

EXHIBIT 1

PART 4

different examiners. Several comments argued that the exchanges between the examiner and applicant would be less efficient and more contentious because applicants would present broader claims and argue rejections more aggressively resulting in higher pendency. Several comments also predicted that applicant would request more interviews which would be more work for both the examiner and applicant. Several comments argued that it is unclear how the exchange between examiners and applicants will be more efficient because there is nothing in the proposal to encourage examiners to be more reasonable and appeals are not more efficient. One comment also argued that the Office is making unexplained assumptions that: (1) The value of a continuing application or a request for continued examination is less than the value of a new application; (2) the changes to continuing applications practice being adopted in this final rule should improve the quality of issued patents, making them easier to evaluate, enforce, and litigate; (3) this small minority of applicants prejudices the public permitting applicants to keep applications in pending status while awaiting developments in similar or parallel technology and then later amending the pending application to cover the developments; and (4) the changes being adopted in this final rule will result in claims issuing faster.

Response: Under this final rule, applicant is permitted to file two continuation or continuation-in-part applications plus one request for continued examination in an application family. These filings will provide sufficient opportunities for applicants to submit amendments, arguments, and evidence. Furthermore, the exchange between applicant and the examiner will be more efficient because applicant can no longer delay the submissions of amendments, argument, and evidence and the examiner will have the information earlier to determine the patentability of the claims. In addition, even if one could argue that additional continuing applications and requests for continued examination are beneficial in the particular application, the marginal value of a third or subsequent continuing application or a second or subsequent request for continued examination vis-à-vis the patent examination process decreases due to the Office resources occupied by the additional continued examination filings for amendments, argument, and evidence that could have been

presented earlier. Nevertheless, an applicant can show on petition that an additional filing is necessary. Finally, the changes being adopted in this final rule require applicant to submit all of the claims that are patentably indistinct in one single application and to identify multiple applications that contain patentably indistinct claims. See §§ 1.75(b) and 1.78(f).

Comment 56: One comment argued that the Office should not impose a limit on the number of continuing applications an applicant may file when the Office can issue any number of rejections and improper final rejections.

Response: In this final rule, the Office has not placed an absolute limit on the number of continued examination filings. Rather, applicant is permitted to file the initial application, two continuing applications, and a request for continued examination in an application family, without any justification, and any third or subsequent continuing application or second or subsequent request for continued examination with a petition and a showing as why the amendment, argument, or evidence sought to be entered could not have been submitted earlier. Applicant may seek review of any improper finality of a rejection by filing a petition under § 1.181, or of any improper rejection by filing a notice of appeal, a request for pre-appeal brief conference, and an appeal brief.

Comment 57: Several comments argued that examiners will have to review larger submissions because applicants will be forced to front-load responses to every Office action with interviews, declarations and other evidence when the attorney's argument alone otherwise might have been sufficient. The comments argued that this would increase pendency. One comment predicted that the rule changes would decrease examiners' production because there would be "more hard cases" and "less easy counts." Several comments stated that the rule changes would require applicant to respond to a first Office action by preparing what would be a *de facto* appeal brief with all of the arguments and evidence because applicant would only file the one permissible continuation or continuation-in-part application or request for continued examination as a last resort after appeal.

Response: Section 1.78 as adopted in this final rule permits an applicant to file two continuing applications plus one request for continued examination in an application family, without any justification. Thus, the changes adopted in this final rule do not require

applicant to respond to a first Office action by preparing what would be a *de facto* appeal brief with all of the arguments and evidence. Nevertheless, the examination will be more efficient when applicant submits a fully responsive reply to each Office action so that the examiner will have the information, including amendments, arguments, and evidence, to determine the patentability sooner rather than later. Even prior to the changes being adopted in this final rule, applicants have been required to file a fully responsive reply to an Office action. See §§ 1.111(b) and (c). A change to the rules of practice that encourages applicants to submit complete, rather than piecemeal, replies will advance prosecution to final disposition with a minimum number of Office actions, continuing applications, and requests for continued examination. Such change streamlines the examination process, thereby benefiting both applicants and the Office.

Comment 58: A number of comments argued that continuation or continuation-in-part applications and requests for continued examination are needed so that applicants can submit prior art that is discovered after the prosecution is closed (e.g., through international search reports or foreign search reports), and amend the claims in view of late newly-discovered art. Several comments suggested that the Office should permit applicants to file a request for continued examination without a petition and showing to submit newly discovered prior art, and art cited by the U.S. International Searching Authority similar to art cited by a foreign patent office, because otherwise applicants would be penalized due to PCT administrative backlogs. One comment sought clarification in the situation where an applicant wishes to withdraw an application from issue to submit new art for consideration and a continuation application has been filed.

Response: Applicant is not required to file a continuation or continuation-in-part application or a request for continued examination in order to submit prior art discovered after the prosecution is closed or an amendment in view of the late discovered art. The Office recently proposed changes to information disclosure statement (IDS) requirements. See *Changes To Information Disclosure Statement Requirements and Other Related Matters*, 71 FR 38808 (July 10, 2006), 1309 *Off. Gaz. Pat. Office* 25 (Aug. 1, 2006) (proposed rule) (hereinafter "Information Disclosure Statement Proposed Rule"). The proposed changes

(if adopted) would permit applicant to submit an IDS after a first Office action on the merits, but before the mailing date of a notice of allowability or a notice of allowance under § 1.311, if applicant files the IDS with the certification under § 1.97(e)(1) and a copy of the foreign search report, or an explanation under proposed § 1.98(a)(3)(iv) and a non-cumulative description under proposed § 1.98(a)(3)(v). Applicant would also be permitted to submit an IDS after allowance, but before the payment of the issue fee, if applicant files the IDS with a patentability justification under proposed § 1.98(a)(3)(vi), including any appropriate amendments to the claims. Applicant would be permitted to submit an IDS after the payment of the issue fee if applicant files a petition to withdraw from issue pursuant to § 1.313(c)(1), the patentability justification under proposed § 1.98(a)(3)(vi)(B), and an amendment to the claims. Prior to the effective date of any final rule based upon the Information Disclosure Statement Proposed Rule, applicant may submit an IDS after the close of prosecution with a petition under § 1.183 if the IDS complies with the applicable requirements set forth in the Information Disclosure Statement Proposed Rule for such an IDS.

B. Treatment of Third and Subsequent Continuation or Continuation-In-Part Applications

Comment 59: Several comments supported the rule changes that permit one continued examination filing without any justification. A number of comments, however, suggested that the Office should permit more than one continued examination filing without requiring a petition and showing. The comments suggested the following without a petition and showing: (1) At least two continuation or continuation-in-part applications; (2) at least three continuation or continuation-in-part applications; (3) three to six continued examination filings; (4) three to five applications per application family; (5) only one patent to be issued from a chain of continuation applications; (6) unlimited number of continuation applications coupled with a requirement for a patentability report in the third or subsequent continuation application or a prior art search and compliance with the requirements under 35 U.S.C. 112; (7) two requests for continued examination, but only one continuation or continuation-in-part application; (8) at least one request for continued examination per application; (9) more than one request for continued examination per application; and (10)

two or three requests for continued examination per application. Several comments suggested that the Office should permit more than one continuation or continuation-in-part application if the applications are filed within a reasonable time period (e.g., one to eight years from the earliest filing date claimed). One comment suggested that the Office should permit requests for continued examination filed within three years of the filing date if applicant has filed a petition to make special for accelerated examination. One comment suggested that the Office should permit applicant to file a request for continued examination, but allow the examiner to refuse the request for continued examination if the first action can be made final. One comment suggested that the Office should eliminate all continuing applications except for divisional applications. One comment proposed that the Office should eliminate all continuing applications, but permit requests for continued examination. One comment suggested that the limitation on the number of continued examination filings should not apply to divisional applications and requests for continued examination.

Response: The Office has modified the proposed provisions that permit applicant to file one continuation or continuation-in-part application or request for continued examination without any justification. Under this final rule, applicant may 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 any third or subsequent continuation or continuation-in-part application or second or subsequent request for continued examination with a petition and showing. The changes being adopted in this final rule will permit the Office to focus its patent examining resources on examining new applications, and thus reduce the backlog of unexamined applications and improve pendency for all applications. Permitting more than two continuation or continuation-in-part applications and more than one request for continued examination in an application family without any justification would significantly decrease the effectiveness of the changes being adopted in this final rule. These final rule requirements for seeking a third or subsequent continuation or continuation-in-part application will not impact the vast majority of the applications.

A time limit requirement for filing continuing applications and requests for continued examination would not be

desirable because it would encourage applicants to file an unlimited number of continued examination filings before the time period expires. Furthermore, a time limit would preclude an applicant from filing appropriate continued examination filings after the time period expires. Additionally, this suggested strategy would also disproportionately impact applications in certain technologies (e.g., biotechnology) that have long prosecutions.

Requiring a patentability report or a prior art search in a continuation application would not increase efficiency in the examination of the initial application. If applicant submits the information earlier in the initial application, applicant most likely would not need to file a third or subsequent continuing application because the examiner would have all of the relevant information to make the patentability determination in the initial application.

The Office recognizes there are appropriate reasons for filing continued examination filings. As a result, the Office did not place an absolute limit on the number of continued examination filings. If the prior-filed application was subject to a requirement for restriction, applicant may file a divisional application directed to a non-elected invention that has not been examined. 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. See § 1.78(d)(1)(ii). Therefore, the changes being adopted in this final rule appropriately balance the need to reduce the large and growing backlog of unexamined patent applications and make the patent examination process more effective.

Comment 60: Several comments expressed concerns that there would be an added economic burden on applicants, particularly small entities, to pursue additional continued examination filings due to the new petition process, and that the economic burden will effectively be a bar to many applicants. The comments stated that even when an additional continued examination filing is completely justified, applicants will suffer undue hardship and will likely be deterred from even attempting to request any additional continued examination filing because of the expense and time involved to review and prepare the petition. One comment suggested that the petition process under §§ 1.78(d)(1)(vi) and 1.114(g) will have a disparate effect on small entities. Several comments suggested that the

Office should provide an exception for filing additional continued examination filings to applicants who are small entities and those that qualify for financial hardship. One comment further suggested that the Office should provide the exception for five years.

Response: The Office notes the concerns expressed in the public comment regarding the proposed changes to §§ 1.78(d) and 1.114(g) that would permit an applicant to file one continuation application, continuation-in-part application, or request for continued examination, without any justification. The Office has made modifications to the proposed provisions 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. Under this final rule, an applicant may also file a divisional application of a prior-filed application for the claims to a non-elected invention that was not examined if the application was 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 continued examination in the divisional application family, without any justification. Applicant may file any additional continuation application or request for continued examination with a petition and showing.

