination are available to an applicant during the prosecution of an initial application to enable an applicant to secure protection on the full scope of an invention with the correct benefit claim. See 35 U.S.C. 120, 121, and 365(c). By contrast, the reissue procedure is available to an applicant after a patent has issued to permit an applicant to correct errors made during the prosecution of the original application without any deceptive intention and to enlarge the scope of the claims of the original patent if the reissue application is filed within two years from the grant of the original patent. See 35 U.S.C. 252. Furthermore, this final rule permits applicant to file two continuation or continuation-in-part applications plus one request for continued examination in an application family, without any justification. These available filings provide sufficient flexibility.

Comment 33: One comment suggested that the rule changes would be contrary to patent harmonization goals. One comment argued that the rule changes would hurt foreign applicants because they would be required to assess the degree of protection much earlier than they normally would, resulting in retaliatory challenges abroad for U.S. applicants.

Response: The Office did not receive any comments from any foreign patent office or authority. The Office does not expect any retaliation from other

countries or any adverse impact. Many countries do not have flexible practices for filing continuation applications, continuation-in-part applications, and requests for continued examination.

Comment 34: A number of comments argued that the rule changes would increase the cost to applicants for prosecuting each application, and for filing more multiple parallel applications, divisional applications, appeals, and petitions under §§ 1.78 and 1.114. Several comments argued that the rule changes would cause applicants to incur excessive expenses before determining whether the invention is commercially viable. One comment argued that the Office would cause applicants to perform patent searches in order to have a good working knowledge of the prior art to draft claims for full coverage. One comment argued that the rule changes would increase practitioner fees because applicants must submit more carefully drafted claims and replies (estimated five additional hours per case for drafting all possible claims, at an average of 150 dollars per hour, the additional cost would be 750 dollars per application or 200 million dollars for 317,000 applications). One comment estimated that the attorney cost in preparing an application would at least double if not increase by a factor of ten, which would place new applications out of reach of small businesses. Several comments argued that it would be practically impossible or at least much more difficult, expensive and time-consuming to obtain patent protection for the full scope of inventions, especially for large, complex inventions. One comment argued that the rule changes are extremely burdensome for patent applicants and practitioners to maintain and develop a cohesive patent strategy. One comment stated that the rule changes were very complex and fraught with ambiguity and would create difficulties and misunderstandings for applicants and practitioners in the implementation, possibly resulting in the loss of inventors' rights and an increase in practitioners' exposure to malpractice.

Response: The Office encourages applicants to diligently prosecute the initial application, two continuation or continuation-in-part applications, and one request for continued examination, without a petition and showing, so that applicants do not need to file a petition and showing to secure a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination and incur the costs associated with these filings. The

patent system best serves the interests of all parties, including the public, when applicants and their representatives are diligent in drafting the claims and replies. Applicant would get a quality patent with desirable claim coverage. The Office would not waste patent examining resources to examine applications that are not diligently prepared. Even prior to the changes being adopted in this final rule, applicants and their representatives had certain duties when prosecuting applications in front of the Office. Applicant is required to submit fully responsive replies to Office actions (see § 1.111) and to particularly point out and distinctly claim what the applicant regards as his or her invention (see 35 U.S.C. 112, ¶ 2). Furthermore, if applicant's lack of knowledge of the prior art (or lack of diligence) causes unnecessary delay or needless increase in the cost of prosecution before the Office, applicant would be violating § 10.18(b)(2)(i).

If applicants need more time to determine the aspect of the invention for which patent protection should be sought, applicant may file a request for deferred examination under § 1.103(d) upon filing the initial application. Applicant should have sufficient time to determine whether to file a divisional application for a non-elected invention because a divisional application is not required under this final rule to be filed during the pendency of the initial application, as long as the copendency requirement of 35 U.S.C. 120 is met. If applicant disagrees with the examiner's rejections, it would be more effective to appeal the rejections than to file a continuing application or a request for continued examination. It should not be burdensome for applicants and their representatives to prosecute diligently by drafting claims that particularly point out and distinctly claim the subject matter which the applicant regards as his or her invention, as well as replies that are fully responsive to the Office actions.

The requirements for seeking third and subsequent continuing applications in this final rule will not have an effect on the vast majority of patent applicants. Approximately 342,600 nonprovisional patent applications (excluding plant and design applications) were filed in the Office in fiscal year 2006. Of those applications, approximately 32,700 were identified as continuation applications, approximately 15,700 were identified as continuation-in-part applications, and approximately 20,600 were identified as divisional applications. In addition, approximately 74,700 requests for

continued examination were filed in the Office in fiscal year 2006. The requirements for seeking a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination would only have affected 2.7 percent of these filings (applications or requests for continued examination). As discussed previously, the changes being adopted in this final rule do not give any advantage to those applicants who file multiple parallel applications containing patentably indistinct claims. See §§ 1.75(b)(4) and 1.78(f).

Comment 35: One comment argued that the rule changes would encourage the courts to have a more liberal view on the doctrine of equivalents. Another comment argued that the rule changes limiting continuation practice takes away the right of the patentee to use continuing applications to secure patent protection for equivalents of the invention claimed in the prior-filed application, citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 68 U.S.P.Q.2d 1321 (Fed. Cir. 2003) (*Festo X*).

Response: The doctrine of equivalents is a patent law concept relating to infringement which protects patentees against efforts of copyists to evade liability for infringement by making only insubstantial changes to a patented invention. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 726–27, 62 U.S.P.Q.2d 1705, 1709 (2002) (*Festo VIII*). The case law on the doctrine of equivalents has been well established since *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 41 U.S.P.Q.2d 1865 (1997) and *Festo VIII*. A concurrence in *Festo X* noted that the demise of the flexible doctrine of equivalents “rule” may encourage applicants to (*inter alia*) use continuation strategies to avoid the lack of flexibility that now exists in the doctrine of equivalents. See *Festo X*, 344 F.3d at 1375, 68 U.S.P.Q.2d 1332. This concurrence in *Festo X*, however, was not espousing some “right” of the patentee to use continuing applications to maintain the doctrine of equivalents, but was simply noting that applicants now use continuing application practice as a substitute for a flexible doctrine of equivalents.

