

EXHIBIT 1

PART 5

applicant submits prior art, there is a presumption of obviousness. One comment suggested that § 1.78(f)(2) was unnecessary because § 1.78(f)(1) provides the Office with sufficient information to require a terminal disclaimer or require the cancellation of claims. One comment stated that many applicants will attempt to circumvent § 1.78(f)(2) by filing multiple applications that meet the criteria set forth in § 1.78(f)(2), but that include both patentably distinct claims and patentably indistinct claims.

Response: The rebuttable presumption set forth in § 1.78(f)(2) is a procedural tool requiring the applicant to help focus and consolidate the examination process and thus is not akin to a presumption of obviousness. The examination is more efficient when double patenting issues are identified and resolved early in the process. Where an applicant chooses to file multiple applications that are substantially the same, it will be the applicant's responsibility to assist the Office in resolving potential double patenting situations rather than taking no action until faced with a double patenting rejection. Although the ultimate determination of double patenting rests with the Office, applicants are in a far better position than the Office to identify applications that may raise double patenting concerns.

Section 1.78(f)(2) requires applicant to resolve the double patenting issues early in the prosecution by either: (1) Filing a terminal disclaimer and an explanation as to why the multiple applications containing patentably indistinct claims are necessary; or (2) explaining how the application contains only claims that are patentably distinct from the claims of other related applications. Therefore, with the benefit of § 1.78(f)(2), double patenting issues could be resolved more expeditiously before the first Office action on the merits, thus saving the examiner time by eliminating the need to search for related applications, analyze the potentially conflicting claims, and make the rejection. Merely identifying the other applications under § 1.78(f)(1) would not result in these benefits.

If the criteria set forth in § 1.78(f)(2) are met, the rebuttable presumption would apply regardless of whether a few of the claims are patentably distinct from the claims in the other related applications because § 1.78(f)(2) provides that "a rebuttable presumption shall exist that a nonprovisional application contains at least one claim that is not patentably distinct * * * ." To rebut this presumption, applicant must explain how the application

contains only claims that are patentably distinct. Merely explaining that some of the claims are patentably distinct would not be sufficient to rebut this presumption.

Comment 113: One comment objected that § 1.78(f)(2) would impose an undue burden on inventors because it creates a presumption that commonly owned patent applications which share a common disclosure and at least one inventor, are patentably indistinct. The comment further asserted that the presumption is not in the interest of American competitiveness as American companies often file numerous patent applications with claims directed to different features of the same new product. One comment suggested that § 1.78(f)(1) places an excessive burden on applicants to anticipate all the unique claims that could be filed at the time of filing the initial application.

Response: Section 1.78(f)(2)(i) requires that the related applications must have the same claimed filing or priority date in addition to being commonly owned with one inventor in common and with substantial overlapping disclosure. Multiple patent applications related to the same product are not precluded by § 1.78(f)(2). In the situation where § 1.78(f)(2)(i) actually applies and the multiple applications relate to patentably distinct features of the same new product, it should not be difficult to explain how the applications contain patentably distinct claims under § 1.78(f)(2)(ii)(A), and thereby rebut the presumption. Thus, the presumption of § 1.78(f)(2)(i) does not impose an undue burden on inventors.

None of the criteria under § 1.78(f)(1) for identifying certain related applications has anything to do with claims that could be filed in the initial application as suggested by the comment. Instead, § 1.78(f)(1) merely requires identification of applications that meet the identified criteria. Accordingly, there is no such burden placed on applicants.

Comment 114: Several comments requested clarification of the language "taking into account any filing date for which a benefit is sought under title 35, United States Code," in § 1.78(f)(1). Those comments also inquired whether this language includes provisional applications for which benefit is sought, merely the first nonprovisional application for which benefit is sought, or every nonprovisional application for which benefit is sought.

Response: Section 1.78(f)(1) requires applicant to consider all provisional, nonprovisional, international, and foreign applications for which benefit is sought. If the filing date of an

application whose benefit is claimed in a nonprovisional application is within two months of the filing date of another pending nonprovisional application, and the nonprovisional applications name at least one inventor in common and are owned by the same person or subject to an obligation of assignment to the same person, each applicant of the nonprovisional applications must identify the other nonprovisional application to the Office. For example, if two nonprovisional applications claim priority of the same foreign application (or two foreign applications filed within two months of each other), name at least one inventor in common, and are owned by the same person, then each applicant of the nonprovisional applications must identify the other nonprovisional application, no matter the difference in time between their U.S. filing dates.

Comment 115: A number of comments suggested that § 1.78(f)(1) could be eliminated if the Office assigned all related applications to the same examiner.

Response: The Office attempts to assign related applications to the same examiner where possible. However, applicant is in the best position to determine and identify when applications are related, not the Office. By meeting the provisions of § 1.78(f), applicants will reduce the burden on the Office to identify which applications are related and facilitate examination of the related application by the examiner.

Comment 116: Several comments suggested that § 1.78(f)(1) would be burdensome to applicants who file a large number of applications in related areas of research. These comments suggested that the examiners working in these areas of technology will also experience a significant burden. A number of comments suggested that the Office has not sufficiently justified how the benefits of § 1.78(f) outweigh the added costs for both applicants and the Office. These comments suggested that the existing rules relating to double patenting and the filing of terminal disclaimers are sufficient to solve the problems of patentably distinct claims, and that the Office's searchable database of applications makes the § 1.78(f) changes unnecessary. The comments argued that examiners can perform common inventor searches as easily as applicants. A number of comments doubted the Office's reasoning that duplicative applications containing "conflicting or patentably indistinct claims" are having a crippling effect on the Office's ability to examine non-continuing applications. A number of comments making such an objection

stated that in fiscal year 2005, less than three percent of the patents granted contained a terminal disclaimer, and accordingly there is no basis for the rebuttable presumption of patentably indistinct claims. One comment suggested that § 1.78(f)(2) would not reduce examiner workloads because examiners would still be required to make their own separate determinations regarding whether claims are patentably distinct in order to evaluate and address arguments made by applicants pursuant to § 1.78(f)(2).

Response: Multiple applications with patentably indistinct claims divert patent examining resources from the examination of new applications. This final rule encourages applicants to submit all of the claims that are patentably indistinct in one single application. See §§ 1.78(f) and 1.75(b)(4). By presenting all of the patentably indistinct claims in one application, applicants can alleviate the Office's burden of searching for multiple applications containing patentably indistinct claims, analyzing the applications for double patenting issues, and requiring cancellation of the claims or a terminal disclaimer. This will also ensure that one single examiner will examine the same invention to provide consistent and focused examination. Furthermore, it will preclude applicant from submitting multiple applications to the same subject matter (with claims that are patentably indistinct), each with five or fewer independent claims or twenty-five or fewer total claims, for the purpose of avoiding the requirement to submit an examination support document.

It is envisioned that many applicants will be proactive by filing fewer applications containing patentably indistinct claims, unless there is a good and sufficient reason to do so. By minimizing such filings, applicants will reduce the Office's burden of examining multiple applications containing patentably indistinct claims. Applicants are in a far better position than the Office to identify related applications pursuant to § 1.78(f)(1). The Office's searchable database is not a sufficient substitute for applicant's knowledge of related applications, particularly in view of the fact that ownership identification is not required when an application is filed, and the fact that applications are often filed without executed declarations that correctly name all of the inventors.

The terminal disclaimer statistic cited in the comment covers all granted patents. It does not specifically relate to the limited situation covered by § 1.78(f)(2). Furthermore, double

patenting issues must be considered in every application where the applicant filed another related application, not only those applications in which applicant filed a terminal disclaimer. For example, the statistic cited in the comment does not include applications in which the applicants canceled the patentably indistinct claims.

The burden on the examiner to evaluate arguments presented by applicant is less compared to the burden of independently identifying and reviewing each application that meets the criteria set forth in § 1.78(f)(2). Furthermore, the issues would be resolved earlier in the prosecution. Without the presumption of at least one patentably indistinct claim and applicant's assistance under § 1.78(f)(2), it is more difficult to resolve potential double patenting situations.

Comment 117: Several comments suggested that the two-month window between filing dates set forth in § 1.78(f)(1) is overly burdensome on both the Office and the applicant.

Response: The identification requirement under § 1.78(f)(1) is consistent with the duty to disclose information that is material to patentability under § 1.56. The two-month window set forth in § 1.78(f)(1) merely provides guidance to applicants for at least those applications that must be identified to the Office. Often, related applications filed outside the two-month window should also be identified to the Office under § 1.56.

Comment 118: One comment stated that compliance with § 1.78(f)(1) would be difficult for corporations that employ multiple law firms to handle their patent prosecution portfolios.

Response: Each corporation typically has a person or a group of people who oversees its outside counsel and manages its patent portfolio. It is not unreasonable for the Office to assume that the person(s) managing the patent portfolio is aware of the contents of the corporation's applications being prosecuted by different law firms. In any event, it is appropriate for the corporation to bear the burden of tracking applications for compliance with § 1.78(f)(1).

Comment 119: One comment suggested that some docketing systems currently used by practitioners do not permit searching by inventor names in a manner that would enable practitioners to identify applications with common inventors that were filed within two months of each other.

Response: The fact that some practitioners do not have a docketing system to identify applications with common inventors that were filed

within two months of each other is not a sufficient reason for the Office to not require the information under § 1.78(f)(1) that would assist the Office in identifying applications that potentially have double patenting issues. Practitioners should have the required information even though their docketing system may not keep track of applications with common inventors. Practitioners should have more reliable information regarding applications with common inventors than the Office's database because many applications are filed without an executed oath or declaration and the actual inventors are not often identified to the Office for a number of months after the filing date. Furthermore, ownership is not required to be identified when an application is filed.

Comment 120: One comment questioned whether extensions of time would be available for applicants attempting to comply with the requirements of § 1.78(f)(1).

Response: Section 1.78(i) as adopted in this final rule provides that "[t]he time periods set forth in [§ 1.78] are not extendable."

Comment 121: A number of comments questioned why applicants would need to identify to the Office applications with a common inventor under § 1.78(f)(1) that contain patentably distinct claims because those applications are not candidates for an obviousness-type double patenting rejection.

Response: Applicant is in the best position to identify to the Office applications with potentially conflicting claims. By taking responsibility for identifying such applications, applicant will be reducing the burden on the Office so that the Office can focus its limited examining resources on examining new applications. The ultimate determination of obviousness-type double patenting remains with the Office, which is why it is critical that applications that meet the criteria of § 1.78(f)(1) be identified to the Office.

Comment 122: A number of comments suggested that while an applicant is in a better position to know of related applications that have been filed, they are not in the position to determine whether the claims of these applications are patentably distinct. This is a function of the Office. One comment argued that the Office is making an unsupported assumption that the applicant is in a far better position than the Office to determine whether there are one or more other applications or patents containing patentably indistinct claims.