The changes to §§ 1.78(d) and 1.114(g) adopted in this final rule apply to all applicants, regardless of whether they are individuals, small businesses or large multinational corporations. These changes do not disproportionately affect individuals and small businesses. Applicants who seek to file a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination are required to file a petition under § 1.78(d)(1)(vi) or 1.114(g) regardless of their status. 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 2.9 percent of the applications or requests for continued examination filed by a small entity in fiscal year 2006. The Office notes that a vast majority of applicants do not file more than two continuation or continuation-

in-part applications and more than one request for continued examination in an application family. Therefore, the \$400 petition fee and the showing requirement will impact only a small minority of applicants.

C. Treatment of Second and Subsequent Requests for Continued Examination

Comment 61: Several comments supported the changes to § 1.114. A number of comments, however, objected to the changes and suggested that the Office should permit applicants to file requests for continued examination without a petition and showing. The comments provided the following reasons: (1) Requests for continued examination are different from continuing applications because requests for continued examination require applicant to advance prosecution and would not cause the Office to issue multiple patents to the same invention; (2) requests for continued examination are not continuation applications, but rather are the same application; (3) requests for continued examination help applicants to deal with deficiencies in the examination process and provide a more efficient, effective and cheaper procedure to advance prosecution and have-art considered than the appeal, petition or reissue process; (4) limiting applicants to one request for continued examination without a petition would lead to more filings of continuation applications and petitions; (5) due to the changes in § 1.75, the Office would issue more final Office actions with new grounds of rejection, which would necessitate the filing of more requests for continued examination; and (6) applicants would file more appeals, and thus the pendency of applications would increase.

Response: The Office has modified the proposed provisions to provide that an applicant may file a request for continued examination in an application family, without a petition and showing. An application family includes the initial application and its continuation or continuation-in-part applications. Under this final rule, applicant may also file a request for continued examination in a divisional application family, without a petition and showing. A divisional application family includes the divisional application and its continuation applications. The provisions of § 1.78(d)(1) are independent of the provisions of § 1.114. Therefore, the filing of a request for continued examination does not preclude an applicant from filing two continuation or continuation-in-part applications.

Similarly, the filing of a continuation or continuation-in-part application does not preclude an applicant from filing a request for continued examination.

When applicant files a request for continued examination, the prosecution of the application is reopened and the examiner conducts another substantive examination on the claims present in the application. Consequently, similar to continuation or continuation-in-part applications, requests for continued examination divert the Office's patent examining resources from the examination of new applications and contribute to the backlog of unexamined applications. The request for continued examination practice should not be used as a substitute for the appeal, petition or reissue process. If the applicant disagrees with the examiner's rejections, then the applicant should pursue the appeal process as a means to more efficiently resolve the disagreement.

In addition, under the Office's new optional streamlined continuation procedure, an applicant may request that a continuation application be placed on an examiner's amended (Regular Amended) docket (see discussions of §§ 1.78(d)(1)(i) and 1.114) which would be picked up for action faster than an application placed on the examiner's new continuing application (New Special) docket. By requesting that the two continuation applications permitted under § 1.78(d)(1)(i) be treated under the optional streamlined continuation application procedure, an applicant may obtain the benefits of faster processing similar to having a second and third request for continued examination without a petition under § 1.114(g).

Comment 62: One comment sought clarification on whether the changes to §§ 1.78 and 1.114 being adopted in this final rule apply to reissue applications.

Response: The changes to §§ 1.78 and 1.114 being adopted in this final rule apply to reissue applications. Under this final rule, applicant may file two reissue continuation applications plus a request for continued examination in the reissue application family, without any justification. Benefit claims under 35 U.S.C. 120, 121, or 365(c) in the application for patent that is being reissued will not be taken into account in determining whether a continuing reissue application claiming the benefit under 35 U.S.C. 120, 121, or 365(c) of the reissue application satisfies one or more of the conditions set forth in §§ 1.78(d)(1)(i) through 1.78(d)(1)(vi). For example, even if the application for the original patent was a second continuation application, applicant may still file two reissue continuation

applications. However, an applicant may not use the reissue process to add to the original patent benefit claims under 35 U.S.C. 120, 121, or 365(c) that do not satisfy one or more of the conditions set forth in §§ 1.78(d)(1)(i) through 1.78(d)(1)(vi) to the original patent, if the application for the original patent was filed on or after November 1, 2007.

Comment 63: One comment suggested that the examiner should not make any new rejections in a request for continued examination, unless the amendment to the claims raises new issues.

Response: When applicant files a request for continued examination in compliance with § 1.114, the prosecution of the application is reopened and the examiner will consider the amendment, argument, or evidence submitted by the applicant. The examiner will conduct another substantive examination, consistent with providing "for the continued examination of application" under 35 U.S.C. 132(b). Limiting the examiner's ability to conduct a patentability determination after the filing of a request for continued examination would not result in efficiency in the examination process.

Comment 64: One comment argued that it would be inconsistent to permit the filing of a request for continued examination in a prior-filed application after a continuation application is filed, but to not permit the filing of a continuation application of an application that has a request for continued examination filed therein. Another comment suggested that the Office should permit an applicant to file a continuation application even though a request for continued examination had been filed in the prior-filed application.

Response: The Office has modified the proposed provisions to provide that an applicant may file a request for continued examination in an application family, without a petition and showing. The provisions of § 1.78(d)(1) are independent of the provisions of § 1.114. Therefore, the filing of a request for continued examination does not preclude an applicant from first filing two continuation or continuation-in-part applications. Likewise, the filing of a continuation or continuation-in-part application does not preclude an applicant from first filing a request for continued examination. Put differently, under this final rule, applicant may file a continuation application of an application in which a request for continued examination has already been filed. Applicant may also file a request

for continued examination in a prior-filed application after a continuation application has been filed.

D. Petitions Related to Additional Continuation Applications, Continuation-In-Part Applications, and Requests for Continued Examination

Comment 65: A number of comments were critical of the showing requirement set forth in §§ 1.78(d)(1) and 1.114. One comment argued that the required showing is a *per se* limit on the number of continuation or continuation-in-part applications and requests for continued examination. Several comments stated that the standard under §§ 1.78(d)(1) and 1.114 is a hindsight standard. The comments argued that except for rare instances when evidence was not in existence prior to filing the additional continuing examination filing, the Office could almost always conclude, in hindsight, that the amendment, argument, or evidence sought to be entered could have been previously submitted. One comment argued that the showing under §§ 1.78(d)(1) and 1.114(g) is too stringent and unrealistic given the practicalities of conventional and reasonable patent prosecution practice and the interests of patent applicants. Several other comments described the showing as exceptionally high, onerous, impossible to meet, restrictive, and ambiguous. Furthermore, several comments asserted that the rule changes required applicants to be aware of all possible prior art. Several other comments stated that the required showing set forth in §§ 1.78(d)(1) and 1.114 appears difficult to meet for any amendment submitted with an application that is not a continuation-in-part application, indicating that it is hard to imagine how one would prove that an amendment or argument "could not have been submitted" in the absence of new matter. One comment objected to the required showing under §§ 1.78(d)(1) and 1.114 because the purpose of filing an additional continuation or continuation-in-part application or a request for continued examination may be to do something other than present a new argument, evidence or amendment, such as protect a different aspect of the invention revealed by research and development subsequent to an initial application filing. One comment stated that given enough time and effort an applicant will almost always be able to come up with some reason why the amendment, argument, or evidence could not have been previously submitted as required by §§ 1.78(d)(1) and 1.114 and that this requirement merely adds a layer of

bureaucracy. One comment in support of the showing under §§ 1.78(d)(1) and 1.114 stated that it is a sensible compromise that does not ban additional continued examination filings, but requires applicants in essence to show good cause for additional continued examination filings. Several comments in support of the showing stated that the proposed rules accommodate the legitimate uses of continuations, limit abuses that can harm the competitive process, and promote the patent system's ability to provide incentives to innovate by reducing pendency.

Response: The Office notes the concerns expressed in the public comment regarding the proposed provisions that would require a petition and showing if an applicant files more than one continued examination filing (a continuation application, a continuation-in-part application, or a request for continued examination). 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. Under this final rule, an applicant may also file a divisional application of an application for the claims to a non-elected invention that was not examined if the application was 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 continued examination in the divisional application family, without any justification. Applicant may file any additional continuation application or request for continued examination with a petition and showing. Therefore, given the multiple opportunities for applicant to submit amendments, arguments, or evidence, it is appropriate to require an applicant to justify why an amendment, argument, or evidence sought to be entered could not have been submitted earlier when filing any third or subsequent continuation application, continuation-in-part application, or second or subsequent request for continued examination. The Office considers the standard set forth in §§ 1.78(d)(1)(vi) and 1.114(g) to be an appropriate balance of the interests of applicants and the need for a better

focused and effective examination process to reduce the large and growing backlog of unexamined applications.

Applicants and practitioners have a duty to refrain from submitting an application or other filing to cause unnecessary delay or needless increase in the cost of prosecution before the Office. See § 10.18(b)(2). Applicants also have a duty throughout the prosecution of an application to make a *bona fide* attempt to advance the application to final agency action. See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 49, 1302 *Off. Gaz. Pat. Office* at 1319. Applicant should be prepared to particularly point out and distinctly claim what the applicant regards as his or her invention. Furthermore, the examination process is more efficient and the quality of the patentability determination will improve when applicant presents the desired claims, amendments, arguments and evidence as early as possible in the prosecution. The changes to §§ 1.78 and 1.114 in this final rule do not require an applicant to be aware of all possible prior art to meet the showing under §§ 1.78(d)(1)(vi) and 1.114(g), but applicant is required to conduct a prior art search for filing an examination support document under § 1.265. Nor do these changes add to applicant's existing duties under § 1.56(a) to disclose to the Office all information known to the applicant to be material to patentability, and under 37 CFR Part 10.

Comment 66: One comment asserted that the Office will not achieve its goal of reducing the number of filings of continuation applications because an applicant could easily show why the amendment, argument, or evidence could not have been previously submitted when the subject matter of the claims in the continuation application is different from the subject matter of the claims of the initial application.

Response: The submission of an amendment to the claims or new claims to different subject matter alone will not be sufficient to meet the showing requirement under § 1.78(d)(1)(vi). Applicant must provide a satisfactory showing that the amendment, argument, or evidence sought to be entered could not have been previously submitted during the prosecution of the initial application, two continuation applications, and the request for continued examination.

Comment 67: One comment stated that the required showing under §§ 1.78(d) and 1.114 might have far-

reaching implications that extend outside the patent process. Several comments expressed concerns that the showing may require applicants to disclose highly sensitive business information such as business strategies, and to alert their competitors as to how the applicants plan to gain a competitive edge. The comments further expressed concerns that the petition procedure may also invoke attorney-client privilege.