The Office is concerned that practitioners and applicants may indeed be increasingly using continuing applications not to advance prosecution but to compensate for changes in the law of the doctrine of equivalents. Such practices would appear to be likely to contravene § 10.18(b)(2)(i), under which a party presenting a paper to the Office

is certifying that the paper is not being presented to cause unnecessary delay or needless increase in the cost of prosecution before the Office. Under *Festo X*, a narrowing amendment gives rise to a presumption that equivalents not covered by the literal language of the claims have been foregone. Permitting two continuing applications plus a request for continued examination in any one of the initial application or two continuing applications as of right should in general assure that applicants have an adequate chance to advocate to the examiners that an amendment is unneeded. Beyond that, the Office is concerned that applications may be continued, rather than disputes on the need for amendment being appealed, for the purpose of delay. A requirement that an applicant at that stage be prepared to justify his or her need for an additional continuing application is reasonable in these circumstances.

Comment 36: A number of comments suggested that the rule changes are arbitrary and capricious, premature, imprudent and ill-advised. A number of comments argued that the Office has no rational basis for the rule change, and has not provided sufficient explanations, data or evidence to justify the rule changes and to show that the rule changes will actually improve the backlog of applications, the quality of examinations, overall examination efficiency, quality of patents, and pendency. In addition, the comments asserted patents would be harder to enforce and litigate because all relevant prior art may not have been considered.

One comment stated that the Office does not have a pendency problem because the average pendency is within zero to three years. One comment argued that the Office provides no studies to show that businesses are being harmed due to delayed prosecution. One comment argued that reducing the backlog is not an appropriate reason for limiting the number of continuing applications and requests for continued examination as a matter of right. Several comments argued that the Office has not identified continuation applications as a major source of the backlog, and therefore, the rule changes would have limited impact on the backlog. One comment pointed out that second and subsequent continued examination filings make up only a small percentage of the total number of continued examination filings. Several comments alleged that the Office's statistics are misleading and the rule changes would only eliminate at most five to ten percent of the continuation applications because the

Office should not have included “involuntary” divisional applications and requests for continued examination. One comment argued that the Office provided no statistical data showing the percentage of applicants that “misuse” the continued examination practice as alleged. One comment also suggested that although the Continuing Applications Proposed Rule cites to data regarding the total number of continuations and the consequential burdens imposed on examiners, no analysis is provided as to the grounds for filing these applications and whether those grounds constituted “abuse.”

Several comments argued that there is no indication that the Office has conducted any serious analysis of how or why requests for continued examination and continuation applications are used by applicants. The comments suggested the following: A suitable analysis would involve review of prosecution histories of patents that were issued from a continuation application or a request for continued examination and determination of whether such patents could have issued if the rule changes were in place; and if such patents would not have issued, the Office should explain how such a loss of rights is consistent with the goals of the patent system. A number of comments asserted that the rule changes should be narrowly tailored to only those few applicants who intentionally delay the conclusion of examination rather than adversely impacting all applicants. A number of comments suggested that the Office should conduct a pilot program on the changes and report the results to the public prior to implementing the rule changes.

Several comments further argued that the Office has not identified any study showing that restricting applicants to a single continued examination opportunity would satisfactorily address its problems without causing substantial harm to the protection of innovation or the patent examining process. Several comments alleged that the Office has not sufficiently considered the effect of the rule changes on U.S. applicants and the U.S. economy and suggested that further study is needed because the ability to file multiple continuing applications helps U.S. applicants to protect their inventions against foreign competitors and the rule changes would cause further outsourcing of American manufacturing and loss of American jobs.

Several comments, however, supported the rule changes. The comments provided the following reasons why the rule changes would be appropriate: (1) They would improve

the Office's productivity, enhance patent quality, and eliminate growing abuses in the patent prosecution process, which would accelerate innovation, especially in the software and hardware technologies that have fast technology evolution and short product life cycle; (2) the rule changes would help the Office reduce backlog and pendency because they would reduce the ancillary loads on the examination process so that examiners can focus on important core issues, and the Office could focus its limited examining resources on faster examination of new applications; (3) the rule changes appropriately address those few applicants who disproportionately contribute to the backlog and provide applicants with the ability to file appropriate continued examination filings and multiple opportunities to present claims and arguments; (4) applicant may correct appropriate mistakes (including by broadening claims) through the reissue process; (5) by eliminating long chains of continued examination filings, the rule changes would provide earlier and greater legal certainty as to the scope of patent rights, reduce wasteful litigation, and encourage negotiations between patent holders and others; (6) the rule changes would likely promote confidence in U.S. patents, stimulate innovation, enhance competition, and increase consumer welfare; and (7) the rule changes would help to deter applicants from strategically using the continued examination practice to disadvantage competitors and their licensees, and would prevent applicants from keeping continuation applications pending for extended periods of time so that they can monitor the development of the market and modify their claims to cover their competitors' products.

Response: In fiscal year 2006, the average pendency to first Office action was 22.6 months for the entire Patent Examining Corps. The average was much higher in certain areas (e.g., in Technology Center 2100 (computer architecture, software and information security) the average pendency to first Office action was 30.8 months, and in Technology Centers 3620 and 3690 (electronic commerce) the average pendency to first Office action was 43.9 months). As several comments noted, long pendency of patent applications is problematic in some industries (e.g., computer software and hardware technologies) where product life cycles are short and new improvements can quickly make the technology obsolete. The Office has the authority and responsibility to establish regulations

that shall govern the conduct of proceedings in the Office and facilitate and expedite the processing of patent applications. See 35 U.S.C. 2(b)(2). The Office has the responsibility to take appropriate action to improve efficiency, patent quality and pendency. The Office does not expect that the changes being adopted in this final rule alone will be sufficient to address the growing backlog of unexamined patent applications. The Office is implementing many initiatives to improve efficiency in the examination process and quality of patents.