Response: The applications whose specifications possibly contain patentably indistinct claims were made by or on behalf of the inventor or applicant, and not the Office or the examiner. See 35 U.S.C. 111(a). Thus, the applicant is in a better position than the Office or examiner to know when such related applications have been filed. While the ultimate determinations of double patenting and patentability remain with the Office, the Office rejects the position that the applicant has no responsibility to facilitate those decisions. The information provided by applicant in compliance with § 1.78(f)(1) is reasonably necessary for the Office to determine double patenting issues. With the information provided before the first Office action on the merits, the Office could make the patentability determination more efficiently and thereby reduce pendency. For example, the examiner could identify and resolve any double patenting issues earlier in the prosecution.

Comment 123: One comment suggested that the requirements of § 1.78(f)(1) would raise inventorship and ownership issues when entities have entered into a confidential research agreement.

Response: The identification of such applications is reasonably necessary for an efficient and effective examination. This requirement is similar to that imposed upon applicants having knowledge of material prior art that became known to them via information covered by a confidentiality agreement. In such an instance, the existence of a confidentiality agreement does not relieve applicants from their duty to disclose this prior art information to the Office. In any event, § 1.78(f)(1) requires identification of only the commonly owned applications (if certain conditions are met), but not identification of the owner. 35 U.S.C. 115 requires that the inventors identify themselves.

Comment 124: One comment suggested that § 1.78(f) will have the greatest adverse impact on small entities.

Response: The rules apply equally to both non-small entities and small entities. The comment did not provide persuasive data or other evidence supporting the conclusion. The Office's experience is that small entities do not file a larger percentage of multiple applications than non-small entities. Thus, it is doubtful that any impact, if adverse, will affect small entities the most.

Comment 125: Several comments questioned whether the Office should

even concern itself with obviousness-type double patenting rejections. They suggested that essentially no harm at all to the public exists through the grant of plural applications having the same, or roughly the same, filing dates, while the technical traps for the unwary and the undue examination burdens established by double patenting rejections unduly complicate procurement and burden the Office.

Response: There are two reasons why the Office still needs to make obviousness-type double patenting rejections in applications filed on or after June 8, 1995, and that are subject to a twenty-year term under 35 U.S.C. 154(a)(2). First, 35 U.S.C. 154 does not ensure that any patent issuing on a utility or plant application will necessarily expire twenty years from the earliest filing date for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c) because 35 U.S.C. 154(b) includes provisions for patent term extension based upon prosecution delays during the application process. Second, § 1.321(c)(3) requires that a terminal disclaimer filed to obviate an obviousness-type double patenting rejection based on commonly owned patentably indistinct claims include a provision that any patent granted on that application be enforceable only for and during the period that the patent is commonly owned with the application or patent which formed the bases for the rejection. This requirement prevents the potential for harassment of an accused infringer by multiple parties with patents covering the same patentable invention. See MPEP § 804.02. If applicant files all of the patentably indistinct claims in one application, applicant could alleviate the Office's burden of searching for multiple applications containing patentably indistinct claims, analyzing the applications for double patenting issues, and requiring cancellation of the claims or a terminal disclaimer.

Comment 126: One comment suggested that § 1.78(f)(2) prevents an applicant from claiming different embodiments unless the embodiments are patentably distinct.

Response: Under this final rule, applicant may present claims during the prosecution of an initial application and two continuation or continuation-in-part applications plus one request for continued examination in the application family, without any justification. Applicant therefore should have sufficient opportunity to present claims to different embodiments of an invention in these filings. Furthermore, applicant is not required to provide an explanation under § 1.78(f)(2)(ii)(B) for a

continuation application or continuation-in-part application of a prior-filed application that has been allowed.

Comment 127: One comment suggested that examiners would not have any incentive to find claims patentably distinct.

Response: Examiners are professionals who perform their duties within the framework of the current patent laws, rules and examination practices. No persuasive explanation was given in support of the suggestion that examiners would be less likely to find claims patentably distinct.

Comment 128: One comment suggested that the rebuttable presumption set forth in § 1.78(f)(2) was inconsistent with the Office's restriction practice. The comment suggested that it was inconsistent to presume that claims are patentably indistinct when, if the claims were filed in one application, they would be found to be patentably distinct, and subject to a restriction requirement.

Response: The changes to § 1.78(f)(2) and restriction practice encourage applicant to file a single application for each patentably distinct invention. For example, if two or more independent and distinct inventions are claimed in a single application, the examiner may make a restriction requirement. See § 1.142. The filing of multiple applications that together claim only one patentable invention (*i.e.*, the applications contain patentably indistinct claims), however, is diverting the Office's limited examining resources from examining new applications. Applicant should file a single application claiming one patentable invention rather than multiple applications claiming the same patentable invention. Applicant may rebut the presumption that claims in multiple applications are not patentably distinct by explaining how the application contains only claims that are patentably distinct from the claims in each of the other applications. Similar to the restriction practice, applicant may maintain multiple applications if the applications contain patentably distinct claims (*i.e.*, each application is claiming one patentably distinct invention).

Comment 129: One comment objected that remarks by applicants under § 1.78(f)(2) to rebut the double patenting presumption would create prosecution history estoppel before the Office issued a rejection that could impact on the certainty and quality of the patent.

Response: First, applicant remarks under § 1.78(f)(2) would be akin to remarks set forth in response to a double

patenting rejection. The Office does not consider the possibility of prosecution history estoppel to be a sufficient reason to forego the presumption built into § 1.78(f)(2). Second, such remarks would not be required if all patentably indistinct claims are included in one application.

Comment 130: One comment suggested that the rebuttable presumption in § 1.78(f)(2) would require applicants who normally file multiple utility applications within two months of each other, each with more than the threshold number of claims and each claiming benefit of the same provisional application, to now file an examination support document for their applications. The comment suggested that this would be especially true for those applications forming a portfolio being developed for a new technology.

Response: The rebuttable presumption provision of § 1.78(f)(2) would apply only if the nonprovisional applications have the same filing date, taking into account any filing date for which a benefit is sought, name at least one inventor in common, are owned by the same person or are subject to an obligation of assignment to the same person, and contain substantial overlapping disclosure. The rebuttable presumption provision of § 1.78(f)(2) does not apply simply because commonly owned applications are filed within two months of each other. In addition, § 1.78(f)(2) provides for a rebuttable presumption that applications contain patentably indistinct claims. The applications thus will be treated as containing patentably indistinct claims for claim counting purposes under § 1.75(b)(4) if the applicant does not explain how the applications do not contain patentably indistinct claims or if the examiner does not agree with the explanation. If an applicant files multiple applications that contain patentably indistinct claims, there is no reason why the Office should treat an applicant who spreads patentably indistinct claims among multiple applications differently than an applicant who presents all of the patentably indistinct claims in a single application.

Comment 131: Several comments suggested that the filing of multiple applications having at least one common inventor and specifications with overlapping disclosures cannot be presumed to be bad faith prosecution because these applications typically claim distinct inventions that relate to the same product or service and such applications are not used to delay prosecution. One such comment stated that the rebuttable presumption under

§ 1.78(f)(2) represents an overreaction to tactics engaged in by a small minority of applicants. Another such comment took offense to § 1.78(f)(2) as appearing to be based on underlying presumptions that applicants are gaming the system and their representatives are acting in bad faith whenever applications are filed meeting the criteria of the rule.

Response: There is no presumption of bad faith on the part of applicant. The rebuttable presumption is simply a procedural tool requiring the applicant to help focus and consolidate the examination process. This will help examiners to resolve double patenting issues early in the examination process and contribute to examination efficiency by eliminating the need to search for related applications.

Comment 132: A number of comments stated that the § 1.78(f)(2) criteria do not automatically lead to the conclusion the claims are patentably indistinct and that applicants may easily maintain multiple applications by preparing claims that are uniquely supported only in the application in which they appear. One comment objected that the mere presence of specifications with overlapping disclosures does not create a *prima facie* case of patentably indistinct claims as evidenced by the fact that an obviousness-type double patenting rejection requires a comparison between the claims of the application being examined and those of the co-owned application or patent, not a comparison of their disclosures.

Response: The § 1.78(f)(2) criteria lead to a rebuttable presumption, which is rebuttable that patentably indistinct claims exist. The rebuttable presumption is not a merits determination of patentability, but is simply a procedural tool requiring the applicant to help focus and consolidate the examination process. Further, an overlapping disclosure is not the only condition for the presumption under § 1.78(f)(2). Section 1.78(f)(2) also specifies that the applications must have the same claimed filing or priority date, name at least one inventor in common, and have common ownership. Accordingly, the presumption is limited so that it only applies to applications that most likely contain patentably indistinct claims. The rebuttable presumption does not equate to a *prima facie* case of patentably indistinct claims. An applicant may rebut the presumption by explaining how the application contains claims that are patentably distinct from the claims in each of the other applications or patents. If the applicant cannot rebut the presumption, applicant must submit a

terminal disclaimer in accordance with § 1.321(c) and explain why there are two or more pending nonprovisional applications which contain patentably indistinct claims.

Comment 133: One comment suggested that the rebuttable presumption should be provisional as the scope of the claims in question may change during the course of prosecution.

Response: Section 1.78(f)(2) as adopted in this final rule requires the appropriate action within the later of: (1) Four months from the actual filing date of an application filed under 35 U.S.C. 111(a) or four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f); or (2) the date on which a claim that is not patentably distinct from at least one of the claims in the other applications is presented. For example, if the presumption under § 1.78(f)(2) applies, applicant must rebut this presumption within four months from the actual filing date of an application filed under 35 U.S.C. 111(a) for the original claims presented on the filing date of the application. If applicant subsequently files an amendment that adds a new claim after four months from the filing date of the application, applicant must rebut this presumption for such a claim when applicant files the amendment.

Comment 134: One comment suggested that since the Office has stated in MPEP § 804.02 that patent applications which give rise to obviousness-type double patenting rejections are in the public interest, it stands to reason that the rules that seek to preclude such applications are against public interest.

Response: The Office stated that the use of a terminal disclaimer in overcoming an obviousness-type double patenting rejection is in the public interest because it encourages the disclosure of additional developments, the earlier filing of applications, and the earlier expiration of patents whereby the inventions covered become freely available to the public. See MPEP § 804.02. The Office did not state that the public interest was served by all applications that contain patentably indistinct claims.

Comment 135: One comment questioned whether applications subject to the requirements of § 1.78(f)(2) would increase examination pendency or add to the Office's backlog since the rejections set forth in applications with patentably indistinct claims are typically overcome by a properly drafted terminal disclaimer.