Response: Applicants or patent owners often present sensitive business information to the Office, such as a showing of unavoidable delay in a petition to revive under § 1.137(a) or a petition to accept late payment of a maintenance fee under § 1.378(b). The Office has procedures in place for applicants and patent owners to submit trade secrets, proprietary material, and protective order material and to prevent unnecessary public disclosure of the material. See MPEP §§ 724–724.06. If it is necessary for an applicant to disclose sensitive business information to the Office to meet the showing under § 1.78(d)(1)(vi) or 1.114(g), applicant may submit the information in compliance with the procedures set forth in MPEP §§ 724–724.06 (e.g., the information must be clearly labeled as such and be filed in a sealed, clearly labeled, envelope or container).

Comment 68: One comment stated that the petitions under §§ 1.78(d)(1) and 1.114 would be scrutinized in court, creating a substantial increase in time and resources devoted to litigating and enforcing otherwise valid patent rights. One comment expressed concern that the petitions under §§ 1.78(d)(1) and 1.114 are unlikely to be granted and are likely to be the subject of an attack in litigation. A number of comments asserted that applicants would be subject to a higher potential for allegations of inequitable conduct. Additionally, one comment argued that the proposed rule changes would increase the frequency of malpractice litigation.

Response: The rules adopted in this final rule require applicants to prosecute their applications with reasonable diligence and foresight. The submission of a showing as to why an amendment, argument or evidence sought to be entered could not have been submitted earlier does not expose an applicant to a greater risk of inequitable conduct or litigation. The failure to disclose material information, or an affirmative misrepresentation of a material fact or submission of false material information or statements, coupled with an intent to deceive or mislead the Office, constitutes

inequitable conduct. The simple submission of a showing as to why an amendment, argument or evidence sought to be entered could not have been submitted earlier does not by itself raise such intent. If an applicant acts with candor and good faith in dealing with the Office, there should be no increased risk that the applicant will be accused of inequitable conduct. Similarly, if patent practitioners abide by the standards of professional conduct expected of practitioners in their relationships with their clients, and comply with the requirements of the patent statutes and rules, there should be no reason for increased exposure to malpractice suits.

Comment 69: Several comments suggested that the Office should adopt an alternate standard for additional continued examination filings in place of the standard set forth in §§ 1.78(d)(1) and 1.114. Some of the comments suggested the following alternatives: (1) A reasonable diligence standard; (2) a certification by a practitioner that it is necessary for the inventor to be adequately protected; (3) the "unduly interferes" standard as set forth in the former § 1.111(b); (4) a requirement that the submission be a *bona fide* attempt to advance prosecution; (5) an explanation of the need for the continued examination filing; (6) a reasonable justification standard; (7) a reasonable under the circumstances standard; or (8) a good cause standard. One of the comments stated that a good cause standard would not place an undue burden on the Office or prejudice the public. Additionally, the comment requested that an application filed for good cause should not count toward the single continued examination filing as a matter of right.

Response: The Office considers the standard that the amendment, argument or evidence sought to be entered could not have been previously submitted set forth in §§ 1.78(d)(1)(vi) and 1.114(g) appropriate for an additional continued examination filing. The standard set forth in §§ 1.78(d)(1)(vi) and 1.114(g) as adopted in this final rule ("a showing that the amendment, argument, or evidence sought to be entered could not have been submitted [earlier]") is more definite than the alternatives suggested in the comments (e.g., "good cause" and "reasonable under the circumstances") and other standards set forth in the patent statutes (see e.g., *Smith v. Mossinghoff*, 671 F.2d 533, 538, 213 U.S.P.Q. 977, 982 (DC Cir. 1982) (noting the absence of guidance concerning the meaning of the term "unavoidable" in 35 U.S.C. 133)). The comments do not provide an explanation as to why any of

these alternatives would be a more effective standard or more definite. Furthermore, §§ 1.78(d)(1) and 1.114(g) as adopted in this final rule do not set an absolute limit on the number of continued examination filings. Applicants are permitted to file two continuation or continuation-in-part applications and one request for continued examination without any justification. Applicants are also permitted to file any third or subsequent continuation or continuation-in-part application or second or subsequent request for continued examination with a petition and showing. If an amendment, argument, or evidence could have been submitted during the prosecution of the initial application, two continuing applications, or a request for continued examination, applicant must present such submission earlier rather than wait to submit it later in a third or subsequent continuation or continuation-in-part application or in a request for continued examination. Thus, the required showing is an appropriate standard.

Finally, as discussed further in this final rule, the Office may grant relief "in an extraordinary situation" in which "justice requires" even if the situation does not technically meet the standard that the amendment, argument or evidence sought to be entered could not have been previously submitted. See § 1.183. The Office, however, does not anticipate granting petitions under § 1.78(d)(1)(vi) on a basis other than a showing that the amendment, argument or evidence sought to be entered could not have been previously submitted.

Comment 70: Several comments suggested that the changes to § 1.78 should only be temporary so that the Office may assess the impact of the changes before adopting the rule. One comment also suggested that if the Office adopts the rule changes, the Office should eliminate the changes once the backlog decreases.

Response: Unrestricted continued examination filings and duplicative applications that contain patentably indistinct claims are significantly hindering the Office's ability to examine new applications to such an extent that it is necessary for the Office to adopt and implement the changes to these practices. After the implementation of the changes being adopted in this final rule, the Office will re-evaluate the rules of practice to determine what, if any, additional changes are necessary.

Comment 71: Several comments suggested that §§ 1.78(d)(1) and 1.114 should be revised from "a showing as to why the amendment, argument, or evidence presented could not have been

previously submitted" to "a showing as to why the new claim, amendment, argument, or evidence presented could not have been previously submitted" to resolve any potential ambiguity in the rules.

Response: The Office notes the comments' concern for ambiguity in the language of the rules. The phrase, "a showing * * * that the amendment, argument, or evidence sought to be entered could not have been submitted" (emphasis added) inherently encompasses a showing as to why a new claim could not have been previously submitted. A new claim presented in a continuing application is considered to be an amendment to the claims of the prior-filed application. Thus, by using the word "amendment" in the standard of §§ 1.78(d)(1)(vi) and 1.114(g), the Office intended to capture new claims sought to be introduced in a third or subsequent continuation or continuation-in-part application or second or subsequent request for continued examination.

Comment 72: One comment recommended that the Office should only require a petition and showing if the claims are presented more than two years after the earliest filing date claimed.

Response: Sections 1.78(d)(1) and 1.114 as adopted in this final rule provide applicant sufficient opportunities to present claims during the prosecution of the initial application, two continuing applications, and a request for continued examination in an application family without a petition under § 1.78(d)(1)(vi) or 1.114(g). The prosecution of these applications and the request for continued examination, most likely, would extend more than two years from the earliest claimed filing date. Therefore, the suggestion, if adopted, would likely increase the number of applicants who would be required to file a petition and showing.

Comment 73: Several comments proposed an exception to the rule changes to permit applicant to file a continuing application or a request for continued examination as a matter of right, without requiring a petition and showing, if the prior application is abandoned prior to examination.

Response: As suggested, the Office has made modifications to the proposed provisions to provide that an applicant may file a continuation or continuation-in-part application without any justification in certain situations in which the prior-filed application was abandoned prior to examination. Section 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 (*i.e.*, the prior-filed application became abandoned due to the failure to timely reply to an Office notice issued under § 1.53(f)), the applicant may file "one more" continuation or continuation-in-part application without a petition and showing under § 1.78(d)(1)(vi). Thus, applicant may file a continuation or continuation-in-part application to correct informalities rather than completing an application for examination under § 1.53. The prior-filed nonprovisional 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 74: Several comments suggested the Office should include exceptions to the petition requirement of §§ 1.78(d)(1) and 1.114 to permit applicant to file a continuing application or a request for continued examination as a matter of right, without requiring a petition and showing, in the following situations: (1) Some of the claims in the prior-filed application have been allowed and the continuation application contains only claims that were rejected in the prior-filed application; (2) the continuation application contains claims to an unclaimed invention disclosed in the prior-filed application; (3) the continuing application is claiming an independent and distinct invention; (4) the continuing application claims species or subgenus that falls within a generic claim that has been allowed or issued in one of the prior-filed applications; (5) the continued examination filing is filed for the purposes of submitting newly discovered prior art or amendments or evidence in view of the newly discovered prior art; (6) the continued examination filing is filed after an unsuccessful appeal; (7) a divisional application of an application that was subject to a restriction requirement is filed for the purposes of claiming the non-elected inventions; (8) the continuation application includes claims that were canceled in the prior-filed application; (9) the applicant certifies that the filing is done in good faith to advance prosecution and without deceptive intent; (10) the continued examination filing is filed for submitting evidence or an amendment to overcome a final rejection; (11) a continuation or continuation-in-part is filed to overcome a lack of utility rejection; (12) the continued

examination filing is filed to submit a declaration under § 1.131 or 1.132; (13) the continued examination filing is filed to submit data or other evidence not available for submission in the parent application to obviate a rejection under 35 U.S.C. 101 or 112, ¶ 1 (e.g., for lack of utility or enablement); (14) the continued examination filing is filed to respond to an examiner's request for additional information; (15) the continued examination filing is filed to respond to a new ground of rejection; (16) the prior-filed application was abandoned in favor of a continuing application that is filed using the Office electronic filing system; and (17) a request for continued examination is filed via the Office electronic filing system. One comment stated that if Congress does not eliminate 35 U.S.C. 135(b)(2), the need to copy claims from published applications should be exempt from the limit of continued examination filings in an application as a matter of right.

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 have required applicant to file a petition and showing for a second or subsequent continuation or continuation-in-part application or request for continued examination. The Office has modified 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.

Other than the situations provided in §§ 1.78(d)(1)(iv) and (d)(1)(v), this final rule permits that a third or subsequent continuing application or any second or subsequent request for continued examination to be filed with a petition and a showing as to why the amendment, argument, or evidence sought to be entered could not have been previously submitted. Sections 1.78(d)(1)(iv) and (d)(1)(v) provide that applicant may file "one more" continuation or continuation-in-part application without a petition and showing in certain situations. Specifically, § 1.78(d)(1)(iv) pertains to the situation where an applicant files a bypass continuation or continuation-in-part application rather than paying the basic national fee (entering the national stage) in an international application in which a Demand for international preliminary examination (PCT Article 31) has not been filed, and the international application does not claim the benefit of any other nonprovisional

application or international application designating the United States of America. See the discussion of § 1.78(d)(1)(iv). Section 1.78(d)(1)(v) pertains to the situation where an applicant files a continuation or continuation-in-part application to correct informalities rather than completing an application for examination under § 1.53. See the discussion of § 1.78(d)(1)(v).