Continued examination filings divert the Office's limited examining resources from the examination of new applications. One of the Office's goals is to focus the limited examining resources on the examination of new applications. The rules do not place an absolute limit on the number of continued examination filings. The Office recognizes there are appropriate reasons for applicant to file a continuing application or request for continued examination. Under this final rule, applicant is permitted to file the initial application, two continuing applications, and a request for continued examination in an application family, without any justification. Thus, applicant has sufficient opportunities to present claims, amendments, arguments, evidence, and prior art 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 and showing as to why the amendment, argument, or evidence sought to be entered could not have been previously submitted. If the amendment, argument, or evidence can be submitted earlier in the prosecution process, applicant is required to do so, rather than delay the prosecution and waste the Office's patent examining resources on a prosecution that is not focused. The examination process is more efficient when the applicant diligently prosecutes the application so that the examiner has all of the relevant information, including amendments, evidence, arguments, and prior art as early as possible. Most applicants who prosecute diligently will not need to file a third or subsequent continuing application. Reviewing the prosecution histories of patents, conducting pilot programs, publishing green papers, etc., would not show all of the reasons why

applicants would file multiple continued examination filings. Applicants could have different reasons for filing continuation applications, continuation-in-part applications and requests for continued examination. The rules appropriately provide applicant the opportunity to show why a third or subsequent continuing application or second or subsequent request for continued examination is needed. The comments do not provide any persuasive data or evidence that shows how the rule changes, or any restrictions on the continued examination filing practice, would have a negative impact on the quality of patents, the U.S. economy, or innovation.

As discussed previously, approximately 342,600 nonprovisional patent applications (excluding plant and design applications) and approximately 74,700 requests for continued examination were filed in the Office in fiscal year 2006. The requirements for seeking a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination would only have affected 2.7 percent of these filings (applications or requests for continued examination). The Office did not include divisional applications in this analysis. The Office included requests for continued examination because when an applicant files a request for continued examination, the examiner reopens the prosecution of the application and conducts another substantive examination similar to a continuation application.

Comment 37: Several comments argued that the amount of resources spent on additional continuing applications or requests for continued examination is not as high as asserted because continuation applications and requests for continued examination take less of the examiner's time than new applications since the examiner is already familiar with the prior art, issues, and subject matter of the application.

Response: The Office expects that limiting the number of continuing applications and requests for continued examination that may be filed without justification will encourage both applicants and examiners to focus on "getting it right the first time." In any event, examiners are given the same amount of time to examine a continuing application or request for continued examination as a new application. Certain continuing applications and requests for continued examination could have more complex issues than a new application, such as evaluating new evidence in a biotechnology application.

Any reduction in the number of continuing applications and requests for continued examination would increase the Office's ability to focus its patent examining resources on the examination of new applications.

Comment 38: Several comments asserted that the premise that expedited examination is more important than protection of inventor's rights is faulty.

Response: The Office did not state such a premise. Applicants may seek full protection of their inventions under this final rule, which does not place any absolute limits on the number of continuing applications and requests for continued examination. Limiting the number of continuing applications and requests for continued examination that may be submitted without justification is not counter to the protection of an inventor's rights.

Comment 39: Several comments predicted that the rule changes would decrease the Office's revenue due to the decrease in continuing applications and requests for continued examination.

Response: The Office's goal is to utilize its patent examining resources more efficiently to reduce backlog and improve pendency. In exchange for greater efficiency, the Office expects there would be some decrease in revenue as the number of continued examination filings declines, as the comment indicates. But, this final rule is not being implemented with a view toward revenue; instead, it is being implemented to improve the patent examination process.

Comment 40: A number of comments argued that there is no public notice problem. The comments argued that most applications (ninety percent) are published, the prosecution of the published applications is open to the public, and competitors are already able to analyze a file history to determine the broadest range of claim protection that may be granted in a patent of a continuing application. Several comments suggested that members of the public could prevent infringement by identifying the novel inventions in the disclosure and avoiding those inventions in their practices. Several comments, however, noted that publication of applications is not sufficient to provide public notice of what the patentee will ultimately claim because a patent may eventually issue with broader or significantly different claims than those published and any delays at the Office will perpetuate uncertainty as to the scope of the eventual patent.

Response: The Office agrees that the publication of an application is not sufficient notice of the scope of

protection afforded by an eventual patent because the claims have not been determined to be patentable at the time of publication. Asking the public to determine the broadest range of claim protection and to prevent infringement based on the publication of an application would defeat the purposes of patent examination and 35 U.S.C. 112, ¶ 2. The patent claims provide the public with notice of the patent protection, not the disclosure of an application.

Comment 41: A number of comments stated that the current patent law already contains its own solution to the problem of long chains of continuing applications. The comments argued that filing and maintenance fees and the twenty-year patent term provision discourage applicants from filing continuing applications. Several comments argued that the Office is acting prematurely because the recent changes (e.g., the Office electronic filing system, the increase in hiring and fees, court decisions on doctrine of equivalents, the twenty-year patent term provisions, and publication of applications) should be sufficient to reduce the backlog and improve public notice. A number of comments alleged that the doctrine of prosecution laches is sufficient to address abuses. One comment argued that the Office should not be concerned with enforcement issues and the problem with public notice should not be a reason for the rule changes. Several comments argued that the Office's concern over public notice is misplaced because the notice function of claims is limited to published or patented claims and it does not extend to any future claims that might arise. Several comments, however, noted that even with the twenty-year patent term provisions, unrestricted continued examination practice still gives applicants incentives to keep continuing applications pending after the issuance of a patent so that the applicants can monitor the industry development and capture other companies' products by changing the scope of the claims in the continuing applications.

Response: The percentage of continued examination filings did not decrease after the implementation of the twenty-year patent term provision of the Uruguay Round Agreement Act (Pub. L. 103-465, 108 Stat. 4809 (1994)). Thus, the twenty-year patent term provisions do not discourage applicants from filing continued examination filings. As discussed previously, this final rule is not intended to address extreme cases of prosecution laches or to codify *Bogese II*. Examiners already have the authority

(with a Technology Center Director's approval) to make a rejection on the grounds of prosecution history laches. See MPEP section 2190. Some of the reasons cited by the comments as to why an indefinite number of continuing applications is needed suggest that continuing applications may be used for purposes of delay more commonly than could be effectively addressed by the Office's application of its equitable prosecution history laches authority. Moreover, even where strategies of delay are not deliberately pursued, the lack of reasonable requirements on the use of continued examination practice may act as a disincentive to the examiner and applicant taking the most effective steps to reach conclusion.

The Office did not place a *per se* limit on the number of continuing applications and requests for continued examination. The rules require applicant to show why a third or subsequent continuing application or second or subsequent request for continued examination is necessary to advance prosecution. The Office recognizes both the adverse effects of unrestricted continued examination practice, and the appropriate uses of continued examination filings. The Office has sought to draw a reasonable balance in order not to discourage appropriate uses of continued examination filings while providing a regulatory setting in which unnecessary prolongation of proceedings can be avoided. The changes being adopted in this final rule are appropriately tailored to permit applicants to file the initial application, two continuation or continuation-in-part applications, and a request for continued examination in any one of these three applications without any justification. An applicant who considers this to be insufficient may file any additional continuation or continuation-in-part application or request for continued examination with a petition and showing as to why the amendment, argument, or evidence sought to be entered could not have been submitted earlier. The changes in this final rule will also permit the Office to focus its limited resources on examination of new applications in order to reduce the backlog of unexamined applications.

