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EXECUTIVE SUMMARY

The United States Patent and Trademark Office (USPTO or Office) established a 21st Century Strategic Plan to transform itself into a quality-focused, highly productive, responsive organization supporting a market-driven intellectual property system. The plan included a study of the changes needed to implement a Patent Cooperation Treaty (PCT) style Unity of Invention standard in the United States. The Office is cognizant that some applicants and the public may not view its current restriction practice as an ideal practice, particularly as it is presently applied. For example, some applicants may need to pursue related claims in multiple applications under the current practice and therefore, the public faces delays in determination of the ultimate scope of patent protection particularly when the applications are filed serially. At the same time, data indicates that the majority of additional inventions presented in applications that are currently restricted are not pursued in divisional applications. Any changes to current practice that would result in the examination of more of these inventions in a single application would then necessarily increase examination workload. The Office must consider the constraints its staffing and other resource limitations impose on the amount of additional workload that could be absorbed in the transition to a new restriction standard, while contemporaneously implementing the other priorities of the 21st Century Strategic Plan.

The USPTO sought public comment on a number of issues to help guide the scope and content of the study on the adoption of a PCT-style Unity of Invention standard in the United States. The public comments suggested broadening the scope of the study beyond just a PCT-style Unity of Invention standard in an effort to determine the best practice for restriction. Suggestions were made for other restriction standards that were considered to better serve the patent system, i.e. by modification of the existing national or PCT procedure, by creating a tiered system of relatedness of inventions, or by revision of the existing statutory interpretation. Four options for restriction reform were developed for further study based on the comments received and a detailed business-case analysis was performed on two of them.

The results of the study demonstrate that the implementation challenges would vary considerably with each of the options. In addition, to maintain an adequate revenue stream after transition to any of the restriction reform options, a revised fee structure would be necessary.

The first option of permitting applicant to request and pay for examination of additional inventions, while retaining the current restriction standard, would be significantly less difficult to implement than the remainder of the options. Its impacts are principally directed to staffing and fee revisions designed to maintain constant revenue. While this option, like all of the others, has a short-term negative impact on office-wide pendency, it is expected to introduce the least amount of uncertainty and negative impact on the overall patent system.

The second option of adopting the unity of invention standard, modified to require that the common feature satisfy the enablement and description requirements in addition to

novelty and non-obviousness, is considered the second best alternative. However, adoption of this standard would include all of the impacts of the first option and a number of others. The second option would require additional initial training and subsequent monitoring of the examiners, as well as serious evaluation of each of the examination changes suggested in the original request for comment, to which the public was strongly opposed (*Request for Comments on the Study of the Changes Needed to Implement a Unity of Invention Standard in the United States*, 68 *Fed. Reg.* 27536 (May 20, 2003), 1271 *Off. Gaz. Pat. Office* 98 (June 17, 2003)). This option is considered to have a somewhat higher degree of uncertainty and negative impact on the overall patent system relative to the first option; nevertheless it has significantly less impact relative to the third and fourth options.

The third (three-tier fee structure) and fourth ("independent and distinct" standard) options introduce even greater changes to the existing system that would produce a number of new, significant challenges, some of which may not be predictable. It is not at all clear that the transition to either of these two options would result in an improved system, and such a transition may even cause significant quality and pendency degradation. Transition to either the third or fourth option is not recommended without an effective pilot evaluation of their long-term impact. Given the initial results, the limited resources of the Office, and the anticipated implementation issues, continued consideration of either of these two options beyond that described in this paper is not recommended.