The Office will decide petitions under §§ 1.78(d)(1)(vi) and 1.114(g) based on their substantive argument and the facts in the record and apply the standard in a consistent manner. There are no situations that will result in a *per se* or *pro forma* grant of a petition under § 1.78(d)(1)(vi) or 1.114(g). Whether specific situations would be a sufficient showing under § 1.78(d)(1)(vi) or 1.114(g) is discussed in the responses to subsequent comments.

Comment 75: Several comments opposed the \$400 fee for filing a petition under §§ 1.78(d)(1) and 1.114. The comments indicated that the proposed petition fee of \$400 is unnecessarily high, especially in view of the filing fees. Furthermore, the comments argued that it is unfair to require the submission of a costly fee and a time-consuming petition regardless of the reason for filing the continuing application or request for continued examination. One other comment stated that the proposed petition fee does not cover the amount of work required to determine if applicant's showing is sufficient to meet the requirements in §§ 1.78(d)(1) and 1.114. Another comment questioned why an applicant must pay a petition fee of \$400 when filing an additional continuation-in-part application simply to add new matter.

Response: The Office considers \$400 to be an appropriate fee for filing a petition under § 1.78(d)(1)(vi) or 1.114(g). 35 U.S.C. 41(d) authorizes the Director to establish fees to recover the estimated average cost to the Office for handling, reviewing and deciding petitions. The Office has determined that the average cost to the Office for handling, reviewing and deciding the petitions under §§ 1.78(d)(1)(vi) and 1.114(g) will be at least \$400. As previously discussed, applicants most likely will be able to avoid the requirements for filing a petition and the required fee if applicants diligently prosecute applications (including the continuing applications and a request for continued examination permitted under §§ 1.78(d)(1) and 1.114(f) without any petition). If an applicant desires to file an application simply to claim new subject matter, the applicant may file a new application (rather than a

continuation-in-part application) without claiming the benefit of the prior-filed applications and avoid paying the \$400 petition fee. As discussed previously, claims to new subject matter will not be entitled to any benefit of the prior-filed application that does not provide support under 35 U.S.C. 112, ¶ 1, for the claimed subject matter and the patent term of any resulting patent of the continuation-in-part application would be measured from the filing date of the prior-filed application.

Comment 76: One comment requested that the Office waive the requirement for a petition fee if applicant submits new art from a foreign search report or related application or files an amendment in response to new arguments made by the examiner.

Response: A petition, the appropriate showing, and the fee set forth in § 1.17(f) are required under § 1.78(d)(1)(vi) or 1.114(g) when applicant files a third or subsequent continuing application or a second or subsequent request for continued examination regardless of the reason for such a filing. In addition, a request to submit new art from a foreign search report or related application is not likely to be a sufficient showing under § 1.78(d)(1)(vi) or 1.114(g) (see discussion relating to the filing of continuing applications and requests for continued examination to obtain consideration of an information disclosure statement). Likewise, the mere fact that the examiner made new arguments or a new ground of rejection in a final Office action would not be considered a sufficient showing. The Office will decide each petition on a case-by-case basis focusing on whether the new ground of rejection in the final Office action could have been anticipated by the applicant.

Comment 77: Several comments stated that there is no public notice of the criteria the Director will apply to meet the required showing under § 1.78(d)(1) or 1.114. A number of comments sought clarification on what type of showing under § 1.78(d)(1) or 1.114 would be necessary to permit the filing of an additional continuing application or request for continued examination. A number of comments specifically sought clarification of the phrase, "could not have been previously submitted," in §§ 1.78(d)(1) and 1.114 regarding the satisfactory showing needed to be permitted to file an additional continuing application or request for continued examination. A number of other comments suggested that prior to the implementation of the final rule, the Office should publish

more specific guidelines such as a non-exclusive set of examples that would constitute a sufficient showing under §§ 1.78(d)(1) and 1.114. In addition, several comments requested that the Office provide an opportunity for public comment on the suggested guidelines.

Response: As discussed previously, the standard set forth in §§ 1.78(d)(1)(vi) and 1.114(g) as adopted in this final rule ("a showing that the amendment, argument, or evidence sought to be entered could not have been submitted [earlier]") is more definite than the alternatives suggested in the comments (e.g., "good cause" and "reasonable under the circumstances") and other standards set forth in the patent statutes (see e.g., *Smith v. Mossinghoff*, 671 F.2d 533, 538, 213 U.S.P.Q. 977, 982 (D.C. Cir. 1982) [noting the absence of guidance concerning the meaning of the term "unavoidable" in 35 U.S.C. 133]). If an amendment, argument or evidence could be submitted during the prosecution of the initial application, two continuing applications, and a request for continued examination in an application family, applicant must present such an amendment, argument or evidence earlier rather than wait to submit it later in an additional continuing application or request for continued examination. Applicants should not rely upon the availability of additional continuing applications or requests for continued examination in prosecuting an application. The Office will determine on a case-by-case basis whether the applicant's showing as to why the amendment, argument or evidence sought to be entered could not have been submitted earlier is satisfactory. In addition to the showing submitted by the applicant, the Office may review the prosecution history of the initial application and the prior continuing applications or require additional information from the applicant in deciding a petition. The following are some factors that the Office may consider when deciding whether to grant a petition under § 1.78(d)(1)(vi) or 1.114(g): (1) Whether applicant should file an appeal or a petition under § 1.181 (e.g., to withdraw the finality of an Office action) rather than a continuing application or request for continued examination; (2) the number of applications filed in parallel or serially with substantially identical disclosures; and (3) whether the evidence, amendments, or arguments are being submitted with reasonable diligence.

With respect to the first factor (whether applicant should be filing an appeal or a petition under § 1.181 rather than a continuing application or request

for continued examination), if the showing under § 1.78(d)(1)(vi) or 1.114(g) relates to an issue that should be petitioned or appealed, the Office will likely not grant the petition for an additional continuing application or request for continued examination. Applicant should address any issues pertaining to inadequate examination by seeking review via a petition under § 1.181 or an appeal, rather than by filing a continuing application or request for continued examination.

If the disagreement between the examiner and applicant is procedural in nature (e.g., an objection), then applicant should file a petition under § 1.181. For example, an applicant should file a petition under § 1.181 to request the withdrawal of the finality of an Office action when the finality was premature, or to review the examiner's refusal to enter an after-final amendment. The Office will likely not grant a petition under § 1.78(d)(1)(vi) or 1.114(g) if applicant argues only that an amendment after final rejection should have been entered in the prior-filed application because the final was premature. Applicant should have addressed the non-entry in the prior-filed application and not later in a petition under § 1.78(d)(1)(vi) or 1.114(g) for a continuing application or request for continued examination. If the issue goes to the merits of a rejection, applicant should file an appeal to the BPAI under 35 U.S.C. 134 and § 41.31.

With respect to the second factor (the number of applications filed in parallel or serially with substantially identical disclosures), the higher the number of applications with identical or substantially identical disclosures or the higher the number of applications in the chain of prior-filed pending applications, the more opportunities applicant had to present the amendment, argument or evidence. Accordingly, a petition under § 1.78(d)(1)(vi) or 1.114(g) is less likely to be granted.

With respect to the third factor (whether the evidence, amendments, or arguments are being submitted with reasonable diligence), the Office will focus on whether the evidence or data submitted with the petition to meet the showing under § 1.78(d)(1)(vi) or 1.114(g) was presented in a reasonably diligent manner. This will take into account the condition of the application at the time of examination (e.g., whether the initial application was in proper form for examination by the time of the first Office action in the initial application or whether it was necessary to first issue Office actions containing

rejections under 35 U.S.C. 112 or objections to have the application placed in proper form for examination), the consistency of the Office's position during prosecution (e.g., whether applicant received wholly new prior art rejections versus prior art rejections slightly modified to address the amendments), and the earnestness of the applicant's efforts to overcome outstanding rejections (e.g., whether replies fully addressed all of the grounds of rejection or objection in the Office actions, or whether amendments or evidence were submitted only when arguments were failing to persuade the examiner).

Comment 78: One comment sought clarification as to whether a petition under § 1.78(d)(1) would be available for "involuntary" divisional applications. Another comment suggested an applicant should be permitted to file any divisional application in response to a restriction requirement.

Response: The Office notes the concerns expressed in the public comment regarding the proposed changes to § 1.78(d)(1)(ii). The Office has modified this provision relative to the proposed changes such that § 1.78(d)(1)(ii) as adopted in this final rule does not require a divisional application to 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. Under this final rule, applicant may file, without any justification, a divisional application containing only claims directed to a non-elected invention that has not been examined if the prior-filed application was subject to a requirement for restriction (an "involuntary" divisional application"). Applicant may also file two continuation applications and a request for continued examination in the divisional application family, without any justification. Furthermore, applicant may file a third or subsequent continuation application or a second or subsequent request for continued examination with a petition and showing.

Comment 79: Several comments sought clarification on whether the Office will grant a petition under § 1.78(d)(1) for filing a divisional application of an application that was subject to a restriction requirement for the purposes of claiming the non-elected inventions.

Response: As previously discussed, the Office has modified the provisions of § 1.78(d)(1)(ii) relative to the proposed changes. In this final rule, § 1.78(d)(1)(ii) does not require a divisional application to 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 provides that an applicant may file a divisional application directed to each non-elected invention that has not been examined if the prior-filed application is subject to a requirement for restriction. Section § 1.78(d)(1)(iii) as adopted in 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. Furthermore, applicant may file an additional continuation application or request for continuation examination with a petition and showing. Under this final rule, applicant should have sufficient time to file a divisional application for claiming a non-elected invention. Therefore, the Office will most likely not grant a petition under § 1.78(d)(1)(vi) to permit an applicant to file a divisional application directed to a non-elected invention.

Comment 80: One comment suggested a petition under § 1.78(d)(1) should be granted when an applicant needs an additional continuing application to partition the claims in the prior-filed application, such that a terminal disclaimer applies only to some but not all claims in the prior-filed application. The comment alternatively suggested changing the regulations to allow the filing of a terminal disclaimer for selected claims.