Response: The changes to § 1.78(f)(2) in this final rule are aimed at reducing pendency and the Office's backlog. Specifically, § 1.78(f)(2) requires applicant to resolve the double patenting issues early in the prosecution (e.g., four months from the actual filing date of the application) by either: (1) Filing a terminal disclaimer and an explanation as to why the multiple applications containing patentably indistinct claims are necessary; or (2) explaining how the application contains only claims that are patentably distinct from the claims of other related applications. Therefore, double patenting issues could be resolved before the first Office action on the merits, thus saving the examiner time by eliminating the need to search for related applications, analyze the potentially conflicting claims, and make the rejection. As a result, examination can be more focused on prior art and other patentability issues.

Without the rebuttable presumption of § 1.78(f)(2), it would be harder for the examiner to identify and resolve the potential double patenting situation. In addition, if an Office action in an application to which the rebuttable presumption applies must include a double patenting rejection, it is because the applicant has not helped to resolve the double patenting situation pursuant to § 1.78(f)(2). Accordingly, a double patenting rejection made for the first time in a second or subsequent Office action will not preclude the Office action from being made final (assuming that the conditions for making a second or subsequent action final are otherwise met). Thus, applicants' responsibility to take the initiative under § 1.78(f)(2) to resolve double patenting situations will expedite examination, even if this responsibility does not result in the prompt resolution of the double patenting situation. Further, the Office envisions that many applicants will file fewer applications containing patentably indistinct claims in light of § 1.78(f)(2) unless there is a good and sufficient reason to do so. Therefore, the Office expects that the requirements of § 1.78(f)(2) will not increase examination pendency or add to the Office backlog.

Comment 136: One comment suggested that the strategy for circumventing the claim requirement set forth in § 1.75 by filing multiple applications in order to receive substantive examination on more than the threshold number of claims conflicts with § 1.78(f)(2).

Response: As suggested by the comment, some applicants might attempt to circumvent the requirements

in § 1.75(b)(1) by filing multiple applications. Such a strategy would be ineffective as a result of the provisions of § 1.75(b)(4) and § 1.78(f). For the purpose of determining whether each of the multiple applications exceeds the five independent claim and twenty-five total claim threshold, the Office will treat each application as having the total number of all of the claims (whether in independent or dependent form) from all of the multiple applications. See § 1.75(b)(4).

Comment 137: Several comments objected that applicants are being required to explain or justify why they are filing patent applications. Some of the comments stated that such a requirement is unnecessarily burdensome and forces applicants to make statements that could lead to prosecution history estoppel issues. One of the comments questioned why § 1.78(f)(2)(ii) requires applicants to explain why the filing of two applications is necessary if a terminal disclaimer has been filed.

Response: The filing of multiple applications containing patentably indistinct claims is impairing the Office's ability to examine new applications. Applicant has the opportunity to avoid drafting and filing applications that satisfy the criteria of § 1.78(f)(2) by filing a single application containing all of the patentably indistinct claims. Furthermore, § 1.78(f)(2)(i) gives applicant the option to rebut the presumption of patentably indistinct claims rather than filing a terminal disclaimer and an explanation. Also note that the § 1.78(f)(3) provision was similarly set forth in former § 1.78(b).

Comment 138: Several comments were critical of § 1.78(f)(2) and stated that the rule would merely result in applicants filing jumbo patent applications with multiple claim sets drawn to patentably distinct inventions in order to force the Office to issue restrictions instead of filing multiple applications on the same day that meet the criteria of § 1.78(f)(2).

Response: Section 1.78(f)(2) permits applicant to file multiple applications claiming patentably distinct inventions. Applicant may rebut the presumption by arguing that the applications claim patentably distinct inventions. Applicant also has the option of filing a single application to claim patentably distinct inventions or when applicant is unsure whether the inventions are patentably distinct. As noted in *Berg*, 140 F.3d at 1434, 46 U.S.P.Q.2d at 1231, applicants achieve no advantage by choosing to file patentably indistinct claims in separate applications because

the claims would be subject to a rejection under the one-way double patenting analysis. The *Berg* court stated that "[i]f a potential applicant is unsure whether it has more than one patentably distinct set of claims, the PTO advises that it file all of the claims as one application." See *id.* at 1435, 46 U.S.P.Q.2d at 1232. The option presented by the Office was considered by the court to be reasonable, notwithstanding the possibility that the examiner might not make a restriction requirement.

Comment 139: One comment suggested that applicants will be unfairly disadvantaged if they fail to convince the examiner that the claims are patentably distinct, as they will likely be simultaneously subject to a final rejection with the probability of just a single continuation application to gain allowance of the claims.

Response: This final rule permits applicant to file two continuation or continuation-in-part applications and one request for continued examination in an application family, without any justification. If a timely rebuttal under § 1.78(f)(2) is filed before the application is taken up for initial examination, the applicant will not be subject to a final rejection in the first Office action on the merits. Only if the rebuttal is not timely filed would the applicant be subject to a final rejection in the succeeding Office action in the event the examiner makes a determination of patentably indistinct claims.

Comment 140: One comment stated that the § 1.78(f)(2) rebuttable presumption of patentably indistinct claims is overreaching and its burden on the applicant cannot be justified since it is very common for an applicant to file multiple applications having a single specification and patentably distinct claims drawn to different inventions.

Response: The rebuttable presumption of § 1.78(f)(2) is not overreaching as it applies only to applications that have the same filing date, taking into account any filing date for which a benefit is sought, name at least one inventor in common, are owned by the same person or are subject to an obligation of assignment to the same person, and contain substantial overlapping disclosure. Thus, it applies only to applications that most likely contain patentably indistinct claims. Applicant who files multiple applications claiming patentably distinct inventions may simply rebut the presumption. Applicant also has the option of filing a single application to claim patentably distinct inventions or when applicant is unsure whether the inventions are patentably distinct. If an

application claims two or more independent and distinct inventions, the examiner may make a restriction requirement. See § 1.142.

Comment 141: Several comments requested clarification as to the standard for "patentably indistinct" as the term appears in § 1.78 and whether this applies to "same invention" double patenting under 35 U.S.C. 101, or "obviousness-type" double patenting, or something different. Several comments requested clarification concerning what would be an adequate explanation under § 1.78(f)(2)(i) to rebut the presumption of patentably indistinct claims.

Response: The standard for "patentably indistinct" as the term appears in § 1.78 is one-way distinctness in an obviousness-type double patenting analysis. See MPEP § 804(II)(B)(1)(a). The presumption under § 1.78(f)(2) may be rebutted by showing that the application claims are directed to a separate invention, or by pointing to a unique claim element(s) in the independent claim(s) that patentably distinguishes them from the claims in the application(s) that gave rise to the § 1.78(f)(2) presumption.

Comment 142: A number of comments questioned whether all patentably indistinct claims in multiple applications meeting the conditions of § 1.78(f)(2) are required to be submitted in a single application absent good and sufficient reason.

Response: If all patentably indistinct claims can be filed in a single application and there is no good and sufficient reason for the patentably indistinct claims to be filed in multiple applications, then applicant should file the patentably indistinct claims in a single application. Section 1.78(f)(3) provides that the Office may require elimination of the patentably indistinct claims meeting the conditions of § 1.78(f)(3) in all but one of the applications in the absence of a good and sufficient reason for there being two or more applications containing patentably indistinct claims.

Comment 143: Several comments suggested that § 1.78(f)(2) be changed to provide that the presumption of patentably indistinct claims be applied to all related applications only when a double patenting rejection is made in one of the related applications.

Response: The suggested change would delay triggering the presumption of patentably indistinct claims and not help reduce the burden on examiners with respect to reviewing and analyzing related applications with potentially conflicting claims.

Comment 144: One comment stated that by requiring more than a terminal disclaimer to overcome an obviousness-type double patenting rejection, the Office is outside its authority.

Response: No more than a terminal disclaimer is required to overcome obviousness-type double patenting if the reference is a patent. However, if the obviousness-type double patenting reference is a pending application, consideration of patentably indistinct claims can be expedited in a single application. Such a requirement is consistent with the Office's statutory authority under 35 U.S.C. 2(b)(2). Nothing in the patent statutes requires the Office to accept patentably indistinct claims in multiple applications absent a good and sufficient reason.

Comment 145: Several comments suggested eliminating the presumption of double patenting in § 1.78(f)(2) and identification of similar applications in § 1.78(f)(1) as such requirements are already in the rules.

Response: The former rules of practice did not expressly require the identification of applications based on filing dates, inventorship and ownership conditions. Some of the applications identified pursuant to § 1.78(f)(1) may be applications with the potential to be material to patentability as prosecution progresses. Section 1.78(f)(2) as adopted in this final rule explicitly sets forth for the first time a presumption of patentably indistinct claims among related applications meeting certain conditions.

Comment 146: Several comments suggested permitting "voluntary" divisional applications instead of requiring an explanation adequate to rebut the § 1.78(f)(2) presumption of patentably indistinct claims.

Response: It is unclear how such a strategy would reduce pendency and promote quality. Anytime a terminal disclaimer is filed under the conditions of § 1.78(f)(2), the applicant would also have to file a satisfactory explanation of why there are two or more commonly owned pending nonprovisional applications naming at least one inventor in common which contain patentably indistinct claims. The alternative to filing a terminal disclaimer with the explanation is to rebut the § 1.78(f)(2) presumption with a showing that the application contains only patentably distinct claims.

Comment 147: Several comments requested clarification as to what constitutes "substantial overlapping disclosure" and whether it encompasses, for example, a single common sentence or disclosed element,

or an incorporation by reference to another application.

Response: As discussed previously, § 1.78(f)(2)(i) provides that substantial overlapping disclosure exists if the other pending or patented nonprovisional application has written description support under 35 U.S.C. 112, ¶ 1, for at least one claim in the nonprovisional application. This written description support may be either by express disclosure or by an incorporation by reference to another application. A single common sentence or disclosed element most likely would not, by itself, constitute "substantial overlapping disclosure."

Comment 148: One comment was critical that § 1.78(f)(2)(i) will force applicants to prove a negative in order to show that there are no patentably indistinct claims among the pending nonprovisional applications.

Response: To rebut the presumption under 1.78(f)(2)(i), applicant could identify claim elements that patentably distinguish the applications from one another. It is not required that the applicant prove a negative.

Comment 149: Several comments objected that § 1.78(f)(3) could effectively promote a ban on continuation applications with patentably indistinct claims, and may unnecessarily limit claim broadening in continuation applications.

Response: Section 1.78(f)(3) is a restatement of former § 1.78(b), which previously gave the Office the same discretion to require elimination of patentably indistinct claims in all but one of the pending nonprovisional applications. The only difference is that the Office will now have the benefit of § 1.78(f)(2)(i) to evaluate when to properly exercise that discretion.

Comment 150: A number of comments noted that § 1.78(f)(3) essentially restates former § 1.78(b) and questioned whether § 1.78(f)(3) would achieve anything beyond what former § 1.78(b) achieved during its existence for over thirty-five years.