Efforts to improve the quality and consistency of the restriction requirements in Technology Center 1600, particularly in applications directed to biotechnology, continued throughout and beyond the study. *See* Appendix XI – TC 1600 Restriction Action Plan. This plan includes additional training and oversight of restriction requirements, as well as posting of the training materials on the USPTO website following completion of the training. These steps should reduce the overall number of improper restriction requirements and should increase the ease with which requirements that are inconsistent with the training examples can be successfully traversed or corrected. The process of improving the quality and predictability of restriction requirements must be a collaborative effort; the TC 1600 Restriction Action Plan and this paper represent only the first step in an ongoing endeavor to discover feasible solutions. It is hoped that the improvements in quality and predictability expected from the restriction action plan alone will be perceived as significant progress toward the goal of achieving an appropriate balance between the priorities of the USPTO user community and limited USPTO resources.

BACKGROUND: RESTRICTION PRACTICE

The statutory basis for USPTO restriction practice arises from 35 U.S.C. § 121 which states "[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions." The guidelines for the application of the current USPTO restriction standard are found in the Manual of Patent Examining Procedure (MPEP), Chapter 800. An application may properly be required to be restricted to one of two or more claimed inventions only if: (1) they are able to support separate patents and they are either independent or distinct; and (2) search and examination of the entire application involves a serious burden, *see* MPEP § 803.

Patent Cooperation Treaty (PCT) Rule 13 provides for the Unity of Invention Standard and applies to international applications filed under the PCT that enter the national stage under 35 U.S.C. § 371. PCT Rule 13.1 states that "[t]he international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept . . . ."

Over the past 11 years, utility, plant, and reissue patent application filings have more than doubled, from 174,553 in fiscal year 1993 to 355,527 in fiscal year 2004. There has also been a shift in filings to more complex technologies (termed "technology creep"). Over that same 11-year period, restriction requirements, as a percentage of first-Office actions, has increased, from 9.8% in fiscal year 1993 to 14.6% in fiscal year 2004.

Restriction practice was designed to balance the interest of granting an applicant reasonable breadth of protection in a single patent against the burden on the USPTO of examining multiple inventions in a single application. One goal of this study was to reevaluate and potentially redefine the circumstances under which the discretionary power of the Director to restrict applications under 35 U.S.C. § 121 would be applied.

SELECTION OF RESTRICTION STANDARD OPTIONS FOR THE STUDY

On May 20, 2003, the United States Patent and Trademark Office ("Office") published a *Request for Comments on the Study of the Changes Needed To Implement a Unity of Invention Standard in the United States*, 68 *Fed. Reg.* 27536 (May 20, 2003), 1271 *Off. Gaz. Pat. Office* 98 (June 17, 2003). This notice sought public comment on a number of issues to help guide the scope and content of a study on the adoption of a Unity of Invention standard in the United States.

In response to this request, the Office received twenty-six (26) public comments, a summary of which can be found in Appendix I.

The comments were generally supportive of efforts by the Office to undertake a study of restriction practice reforms. In general, a desire to immediately address inconsistent practices under the current restriction standard was expressed. The public comments suggested broadening the scope of the study and any resulting reforms beyond just a PCT-style Unity of Invention standard in an effort to determine the best practice for restriction. A number of goals for restriction reforms were proposed:

- Increase cost-effectiveness,
- Promote quality patents,
- Enhance predictability of restrictions,
- Encourage the examination of all claims to the same invention or inventive concept by the same examiner,
- Encourage the filing of fewer divisional applications to reduce the number of patent file histories directed to related claims, and
- Promote harmonization.

In addition to modification of the current "independent or distinct" standard and the PCT unity of invention standard, suggestions were made for other restriction standards. Four restriction reform options were developed for further study based on the comments received:

1. Current national restriction practice with an option to pay for the examination of additional invention(s) within the original application.
2. Modified PCT unity of invention standard with: 1) an additional requirement that the special technical/common feature comply with 35 U.S.C. § 112, 1st paragraph and 2) an option to pay for additional invention(s).
3. Three-tiered fee structure dependent upon the search burden associated with, and the presence of different patentability issues between, various inventions.
4. Independent and distinct standard (as opposed to independent or distinct).