Comment 42: One comment argued that the Office's assertion that multiple patents tend to defeat the public notice function of patent claims does not justify the rule changes because the restriction practice tends to increase the number of patents. One comment argued that the Office is making unsupported assumptions that: (1) The possible issuance of multiple patents

arising from continuing applications tends to defeat the public notice function of patent claims; and (2) the public is left uncertain as to what a set of patents resulting from the initial application will cover when multiple applications with patentably indistinct claims are filed.

Response: Restriction practice encourages applicant to file a single application for each patentably distinct invention. The public notice function of patent claims is undermined, however, when multiple patents together claim only one patentable invention (*i.e.*, the patents contain patentably indistinct claims). In such case, applicant should file a single application claiming one patentable invention rather than multiple applications claiming the same patentable invention. The Office is not making unsupported assumptions that the possible issuance of multiple patents arising from continuing applications tends to defeat the public notice function of patent claims, and that the public is left uncertain as to what a set of patents resulting from the initial application will cover when multiple applications with patentably indistinct claims are filed. *See, e.g., To Promote Innovation: The Proper Balance of Competition and Intellectual Property Law and Policy*, Ch. 4 at 26–31 (Federal Trade Commission 2003); Lemley and Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. Rev. at 100 (eliminating continuing application practice would be consistent with the policy goal of giving adequate notice about what is and is not covered by a patent).

Comment 43: Several comments predicted that the rule changes would discourage public disclosure of technology, thereby hurting industrial growth and innovation. Several comments argued that by limiting an applicant's ability to claim everything that is disclosed in the application, the rule changes would cause the applicant to submit more narrow disclosures to avoid inadvertent dedication of the subject matter to the public (citing *Johnson & Johnston Associates, Inc. v. R.E. Service Co.*, 304 F.2d 1235, 62 U.S.P.Q.2d 1225 (Fed. Cir. 2002) (*en banc*)). Several comments noted that the rule changes would force applicants to delay filing until all foreseeable information has been obtained or forego continuation-in-part filings that contain additional information. Several comments stated that small entities that have limited resources would not disclose alternative embodiments or would file applications with narrow disclosures to avoid restriction requirements. Several comments

averred that inventors would delay the filing of applications until after clinical or market testing is concluded, a potentially commercially viable product is identified, or other refining of the invention is completed. The comments also predicted that some inventors would keep the invention secret from the public and/or limit the scope of the disclosure to avoid dedicating potentially commercial embodiments to the public. One comment argued that the Office is making an unsupported assumption that continuing applications and multiple applications containing patentably indistinct claims impose a burden on innovation. One comment argued that applicants would file multiple applications having divergent subject matter rather than a single application and applicants would omit certain concepts from the applications. One comment stated that the prior art complications caused by the inability to claim priority of an earlier filed application through intermediate applications would severely curb disclosure because applicants would avoid creating their own prior art under 35 U.S.C. 102(b) on a possible important commercial embodiment. One comment stated that the current continued examination practice encourages early disclosure of multiple embodiments of inventions developed through the iterative design process. One comment stated that large applications that disclose everything are good and advance the Office's mission. One comment argued that the proposed rule changes to the examination of claims will force applicants to file applications that incorporate secondary features into their own separately filed application. One comment argued that the new rules would result in omnibus filings on anything and everything.

Response: The Office has made modifications to the proposed rules concerning both continuing applications and examination of claims practices. First, this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Second, this final rule permits applicants to present more than five independent claims or more than twenty-five total claims in an application if applicant files an examination support document before the first Office action on the merits of the application. Taken together, the changes to continuing application and examination of claims practices adopted in this final rule permit applicant to file as many claims as desired in one

application and give applicant sufficient opportunity to seek appropriate protection for the disclosed invention. Accordingly, the changes being adopted in this final rule do not place a *per se* limit on the number of claims presented in an application, nor do they place a *per se* limit on the number of continuing applications and requests for continued examination available in an application family. The changes being adopted in this final rule likewise do not give any advantage to those applicants who file multiple applications that contain patentably indistinct claims because such applicants would be required to identify the multiple applications that contain patentably indistinct claims. *See* §§ 1.75(b) and 1.78(f).

The changes adopted in this final rule will not discourage applicants from filing patent applications because the substantive criteria for entitlement to a patent (exclusive rights) have not changed. Whether applicants file narrow or broad disclosures, the changes in this final rule will reduce uncertainty with respect to what the applicant is claiming as the invention. The Office also does not expect applicants to delay the filing of an application because any commercial activities and public disclosures that occurred more than one year prior to the filing of an application would still be considered prior art under 35 U.S.C. 102(b). The changes being adopted in this final rule simply require applicants to prosecute their applications diligently and submit amendments, argument, and evidence early in the prosecution of the initial application, two continuing applications and a request for continued examination. As previously discussed, applicant has sufficient time to determine whether to file a divisional application. If applicant needs more time to determine which aspect of the invention to seek protection for, applicant may file a request for deferral of examination under § 1.103(d).

Comment 44: Several comments alleged that the rule changes would have a significant adverse impact on applicants if the first-to-file system is adopted because applicants would need to file more continuing applications to protect their inventions because applicants would need to file as soon as possible with broadly conceptualized disclosures and subsequently file continuing applications (*e.g.*, continuation-in-part applications) on the improvement or detailed embodiments.

Response: The United States currently does not have a "first inventor-to-file"

standard. Other countries that have a "first inventor-to-file" standard have less flexible continued examination practice than the United States. For example, the Japan Patent Office does not permit continuation-in-part applications. Under the JPO practice, applicant may only submit an application on an improvement as a new application. The Office will continue to consider the issues related to the "first-to-invent" standard and the "first inventor-to-file" standard in determining the rights to a patent in the context of international harmonization efforts.