Response: This final rule permits applicant to file two continuation or continuation-in-part applications plus a request for continued examination in an application family, without justification. Therefore, applicant may use one of the two permitted continuation or continuation-in-part applications to partition the claims such that a terminal disclaimer applies to the prior-filed application but does not apply to the continuation application. Notably, applicant may avoid this situation by presenting all of the patentably indistinct claims in a single application. As discussed previously, multiple applications with patentably indistinct claims divert the Office's patent examining resources from the examination of new applications. Applicant should submit all patentably indistinct claims in a single application. See §§ 1.75(b)(4) and 1.78(f). Under this final rule, applicant must identify such multiple applications with patentably indistinct claims to the Office and assist the Office in resolving double patenting issues early in the prosecution. In the

situation in which an application contains at least one claim that is patentably indistinct from at least one claim in another application, the Office will treat the claims in both applications as being present in each of the applications for the purposes of determining whether each application exceeds the five independent claim and twenty-five total claim threshold under § 1.75(b). See the discussion of § 1.75(b)(4). Accordingly, the Office is not likely to grant a petition for the sole purpose of partitioning claims to avoid a terminal disclaimer.

Additionally, a disclaimer of a terminal portion of the term of an individual claim, or individual claims, is not allowed by statute. 35 U.S.C. 253 provides that "any patentee or applicant may disclaim or dedicate to the public * * * any terminal part of the term, of the patent granted or to be granted." (Emphasis added.) Therefore, under 35 U.S.C. 253, a terminal disclaimer must be of a terminal portion of the term of the entire patent and cannot be applied to selected claims as advocated in the comment.

Comment 81: Several comments asserted that an applicant filing an additional continuation-in-part application would be able to argue successfully that the amendment or argument could not have been previously submitted because the subject matter was not present at the time of filing the initial application. Thus, the proposed rules would force these applicants to file a *pro forma* petition.

Response: The mere fact that the subject matter was not present at the time of filing the prior-filed application would not be a sufficient showing under § 1.78(d)(1)(vi). The Office will decide these petitions on a case-by-case basis based on the prosecution history of the prior-filed application as well as the records of the continuation-in-part application. The Office will consider the showing of why the new subject matter sought to be entered could not have been previously submitted in the prior-filed application. The Office will also consider the amendment including any new claims to determine whether the claims in the continuation-in-part application are directed to the new subject matter or mainly to the subject matter disclosed in the prior-filed application. For example, if the new subject matter is not being claimed in the continuation-in-part application, but merely being added to circumvent the rule, the Office will not grant the petition. Furthermore, 35 U.S.C. 120 requires that the prior-filed application disclose the subject matter of at least

one claim of the later-filed application in the manner provided by 35 U.S.C. 112, ¶ 1, for the later-filed application to actually receive the benefit of the filing date of the prior-filed application. Thus, any claim in the continuation-in-part application that is directed to the subject matter not disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application would be entitled only to the actual filing date of the continuation-in-part application (not the filing date of the prior-filed application), and subject to prior art based on the actual filing date of the continuation-in-part application. Applicant should not claim the benefit of the prior-filed application if all of the claims in the continuation-in-part application are directed to the new subject matter. The continuation-in-part application would not be entitled to the benefit of the filing date of the prior-filed application, and 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. That is, applicant would not receive any benefit of the earlier application but would have a patent term that is measured from the filing date of the earlier application. If there are any claims in the continuation-in-part application that are directed solely to subject matter disclosed in the prior-filed application, applicant must submit those claims in the prior-filed application rather than filing a continuation-in-part application unless applicant provides a showing as to why these claims could not have been previously submitted.

Comment 82: Several comments requested that the Office permit an applicant to file an additional continuing application or request for continued examination when the applicant indicates why the new invention could not otherwise be protected using another type of application, such as a reissue application or a reexamination proceeding. These comments also requested that the Office permit an additional continuing application or an additional request for continued examination that contains claims broader than in the previous application to which priority is claimed and contain claims not subject to a double patenting rejection.

Response: The Office will likely not grant such a petition. Applicant may file a reissue application under 35 U.S.C. 251 or a reexamination proceeding, if appropriate, to submit claims with different scope. A desire to avoid the requirements governing reissue

applications or reexamination proceedings would not be a sufficient showing under § 1.78(d)(1)(vi) or 1.114(g).

Comment 83: One comment sought clarification on whether the required showing under §§ 1.78(d)(1) and 1.114 will preclude explanations that are permitted when filing a reissue application. A further comment stated the required showing under §§ 1.78(d)(1) and 1.114 is greater than the showing required to file a reissue application.

Response: 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. 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 that the amendment, argument, or evidence sought to be entered could not have been submitted previously. As previously discussed, if an amendment, argument, or evidence could have been submitted during the prosecution of the initial application, two continuation or continuation-in-part applications or a request for continued examination, applicant must submit the amendment, argument or evidence in one of these filings, rather than in a third or subsequent continuing application or second or subsequent request for continued examination to ensure that applicant advances the prosecution to final action and does not impair the ability of the Office to examine new applications.

Under 35 U.S.C. 251, applicant may file a reissue application to correct an error in the patent which was made without any deceptive intent, where, as a result of the error, the patent is deemed wholly or partly inoperative or invalid. See MPEP section 1402. The required showing under §§ 1.78(d)(1)(vi) and 1.114(g) is different than the explanation required for filing a reissue application. The showing under §§ 1.78(d)(1)(vi) and 1.114(g) does not require an error made without any deceptive intent and does not require as a result of the error, the patent to be deemed wholly or partly inoperative or invalid. If it is more appropriate for applicant to file a reissue application, applicant should file a reissue application under 35 U.S.C. 251 rather than filing a continuing application.

Comment 84: Several comments suggested that if the Office permits applicant to provide additional evidence of unexpected results with the filing of an additional continued

examination filing, then the experimentation leading to the evidence must have been conducted diligently and commenced within six months of the filing of the initial application. Another comment further suggested evidence that an applicant had not previously learned or known that others had developed similar or parallel technology should not be considered as evidence that an amendment, argument or evidence could not have been submitted previously under § 1.78(d)(1) or 1.114.

Response: The Office will decide petitions under § 1.78(d)(1)(vi) or 1.114(g) on a case-by-case basis. The Office will focus on whether the evidence or data submitted with the petition to meet the showing under § 1.78(d)(1)(vi) or 1.114(g) was presented in a timely manner and was diligently obtained. Any evidence or data that petitioner did not act diligently in obtaining in response to a rejection or requirement in an Office action will be considered unfavorably when deciding a petition under § 1.78(d)(1)(vi) or 1.114(g). For example, the Office will likely not grant a petition if the examiner made the rejection in the first Office action of the initial application and maintained it in the subsequent Office actions, but applicants responded only with arguments, instead of with evidence or an amendment, until after the final Office action. In contrast, the Office will likely grant a petition if, in a continuing application or request for continued examination, the data necessary to support a showing of unexpected results just became available to overcome a new rejection under 35 U.S.C. 103 made in the final Office action, and the data is the result of a lengthy experimentation that was diligently commenced and could not have been completed earlier. Applicant should exercise reasonable foresight to commence any appropriate experimentation early rather than wait until the examiner makes a rejection or finds applicant's arguments unpersuasive.

Comment 85: Several comments sought clarification on whether an additional continued examination filing would be permitted under § 1.78(d)(1) or 1.114 for submitting an information disclosure statement or an amendment in view of an information disclosure statement in the following situations: (1) To submit a newly discovered reference, including a reference cited in a foreign counterpart application; (2) to submit a new reference that was not publicly available at the time the previous amendment was filed; (3) to submit an amendment to the claims that is

necessitated by previously cited prior art or newly discovered prior art; and (4) to submit broadened claims after receipt of a foreign search or examination report citing new art. One comment argued that submissions of late discovered prior art should be permitted because the consideration of the prior art will improve patent quality and eliminate allegations of inequitable conduct in obtaining patent rights.

Response: The Office will likely not grant such a petition for submitting an information disclosure statement (IDS) or an amendment necessitated by (or in view of) newly discovered prior art. The effectiveness and quality of the examination process as well as patentability determinations would improve if the most pertinent information were presented early in the examination process. An additional continued examination filing is not necessary for the consideration of newly discovered prior art or an amendment to the claims that is necessitated by the newly discovered prior art. See *Changes To Information Disclosure Statement Requirements and Other Related Matters*, 71 FR at 38812-16, 38820-22, 1309 *Off. Gaz. Pat. Office* at 27-31, 34-36 (proposed changes to §§ 1.97 and 1.98 permit applicant to submit prior art for consideration by the examiner, when applicant complies with specific requirements at various time periods, including after final action, notice of allowance and payment of the issue fee).

The proposed IDS changes (if adopted) would permit applicant to submit an IDS after a first Office action on the merits, but before the mailing date of a notice of allowability or a notice of allowance under § 1.311, if applicant files the IDS with either: (1) The certification under § 1.97(e)(1) and a copy of the foreign search report, or (2) an explanation under proposed § 1.98(a)(3)(iv) as to why each reference is being cited, and a non-cumulative description under proposed § 1.98(a)(3)(v) as to how each reference is not cumulative of any other reference cited. Applicant would also be permitted to submit an IDS after allowance but before the payment of the issue fee, if applicant files the IDS with a patentability justification under proposed § 1.98(a)(3)(vi), including any appropriate amendments to the claims.

Applicant would also be permitted to submit an IDS after the payment of the issue fee if applicant files a petition to withdraw from issue pursuant to § 1.313(c)(1), the patentability justification under proposed § 1.98(a)(3)(vi)(B), and an amendment to the claims. Prior to the effective date of the final rule of the changes to IDS

requirements, applicant may submit an IDS after the close of prosecution with a petition under § 1.183 if the IDS submission complies with the proposed rule requirements in §§ 1.97 and 1.98.

Comment 86: Several comments sought clarification as to whether an additional continued examination filing would be permitted under §§ 1.78(d)(1) and 1.114 in the following situations: (1) When the examiner found the earlier arguments and amendments by applicants to be unpersuasive; (2) when the examiner's interpretation of the claims is unusual and only recently understood by the applicant; (3) when the examiner changes his or her interpretation of claim language; and (4) when the practitioner discovers that the examiner is under a misunderstanding.

Response: These circumstances alone more than likely would not be sufficient to establish a showing under § 1.78(d)(1)(vi) or 1.114(g). Applicant should request an interview with the examiner to resolve these types of issues during the prosecution of the initial application, two continuation or continuation-in-part applications and request for continued examination. In addition, applicant in each reply to an Office action must distinctly and specifically point out the supposed errors in the Office action and must reply to every ground of objection and rejection raised in the Office action. See § 1.111(b). The reply must also present detailed explanations of how each claim is patentable over any applied references. See §§ 1.111(b) and (c). If applicant disagrees with the examiner's decision to maintain a rejection on the basis that the applicant feels that the examiner is misinterpreting the claims, applicant should seek an appeal rather than file additional continuing applications or requests for continued examination.