SUMMARY OF THE FOUR OPTIONS

OPTION 1 – CURRENT PRACTICE WITH OPTION TO PAY FOR ADDITIONAL INVENTIONS

The current 35 U.S.C. §121 "independent or distinct" standard for restriction would be retained and applicants would be given the option to request and pay for examination of up to 2 additional **independent or distinct** inventions beyond that which would be examined in the current practice. Applicants would also have the option to request and pay for examination of up to 10 species separately claimed, or claimed within a genus or Markush group, at an additional per species cost. A detailed explanation of the standard can be found in Appendix II.

OPTION 2 – MODIFIED PCT UNITY OF INVENTION

The current PCT "unity of invention" standard, modified to require that any purported special technical/common feature comply with 35 U.S.C. §112, 1st paragraph (in addition to being novel and non-obvious), would be applied to all US applications. Applicants would be given the option of concurrent examination of up to two additional inventions that lack unity of invention for an additional fee. A detailed explanation of the standard can be found in Appendix III.

OPTION 3 – THREE-TIERED FEE STRUCTURE

The standard would be based upon whether inventions are "related or unrelated" and the amount of fees paid in any particular application would be based upon a three-tiered structure. The fees would be determined by the search burden associated with, and the presence of different patentability issues between, the various inventions claimed in the application. In the first tier, applicants would pay a base fee if only claims directed to "substantially similar" inventions were elected. In the second tier, an additional fee or surcharge above the base fee would be charged for election of a number of "related" inventions that raise substantially different patentability issues but do not require a substantially different search. The third tier would comprise "unrelated" inventions that require additional searching and also present dissimilar patentability issues. (If Option 3 were ultimately adopted, the Office would permit inventions in the first two tiers to be examined in the same application, but would not permit inventions in the third tier to be examined in the same application.[1]) A detailed explanation of the standard can be found in Appendix IV.

OPTION 4 – "INDEPENDENT AND DISTINCT" INVENTIONS

Under this option, the 35 U.S.C. § 121 standard would be re-interpreted to require that inventions subject to restriction be both "independent *and* distinct" (rather than "independent

[1] This is consistent with the July 21, 2003 public comments from the Biotechnology Industry Organization (BIO) at pages 4 and 9 and from Genentech, Inc. at page 10.

or distinct" per current practice). Inventions would be distinct if they are patentable over each other. Inventions would be independent if there is no common feature(s) among the inventions. In addition, inventions would be independent if they share a common feature(s), but the common feature(s) does not define over the prior art and/or satisfy the enablement and written description requirements of 35 U.S.C. § 112. Under this option, applicant would be required to pay an additional fee upon election to offset the potential additional search and examination burden.

In setting forth and initial restriction requirement where the independent inventions share a common feature(s), the examiner should infer that the common feature(s) fails to define over the prior art. The inference that the common feature(s) fails to define over the prior art may be rebutted. If the elected invention is not patentable, any restriction requirement would be maintained and claims to any non-elected inventions would remain withdrawn. However, if such an inference is made and the elected invention is patentable, the examiner would continue to search the common feature(s) either by searching a nonelected invention that requires the common feature(s) or by searching the common feature(s) by itself. The search would continue until either the common feature(s) or a previously nonelected invention that requires the common feature(s) was determined not to be patentable, or until all the previously nonelected inventions are determined to be patentable. A detailed explanation of the standard can be found in Appendix V.

A comparison chart of the main features of each option can be found in Appendix VI.

The proposed examination processes to be followed for each option can be found in Appendix VII, with process flow charts of each option in Appendix VIII.

DEVELOPMENT OF RESTRICTION STANDARD OPTIONS FOR THE STUDY

As previously indicated, in addition to modification of the current "independent or distinct" standard and the PCT unity of invention standard, suggestions were made for other restriction standards. Four options for restriction reform were developed based on the comments received. The comments provided general ideas for various restriction standards, but lacked sufficient detail concerning the manner in which such standards could be reproducibly implemented. Therefore, supplemental details necessary for implementation were added to options 2-4 even though those details may not have been suggested or envisioned by the public comments. (Option 1 embodies the current standard modified to provide an option to pay for additional inventions; therefore, no further details for implementation of that standard were required.)