Response: This provision will be more effectively utilized with the other changes to § 1.78(f).

Comment 151: A number of comments requested clarification of the procedure for reviewing a determination of multiple applications with patentably indistinct claims. One comment requested clarification as to whether an adverse determination is redressed by way of appeal to the BPAI or to a district court.

Response: Applicants may petition the Director for review of administrative requirements by an examiner or other Office official, such as a requirement for

an examination support document under § 1.265 when claims in multiple applications are determined to be patentably indistinct thus causing the involved applications to exceed the five independent claim and twenty-five total claim threshold set forth in §§ 1.75(b)(1), (b)(3), and (b)(4), as well as a requirement that claims in multiple applications that are determined to be patentably indistinct be canceled from all but one application.

The BPAI's jurisdiction and appeal procedure in general has not been changed as a result of this final rule. As before, applicant may appeal the decision of the examiner to the BPAI under 35 U.S.C. 134 and § 41.31 if at least one claim has been twice rejected (*see* § 41.31(a)), including an obviousness-type double patenting rejection.

Comment 152: A number of comments were critical of the "may require elimination" in § 1.78(f)(3), suggesting that the discretion would be arbitrarily applied by individual examiners and inconsistently applied by the Patent Examining Corps. Some comments requested clarification of the procedure and questioned whether the Office will make a double patenting rejection and/or require elimination of patentably indistinct claims. Some comments questioned whether a requirement to eliminate patentably indistinct claims would apply to all but a single application.

Response: Section 1.78(f)(3) provides that, in the absence of good and sufficient reason for there being multiple commonly owned applications that contain patentably indistinct claims, the Office may require elimination of the patentably indistinct claims from all but one of the applications. The term "may" provides both the Office and applicants with the necessary discretion and flexibility either to eliminate the identified claims found to be patentably indistinct, or to merge multiple applications into one. Substantively, § 1.78(f)(3) is a restatement of former § 1.78(b).

Comment 153: A number of comments stated that requirements to eliminate patentably indistinct claims from all but one of the applications will lead to applicant appeals or petitions before examination resulting in a substantial increase in pendency while consuming Office and applicant resources. Some comments stated that § 1.78(f)(3) requirements will discourage applicants from acknowledging claims that are patentably indistinct and result in increased challenges to double patenting rejections.

Response: As discussed previously, it is envisioned that many applicants will file fewer applications containing patentably indistinct claims unless there is a good and sufficient reason to do so. Because any requirement under § 1.78(f)(3) would be made during examination, there can be no petitions to the Director, or appeals, filed before examination as suggested by the comment. The comment provided no reasoning as to why § 1.78(f)(3) would have the negative impact anticipated by the comment when § 1.78(f)(3) is a restatement of former § 1.78(b).

Comment 154: One comment suggested allowing multiple related applications, keeping the requirement to identify related applications, and adding a requirement for applicant to briefly explain the subject matter claimed in each related application.

Response: The proposed solution would not meet the objectives of these rules and would not prevent the Office from unnecessarily expending the Office's resources in the examination of multiple applications with patentably indistinct claims.

Comment 155: Several comments questioned whether excess claim fees would be refunded upon elimination of patentably indistinct claims pursuant to § 1.78(f)(3).

Response: Applicant may request a refund of any excess claims fees paid on or after December 8, 2004, if applicant cancels the claim before an examination on the merits has been made of the application. *See* § 1.117.

Comment 156: Several comments questioned why there is different language in §§ 1.78(f)(3) and 1.75(b)(4), and questioned whether the language should be the same.

Response: As the comment noted, the proposed provisions that the Office may require elimination of the patentably indistinct claims from all but one of the applications in §§ 1.78(f)(3) and 1.75(b)(4) were duplicative and might have appeared different. In view of the comment, the Office did not adopt the proposed provision that the Office may require elimination of the patentably indistinct claims from all but one of the applications in § 1.75(b)(4). The Office adopted this provision in § 1.78(f)(3) which is substantively a restatement of former § 1.78(b). *See* the discussion of §§ 1.75(b)(4) and 1.78(f)(3).

Comment 157: Several comments requested that implementation of § 1.78(f)(3) be delayed until other rule changes can be evaluated.

Response: Section 1.78(f)(3) is a restatement of former § 1.78(b) which has been in effect since April 30, 1971.

See Conflicting Claims, 36 FR 7312 (April 17, 1971) (final rule).

Comment 158: One comment stated that the patentably indistinct claims in multiple applications are a necessary and desirable component of United States patent law.

Response: The comment did not provide a reason why the need for applicants to have separate applications with patentably indistinct claims outweighs the needs of the Office to reduce the resources exhausted during the examination of different applications with patentably indistinct claims.

Comment 159: One comment stated that § 1.78(f)(3) imposes an overly stringent standard that jeopardizes applicant's ability to ensure patented claims will be held valid if challenged during litigation. One comment stated that the § 1.78(f) changes are based on the presumption that all patentably indistinct claims can be supported and examined in the same application, but that is not always the case.

Response: Section 1.78(f)(3) is a restatement of former § 1.78(b), which previously gave the Office the same discretion to require elimination of patentably indistinct claims in all but one of the pending nonprovisional applications. Therefore, § 1.78(f)(3) does not introduce a new standard as suggested in the comment. Applicant may file multiple applications, but applicant must, in each application, submit a terminal disclaimer in accordance with § 1.321(c) and explain why there are two or more pending nonprovisional applications containing patentably indistinct claims.

Comment 160: One comment suggested allowing applicants to add patentably indistinct claims to an application after determination that an original set of claims is allowable.

Response: Patentably indistinct claims should not be added to an application upon allowance of the original claims, but should instead be presented earlier.

Comment 161: One comment questioned whether it is really a burden on the examiner to search two applications with patentably indistinct claims versus one application with the claims of both.

Response: It is less burdensome to the Office to have patentably indistinct claims in a single application. A related application with conflicting claims would have to be identified, reviewed and analyzed for double patenting issues.

Comment 162: One comment suggested providing for immediate and expedited review of all decisions

relating to new submissions required by § 1.78.

Response: The Office will strive to promptly act on all petitions related to the changes to § 1.78 in this final rule.

Comment 163: One comment suggested that § 1.78(g) should be amended to require that in response to a statutory or obviousness-type double patenting rejection, the Office may require the assignee to state whether the claimed inventions were commonly owned or subject to an obligation of assignment to the same person at the time the later invention was made, and if not to indicate which named inventor(s) is/are the prior inventor, unless applicant traverses the rejection.

Response: Section 1.78(g) contains the provisions of former § 1.78(c). The Office believes that these provisions, as well as the information that may be required, are currently sufficient for the Office to achieve its goals with respect to identifying commonly owned cases that come within the provisions of 35 U.S.C. 103(c) or with respect to determining the prior invention.

F. Changes to Practice for Examination of Claims

Comment 164: Several comments supported the concept of representative claims. One comment stated that the rules promote more focused examination, reduce delay and help conserve scarce Office resources, require little effort on the part of most applicants, and still make certain that no patent claims will issue without a complete examination. The comments also expressed support for limiting the number of claims that need to be examined and encouraged the Office to reduce overwhelming numbers of claims in favor of quality examinations. One comment suggested that the Office should adopt a rule that only independent claims are examined.

A number of comments, however, argued in a variety of terms that the "representative claims" examination approach would lead to piecemeal examination and prolonged examination, would require additional searching when features from non-designated dependent claims are added to designated dependent or independent claims, and would lead to additional filings, increased appeals, and less thorough examination. Several comments suggested that the number of claims examined should not be limited *per se* because the line of novelty in a claim family often falls between the broad independent claims and the narrowest dependent claim. One comment stated that the "representative claims" examination approach may

adversely affect the treatment given to dependent claims in court. One comment argued that the Office's statistics on applications having more than ten independent claims ignore how many total claims had to be presented to lead to those independent claims.

Several comments argued that since excess claim fees have presumably been determined based on the resources necessary to carry out search and examination of all of the claims, it is not appropriate for the Office to neglect to fully search and examine the entire application for which all fees have been paid. One comment stated that there is no basis for limiting the consideration of a dependent claim during examination because under 35 U.S.C. 112, ¶ 4, a dependent claim is treated as a claim that incorporates all the limitations of the preceding claims.

A number of comments argued that the "representative claims" examination approach may be appropriate in other proceedings (such as before the BPAI) or even during examination, but not before first Office action on the merits. One comment argued that statistical data from the appeal stage is misleading because there are fewer issues during an appeal than during prosecution of an application before the examiner. Several comments stated that the BPAI would be forced to perform examination on the merits of the non-representative claims.

A number of comments suggested that the Office should address excessive claiming concerns in a simple and straightforward manner by limiting the number of claims permitted and fully examined under the basic fee structure to, for example, six independent and thirty total numbered claims, and allowing multiple dependent claims that depend on other multiple dependent claims. Several comments suggested that the Office specify that excess claims over a certain number will only be examined if accompanied by an independent search report, rather than burdening all applicants with the requirement to designate claims. Several comments suggested that instead of representative claims, applicants should be allowed to select claims that stand or fall together.

Finally, a number of comments also raised implementation issues, requested clarification concerning implementation issues, or provided suggestions concerning the implementation of the "representative claims" examination approach.

Response: As a result of the public comment, the Office is not adopting the "representative claims" examination approach under which the Office would limit the initial examination of an

application to the "representative claims" (the independent claims and the dependent claims that are expressly designated by the applicant for initial examination). The Office is instead making the presentation of more than five independent claims or more than twenty-five total claims (rather than the presentation of more than ten representative claims) the threshold for invoking the examination support document requirement. Thus, this final rule provides that if the number of independent claims is greater than five or the number of total claims is greater than twenty-five, the applicant must provide additional information to the Office in an examination support document covering all of the claims in the application (whether in independent or dependent form).

Although, the "representative claims" examination approach is not being adopted, the Office disagrees that such an approach amounts to piecemeal examination or that it would be less efficient than the current examination process. Under such an approach, the Office would have examined a claim before applicant could seek review of any rejection of the claim on appeal, regardless of whether the claim was designated or non-designated under the "representative claims" examination approach.

Regarding escalating fees, the Office previously proposed a system of escalating fees and it was overwhelmingly opposed by user groups. The Office has also determined that charging higher fees for large numbers of claims would likely still not result in the desired increase in quality since many applicants would simply pay the higher fees. Furthermore, claim fees are set by statute, not the Office. As discussed previously, 35 U.S.C. 112, ¶ 5, prohibits multiple dependent claims depending on other multiple dependent claims.

Comment 165: One comment stated that examining many claims aids in understanding the invention.