Comment 87: Several comments sought clarification on whether an additional continued examination filing would be permitted under §§ 1.78(d)(1) and 1.114 when the examiner makes a new ground of rejection in a final Office action using a new prior art reference, a reference already of record but not previously applied, a new basis for the rejection (e.g., changing a rejection under 35 U.S.C. 102 to a rejection under 35 U.S.C. 103), or a different reasoning (e.g., the supporting arguments have changed or the rejection refers to a new portion of the applied art). Several comments stated that permitting a final rejection based on a new ground of rejection while not allowing further opportunity to amend through continued examination applications is

unfair and presents an opportunity for abuse.

Response: The Office will decide each petition for an additional continued examination filing on a case-by-case basis, focusing on whether the new ground of rejection in the final Office action could have been anticipated by the applicant. For example, the Office will likely grant a petition if the final rejection, after the two continuing applications and request for continued examination permitted under §§ 1.78(d)(1) and 1.114(g) without a petition, contains a new ground of rejection that could not have been anticipated by applicant. However, the Office will likely not grant a petition under § 1.78(d)(1)(vi) or 1.114(g) if the examiner only changed a rejection under 35 U.S.C. 102 to a rejection under 35 U.S.C. 103 (or maintained a rejection under 35 U.S.C. 103) with the addition of a new secondary reference in response to an amendment adding a new claim limitation because such a new rejection should have been anticipated by the applicant. Therefore, the mere fact that the examiner made a new ground of rejection in a final Office action probably would not constitute a sufficient showing.

Comment 88: Several comments sought clarification on whether an additional continued examination filing would be permitted under §§ 1.78(d)(1) and 1.114 in the following situations: (1) When the examiner indicates in an advisory action that an after-final amendment would require a new search; or (2) to submit evidence or an amendment to overcome a final rejection.

Response: The Office will likely not grant a petition based on the mere showing that the examiner indicates in an advisory action that the entry of an after-final amendment would require a new search, or that the evidence or amendment sought to be entered will overcome a final rejection. Applicants are permitted to submit any desired amendment, argument, or evidence during the prosecution of the initial application, two continuation or continuation-in-part applications and one request for continued examination. Since numerous opportunities are given to submit any desired amendment, argument, or evidence, the mere fact that an amendment, argument, or evidence is refused entry because prosecution in the prior-filed application is closed will not, by itself, be a sufficient reason to warrant the grant of a petition under § 1.78(d)(1)(vi) or 1.114(g). Rather, an applicant will be expected to demonstrate why the amendment, argument, or evidence

sought to be entered could not have been submitted prior to the close of prosecution in the prior-filed application.

Comment 89: Several comments sought clarification as to whether the Office will likely grant a petition for an additional continuing application if some of the claims in the prior application are rejected and other claims are allowed, and applicant wishes to appeal the rejected claims and obtain a patent on the allowed claims.

Response: The Office is not likely to grant a petition under § 1.78(d)(1)(vi) in this situation in the absence of special circumstances. Section 1.78(d)(1)(i) permits an applicant whose initial application contains rejected claims and allowed claims to obtain a patent on the allowed claims, and continue prosecution of the rejected or other claims in a continuation or continuation-in-part application. The applicant is expected to use the two continuation or continuation-in-part applications permitted without any petition or showing under § 1.78(d)(1)(i) for this purpose. The applicant needs to pursue an appeal (or cancel the rejected claims) if the application still contains rejected claims after a second continuing application and request for continued examination.

Comment 90: Several comments suggested that applicant should be permitted to file an additional continuing application under § 1.78(d)(1) or request for continued examination under § 1.114 for changing the scope of the claims in the following situations: (1) Pursue claims that have the same or narrower scope as the claims in an allowed application; (2) claim a species or subgenus that falls within a generic claim that has been allowed or issued in one of the prior-filed applications; (3) pursue the rejected or broader claims when other claims are allowable; (4) file broader claims, when applicant recently discovered a limitation in an allowed claim that was unduly limiting; (5) pursue broader claims, or claim aspects of the invention that are disclosed, but not claimed, in the prior-filed application (contains claims to an unclaimed invention disclosed in the prior-filed application); (6) pursue narrower claims; (7) claim inventions of a different scope when the scope of new claims finds specific support in the application as filed; (8) pursue new claims when the scope of new claims was unintentionally omitted from the initial application; or (9) protect a different aspect of the invention revealed by research and development

subsequent to an initial application filing.

Response: If a claim can be submitted during the prosecution of the initial application, two continuation or continuation-in-part applications and one request for continued examination, applicant must present such a claim early in these filings rather than wait to submit it later in an additional continuing application or request for continued examination. The situations described in the comments do not present any reason why claims directed to claims with the same, narrower, or broader scope could not have been submitted earlier. Applicants may file a reissue application under 35 U.S.C. 251, if appropriate, to submit claims with a different scope.

Comment 91: Several comments sought clarification on whether an additional continued examination filing would be permitted under §§ 1.78(d)(1) and 1.114 for the following situations: (1) When a product recently becomes commercially viable; (2) when a competing product is newly discovered; (3) when new information is discovered that could not have been provided in the prior application; (4) when applicant discovered new inherent properties that he or she now wishes to claim; (5) when applicant now has the financial resources to file previously unclaimed inventions; (6) when clinical trials indicate the previously unclaimed subject matter may be useful; or (7) when the court determined that the format of a patented claim is improper and applicant wishes to file a continuing application to seek the proper protection.

Response: The Office likely will not grant such a petition in these situations. Applicant is permitted to file two continuation or continuation-in-part applications and a request for continued examination without a petition and showing. Applicant should have sufficient time to submit any desired claims. Applicant should also know what the applicant regards as his or her invention and claim his or her invention during the prosecution of these applications, regardless of whether applicants have recently discovered a commercially viable product, financial resources, useful subject matter, a competing product, or similar or parallel technology on the market. Applicants may file a reissue application under 35 U.S.C. 251, if appropriate, to correct or amend any patented claims. The Office would not likely grant a petition to permit an applicant to end-run the two-year filing period requirement of 35 U.S.C. 251, ¶ 4.

Comment 92: Several comments suggested allowing an applicant to file an additional continuing application or request for continued examination to claim inventions related to drugs undergoing the FDA approval process. In particular, one comment suggested two ways of satisfying the required showing under §§ 1.78(d)(1) and 1.114: (1) An applicant provides an affidavit or other statement to the Office confirming that the applicant is presently engaged in obtaining information needed for submitting an Investigational New Drug (IND) application for that drug; or (2) an applicant provides evidence to the Office that the applicant has already submitted an IND or a Biologics License Application (BLA) (or an amended IND application or amended BLA) for the particular drug.

Response: Such evidence of ongoing FDA review for a drug allegedly claimed in an application would not by itself be considered a sufficient showing under § 1.78(d)(1)(vi) or 1.114(g). Applicant should know what the applicant regards as his or her invention upon filing an application and should claim the invention prior to, or regardless of, any FDA approval. There is no reason why an applicant must have FDA approval prior to deciding for which aspect(s) of the invention or which invention(s) to seek patent protection. See *In re Brana*, 51 F.3d 1560, 1568, 34 U.S.P.Q.2d 1436, 1442 (Fed. Cir. 1995) ("FDA approval * * * is not a prerequisite for finding a compound useful within the meaning of the patent laws."). The changes adopted in this final rule permit an applicant to file two continuation or continuation-in-part applications and one request for continued examination in the application family, without any justification. In addition, applicant may file a divisional application directed to each non-elected invention that has not been examined if the prior-filed application was subject to a restriction requirement and the claims to the non-elected invention are cancelled upon filing of the divisional application. Applicant may also file two continuation applications of the divisional application and a request for continued examination in the divisional application family, without justification. And, applicant may file a third of subsequent continuation application or a second request for continued examination with a petition and showing. If applicant is not prepared to particularly point out and distinctly claim what the applicant regards as his or her invention during the prosecution of the initial application, its two continuing applications, and a request

for continued examination in each application family, applicant should consider using the deferral of examination process. See § 1.103(d).

The Office recognizes that, in certain unpredictable arts (including, for example, biotechnology and certain pharmaceuticals), there may be a need for research or testing to obtain additional evidence or data to obviate a rejection for lack of utility under 35 U.S.C. 101 (and consequently for lack of enablement under 35 U.S.C. 112, ¶ 1). The case law, however, does not shift the burden to the applicant to provide rebuttal evidence or data concerning the invention's utility until the examiner "provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility." *Brana*, 51 F.3d at 1566, 34 U.S.P.Q.2d at 1441 (citing *In re Bundy*, 642 F.2d 430, 433, 209 U.S.P.Q. 48, 51 (CCPA 1981)). Even in situations in which a requirement for such additional evidence is appropriate, the evidence or data that would warrant an applicant's decision to initiate the FDA regulatory process should be sufficient to establish utility for purposes of compliance with 35 U.S.C. 101 and 112, ¶ 1. See MPEP § 2107.03 (as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility). With respect to situations in which it is questionable as to whether there is sufficient enablement for the invention as claimed, evidence submitted to the FDA to obtain approval for clinical trials may be submitted. However, considerations made by the FDA for approving clinical trials are different from those made by the Office in determining whether a claim is sufficiently enabled. See MPEP § 2164.05 (citing *Scott v. Finney*, 34 F.3d 1058, 1063, 32 U.S.P.Q.2d 1115, 1120 (Fed. Cir. 1994)). Thus, situations in which it is necessary for an applicant to submit data to the Office to demonstrate patentability using data obtained from research or testing carried out as part of the FDA regulatory process should be rare.

Nevertheless, in the situation in which there is a rejection such as lack of utility under 35 U.S.C. 101 (and/or consequently for lack of enablement under 35 U.S.C. 112, ¶ 1) in an application claiming subject matter in such an unpredictable art, the Office will likely grant a petition under § 1.78(d)(1)(vi) or 1.114(f) if, in a continuing application or request for

continued examination, the evidence or data to demonstrate utility or enablement just became available or could not have been otherwise earlier presented, and the evidence or data resulted from research or testing that was commenced with reasonable diligence. However, this presupposes that the applicant has taken reasonable steps to resolve the issue during the prosecution of the initial (or divisional) application, its two continuing applications, and a request for continued examination in each application family. In particular, the Office will consider, *inter alia*, whether the applicant: (1) Sought review of the rejection via an appeal that proceeded to at least the appeal conference stage and resulted in an examiner's answer (rather than simply filing continuing applications or a request for continued examination without the evidence or data to again argue patentability before the examiner); (2) initiated the research or testing promptly (rather than waiting for a decision to initiate the FDA regulatory review process); and (3) sought suspension of action (§ 1.103(a) or (c)) or deferral of examination if applicable (§ 1.103(d)) in the continuing applications or the request for continued examination and alerted the Office of the research or testing.

Comment 93: Several comments sought clarification whether the Office will grant a petition for an additional continuing application or request for continued examination to correct the inventorship of the application due to information discovered after prosecution of the application has closed.