Under Option 2, multiple inventions are considered to constitute a single inventive concept, and therefore, have unity of invention, if there is a technical relationship among the claimed inventions involving one or more of the same or corresponding "special technical features." In USPTO PCT practice, the first claimed invention is always searched, and therefore, provides a reference point against which a determination can be made as to whether a particular feature in subsequent claims is the "same or corresponding" feature. Such determinations are particularly important in applications containing large numbers of inventions (e.g. chemical or biotechnology inventions). However, public comments indicated a preference that applicants be given the opportunity to choose the "main" invention whenever possible. For the purposes of this study, only applications containing a restriction requirement and election were reviewed, therefore, a group of claims had already been elected and hence, served as the point of reference to determine if features in other claims were the "same or corresponding." If this option were to be selected for future restriction practice, in applications containing large numbers of inventions, an invitation to applicant would be required to identify a reference invention to facilitate the required determination.

In USPTO PCT practice, if no response is received to an Invitation to Pay Additional Fees where unity of invention is found lacking, then search proceeds on the basis of the first mentioned invention. As indicated above, public comments indicated a preference to choose the "main" invention whenever possible, with limited support for a default to the first mentioned invention in the event of non-response to the invitation. Under current practice, the application would become abandoned if an applicant does not respond to a restriction requirement. This same practice would be adopted if Option 2 were selected. A default to the first mentioned invention rather than abandonment is not necessary and could very well lead to expenditure of resources on the substantive examination of an invention that applicant does not wish to pursue.

Option 3 was developed on the basis of two public comments. One proposal specifically indicated that the USPTO should adopt a standard that differentiates between related and unrelated inventions based on the nature of the substantial patentability issues likely to arise during examination. The proposal further indicated that requirements for restriction based on related and unrelated inventions, like restriction analyses under the PCT unity-

of-invention standard, are likely to be much more straightforward than restrictions under the independent and distinct standard.

While the proposal seems to suggest replacement of the "independent or distinct" standard with a "related or unrelated" standard for restriction, it does not provide a definition or any guidance by which to determine how to group the claims before beginning the restriction analysis and therefore, it is not clear what should be compared to determine relatedness. For example, could a single claim fall into multiple groups? Or should each independent claim and all its dependent claims be grouped together? Or could a dependent claim be grouped separately from the claim on which it depends? For independent claims directed to, e.g., a method of making and a product, what degree of similarity between the claims would be necessary to determine whether or not these independent claims would be grouped together? Due to the need to establish groups of claims for the determination of relatedness, the current, familiar "independent or distinct" standard was used.

Once groups of claims setting forth restrictable inventions are identified, applicant would be invited to elect at least one group to prevent abandonment, as in current restriction practice. Election of an invention is required to provide a reference point for determination of the relatedness of the remaining inventions, similar to the determination of whether a particular feature in a claim is the "same or corresponding" as in Option 2. In addition to election of an invention, applicant would be invited at the same time to indicate whether or not placement of the remaining inventions into tiers indicating the degree of relatedness is desired. If placement into tiers is not desired, examination would proceed on the elected group only. If placement into tiers is requested and paid for, a second communication would be issued providing the placement, together with an invitation to pay for up to 4 additional inventions in tier 2. No additional fees would be required for tier 1 inventions and no option would be provided for payment of additional inventions in tier 3. The decision not to provide a payment option for tier 3 inventions was based upon the significance of the implementation issues (see Impact on Quality and Predictability section) as well as the fact that the two public comments from which this option was developed proposed that the USPTO could require restriction of such inventions (*see* the July 21, 2003 public comments from the Biotechnology Industry Organization (BIO) at pages 4 and 9 and from Genentech, Inc. at page 10).