Response: The experience of those who actually examine applications is that examining a large number of claims does not aid in understanding the invention but rather obfuscates the invention. In addition, the issuance of patents containing an excessive number of claims has also long been considered an abuse of the courts and the public, rather than an aid in understanding the invention. See *Carlton v. Bokee*, 84 U.S. (17 Wall) 463, 471-72 (1873) (needless multiplication of nebulous claims deemed calculated to deceive and mislead the public); *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1551

n.6, 10 U.S.P.Q.2d 1201, 1206 n.6 (Fed. Cir. 1989) (presentation of the infringement issue on an overgrown claims jungle to a jury and judge at trial is an unprofessional exercise in obfuscation).

Comment 166: A number of comments argued that more claims are needed to protect an applicant's invention adequately, especially in light of restrictions on the doctrine of equivalents, decisions by the Federal Circuit on unclaimed subject matter, the proposed limitations on continuation practice, and because the complexity of some inventions requires more claims to protect the subject matter appropriately. One comment argued that the effects of prosecution history estoppel and the constraints put on reissue applicants by the recapture doctrine demand a broad range of claims. Several comments argued that the proposed changes disproportionately affect the biotechnology and pharmaceutical industries. One comment argued that in chemical or pharmaceutical applications full protection requires applicant to claim a chemical substance, a composition containing the substance, method of making the substance, the chemical substance prepared by a claimed process and at least one method of use, where there is varying scope within each category of invention. The comments argued that individuals and small businesses would be unable to afford the costs of pursuing their inventions and may be discouraged from using the patent system due to the financial and procedural burdens they must overcome to obtain adequate patent protection of their invention. Several comments argued that the proposed rules would have a disproportionate impact on small entities. One comment stated that in the post-*Festo* environment, patent-drafting techniques would suggest filing a large number of picture claims in multiple statutory classes for easy understanding of the invention by the Federal Circuit. One comment stated that the primary reason why large numbers of claims are filed is that the applicants or their representatives do not want the effort and responsibility of determining the differences between the prior art and the invention, and that another reason is that attorneys who are paid a flat fee for applications attempt to induce a restriction requirement.

Response: This final rule provides that if the number of independent claims is greater than five or the number of total claims is greater than twenty-five (a strategy based upon whether an application contains more than a given number of independent and total

claims), the applicant must provide additional information to the Office in an examination support document under § 1.265. The overall goal of these changes is to promote early presentation of claimed inventions, enhance quality and improve pendency. The rules do not impose a *per se* limit on the number of claims which can be presented to protect applicant's inventions. Rather, applicant may file any desired number and scope of claims necessary to adequately protect the applicant's invention as long as an examination support document is provided before the issuance of the first Office action on the merits of an application that present more than five independent claims or twenty-five total claims.

The Office notes that, during fiscal year 2006, the percentage of small entity applications that exceeded the five independent claim and twenty-five total claim threshold appeared slightly higher than the percentage of total applications that exceeded the five independent claim and twenty-five total claim threshold (24.4 percent as opposed to 23.7 percent). The Office does not consider this slight differential as establishing that the changes in this final rule have a disproportionate economic impact on small entities. While it is possible to engage in a mathematical exercise to exaggerate the significance of any slight differential, these percentages are based upon data that is available in the Office's PALM system for applications filed during the most recent fiscal year, and this slight differential is not sufficient to establish that the changes in this final rule have a disproportionate economic impact on small entities. In addition, there is no apparent reason why small entity applicants would inherently require more claims to adequately cover their inventions. Thus, even higher differences in these percentages could easily be explained by the fact that small entity applicants pay only one-half of the fees that other applicants pay for excess claims. Moreover, the five independent claim and twenty-five total claim threshold adopted in this final rule has a smaller differential than other alternatives suggested in the comments. For example, in fiscal year 2006: (1) 17.1 percent of small entity applicants exceeded a six independent claim and thirty total claim threshold where only 15.7 percent of all applications exceeded a six independent claim and thirty total claim threshold; (2) 10.3 percent of small entity applicants exceeded a six independent claim and forty total claim threshold where only 9.2 percent of all applications exceeded

a six independent claim and forty total claim threshold; and (3) 5.0 percent of small entity applicants exceeded a ten independent claim and fifty total claim threshold where only 4.1 percent of all applications exceeded a ten independent claim and fifty total claim threshold.

The remaining explanations (post-*Festo* patent-drafting techniques, not wanting the responsibility of determining the differences between the prior art and the invention, and attempts to induce a restriction requirement) may be "reasons" why some applicants submit a large number of claims. These reasons, however, do not justify not going forward with a change to the rule of practice to require applicants who place an extensive burden on the Office to help focus examination by providing additional information in the form of an examination support document to the Office.

Comment 167: One comment argued that choosing dependent claims to designate at the outset of prosecution forces applicant to make a threshold decision regarding claim scope without the benefit of analyzing cited prior art following an Office action. Thus, applicants either have to guess, or perform their own prior art search prior to filing, which puts a burden on applicant and results in the need to file a previously unnecessary information disclosure under § 1.56.

Response: The Office is not adopting the proposed "representative claim" approach. Therefore, no designation is required by this final rule. This final rule requires applicants who present more than five independent claims or more than twenty-five total claims to file an examination support document before the issuance of a first Office action on the merits of an application. Applicants are encouraged to conduct a preexamination search and review the references uncovered from the preexamination search so applicants can better understand where their invention fits in the overall patent landscape. Such action would facilitate presentation of claims more likely to be patentable over the closest prior art, thereby alleviating some of the burden on Office resources. Nevertheless, if applicant chooses not to conduct a preexamination search and does not submit an examination support document before the first Office action on the merits of the application, this does not constitute a justification for filing more than five independent claims or more than twenty-five total claims.

Comment 168: One comment stated that it is unclear as to whether all claims, or only independent (or designated) claims, are counted for the purposes of § 1.75(b)(4).

Response: Pursuant to § 1.75(b)(4) as adopted in this final rule, the Office will count all of the claims in copending applications containing patentably indistinct claims (including applications having a continuity relationship) but not in issued patents containing patentably indistinct claims, in determining whether each such application contains more than five independent claims or more than twenty-five total claims and thus whether an examination support document in compliance with § 1.265 is required. Claims withdrawn from consideration under §§ 1.141 through 1.146 or § 1.499 as drawn to a non-elected invention or inventions, however, will not, unless they are reinstated or rejoined, be taken into account in determining whether an application exceeds the five independent claim and twenty-five total claim threshold set forth in §§ 1.75(b)(1), (b)(3), and (b)(4). See § 1.75(b)(5). As discussed previously, this final rule does not implement a "representative claims" examination approach.

Comment 169: One comment stated that the rules do not provide speedy and economical administrative relief when the Office errs in determining whether claims are patentably indistinct, or whether there is adequate support in an application for a claim filed in another application.

Response: As discussed previously, the Office already has timely and efficient procedures in place that provide for an applicant to seek relief with respect to matters subject to appeal (e.g., the rejection of claims) by way of an appeal to the BPAI under 35 U.S.C. 134 and § 41.31 *et seq.*, and to seek relief with respect to actions or requirements not subject to appeal by way of a petition to the Director under § 1.181. For example, if a double patenting rejection is made because the claims of two applications are patentably indistinct, applicant may seek relief by way of an appeal to the BPAI. If the Office issues a notice under § 1.75(b) requiring an examination support document in each of the multiple applications that contain patentably indistinct claims, applicant may seek relief by way of a petition to the Director under § 1.181. A grant of relief in a petition, however, does not preclude a subsequent double patenting rejection.

Comment 170: One comment argued that the rule will create more work for examiners by requiring review of all patents and applications assigned to one assignee of an application under examination, and that if certain examiners fail to do so, the rule will be unfairly applied within the Office. One comment argued that implementation of the rules will have a disproportionate effect on assignees holding small patent portfolios because due to time constraints, examiners will be able to review small patent portfolios more thoroughly than large ones.

Response: The rules do not require examiners to review all patents and applications assigned to the same assignee, but rather require applicant to identify certain commonly assigned applications having a common inventor. See § 1.78(f)(1). Examiners already face the situation of having to evaluate a potentially large number of commonly assigned patents and applications for the purpose of determining whether a prior art or double patenting rejection is warranted. The rules will enable the examiners to do this analysis more thoroughly and in less time, thus enhancing quality and reducing pendency.

Comment 171: One comment argued that implementation of the rules will create an additional area of contention between examiners and applicants, and an additional drain on examiners' time. The comment further argued that the drain will be greater than that associated with double patenting because double patenting rejections can be overcome by filing terminal disclaimers.

Response: No new issues between the examiner and the applicant are introduced by the changes being adopted in this final rule. Rather, the rules allow the examiner to identify and address issues more thoroughly. Furthermore, as a result of the rules, applicants will be made aware of issues earlier in the prosecution, thus giving applicants more time to formulate appropriate responses. Terminal disclaimers will continue to be available for use as appropriate to obviate non-statutory double patenting rejections.

Comment 172: One comment argued that the changes concerning claims are superfluous in view of the rule changes concerning continuation practice, and that a penalty for filing excessive continuations is already provided in the continuations rules.

Response: The changes to the practice for examination of claims will operate in concert with the changes to the practice for continuing applications and requests for continued examination. The changes for the continued examination

filing practice do not by themselves act to lessen the examiner's burden when faced with a large number of claims for examination.

Comment 173: One comment questioned how the Office will implement review of two applications containing claims to the same invention.

Response: If two or more commonly assigned applications contain patentably indistinct claims, the Office will track the applications via the PALM system. The applicant may explain why the claims of one application are patentably distinct from the claims of the other(s). If at least one claim is not patentably distinct and there are a total of more than five independent claims or more than twenty-five total claims in the applications, the applicant will be required to file an examination support document before the first Office action on the merits in each application. Applicant may file a terminal disclaimer to obviate an obviousness-type double patenting rejection.

Comment 174: One comment suggested that the requirement that claims differ substantially according to § 1.75(b) should only apply to independent claims.

Response: The provision that "[m]ore than one claim may be presented provided they differ substantially from each other and are not unduly multiplied" has been set forth in § 1.75(b) even prior to this final rule. The comment provides no reason why the requirement that claims differ substantially from each other and not be unduly multiplied should not also apply to dependent claims.

Comment 175: One comment inquired about designation of claims during reexamination. The comment stated that the rules should not apply to reexaminations of patents granted prior to enactment of the rules.

Response: The changes to § 1.75 adopted in this final rule do not apply to reexamination proceedings. Furthermore, this final rule does not adopt the "representative claims" examination approach (which provided for a designation of dependent claims).

Comment 176: A number of comments argued that the changes limit the protection paid for by applicant. One comment argued that as a result of the limitation on the number of claims, companies that invest in research and development could be expected to keep more inventions as trade secrets due to the threat posed by "free riders" who make minor modifications in an attempt to avoid infringement.