Response: The Office will likely not grant such a petition. Applicant should make the correction early in the examination process. Furthermore, the Office has recently proposed changes to § 1.312 to provide that the Office may permit a correction of the inventorship filed in compliance with § 1.48 after the mailing of a notice of allowance if certain requirements are met, such as if the correction is filed before or with the payment of the issue fee or if the correction is filed with the processing fee set forth in § 1.17(i) and in sufficient time to permit the patent to be printed with the correction. See *Changes To Information Disclosure Statement Requirements and Other Related Matters*, 71 FR at 38817-8, 38823, 1309 *Off. Gaz. Pat. Office* at 32, 37. Finally, after the patent has issued, applicant may correct the inventorship by filing a reissue application under 35 U.S.C. 251 or pursuant to 35 U.S.C. 256.

Comment 94: One comment discussed that the limitations on continuing

applications may create due process issues because there may be different treatment of joint inventors of an application. The comment provided an example of an application filed naming joint inventors, e.g., Inventors C and D, and ensuing problems caused by the proposed rules as follows: Inventor C files a continuation application to prosecute his or her invention. Inventor D may be deprived of filing a continuation application on his invention because the filing by Inventor D would be a second or subsequent continuing application that would require a petition under § 1.78(d)(1).

Response: This final rule permits applicants to file two continuation or continuation-in-part applications plus one request for continued examination without justification. Applicants may 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. Under § 1.78(d)(1)(i), Inventor C is permitted to file a continuation application (the first continuation application) to prosecute his or her invention, and Inventor D is permitted to file a continuation application (the second continuation application) to prosecute his or her invention.

Comment 95: Several comments sought clarification whether the Office will grant a petition for an additional continuing application or request for continued examination for the purpose of provoking an interference.

Response: The Office will likely not grant a petition with a showing that the additional continuation or continuation-in-part application or request for continued examination is solely for the purpose of provoking an interference. In most situations, applicants should have sufficient opportunity to provoke an interference and copy claims in a timely manner in compliance with 35 U.S.C. 135(b)(2) in the initial application, two continuation or continuation-in-part applications, and one request for continued examination, all of which are available without any justification. In any event, the Office is likely to require that a request for a statutory invention registration under § 1.293 be submitted as a condition of granting any petition under § 1.78(d)(1)(vi) in the situation where a third or subsequent continuation or continuation-in-part application or second or subsequent request for continued examination is for the purpose of provoking an interference. The Office, however, would likely grant a petition under § 1.78(d)(1)(vi) (without requiring a request for a statutory invention

registration under § 1.293) in a limited situation where an interference is declared in a second continuation or continuation-in-part application that contains both claims corresponding to the count and claims not corresponding to the count, and the BPAI suggests that the claims not corresponding to the count be canceled from the application subject to the interference and pursued in a separate application.

Comment 96: Several comments sought clarification as to whether the Office will grant a petition for an additional continuing application or request for continued examination when the Office changes the examiner assigned to the application either on its own initiative or in response to the applicant's request.

Response: The Office will not grant such a petition. The mere fact that the Office changes the examiner assigned to the application would not be a sufficient showing under § 1.78(d)(1)(vi) or 1.114(g).

Comment 97: Several comments sought clarification as to whether the Office will grant a petition for an additional continuing application or request for continued examination when applicant changes the practitioner of record, when applicant states that the change of practitioner was made in good faith and certifies that the applicant was dissatisfied with the prior practitioner's claim drafting, or when the delay in filing claims was due to practitioner's error or inaction and was not the fault of the applicant. One comment expressed concern that if changing the practitioner of record is an acceptable reason, it will promote attorney swapping.

Response: The Office will not grant such a petition for these circumstances. A change of practitioner, or errors or delays caused by the practitioner, would not be considered sufficient showings. An applicant is bound by the consequences of the acts or omissions of the applicant's duly authorized and voluntarily chosen legal representative. See *Link v. Wabash R. Co.*, 370 U.S. 626, 633-34 (1962).

Comment 98: One comment suggested that an applicant should be permitted to file an additional continuation or continuation-in-part application when the practitioner does not present the claims in the prior application because of excusable neglect.

Response: Rule 60(b) of the Federal Rules of Civil Procedure (Rule 60(b)) does provide "excusable neglect" as a basis (among others) for relieving a party of a judgment or order. See Fed. R. Civ. P. 60(b)(1), Rule 60(b), however, further provides that a motion based

upon "excusable neglect" must be "made within a reasonable time," and "not more than one year after the judgment, order, or proceeding was entered or taken." See Fed. R. Civ. P. 60(b). Sections 1.78(d)(1) and 1.114 as adopted in this final rule permit an applicant to file an initial application, two continuation or continuation-in-part applications, and a request for continued examination in any one of these three applications without justification. Given the numerous opportunities provided in §§ 1.78(d)(1) and 1.114 to prosecute an application for patent, the "mistake, inadvertence, surprise, or excusable neglect" standard set forth in Rule 60(b)(1) is not an appropriate basis for seeking yet another opportunity to prosecute the application. Therefore, the Office is not likely to grant a petition under § 1.78(d)(1)(vi) or 1.114(g) solely on the basis of "excusable neglect."

Rule 60(b)(6), however, does provide for relief on the "catchall" basis of "any other reason justifying relief from the operation of the judgment." See Fed. R. Civ. P. 60(b)(6). While this language appears to be open-ended, this provision is typically limited to exceptional or extraordinary circumstances suggesting that a party was faultless in the delay. See *Marquipp, Inc. v. Fosber Am., Inc.*, 198 F.3d 1363, 1370, 53 U.S.P.Q.2d 1015, 1020 (Fed. Cir. 1999) (citing *Pioneer Inv. Serv. Co. v. Brunswick Assocs. Ltd. P'ship*, 507 U.S. 380, 393 (1993)). The patent rules of practice (§ 1.183) provide that "in an extraordinary situation" in which "justice requires," the Office may waive or suspend any requirement of the regulations in 37 CFR part 1, which is not a requirement of statute. The Office does not anticipate granting petitions under § 1.78(d)(1)(vi) or 1.114(g) on a basis other than a showing that the amendment, argument or evidence sought to be entered could not have been previously submitted. However, in the rare exceptional or extraordinary situation in which an applicant was faultless in the delay, and the situation does not meet the standard that the amendment, argument or evidence sought to be entered could not have been previously submitted, the Office may grant relief pursuant to § 1.183.

Comment 99: Several comments sought clarification as to whether the Office will likely grant a petition for an additional continuing application or request for continued examination if the prior-filed application was abandoned in favor of a continuing application that was filed using the Office electronic filing system or if the request for

continued examination was filed using the Office electronic filing system.

Response: The Office will likely not grant such a petition. The mere fact that a continuing application or request for continued examination is electronically filed via the Office electronic filing system would not be a sufficient showing as to why the amendment, argument or evidence sought to be entered could not have been previously submitted.

Comment 100: A few comments sought clarification as to whether the Office will likely grant a petition for an additional continuing application or request for continued examination if the applicant becomes disabled for a lengthy time during pendency of application.

Response: The Office will likely not grant such a petition on the mere showing that the applicant becomes disabled for a lengthy time during pendency of application. The changes being adopted in this final rule permit applicants to file two continuation or continuation-in-part applications and a request for continued examination, without a petition and showing. 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. Furthermore, applicant may file a petition for suspension of action under § 1.103(a) or a request for deferral of examination under § 1.103(d), when necessary.

Comment 101: Several comments suggested an applicant should be permitted to file an additional continuation or continuation-in-part application or a request for continued examination for patent term extension reasons.

Response: No patent term extension benefits under 35 U.S.C. 154 and 156 will accrue to applicant by filing a third or subsequent continuing application or a second or subsequent request for continued examination. Therefore, a desire to obtain a patent term extension would not be a sufficient reason to permit a third or subsequent continuing application or a second or subsequent request for continued examination. In fact, the filing of a continuing application or request for continued examination may result in the loss of a patent term adjustment under 35 U.S.C. 154(b).

Comment 102: A number of comments expressed concern regarding an example provided by the Office that would meet the showing under §§ 1.78(d)(1) and 1.114 to permit the filing of an additional continuing

application or request for continued examination. This example permits the applicant to file an additional continuing application or request for continued examination when the applicant can show that collection of the data necessary to demonstrate unexpected results was started after the applicant received the rejection for the first time, and was completed only shortly before filing the petition for an additional filing. A number of comments stated that granting a petition should only depend on when the information becomes available and not when the tests begin. One other comment stated that experiments are typically ongoing from the date of invention and that it would be inappropriate for the Office to require experimentation to overcome an obviousness rejection to commence only after the rejection has been made for the first time. One comment suggested removing the language, "could not have been anticipated by applicant," from the example provided by the Office of an adequate showing under § 1.78(d)(1) or 1.114. The comment expressed concern that the Office's example is vague and subjective, and that removal of the language, "could not have been anticipated by applicant," would make the standard less arbitrary.

Response: The example is merely one illustration of when a petition under § 1.78(d)(1)(vi) or 1.114(g) will likely be granted. Other appropriate showings could result in a petition under § 1.78(d)(1)(vi) or 1.114(g) being granted. As discussed previously, the Office will focus on whether the evidence or data submitted was obtained and presented in a reasonably diligent manner.

Comment 103: One comment expressed concern regarding the requirement under § 1.78(d)(1) that an applicant must submit a petition within four months from the actual filing date of the later-filed continuing application, stating that applicant may need more time to complete the experimentation or to prepare the submission in response to a rejection or a requirement for information. This comment suggested that the Office should accept an interim statement from the applicant when more time is needed, such as a statement that the experimentation is progressing, but is not completed.

Response: Applicant should prepare a reply diligently upon receiving the final Office action in the prior application, which provides a six-month statutory period for reply. There is no reason why an applicant should delay preparing a petition under § 1.78(d)(1)(vi) until a third or subsequent continuing application has been filed. Applicants

should not rely solely upon the four-month time period under § 1.78(d)(1)(vi) to prepare and file a petition under § 1.78(d)(1)(vi) for a third or subsequent continuing application. Therefore, the four-month time period from the actual filing date of a third or subsequent continuing application is a reasonable deadline to file a petition under § 1.78(d)(1)(vi).

Comment 104: A number of comments requested clarification regarding who will decide the petitions under §§ 1.78(d)(1) and 1.114. Several comments argued that examiners should not decide the petitions under §§ 1.78(d)(1) and 1.114. Furthermore, a number of comments argued that there is a danger that the standard would be applied differently in different Technology Centers. Several comments suggested that the Office of Petitions should decide the petitions to encourage consistency, ensure uniform interpretation of the rules, and reduce the impact on examining resources. Yet another comment suggested that the BPAI should review the showing required under §§ 1.78(d)(1) and 1.114. The comments further argued that there is a potential for both disparate treatment and inconsistent application of §§ 1.78(d)(1) and 1.114 depending on who decides the petitions and that the potential of either would violate the concept of equal protection under the law.