Many of the details for Option 4 were set forth in the "Summary of Public Comments and the Restriction Reform Options to be Studied by the United States Patent and Trademark Office" signed on November 20, 2003 and posted on the USPTO web site (hereinafter "Summary"). This option would require that the examiner establish that the inventions are independent *and* distinct. The "Summary" indicates that one manner in which the examiner may establish inventions as independent would be by making an inference that the common feature(s) fails to define over the prior art. However, no details were provided regarding the circumstances under which this inference should be made. Thus, a procedure was developed. It was decided that the inference should be made *a priori* in all applications where there is a common feature(s) and that the inference would be continuously reassessed as the search develops. For example, if the elected invention is

found to be unpatentable over the prior art, then *a fortiori* the common feature(s) would be unpatentable over the prior art and the inference would have been correct. As another example, if the elected invention is found to be patentable over the art, then the common feature(s) may or may not be patentable over the art. If the elected invention complies with all the statutory requirements for patentability, the common feature(s) would be searched either by (1) searching the next invention (and any additional inventions) until (a) one of the inventions is found to be unpatentable or (b) all of the inventions are found to be patentable or (2) searching the common feature(s) by itself.

The "Summary" also states that "[a]pplicant would 'provisionally elect' one of the related inventions for examination and define the feature(s) they consider to be in common between the related inventions." In practice, however, if applicant were to define the feature(s), they would need to do so before the examiner reviews the application to determine whether a restriction/election requirement is appropriate. Thus, applicant may need to define the feature(s) upon filing. If applicant did not identify the common feature(s) in a timely manner, the examiner would identify this feature(s) in the restriction/election requirement. Applicant would then have an opportunity to rebut the examiner's identification of the common feature(s).

Another issue raised by Option 4 is that of the possibility of multiple groupings of independent and distinct inventions in a single application. If all of the inventions that are independent and distinct have the same common feature(s), then the inventions would be considered to fall into one grouping. However, an application may contain multiple groupings wherein each grouping includes a distinct common feature(s). In this situation, applicant would be required to elect one grouping and one invention within that grouping.

Finally, an additional fee would be required in all applications where a restriction/election requirement is made under Option 4 and the inventions include at least one common feature. In this situation, a determination cannot be made at the outset as to how many inventions would be examined, nor whether inventions that did not include the common feature(s) on filing would be amended to contain this common feature(s). Thus, it was concluded that a single additional fee would be required in all applications where a restriction/election requirement is made.

One goal of this study was to achieve an appropriate balance between the priorities of the USPTO and those of its user community by reevaluating and potentially redefining the circumstances under which the discretionary power of the Director to restrict applications under 35 U.S.C. 121 would be applied. Discontent with the existing standard for restriction prompted consideration of new standards. The development of the standards reflected in Options 3 and 4, however, highlights the difficulty in the formulation of any new standard. Another example highlighting this difficulty is that the Working Group formed within the World Intellectual Property Organization Standing Committee on Patents to consider possible new standards was ultimately unable to formulate any viable alternatives to existing practices.

While a new standard aims to resolve known problems, it will also likely produce new, perhaps even more difficult problems, both inside and outside the USPTO. One foreseeable problem with a new standard is the provision of additional staff and resources both for the initial training of the entire examining corps and for subsequent continual supervisory monitoring.

A new standard should be both easy to understand and to implement. Unfortunately, the standards embodied in Options 3 and 4 proved to be neither easy to understand nor to implement. While a good faith effort was made to develop workable standards for Options 3 and 4, completion of the review process of sampled applications revealed the extreme difficulty in the comprehension and application of these two standards. As illustrated in Appendix IX, Results of Feedback Survey for Reviewers, Options 3 and 4 were rated as highly difficult to understand and highly difficult to subsequently train other examiners. Likewise, the process for implementation of either option was determined to be unfeasible. Appendix VII, Proposed Examination Processes for each Option, highlights the Option 3 double decision-making processes required by the examiner and the applicant, as well as the complicated pathway to be followed in Option 4. Appendix VIII, Process Flow Charts of the Four Options, graphically illustrates the relative complexities: Options 1 and 2 are depicted on one page each; Option 3 requires 2 pages for depiction; and Option 4 requires 3 pages for depiction.