Comment 45: A number of comments argued that the rule changes would disproportionately impact small entities including universities, start-up companies, biotechnology companies, and public health industry because they are more likely to file continuing applications and requests for continued examination and have less resources. The comments provided the following reasons: (1) The proposed rule would require significant expenses early in the prosecution of the application that would cause small entities and independent inventors economic hardship; (2) the rule changes would encourage large companies that have more financial resources to "steal" inventions from the small entities because the increased cost of obtaining patent protection would prevent small entities from obtaining full protection of their inventions and cause many small entities not to seek patent protection; (3) small entities need the flexibility to respond to changing conditions by refining claims and they cannot afford up-front parallel filings as large companies can; (4) independent inventors and small entities need the ability to file multiple continued examination filings to spread the costs; (5) the rule changes could stifle the building of patent portfolios for small companies and cause a reduction of capital investment in these companies and in new technologies; (6) applicants should be permitted to get a patent on the allowed claims and then continue to prosecute the broader or rejected claims or to claim subject matter not previously claimed in a continuing application, in order to bring technologies to the market sooner, which would permit small entities to attract investors and obtain financing for further product development and patent prosecutions; (7) continued examination filings are more likely needed in complex fields like biotechnology because examiners are less likely to comprehend the invention fully in the limited time

allotted for the initial search and examination and more likely to make restriction requirements, and applicants need additional opportunities to address technical issues arising during prosecution and submit evidence and clinical testing data; (8) companies in the life sciences need continued examination filings to obtain multiple patents that protect innovations and improvements that arise over the long time period of research and development, clinical testing, and the Food and Drug Administration (FDA) approval process; (9) in biotechnology, applicants may not know at the time of filing which embodiments of the invention have commercial value or how a competitor may attempt to copy the invention or circumvent the patent. One comment that supports the rule changes noted that large entities also operate within limited filing budgets, and the effects of the rules will apply across the board because any applicant must decide what level of filing activity it can reasonably afford, and make filing decisions accordingly. The comment further stated that small entities already receive a fifty percent discount on fees and can take advantage of inexpensive provisional applications to delay paying filing fees. Several comments argued that the rule changes will disproportionately impact small entities and that the Office obscures this fact by including requests for continued examination into the analysis. The comments stated that: 32 percent of patents to the top nineteen universities are continuation or continuation-in-part applications; 35.2 percent of first continuations and continuation-in-part applications are filed by small entities; and 37.9 percent of second continuations and continuation-in-part applications are filed by small entities.

Response: The Office notes the concerns expressed in the public comment particularly by small entities regarding the proposed changes to §§ 1.78(d)(1) and 1.114 that would have permitted an applicant to file only one of the following: A continuation application, a continuation-in-part application, or a request for continued examination, without any justification. The Office has made modifications to these proposed changes such that this final rule will permit an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Under this final rule, an applicant may file a divisional application directed to a non-elected invention if the prior-filed

application is subject to a requirement for restriction. The divisional application need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. This final rule also permits applicant to file two continuation applications of a divisional application plus a request for continuation examination in the divisional application family, without any justification. Applicant may also file any third or subsequent continuation or continuation-in-part application, or any second or subsequent request for continued examination in an application family, with a petition and showing. Therefore, applicants should have sufficient time to determine whether to seek protection for a particular aspect of an invention and should have sufficient opportunities to present claims, amendments and evidence for that aspect. For example, applicant is permitted to obtain a patent on the allowed claims from the initial application, and then continue to prosecute the broader or rejected claims in two continuation or continuation-in-part applications, and one request for continued examination without justification. Beyond those filings, applicant may seek a third or subsequent continuation or continuation-in-part application and a second or subsequent request for continued examination with a petition and showing. As previously discussed, the changes being adopted in this final rule do not give any advantage to those applicants who file multiple parallel applications containing patentably indistinct claims. See §§ 1.75(b)(4) and 1.78(f).

Applicant should also have sufficient opportunities to spread the cost of prosecution. Applicant has a one-year grace period under 35 U.S.C. 102(b) before filing a patent application to test the market or obtain capital resources. Before the end of the one-year grace period, applicant may file a provisional application to obtain a U.S. filing date and wait up to twelve additional months to file an initial nonprovisional application. During this two-year time period, applicants may determine the commercial value of each aspect of the invention before filing the initial nonprovisional application. Applicant may also request a deferral of examination under § 1.103(d) and defer the examination up to three years from the earliest filing date claimed (e.g., the filing date of the provisional application). See § 1.103(d). By

requesting a deferral of examination, applicant would have even more time to determine the commercial value of the invention or obtain capital resources and would avoid the cost of filing and prosecuting multiple continued examination filings. Furthermore, divisional applications need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met.

The changes being adopted in this final rule do not disproportionately impact small entities. The Office estimates that the change would have required such a petition and showing in only 2.9 percent of the 112,210 small entity applications and requests for continued examination filed in fiscal year 2006. The Office included the number of requests for continued examination into the analysis because requests for continued examination divert the Office's patent examining resources from the examination of new applications and contribute to the increasing backlog of unexamined applications, just like continuation and continuation-in-part applications.

The Office notes that, during fiscal year 2006, it appears that the percentage of small entity continued examination filings that would have required a petition is slightly higher than the percentage of total continued examination filings that would have required a petition (2.9 percent small entity as opposed to 2.7 percent for all applicants). The Office also notes that, during fiscal year 2006, it appears that the percentage of small entity applications that exceeded the five independent claims and twenty-five total claim threshold is also slightly higher than the percentage of total applications that exceeded the five independent claim and twenty-five total claim threshold (24.4 as opposed to 23.7). These percentages are based upon data that is available in the Office's PALM system for applications filed during the most recent fiscal year. The Office does not think these slight differences establish that the changes in this final rule will have a disproportionate economic impact on small entities since these differences are within the margin of error. In addition, the comments provide no reason, and there is no apparent one for why small entity applicants would inherently require more continued examination filings to prosecute the applications to completion or more claims to adequately cover their inventions. Thus, even higher differences in these percentages could easily be explained by the fact that small entity applicants

pay only one-half of the fees that other applicants pay for continuing applications, requests for continued examination, and excess claims.