Response: The patent statute requires that an applicant pay certain filing fees (the filing, search, examination, excess

claims, and application size fees) on filing an application for patent. See 35 U.S.C. 41(a). The payment of these patent filing fees does not amount to a purchase of patent protection but are simply to help cover the costs of examination and application processing.

Section 1.75 does not limit the number of claims that applicant can present in an application. Section 1.75(b)(1) permits an applicant to present five independent claims and twenty-five total claims for examination without the need for an examination support document. An applicant who considers five independent claims or twenty-five total claims to be insufficient may present more than five independent claims or twenty-five total claims by submitting an examination support document under § 1.265 before the first Office action on the merits of an application.

Comment 177: One comment suggested that if the rules are implemented, the Office should reduce the examination fee and wait to charge the excess claim fees, or refund the excess claim fees if the application goes abandoned.

Response: The basic filing, search, examination, and excess claims fees are set by statute, which the Office cannot change by rule making. The filing fees are due upon filing of the application and the excess claims fees are due when the claims are presented. See 35 U.S.C. 41. Applicant may request a refund of any previously paid search and excess claims fees if applicant expressly abandons an application filed under 35 U.S.C. 111(a) on or after December 8, 2004, by filing a petition under § 1.138(d) before an examination has been made of the application. An "examination has been made of the application" for purposes of § 1.138(d) once there has been a requirement for restriction including an election of species, requirement for information under § 1.105, first Office action on the merits, notice of allowability or allowance, or action under *Ex parte Quayle*. Applicant may also request a refund of any excess claims fees paid on or after December 8, 2004, if an amendment canceling the excess claims is filed before an examination on the merits has been made of the application. See § 1.117. An "examination on the merits has been made of the application" for purposes of § 1.117(a) once there has been a first Office action on the merits, notice of allowability or allowance, or action under *Ex parte Quayle*.

Comment 178: One comment argued that the small number of problematic cases with excessive claims that confuse

or obscure the invention can be adequately handled through the use of undue multiplicity rejections.

Response: Undue multiplicity rejections based on 35 U.S.C. 112, ¶ 2, are rare. See MPEP § 2173.05(n). The rule changes are designed to provide a more focused quality examination of all applications. The Office would not be able to obtain the desired gains in efficiency and quality by merely relying on the use of undue multiplicity rejections.

Comment 179: One comment argued that the impact of the rules on the backlog will be minimal and referred to the Inspector General Report of 2004 which identified suboptimal incentives for examiners as the cause of the backlogs, not the excess number of claims.

Response: The September 2004 Inspector General Report (Final Inspection Report No. IPE-15722), available at <http://www.oig.doc.gov/oig/reports/2004/USPTO-IPE-15722-09-04.pdf>, concluded that the Office should reevaluate patent examiner production goals, appraisal plans, and award systems. The September 2004 Inspector General Report was not the result of a general study of the causes of the growing backlog of unexamined patent applications, but was the result of a review of only patent examiner production goals, appraisal plans, and award systems. Thus, the September 2004 Inspector General Report does not discuss other causes of the growing backlog of unexamined patent applications (e.g., changes in applicant filing tendencies) and does not warrant the conclusion that the September 2004 Inspector General Report identifies suboptimal incentives for examiners as the sole cause of the growing backlog of unexamined patent applications. In any event, the Office is in the process of reassessing patent examiner production goals, appraisal plans, and award systems as recommended in the September 2004 Inspector General Report. Absent significant changes to the patent examination process, the Office does not consider it reasonable to expect that changes to patent examiner production goals, appraisal plans, and award systems alone will be sufficient to address the growing backlog of unexamined patent applications while maintaining a sufficient level of quality.

Comment 180: One comment argued that the Office admitted to previously abandoning a proposal to limit the number of total and independent claims. The comment argued that if such a proposal was deemed inappropriate, it is difficult to see how

limiting claims before initial examination is also not inappropriate.

Response: The previous proposal was not abandoned because it was deemed inappropriate; rather, it was abandoned because it was unpopular. The Office subsequently sought increases in excess claims fees via legislative change. There was insufficient public support for all the fee increases that the Office considered necessary and the current fees are not adequately addressing the problem of large numbers of claims. The comments submitted in response to the Claims Proposed Rule indicate that many view an approach similar to that proposed in 1998 to be preferable. The changes being adopted in this final rule (in contrast to the changes proposed in 1998) do not place a limit on the number of claims (independent or dependent) that may be presented in an application. These changes adopted in this final rule simply require the submission of an examination support document if an applicant chooses to present more than five independent claims or more than twenty-five total claims in an application. Furthermore, the backlog of unexamined applications has increased from 224,446 at the end of fiscal year 1998 to 701,147 at the end of fiscal year 2006. The Office expects the backlog of unexamined applications to continue to increase without significant changes to the patent examination process. In addition, the average number of claims per application has not decreased since 1998. Thus, the Office does not consider the fact that the changes being adopted in this final rule may not be popular to be an adequate reason for not going forward at this time.

Comment 181: One comment pointed out inconsistencies between proposed § 1.75(b)(3)(iii), which requires a suggested restriction to be drawn to "no more than ten" claims, and the preamble to the proposed rule, which requires the restriction to be drawn to "fewer than ten" claims.

Response: Proposed § 1.75(b)(3)(iii) provided that an applicant may file a suggested requirement for restriction accompanied by an election without traverse of an invention to which there are drawn no more than ten independent claims and no more than ten representative claims. This final rule did not adopt the proposed "representative claims" examination approach, but requires applicant to file an examination support document when the application contains more than five independent claims or more than twenty-five total claims. Under § 1.142(c) as adopted in this final rule, applicant may file a suggested

requirement for restriction accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims.

Comment 182: One comment argued that applicants would circumvent the proposed rules by designating a "picture claim" in all applications, thereby forcing the examiner to perform a complete search and examination, thus obviating any time or effort saved through the proposed changes.

Response: The Office has no objection to an applicant presenting a claim that recites in detail all of the features of an invention (*i.e.*, a "picture" claim) in an application. Nevertheless, the mere fact that a claim recites in detail all of the features of an invention is never, in itself, justification for the allowance of such a claim. See MPEP § 706.

Comment 183: One comment argued that according to *In re Wakefield*, 422 F.2d 897, 164 U.S.P.Q. 636 (C.C.P.A. 1970), applicant should be allowed to determine the necessary number and scope of claims.

Response: The changes adopted in this final rule do not set a *per se* limit on the number of claims that an applicant may file in an application. The applicant is free to file as many claims as necessary to adequately protect the invention. Applicant may present more than five independent claims or more than twenty-five total claims in an application if applicant files an examination support document before the first Office action on the merits of the application. The information provided by the applicant in the examination support document will assist the examiner in understanding the claimed invention, determining the effective filing date of each claim and the claim interpretation before the prior art search, understanding the state of the art and the most closely related prior art cited by the applicant, and determining the patentability of the claims. Thus, the examiner will be able to perform a better examination on the claims.

Comment 184: A number of comments argued that the rules would lessen the applicant's ability to file applications due to budget constraints and would increase costs for counseling applicants to get the best patent protection. One comment argued that the rules will increase applicant's costs to such an extent that individual inventors and small companies will not be able to afford patent protection. Furthermore, the costs to comply with the rules will cause many people with technology that can spur innovation to be frozen out of the patent process.

Response: The current rules will only impact those applications that are filed with more than five independent claims or more than twenty-five total claims. If applicant presents more than five independent claims or more than twenty-five total claims, then applicant will be required to submit an examination support document under § 1.265. If an application is so significant that the applicant must present more than five independent claims or more than twenty-five total claims, then the additional costs should not be a deterrent.

Comment 185: One comment suggested that if the Office were to follow *Muncie Gear Works v. Outboard Marine & Mfg Co.*, late claiming of applications would likely decrease.

Response: In *Westphal v. Fawzi*, 666 F.2d 575, 577 (C.C.P.A. 1981), the Court of Customs and Patent Appeals discredited the idea that *Muncie Gear Works v. Outboard Marine & Mfg. Co.*, 315 U.S. 759 (1942) should be read as announcing a new "late claiming" doctrine. Rather, the Court of Customs and Patent Appeals interpreted the *Muncie Gear Works* holding of invalidity as grounded in the statutory prohibition against new matter.

Comment 186: A number of comments suggested that claims written in alternative form should not be treated differently from other claims, and that the Office should use election of species practice to identify alternatives to be used as representative claims. Several comments stated that claims drafted using Markush or other alternative language should be treated as single claims rather than treating each alternative as a separate claim. One comment stated that if members of Markush groups are counted separately, biotechnology and chemical applicants will file more multiple parallel applications. One comment requested clarification as to whether each element of a Markush claim would be considered to be an independent claim. One comment stated that Markush claims are beneficial to both the Office and applicants, and stated that the proposed changes would unfairly disadvantage members of the pharmaceutical community. One comment suggested that encouraging applicants to adhere more closely to existing 35 U.S.C. 112, ¶ 1 and 35 U.S.C. 101 requirements is a better means of managing the breadth of Markush claims than individualized claim counting schemes and required showings. One comment suggested that the Office should treat a Markush claim as a broad or generic claim. One comment asserted that the Office has

not provided any study or anecdotal evidence that identifies an abuse of Markush practice. One comment stated that the MPEP has never required that individual elements in a Markush group be treated separately, and that it is unfair to an applicant to use up claim designations on the individual elements of a Markush group because a reference teaching one element is applied to all.

Several comments argued that the proposed rule relating to determining the presence of separate claims in a Markush grouping will slow down prosecution, in part due to an increased number of petitions to review.

Response: The Office requested comments on how claims written in the alternative form, such as claims in an alternative form permitted by *Ex parte Markush*, 1925 Dec. Comm'r Pat. 126 (1924), should be counted for purposes of proposed § 1.75(b). See *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR at 64, 1302 *Off. Gaz. Pat. Office* at 1331. This final rule does not change the practice of the Office with regard to claims containing Markush or other alternative language. That is, a claim containing Markush or other alternative language would be considered as one claim for the purposes of determining whether an application exceeds the five independent claim and twenty-five total claim threshold set forth in § 1.75(b). However, the Office is evaluating changes to Markush practice, which could be implemented in a separate rule making.