Several comments requested clarification regarding the procedures for appealing the denial of a petition under § 1.78(d)(1)(vi) or 1.114(g). Specifically, the comments questioned whether a denial of a petition should be appealed to the BPAI or petitioned to the Director. The comment further requested that the Office publish the decisions to encourage consistency and understanding of the standard. One comment sought clarification on the remedies available to an applicant if the Office denies a petition for an additional continuing application or request for continued examination when the examiner introduced new prior art in a final Office action. One comment questioned whether petitions under §§ 1.78(d)(1) and 1.114 could be decided objectively due to the Office's desire to dramatically curtail continuing applications and requests for continued examination.

Response: The Office is making every effort to become more efficient, to apply the rules and statutes uniformly, and to allocate Office resources properly. 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). A decision on a petition under § 1.78(d)(1)(vi) or 1.114(g) is not appealable to the BPAI. The denial of a petition under § 1.78(d)(1)(vi) or 1.114(g) may be viewed as a final agency action for the purposes of judicial review under 5 U.S.C. 704. See MPEP § 1002.02. Final decisions of the Office of the Commissioner for Patents are accessible in the Freedom of Information Act (FOIA) section of the Office's Internet Web site at (<http://www.uspto.gov/web/offices/com/sol/foia/comm/comm.htm>).

The Deputy Commissioner for Patent Examination Policy and officials under the Deputy Commissioner for Patent Examination Policy will decide petitions under §§ 1.78(d)(1)(vi) and 1.114(g) on their merits and the facts in the record and apply the standard in a consistent manner. The officials who will decide petitions under §§ 1.78(d)(1)(vi) and 1.114(g) are professionals who perform their duties within the framework of the law, rules, and examination practice. The Office only desires to curtail continuing applications and requests for continued examination in situations in which the continued examination filing is for the purpose of presenting an amendment, argument or evidence that could have been, but was not, submitted earlier. The Office recognizes the need for continued examination filings for presenting an amendment, argument or evidence that truly could not have been submitted earlier.

Comment 105: A number of comments requested that the Office set a time limit for rendering decisions on petitions under §§ 1.78(d)(1) and 1.114. The comments suggested that the Office should set up an adequately staffed office to decide the petitions promptly, and in any event, before the close of prosecution of the parent application so that applicants are advised of their prosecution options. The comments further suggested that the Office should grant the petition if it is not decided prior to the close of prosecution.

Response: The Office is continuing to ensure prompt and consistent decisions on petitions. It is the general policy of the Office that petitions are decided in the order that they are filed in the Office. Moreover, the Office will likely deny any petition under § 1.78(d)(1)(vi) or 1.114(g) filed before the close of prosecution because applicant may still submit the amendment, argument, or evidence in the application if the prosecution is open. Further, in such situation, it is unlikely that applicants

will be able to show that the amendment, argument, or evidence sought to be entered could not have been previously submitted.

Comment 106: One comment sought clarification regarding the status of an application during consideration of the petition. Specifically, the comment questioned whether an applicant who had filed a petition under § 1.78(d)(1) or 1.114 would be permitted to file a notice of appeal under § 41.31(a) within the time period provided in § 1.134 to avoid abandonment of the application if the petition is dismissed. The comment also inquired whether the notice of appeal fee would be refunded if the petition were granted. Several other comments suggested that the filing of a petition under § 1.78(d)(1) or 1.114 should serve as a notice of appeal if the petition is dismissed. In the alternative, several comments suggested that the Office should allow applicants additional time to file a notice of appeal after the dismissal of a petition.

Response: The Office will make every effort to decide the petitions in a timely manner. The rules have not changed the time period for filing a notice of appeal or an appeal brief. Pursuant to § 41.31(a)(1), an applicant must file a notice of appeal accompanied by the fee set forth in § 41.20(b)(1) within the time period for reply set forth in the Office action. The notice of appeal fee is set by statute and is non-refundable. If the Office grants the petition prior to a decision on the merits by the BPAI, the fees paid for the notice of appeal and the appeal brief can be applied to a later appeal on the same application. See MPEP § 1207.04. Additionally, the filing of a petition will not serve as a notice of appeal, and the Office will not allow more time to file a notice of appeal. The filing of a petition, moreover, does not toll the period for reply to any outstanding Office action. An applicant should not use the continued examination practice as a substitute for an appeal. Rather, an applicant should appeal the decision if warranted.

Comment 107: One comment sought clarification of the status of the application if, after filing a notice of appeal under § 41.31(a), an applicant later files a petition under § 1.114 with a request for continued examination (with a submission and the appropriate fees), which is dismissed. The comment questioned whether the application would be abandoned given that the filing of a request for continued examination would be treated as a request to withdraw the appeal.

Response: In the situation described in the comment, the application would be abandoned if the application has no

allowed claims because the request for continued examination would be treated as a request to withdraw the appeal. See MPEP § 1215.01.

In the situation where applicant already filed a request for continued examination in the application family, a better alternative is for applicant to file the request for continued examination with a petition under § 1.114(g), and then if the petition is not decided prior to the expiration of the statutory period for reply to the final Office action, applicant may file a notice of appeal within the period for reply (and petition for any extension of this period under § 1.136(a) or (b), if necessary) to avoid abandonment of the application. If the Office subsequently dismisses the petition, the request for continued examination will be treated as an improper request for continued examination. However, the request for continued examination will not be treated as a request to withdraw the appeal because the request for continued examination was filed before the notice of appeal (*i.e.*, the application was not on appeal at the time of filing the request for continued examination).

E. Treatment of Multiple Applications

Comment 108: A number of comments suggested the four-month time period provided in § 1.78(f)(1) for identifying to the Office applications that meet the criteria set forth in § 1.78(f)(1) is unreasonably short and is impractical in view of the time often required by the Office to assign application numbers and communicate these numbers to the applicants. One comment suggested the time period provided in § 1.78(f)(1) for identifying to the Office applications that meet the criteria set forth in § 1.78(f)(1) does not permit an applicant to timely identify an international application designating the United States of America that entered the national stage thirty months after the filing date of a nonprovisional application filed under 35 U.S.C. 111(a) when these two applications meet the criteria set forth in § 1.78(f)(1).

Response: The Office notes the concerns expressed in the public comments concerning the proposed changes to § 1.78(f)(1). The Office has modified this provision relative to the proposed changes such that § 1.78(f)(1) as adopted in this final rule provides applicant four months from the actual filing date of a nonprovisional application filed under 35 U.S.C. 111(a), four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in a nonprovisional application which entered the national stage from an international application

after compliance with 35 U.S.C. 371, or two months from the mailing date of the initial filing receipt in the other nonprovisional application, to identify other nonprovisional applications in compliance with § 1.78(f)(1).

Comment 109: A number of comments requested identification of any consequences for failing to identify one or more applications that meet the criteria set forth in § 1.78(f)(1), or for failing to identify such applications within the time period set forth in § 1.78(f)(1).

Response: If applicant inadvertently fails to identify the other nonprovisional applications in compliance with § 1.78(f)(1)(i) within the time period provided in § 1.78(f)(1)(ii), applicant should submit the identification to the Office as soon as practical. If the submission necessitates a new rejection based upon double patenting (including an obviousness-type double patenting rejection) in a second or subsequent Office action on the merits, the examiner may make such an action final (assuming that the conditions for making a second or subsequent action final are otherwise met). The Office may also refer any registered practitioner who repeatedly fails to comply with the rule requirements to the Office of Enrollment and Discipline for appropriate action. Applicants and practitioners are strongly encouraged to revise their practices to ensure timely submissions of the required identification. Applicants and registered practitioners are reminded of their duties under § 10.18 and other professional responsibility rules, and the consequences of any violations (*e.g.*, §§ 10.18(c), 10.18(d) and 10.23).

Comment 110: A number of comments requested clarification of § 1.78(f)(1) and how it interacts with § 1.56, including the preexisting duty of an applicant to disclose similar information to the Office under § 1.56. Several comments stated that § 1.78(f)(1) imposes burdens on the applicants that provide a new basis for inequitable conduct allegations.

Response: Section 1.78(f)(1) provides that an applicant must identify other pending applications or patents that are commonly owned, have a common inventor, and have a claimed filing or priority date within two months of the claimed filing or priority date of the application. This requirement does not supplant an applicant's duty to bring other applications that are "material to patentability" of an application (*e.g.*, applications containing patentably indistinct claims) to the attention of the examiner. Section 1.78(f)(1) does not provide a new basis for allegations of

inequitable conduct when § 1.78(f)(1) is considered in light of the duties concurrently imposed on applicants and practitioners by § 1.56 and the ethics rules in 37 CFR Part 10, such as § 10.18. *See also Dayco*, 329 F.3d at 1365–69, 66 U.S.P.Q.2d at 1806–08 (individuals covered by § 1.56 cannot assume that the examiner of a particular application is necessarily aware of other applications which are "material to patentability" of the application under examination, but must instead bring such other applications to the attention of the examiner).

Comment 111: Several comments requested clarification regarding the applications that must be identified pursuant to § 1.78(f)(1) when common inventor(s) and common ownership exist.

Response: Applicant must identify those pending nonprovisional applications that are filed within two months of each other taking into account any filing date for which benefit is sought, that name at least one common inventor, and that are owned by the same person or subject to an obligation of assignment to the same person. For example, the applicant for application A is required to identify application B and the applicant for application B is required to identify application A in the following situation: The actual filing date of application A is August 8, 2006. Application A claims priority of a foreign application filed on August 10, 2005. The actual filing date of application B is April 11, 2006. Application B claims the benefit of a prior-filed nonprovisional application filed on October 4, 2005, and claims the benefit of a prior-filed provisional application filed on January 4, 2005. Application A and application B have at least one common inventor and common ownership. Each applicant must identify the other application because application A has a filing date (August 10, 2005, the foreign priority date) within two months of a filing date of application B (October 4, 2005, the filing date of the nonprovisional application whose benefit is claimed by application B). "Filing date" includes the actual filing date, foreign priority date, and the filing date of a provisional, nonprovisional, or international application whose benefit is sought under title 35, United States Code.

Comment 112: A number of comments objected that §§ 1.78(f)(1) and (2) require applicants to identify and resolve a possible double patenting issue prior to a rejection being issued by the examiner. One comment suggested that the rebuttable presumption in § 1.78(f)(2) was akin to saying that if an