Comment 46: A number of comments predicted the rule changes would limit applicants' opportunities to present claims, which would reduce the scope of the patent claims because applicants would be pressured to pursue and accept narrower claims. The comments argued that inventors would not be able to adequately protect their inventions and would in turn lose patent protection to certain aspects of their inventions, which would have an adverse impact on the value of patents, patent quality, innovations, research and development, the competitiveness of U.S. companies, and the U.S. economy and would eliminate U.S. jobs. The comments provided the following reasons: (1) The Office has not appropriately addressed applicants' interests in maximizing patent protection and receiving a fair consideration of all claims submitted; (2) the rule changes would require applicants to claim all aspects of the disclosed invention initially, even though applicants often file applications without knowing the value of their inventions in order to determine which embodiment will have value and be worthy of the investment in patent protection; (3) applicants would not be able to identify and address all claim permutations in the initial application and one continuation application, and complex inventions often need more claims and more than one continuation application to protect the invention; (4) the Office should provide applicants the flexibility to prosecute different embodiments at a later time; (5) the applicant should be permitted to present claims (or change the scope of the claims) in continuing applications to cover an embodiment of the invention disclosed in the initial application when the applicant later determines the commercial value of the embodiment, develops the actual product, or discovers a potential infringer's product; (6) competitors could easily circumvent the patent claims because applicant would not have the ability to change the scope of the claims to cover the competitor's product in a continuing application; (7) in view of the courts' restrictive claim interpretation, the required showing under §§ 1.78(d)(1) and 1.114 would eliminate a vast number of legitimate continuing applications and requests for continued examination needed to provide coverage of alternate aspects of an invention.

Response: This final rule does not place any *per se* limits on the number of continued examination filings that

may be filed or on the number of claims an applicant may present in an application. Applicant is permitted to submit all of the claims that applicant desires during the prosecution of the initial application, two continuation or continuation-in-part 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 sought to be entered could not have been submitted earlier. For most applicants who prosecute their applications diligently, additional continued examination filings would not be needed. Applicant may also file a reissue application under 35 U.S.C. 251, if appropriate, to submit claims with different scope. Further, the use of continuation practice to circumvent statutory requirements for reissue and reexamination proceedings is not appropriate. In addition, the rules require an applicant to advance prosecution and not waste the Office's resources examining an application when the applicant is not ready to particularly point out and distinctly claim the subject matter which the applicant regards as his or her invention. *See also* § 10.18(b)(2)(i) and *Hyatt v. Dudas*, 2007 U.S. App. LEXIS 15350 (Fed. Cir. Jun. 28, 2007). Applicant should not use continued examination practice to delay the prosecution of the application because this adversely impacts the Office's ability to examine new applications and reduce the backlog of unexamined applications.

Comment 47: One comment predicted that the rule changes would discourage first action allowances because some applicants would intentionally file applications with at least one defect in order to receive a rejection to drag out pendency so that they can have more time to determine whether to file continuing applications.

Response: There is no reason why the new changes being adopted in this final rule will encourage an applicant to intentionally file an application with at least one defect to delay prosecution. Additionally, such an action by an applicant would violate § 10.18(b)(2)(i). By presenting to the Office any paper (including an application), the applicant is certifying that to the best of the applicant's knowledge, information and belief, formed after an inquiry reasonable under the circumstances, that the paper is not being presented to cause unnecessary delay or needless

increase in the cost of prosecution before the Office.

Comment 48: One comment sought clarification as to whether an applicant is permitted to amend the claims and/or file a continuation application to claim allowable subject matter presented in dependent claims.

Response: Applicant may amend the claims of an initial application to claim allowable subject matter presented in dependent claims if the amendment complies with the rules of practice (e.g., § 1.116). For example, applicant may submit such an amendment in the initial application in response to a non-final Office action in the initial application. Such an amendment, however, will not be entered in the initial application as a matter of right after a final Office action. Under this final rule, applicant alternatively may file two continuation or continuation-in-part applications plus one request for continued examination in an application family, without any justification and pursue the amendment in one of those two applications or in the request for continued examination.

Comment 49: Several comments argued that the combined effect of the limit on the number of representative claims and the limit on the number of continuing applications and requests for continued examination as a matter of right would increase the number of multiple parallel applications and divisional applications because applicants would file more multiple parallel applications with small numbers of claims or present claim sets that would provoke restriction requirements. Either way, the comments contended that the backlog will increase. One comment further alleged that applicants would file more continued examination filings and appeals because by limiting the number of claims examined, two Office actions would be insufficient, thus resulting in an increase in pendency and cost. One comment argued that the rule changes would disproportionately impact inventions that require more claims, continuing applications, or examiner time. One comment stated that the limitations on continued examination filings and claims would cause more litigation because they would create more uncertainty in infringement and validity.

Response: As discussed previously, the Office is not adopting the "representative claims" examination approach or restricting the number of continued examination filings to one without any justification. Rather, this final rule permits applicant to present more than five independent claims or

more than twenty total claims in an application if applicant files an examination support document. Applicant is also permitted to file two continuation or continuation-in-part applications, plus a request for continued examination in an application family, without any justification. The changes being adopted in this final rule do not place *per se* limits on the number of claims which applicant may present in an application or on the number of continued examination filings. The changes being adopted in this final rule do not encourage applicant to file multiple parallel applications that contain patentably indistinct claims. See §§ 1.75(b)(4) and 1.78(f). Applicants would obtain little benefit from filing multiple applications that contain patentably indistinct claims because the Office would treat each application as having the total of all of the claims (whether in independent or dependent form) in all such applications for purposes of determining whether an examination support document is required by § 1.75(b)(1) (but not for purposes of calculating the excess claims fee due in each application). Likewise, this final rule will not cause the number of divisional applications to increase because this final rule permits divisional applications to be filed serially. Therefore, applicant should have sufficient time to determine whether to file a divisional application to claim a non-elected invention.

Comment 50: A few comments suggested that the limits set in §§ 1.75(b)(4) and 1.78(d)(1) are inconsistent with interference practice under 35 U.S.C. 135 of copying claims for purposes of preserving the right to provoke an interference. One comment suggested that the changes to § 1.78 eliminates an applicant's right to add claims to an application to cover a similar or parallel technology, provided that the added claims find support in the specification, citing *PIN/NIP, Inc., v. Platt Chemical Co.*, 304 F.3d 1235, 1247, 64 U.S.P.Q.2d 1344, 1352 (Fed. Cir. 2002). One comment stated that subjecting patentably indistinct claims in multiple commonly owned applications to elimination under § 1.78(f)(3) violates case law, for example *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874, 9 U.S.P.Q.2d 1384, 1390 (Fed. Cir. 1988).