The Office is also clarifying second action final practice with respect to using alternative language (*e.g.*, Markush claims). MPEP § 803.02 indicates that if an applicant amends a rejected Markush claim to exclude species anticipated or rendered obvious by the prior art, a second action on the rejected claims can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed under § 1.97(c) with the fee set forth in § 1.17(p). MPEP § 803.02 provides this instruction in the context of the situation in which the examiner has determined that the Markush claim encompasses at least two independent or distinct inventions, has required applicant to make a provisional election of a single species, and has rejected the Markush claim on prior art grounds. This has led to some confusion as to when a second action on the rejected claims can be made final when the examiner has not found that the claim encompasses at least two independent

or distinct inventions and applicant amends a claim to exclude unpatentable alternatives. If a Markush claim or other claim that sets forth alternatives is rejected under 35 U.S.C. 102 or 103 on the basis of prior art that anticipates or renders obvious the claim with respect to any one of the alternatives or on any other basis (e.g., 35 U.S.C. 101 or 112) with respect to any one of the alternatives, a second or any subsequent Office action on the merits may be made final. However, such an Office action may not be made final if it contains a new ground of rejection that is not: (1) Necessitated by applicant's amendment of the claims (including amendment of a claim to eliminate unpatentable alternatives); (2) necessitated by applicant's providing a showing that a claim element that does not use the phrase "means for" or "step for" is written as a function to be performed and does not otherwise preclude application of 35 U.S.C. 112, ¶ 6; (3) based on information submitted in an information disclosure statement filed during the period set forth in § 1.97(c) with the fee set forth in § 1.17(p); or (4) based upon double patenting (statutory or obviousness-type double patenting). The provision in MPEP § 904.02 that a search should cover the claimed subject matter and should also cover the disclosed features which might reasonably be expected to be claimed does not preclude an examiner from making the second or any subsequent Office action on the merits final if the Office action contains a new ground of rejection that was necessitated solely by applicant's amendment of the claims to eliminate the unpatentable species.

Comment 187: A number of comments supported the appropriate use of the proposed requirement in § 1.105(a)(1)(ix) where this information is needed to resolve a reasonable question which is relevant to the determination of a patentability issue before the examiner.

Response: The Office is adopting the change to § 1.105.

Comment 188: One comment argued that the provision in § 1.105(a)(1)(ix) serves no purpose and may be abused. The comment argued that examiners could simply shift the burden on applicant to prove support when there is no basis for making a rejection under 35 U.S.C. 112, ¶ 1. One comment argued that the changes to § 1.105(a)(1)(ix) are unnecessary since examiners already have the power to request such information.

Response: One purpose of the provision in § 1.105(a)(1)(ix) is to assist the examiner in properly examining the application when it is not readily

apparent where the specification of the application provides support under 35 U.S.C. 112, ¶ 1, for a claim or a limitation of a claim. This is information that the applicant should be aware of and should be able to provide to the examiner. The Office considers this authority to be inherent under the patent statute and rules existing prior to this rule change, including the previous version of § 1.105, and thus there is no reason to expect such provision to be abused. The Office agrees that examiners inherently have the authority to request this information. See *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 73 USPQ2d 1409 (Fed. Cir. 2005). The Office is amending § 1.105 to make the authority explicit.

Comment 189: One comment suggested that the Office should encourage examiners to use § 1.105 to require a concise, plain-English explanation of the invention and claim set when the application contains large claim sets or the invention cannot be understood.

Response: The examination support document will assist the examiner when there are large numbers of claims. If the invention cannot be understood, the examiner could use § 1.105 to require an explanation.

Comment 190: Several comments suggested that language should be added to the rules to indicate that the information required by § 1.105(a)(1)(ix) is not to be used to read limitations into the claims.

Response: Such a change is not necessary. It is well established that the meaning of the terms in the claims is to be ascertained in light of the specification but that limitations from the specification are not to be read into the claims. See *Phillips v. AWH Corp.*, 415 F.3d 1301, 1316, 75 U.S.P.Q.2d 1321, 1329 (Fed. Cir. 2005); *In re American Academy of Science Tech Center*, 365 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004); *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Comment 191: A number of comments supported the extension of the Office's refund authority beyond the expiration date of the legislation and encouraged the Office to accelerate implementation of § 1.117.

Response: The Office is working to make the patent fee and fee structure provisions of the Consolidated Appropriations Act, 2005 (Pub. L. 108-447, 118 Stat. 2809 (2004)), permanent. The Revised Continuing Appropriations Resolution, 2007 (Pub. L. 110-5, 121 Stat. 8 (2007)), keeps the patent fee and fee structure provisions of the Consolidated Appropriations Act, 2005,

in effect during fiscal year 2007. The Office is implementing § 1.117 in this final rule.

Comment 192: Several comments questioned whether excess claim fees would be refunded if claims are eliminated pursuant to § 1.78(f)(3).

Response: Applicant may request a refund of any excess claims fees paid on or after December 8, 2004, if an amendment canceling the excess claims is filed before an examination on the merits has been made of the application. See § 1.117. Applicant may also request a refund of any previously paid search and excess claims fees if applicant expressly abandons an application filed under 35 U.S.C. 111(a) on or after December 8, 2004, by filing a petition under § 1.138(d) before an examination has been made of the application.

Comment 193: One comment suggested that the Office should refund eighty percent of the fees for claims that are withdrawn because of a restriction requirement.

Response: The Office does not have the statutory authority to refund the excess claims fees for claims that are still pending in an application where the fees were properly paid. The Consolidated Appropriations Act, 2005, authorizes a refund only for a claim that has been canceled before an examination on the merits has been made of the application under 35 U.S.C. 131. See 35 U.S.C. 41(a)(2)(C). Claims that are withdrawn due to a restriction requirement are still pending in the application. Applicant may cancel the withdrawn claims prior to a first Office action on the merits of the application and request for a refund of any excess claims fees paid on or after December 8, 2004. See § 1.117.

Comment 194: A number of comments noted that since very few examination support documents are likely to be filed, there is not likely to be any opportunity to reduce a patent term adjustment.

Response: The Office is not adopting the changes in this final rule for the purpose of reducing patent term adjustment. The Office simply does not want an applicant to obtain patent term adjustment by delaying compliance with the examination support document requirements.

Comment 195: Several comments argued that it was unfair to reduce patent term adjustment for not complying with the rules for applications pending before the effective date.

Response: Section 1.704(c)(11) as adopted in this final rule is applicable only to applications under 35 U.S.C. 111(a) filed on or after November 1,

2007, or international applications that have commenced the national stage after compliance with 35 U.S.C. 371 on or after November 1, 2007. Thus, other applications for which an examination support document (or other appropriate action) is required would not encounter a patent term adjustment reduction unless the applicant failed to properly reply to an Office notice requiring an examination support document (or other appropriate action) within three months of the date the notice was mailed to the applicant.

Comment 196: One comment argued that § 1.704(c)(11) is contrary to statute because 35 U.S.C. 154(b)(2)(C)(ii) guarantees a minimum of three months to respond before patent term adjustment is lost.

Response: 35 U.S.C. 154(b)(2)(C)(ii) provides that “[w]ith respect to adjustments to patent term made under the authority of [35 U.S.C. 154(b)(1)(B)], an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.” See 35 U.S.C. 154(b)(2)(C)(ii). The patent term adjustment reduction provision of 35 U.S.C. 154(b)(2)(C)(ii) is applicable where the applicant’s failure to engage in reasonable efforts to conclude processing or examination of an application involves a failure to reply to an Office action or notice within three months of the date the Office action or notice is mailed or given to the applicant. 35 U.S.C. 154(b)(2)(C), however, contemplates other circumstances that may constitute an applicant’s failure to engage in reasonable efforts to conclude processing or examination, by further providing that “[t]he Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” See 35 U.S.C. 154(b)(2)(C)(iii). The provisions of § 1.704(c), including § 1.704(c)(11), are promulgated under the Office’s authority in 35 U.S.C. 154(b)(2)(C)(iii) to prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. For example, an examination support document is required to be filed before the issuance of a first Office action on

the merits when the application contains or is amended to contain more than five independent claims or more than twenty-five total claims. See § 1.75(b)(1). Therefore, § 1.704(c) provides for a reduction of any patent term adjustment when there is a failure to comply with § 1.75(b), e.g., a failure to file an examination support document in compliance with § 1.265 when necessary under § 1.75(b). The Office does not issue a notice requiring an examination support document (or other appropriate action) until the Office has determined that an examination support document is required under § 1.75(b), but applicant failed to submit an examination support document.

Comment 197: Several comments argued that § 1.704(c)(11) would adversely affect small businesses. One comment argued that some patents owned by universities and small biotechnology companies have values of one million dollars per day, and these patents often have hundreds of days of patent term extension. The comment argued that the proposed reductions in patent term would easily cost small businesses one hundred million dollars per year.

Response: An applicant can avoid a reduction in patent term adjustment simply by providing an examination support document in compliance with § 1.265 before the first Office action on the merits or taking other appropriate action (if necessary) in a timely manner.

Comment 198: One comment questioned whether the proposed changes to § 1.75 (the “representative claims” examination approach) as applied to national stage applications violate the PCT. Another comment suggested that the proposed changes to § 1.75 are contrary to PCT Article 17.

Response: As discussed previously, this final rule does not implement a “representative claims” examination approach. Nevertheless, nothing in the PCT or the regulations under the PCT requires a designated Office to examine all claims presented (in any particular order or at a particular stage) in a national stage application. Furthermore, PCT Article 27(6) provides that the national law may require that the applicant furnish evidence in respect of any substantive condition of patentability prescribed by such law. Under this final rule, applicant is free to submit as many claims as he or she chooses, as long as applicant files an examination support document before the first Office action on the merits if there are more than five independent claims or more than twenty-five total claims. Article 17 of the PCT concerns

procedures before the international searching authorities. The changes to § 1.75 do not apply to international searching authorities and, accordingly, do not conflict with Article 17.

G. Number of Independent and Total Claims Permitted Without an Examination Support Document

Comment 199: A number of comments argued that the proposed change in the definition of an independent claim for determining the number of designated claims and calculating additional claims fees would be complicated and confusing. A number of comments argued that the statutory classes of invention are not necessarily mutually exclusive. A number of comments expressed the opinion that the proposed changes to the way claims are treated for fee purposes will further burden the Office. One comment stated that it would cause disputes and slow down the examination process. One comment argued that it would likely produce inconsistent results. One comment argued that the rule change makes it very difficult to calculate claim fees for anyone other than a registered practitioner. Several comments opined that as a result of the proposed rule, the fee calculation process would no longer be merely administrative, but would involve a legal opinion. The comments questioned whether fee calculations will be handled by examiners, and what the process for dispute resolution will be. A number of the comments also argued that the change would effectively increase fees.

Response: Designation of claims for initial examination is not required because this final rule did not adopt the “representative claims” examination approach. This final rule, however, requires applicant to file an examination support document in compliance with § 1.265 before the issuance of a first Office action on the merits of an application that contains more than five independent claims or twenty-five total claims, counting all of the claims in any other copending application having a patentably indistinct claim. If an examination support document in compliance with § 1.265 is not filed before the issuance of a first Office action on the merits of the application, the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims.