Response: The Office has modified proposed § 1.75(b)(4) and § 1.78(d)(1). This final rule permits an applicant to file two continuation or continuation-in-part applications plus one request for continued examination in an

application family, without any justification. Applicant may also file a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination with a petition and showing. This final rule permits applicant to present up to five independent claims or twenty-five total claims in each application, without an explanation. Applicant may also present more than five independent claims and more than twenty-five total claims if applicant files an examination support document before the first Office action on the merits of the application. Applicant may file as many claims as necessary to claim the full scope of his or her invention. This final rule provides sufficient opportunities for applicant to present claims to provoke an interference during the prosecution of these applications. Therefore, the changes to §§ 1.75(b)(4) and 1.78(d)(1) being adopted in this final rule are not inconsistent with 35 U.S.C. 135. Furthermore, applicant may also file a reissue application under 35 U.S.C. 251, if appropriate, to submit claims for provoking an interference. In other situations, however, applicant is not permitted to maintain an application in pending status, without advancing prosecution, for the sole purpose of awaiting developments in similar or parallel technology. As previously discussed, such practice does not advance prosecution before the Office and impairs the ability of the Office to examine new and existing applications.

In other situations, however, applicant is not permitted to maintain an application in pending status, without advancing prosecution, for the sole purpose of awaiting developments in similar or parallel technology. As previously discussed, such practice does not advance prosecution before the Office and impairs the ability of the Office to examine new and existing applications.

The Federal Circuit noted in *PIN/NIP* that one may amend an application for the purpose of encompassing devices or processes of others, subject to compliance with the requirements of the patent statute and regulations (the claim at issue was determined to be invalid under 35 U.S.C. 112, ¶ 1, for lack of written description support). See *PIN/NIP*, 304 F.3d at 1247, 64 U.S.P.Q.2d at 1352. As such, *PIN/NIP* cannot be relied upon to support a "wait and see" concept under which an applicant files an initial application followed by a stream of continuation applications just to wait for any competitor to develop and market an invention not claimed in the initial application. *PIN/NIP*, 304

F.3d at 1247, 64 U.S.P.Q.2d at 1352. Further, in *Kingsdown*, the Federal Circuit opined: "Nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application. Any such amendment or insertion must comply with all statutes and regulations, of course, but, if it does, its genesis in the marketplace is simply irrelevant." *Kingsdown*, 863 F.2d at 874, 9 U.S.P.Q.2d at 130. This statement does not equate to a pronouncement that an applicant has a "right" under the patent statutes to file a continuous stream of continuing applications to ensure that there is always a pending application in which to present claims encompassing devices or processes of others.

Further continuation practice is not intended to supplant or permit circumvention of reissue practice. The patent statute at 35 U.S.C. chapter 25 provides for the correction of patents, and specifically provides for the reissue of a patent in those situations in which a "patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of * * * the patentee claiming more or less than he had a right to claim in the patent." See 35 U.S.C. 251. See also *Toro Co. v. White Consol. Indus.*, 383 F.3d 1326, 1333, 72 U.S.P.Q.2d 1449, 1454 (Fed. Cir. 2004) (citing *Johnson & Johnston*, 304 F.2d at 1055, 62 U.S.P.Q.2d at 1231). Nothing, however, suggests that an applicant has a "right" under the patent statutes to file a continuing application to avoid the requirements of the reissue statute when seeking to correct or enlarge the scope of a patent. There is a difference between adding claims to an application that are otherwise pending, and deliberately prolonging prosecution in order to be able to do so. Deliberately prolonging a proceeding before the Office would not be consistent with the requirements of § 10.18.

Applicant may copy claims from another application or patent that is not commonly owned for the purposes of provoking an interference, without triggering § 1.78(f)(3). Section 1.78(f)(3) applies only to multiple commonly owned applications that contain patentably indistinct claims. Section 1.78(f)(3) is a restatement of former § 1.78(b), which previously gave the Office the same discretion to require elimination of patentably indistinct claims in all but one of the pending nonprovisional applications. The Office is not preventing applicants from providing such patentably indistinct claims in a single application, or in

multiple applications if applicant submits a terminal disclaimer in accordance with § 1.321(c) and explains why submitting patentably indistinct claims in separate applications is necessary.

Comment 51: Several comments suggested that if the Office implements the limits on continued examination filings, the limits on the number of claims would be unnecessary.

Response: The comment provides no explanation as to how or why implementation of the continued examination filing changes would make the claims provisions unnecessary. The Office determined that the implementation of the changes to the continued examination practice and practice for examination of claims in patent applications are necessary to achieve quality and efficiency in the patent examination process.

Comment 52: A number of comments argued that applicants should be permitted to file more than one continuation or continuation-in-part application or request for continued examination as a matter of right because there are many legitimate reasons for the filings. The comments provided the following examples: (1) The process of developing the best prior art and obtaining the broadest possible protection is a complex process and may extend the prosecution process; (2) applicants may use strategies that would avoid prosecution history estoppel and preserve doctrine of equivalents protection; (3) applicants may maintain a continuing application so that they could respond to any adverse court decisions and associated uncertainties; (4) the quality of the examination process may cause delays; (5) examiners would allow broader claims in a continuation application after becoming more familiar with the subject matter and have more time to improve the search and analysis; (6) applicants may maintain a continuing application pending to prevent competitors from copying the invention or circumventing the initial patent claims because the courts are less inclined to interpret the scope of invention beyond the literal meaning of the claims, precluding claim scope that once was captured under the doctrine of equivalents; (7) applicants may file continuation applications as an "insurance policy" so that applicants can correct any defects found in the first patent or adjust the claim coverage without surrendering the patent (as in the reissue and reexamination practices); (8) applicants may file continuing applications to build large patent portfolios and attract capital investments; (9) applicants want time to

conduct testing and to reevaluate the claim scope in light of new prior art, market experience, and technology development; (10) for complex technologies, it may take several prosecutions to determine the bounds of patentable subject matter; (11) applicants may want many patents on an invention to strengthen the protection; (12) applicants may file continuing applications to correct errors in the initial prosecution including those made by inexperienced representatives or applicants; and (13) applicants who are in a crowded or highly valuable field need to keep a continuing application pending for the purposes of provoking interference.

Response: The Office recognizes that there are some appropriate reasons for filing multiple continuing applications and requests for continued examination. There are, however, a number of reasons given for multiple continuing applications and requests for continued examination that are not considered appropriate. The changes being adopted in this final rule are tailored to permit applicants to file the initial application, two continuation or continuation-in-part applications, and a request for continued examination in an application family, without any justification. Any applicant who considers this to be insufficient may file an additional continuation or continuation-in-part application or a request for continued examination with a petition showing why the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior filings. Applicants are required to prosecute diligently and to particularly point out and distinctly claim the subject matter which the applicant regards as his or her invention, upon filing the application. If applicant's lack of knowledge of prior art, or lack of diligence during the prosecution of the application, causes unnecessary delay or needless increase in the cost of prosecution before the Office, applicant would be violating his or her duty under § 10.18. See § 10.18(b)(2)(i).

Comment 53: A number of comments argued that many continuing applications and requests for continued examination are caused by inadequate examinations, the final Office action practice, and the examiner production system. The comments provided the following examples: (1) It may take several exchanges between the examiner and applicant before the examiner appears to understand the invention; (2) examiners' lack of experience in the art and patent law; (3) some examiners have difficulty using the English

language in oral and written communications; (4) the Office has large turnover in examining personnel; (5) examiners make too many restriction requirements; (6) examiners want to obtain additional "counts"; (7) examiners make improper rejections; (8) examiners refuse to enter any after-final replies; (9) examiners are not given sufficient time to conduct a proper search and examination in the initial application; (10) examiners did not read the specification and claims; (11) examiners do not adequately consider arguments made by the applicants; (12) examiners make premature final rejections; (13) examiners conduct piecemeal examination; (14) examiners are being overturned by supervisors or quality control; (15) examiners do not indicate allowable claims; (16) examiners do not set forth the rejections clearly in the Office actions; (17) examiners do not apply legal standards consistently; and (18) examiners make new grounds of rejection or cite new art in final Office actions.

Response: The Office provides applicant with procedures to address inadequate examination issues. Applicant should not use the continued examination practice as a substitute for the petition or appeal process. The practice of permitting an unlimited number of continuing applications and requests for continued examination appears to have created lax practices. Applicants should raise any issue of inadequate examination before the examiner and/or the examiner's supervisor. For example, applicants should raise any question as to prematurity of a final rejection before the primary examiner. Applicant may seek review of the examiner's decision on the finality of the Office action by petition under § 1.181, if appropriate. See MPEP §§ 706.07(c) and 1002.02(c). Restriction requirements are also reviewable by petition under § 1.181. Applicants may request an interview with the examiner to ensure that the examiner understands the invention or claims correctly, or to seek clarification of the rejections or Office action. See § 1.133(a)(2). If applicant disagrees with the examiner's rejections, applicant may appeal the rejections to the BPAI and/or request a pre-appeal brief conference, if appropriate.

Comment 54: A number of comments argued that filing continuing applications and requests for continued examination is more efficient and cost-effective in dealing with deficiencies of the examination process (even before a "stubborn examiner") because the factual record is fixed on appeal and the appeal process takes a longer time and

is expensive, especially for independent inventors and small entities. The comments predicted that the rule changes would increase the number of pre-appeal brief conferences, examiner's answers and appeals, and force applicants to appeal applications that are not in condition for appeal (e.g., the record has not been fully developed and unamended claims may be appealed). Several comments pointed out that continuing applications and requests for continued examination help applicants to place the application in better condition for appeal because most examiners refuse to enter the after-final amendments. One comment stated that some applicants might file the appeal simply to preserve pendency. Some of the comments suggested that the Office should wait and see what effect a quicker appeal process would have on the backlog before implementing the rule changes. The comments stated that once applicants appreciate the appeal process changes, more applicants would file appeals rather than continuing applications and requests for continued examination. Furthermore, the comments noted that a study conducted by a firm shows that out of 121 appeal briefs (appeals from January 1, 2004 to March 23, 2006), examiners issued only nine answers, which represents an enormous waste of applicants' time and money. One comment predicted that the BPAI would be quickly overwhelmed and a broken appeal process would create more damage to the examination process than the current problems.

Response: If applicant disagrees with the examiner's rejections, applicants should file an appeal rather than filing a continuation application or a request for continued examination. The appeal process offers a more effective resolution than the filing of a continuation application or a request for continued examination. The pre-appeal brief conference program provides applicant a relatively expeditious and low cost review of rejections by a panel of examiners. If, after the conference, the prosecution is reopened, the applicant will have a further opportunity to prosecute in front of the examiner. Applicant would not need to file an appeal brief. If the Office decides that the application should remain under appeal, it would be more efficient to appeal the rejection to the BPAI by filing an appeal brief rather than delay the appeal by filing a continuation application or a request for continued examination. Furthermore, the pendency of an appeal is relatively short. The current (as of the end of the second quarter of fiscal year 2007)

pendency of a decided appeal was 5.6 months. The pendency of an appeal is the period between the assignment of an appeal number and the mailing date of the decision. In addition, the BPAI has reduced the inventory of pending appeals from 9,201 at the close of fiscal year 1997 to 1,357 at the close of fiscal year 2006. Nevertheless, continuing applications and requests for continued examination as a percentage of total filings have increased as BPAI appeal pendency and inventory of pending appeals has decreased. Applicants should have sufficient opportunity to place the application in condition for appeal during the prosecution of the initial application, two continuing applications, and one request for continued examination in an application family. An applicant who considers this to be insufficient may file any third or subsequent continuation or continuation-in-part applications or second or subsequent requests for continued examination with a petition showing why the amendment, argument, or evidence sought to be entered could not have been previously submitted.

Comment 55: Several comments alleged that the Office has provided no evidence for the assertion that the exchange between applicants and examiners becomes less beneficial and suffers from diminished returns after the initial application. A number of comments also argued that the Office did not provide any investigation or analysis of the frequency with which the value of exchanges between the examiner and applicant decrease after the first continuing application or request for continued examination. A number of comments suggested that continuing applications and requests for continued examination permit additional mutually beneficial interaction between the examiner and applicant because: (1) The examiner and applicant already are familiar with the issues in the prosecution; (2) they give the examiner more time to examine the same subject matter and gain better understanding of the prior art; and (3) they permit applicants multiple opportunities to refine the claims and present additional data or evidence which would result in better quality patents with valid claims and clearly defined subject matter. Several comments argued that the rule changes would not improve public notice and the exchanges between the examiner and applicant because applicants would file multiple parallel applications rather than one single application and the applications would be assigned to