This final rule adopts the proposed changes to § 1.75(b)(2) to provide that a claim that refers to a claim of a different statutory class of invention will also be treated as an independent claim for fee

calculation purposes and for purposes of determining whether an application exceeds the five independent claim and twenty-five total claim threshold under § 1.75(b). Section 1.75(b) (introductory text) as adopted in this final rule clarifies that a dependent claim must contain a reference to a claim previously set forth in the same application, incorporate by reference all the limitations of the previous claim to which such dependent claim refers, and specify a further limitation of the subject matter of the previous claim. See 35 U.S.C. 112, ¶ 4; see also *Pfizer*, 457 F.3d at 1291–1292, 79 U.S.P.Q.2d at 1589–1590. If a claim does not incorporate by reference all the limitations of the previous claim to which it refers, it is not a dependent claim under 35 U.S.C. 112, ¶ 4. It would be proper for the Office to consider such a claim as an independent claim for fee calculation purposes and for purposes of determining whether an examination support document is required. The determination of whether a claim is independent or dependent could be difficult when applicant did not clearly draft the claim as an independent claim or a dependent claim under 35 U.S.C. 112, ¶ 4. Applicant may minimize issues related to fee calculation for claims by drafting claims that are in compliance with 35 U.S.C. 112, ¶ 4, and § 1.75(b) (e.g., not presenting claims that refer to another claim of a different statutory class of invention or claims that refer to another previous claim but do not incorporate by reference all of the limitations of the previous claim). Once a determination of whether a claim is independent or dependent has been made, the fee calculation is simple. If applicant disagrees with the Office's determination that a claim is an independent claim, applicant should provide a showing of how the claim is a dependent claim in compliance with 35 U.S.C. 112, ¶ 4, and § 1.75(b) either in a reply to a notice requiring a claim fee or a request for a refund.

Comment 200: One comment stated that a claim that does not make reference to another claim is an independent claim, and a claim that does make reference to another claim is a dependent claim. One comment stated that the Office cannot charge independent claim fees for dependent claims because to do so would violate statute. One comment questioned how a claim can fail to incorporate by reference all of the limitations of the claim to which it refers, and yet be statutory. The comment suggested that the proposed rule is unnecessary and not supported by the case law cited by

the Office. One comment suggested that the changes to § 1.75(b)(2) (e.g., treating a claim that refers to a claim of a different statutory class of invention as an independent claim for fee calculation purposes and for purposes of determining whether an examination support document is required) might be contrary to judicial precedent set forth in *In re Ochiai*, 71 F.3d 1565, 37 U.S.P.Q.2d 1127 (Fed. Cir. 1995). The comment also argued that these changes would create a “tricky fee structure” and a “trap for the unwary” and would increase the administrative/non-substantive workload on the examiner.

Response: A claim that merely refers to another claim is not a dependent claim in compliance with 35 U.S.C. 112, ¶ 4. A proper dependent claim must also incorporate by reference all the limitations of the claim to which it refers and specify a further limitation of the subject matter in the claim to which the dependent claim refers. Some applicants present claims that refer to a previous claim, but fail to comply with the requirements of 35 U.S.C. 112, ¶ 4. See e.g., *Pfizer*, 457 F.3d at 1291–1292, 79 U.S.P.Q. 2d at 1589–1590. The provisions of § 1.75(b)(2) are consistent with 35 U.S.C. 112, ¶ 4, and judicial precedent including *Ochiai* (the use of *per se* rules in determining nonobviousness under 35 U.S.C. 103). A claim that refers to a previous claim of a different statutory class of invention could require a separate search and patentability determination because the patentability of such a claim might not stand or fall together with the previous claim. For example, if claim 1 recites a specific product, a claim for method of making the product of claim 1 in a particular manner would require a separate patentability determination because in accordance with *Ochiai*, there is no *per se* rule in applying the test for obviousness under 35 U.S.C. 103. Furthermore, a claim that refers to a previous claim of a different statutory class of invention does not comply with 35 U.S.C. 112, ¶ 4, because such a claim does not further limit the subject matter of the previous claim.

Comment 201: A number of comments recommended that the Office issue guidance for use by Office employees as well as the public in distinguishing among statutory classes of invention. One comment stated that it is unclear how “a different statutory class of invention” will be applied. The comment questioned whether the last sentence of § 1.75(b)(2) would apply only to combination method-apparatus claims or whether it might also be applied to regular dependent claims which add additional limitations of a

similar kind such as a method limitation for a method claim or an apparatus limitation for an apparatus claim. One comment stated that § 1.75(b)(2) provides clarification that claims which refer to a claim of a different statutory class would be regarded as independent. One comment stated that § 1.75(b)(2) appears to be a statement of the current state of the law.

Response: The statutory classes of invention are set forth in 35 U.S.C. 101. If a method claim depends from another method claim, incorporates by reference all of the limitations of the method claim from which it depends, and adds additional method limitations, such a claim will be considered as a dependent claim. However, if a method claim refers to a composition claim (e.g., “A method of using the composition of claim 1 comprising * * *”), it will be treated as an independent claim. The Office will issue any guidance as necessary and appropriate for the implementation of the rules.

Comment 202: Several comments argued that § 1.75(b) is a problem for software-based inventions because it is common for applications to include claims to different classes of invention. The comments argued that there is no reason to discourage a claim drawn to one class of invention which depends from a claim drawn to another class when little additional work is required of the examiner to examine both claims, citing the example of a claim drawn to a manufacture which depends from a claim drawn to a process for making a manufacture.

Response: The rule does not discourage an applicant from submitting whatever claims may be considered desirable for protection of the invention, and does not discourage submission of claims to any statutory class of invention. Rather, the rule clarifies how claims will be treated for the purposes of fee calculation and determination whether an examination support document is required under § 1.75(b)(1).

Comment 203: A number of comments argued that ten representative claims are not sufficient for adequate patent protection and suggested various numbers for the representative claim limit including at least twenty claims, twenty-five claims, or at least thirty claims. Several comments suggested twenty claims, with a maximum of three independent claims, as being more consistent with the fee schedule. Several comments suggested that the limit should be six independent and forty total claims. One comment suggested that the limit should be twelve independent claims and fifty total claims. One comment suggested

that the limit should be ten independent claims and sixty total claims. Several comments suggested that there should be no limit. One comment suggested that there should be no limit on dependent claims.

Several comments stated that the rules affect the vast majority of applications that contain an ordinary number of claims, rather than targeting the small number of problem applications with excessive claims. One comment stated that it was unclear why all applicants should be limited to representative claims when approximately ninety percent of all non-provisional applications currently filed contain six or fewer independent claims and forty or fewer total claims. The comment argued that examining forty or fewer claims does not appear to constitute an undue examination burden. One comment suggested that the rule changes should be more narrowly tailored with respect to the technology areas where the inventions are not capable of being adequately protected using only twenty claims. One comment inquired about the need for establishing a separate procedure for examination of claims if only 1.2 percent of applications fall within the category of excess claims. Several comments argued that there is a lack of statistical analysis relating to the number of applications containing more than ten total claims.

Response: The Office notes the concerns expressed in the public comments concerning the proposed "representative claims" examination approach. The Office did not adopt this approach in this final rule. This final rule provides that if the number of independent claims is greater than five or the number of total claims is greater than twenty-five, the applicant must provide additional information to the Office in an examination support document under § 1.265 covering all of the claims in the application (whether in independent or dependent form).

The Office received a significant number of comments suggesting a threshold of six independent claims and thirty total claims. The Office also received a number of comments suggesting independent claim thresholds ranging from three to ten and total claim thresholds ranging from twenty to sixty (or no limit). The comments, however, provided no justification for deeming any particular independent and total claim threshold to be the ideal threshold or even superior to any other possible independent and total claim threshold. The Office arrived at the five independent claim and twenty-five total

claim threshold primarily for the following reasons.

First, a significant number of comments suggested a threshold of six independent claims and thirty total claims, but did not suggest such a threshold if it were not considered sufficient to provide adequate patent protection for an invention.

Second, the majority of applications contain no more than five independent claims and no more than twenty-five total claims. Specifically, over 92 percent of the applications filed in fiscal year 2006 contained no more than five independent claims, and over 78 percent of the applications filed in fiscal year 2006 contained no more than twenty-five total claims. These figures do not take into account that many applications contained claims to more than one distinct invention, and the changes in this final rule permit an applicant to suggest a restriction requirement and elect an invention to which there are drawn no more than five independent and twenty-five total claims. In addition, the majority of applications in every Technology Center contain five or fewer independent claims and twenty-five or fewer total claims. Therefore, there is no support for the position that there are technology areas that are just not capable of being adequately protected with five or fewer independent claims and twenty-five or fewer total claims. Finally, the Office notes that the most common number of independent claims presented in an application is three, and the most common number of total claims presented in an application is twenty.

Third, an applicant may present up to fifteen independent claims and seventy-five total claims via an initial application and two continuation or continuation-in-part applications that are prosecuted serially without providing either an examination support document or a justification as discussed previously. Only about five percent of the applications filed in fiscal year 2006 were in an application family that contained more than fifteen independent claims or more than seventy-five total claims.

Finally, this final rule does not preclude an applicant from presenting more than five independent claims or more than twenty-five total claims. Rather, an applicant may present more than five independent claims or more than twenty-five total claims in an application with an examination support document in compliance with § 1.265 if the applicant considers it necessary or desirable in the particular application. Specifically, this final rule

requires applicant to file an examination support document in compliance with § 1.265 before the issuance of a first Office action on the merits of an application that contains more than five independent claims or twenty-five total claims, counting all of the claims in any other copending application having a patentably indistinct claim. If an examination support document in compliance with § 1.265 is not filed before the issuance of a first Office action on the merits of the application, the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims.

Comment 204: A number of comments suggested that the Office should explore the possibility of examining multiple dependent claims that are dependent on other multiple dependent claims to reduce examination burden and better focus the examination process. The comments argued that most foreign countries permit such claims and that this would significantly reduce the number of claims. One comment argued that if the Office adopts representative claims rules, it will move towards the European style of claim sets, but without the benefit of multiple dependent claims and claims stated in the alternative. Several comments expressed the opinion that multiple dependent claims should be encouraged because examining a multiple dependent claim is no more work than examining a single dependent claim.

Response: As discussed previously, the Office did not adopt the "representative claims" examination approach in this final rule. Further, 35 U.S.C. 112, § 5, prohibits multiple dependent claims that are dependent on other multiple dependent claims. Moreover, the examination of multiple dependent claims that are dependent on other multiple dependent claims would be at least as burdensome as if these claims were presented as a plurality of single dependent claims or as permitted multiple dependent claims. The Office disagrees that permitting multiple dependent claims that depend on other multiple dependent claims would reduce the examination burden or better focus the examination process. The Office's experience is that multiple dependent claims are significantly more difficult to search and evaluate than a plurality of single dependent claims. Multiple dependent claims that depend on other multiple dependent claims would be even more burdensome. While the use of multiple dependent claims may be a convenient shorthand mechanism, a multiple dependent claim