As a result of the significance of the implementation issues, no business case analysis was performed on Options 3 and 4.

Clearly, the resolution of problems associated with the current restriction standard exceeds the capacity of the USPTO alone. The effort must be collaborative. The TC 1600 Restriction Action Plan and this paper represent only the first step in an ongoing endeavor to discover feasible solutions.

SAMPLING OF APPLICATIONS

The business-case analysis was based upon data collected from a random selection of patent applications in which a restriction requirement had been made. These applications were reviewed under each of the four restriction standard options to determine the relative number of inventions and the relative number of claims per invention. This information was compared to the same information extracted from the restriction requirement made in each patent application under the current restriction standard. The difference in the number of inventions was used to determine the difference in workload and examination resources required under each option.

The applications were selected from the one-year period of December 15, 2002 through December 13, 2003, which represented the time period beginning with the second quarter of FY2003 and ending with the first quarter of FY2004. Random selection of applications from the most current complete four-quarter time period captured any fluctuations in restriction practice over the course of a fiscal year, while still analyzing the most current claim-drafting styles and resulting restriction activity possible.

Below are a number of key aspects of the sampling methodology and application review process:

- Based on workload estimates, a target sample size of 475 applications over a one-year period was used, with a target error rate of 4.5 to 5 percentage points at a 95% level of confidence.
- A stratification and a post-weighting methodology were used to allocate applications for review across Technology Centers to ensure accurate representation in the review sample.
- Applications actually reviewed were monitored to assure that there was no relationship between the characteristics of the unavailable randomly selected applications and any characteristics relevant to this study.

Ensuring consistency in an application review that requires the application of new and unfamiliar standards is challenging. Even the current restriction standard involves a certain degree of discretion. The following precautions were taken to control the consistency, or non-sampling error, to the extent possible:

- The team of reviewers consisted of managers within the Patent Examining Technology Centers with specific patent examining and restriction practice expertise in their respective technologies.
- The reviewers met on a regular basis with the study team to assure that the standards were consistently interpreted and applied.
- The reviewers completed a feedback survey to gauge their opinions of the standards and processes.
- Independent reviewers performed a second review on 15% of the already reviewed applications to monitor variability.

IMPACT ON QUALITY AND PREDICTABILITY

IMPACT GENERIC TO ALL OPTIONS

TRAINING

Any changes to the existing restriction standard and corresponding business processes would require initial training and continued monitoring of all personnel to assure proper and consistent implementation. The extent of such training depends upon the significance of the changes from current practice.

To gauge the relative complexity of the four options to that of current restriction practice, the employees that performed the reviews of applications under each option completed a feedback survey (s*ee* Appendix IX). The perceived difficulty to train and achieve consistent implementation increased with each option from 1-4.

EXAMINATION OF MULTIPLE INVENTIONS IN A SINGLE APPLICATION

Consideration of one specification for multiple inventions may produce some gain in efficiency; however, this gain would be counterbalanced by the increased complexity of searching more claims, reviewing more prior art, and formulating opinions on each additional invention.

IMPACT SPECIFIC TO EACH OPTION

OPTION 1

This option retains the current 35 U.S.C. §121 "independent or distinct" standard with the option to request and pay for examination of additional inventions, therefore, it would require less extensive examiner training than the other options in this study.

The feedback survey indicated that implementation of and examination under this option was considered to be only slightly more difficult relative to current practice. S*ee* Appendix IX.

OPTION 2

The current PCT "unity of invention" standard, modified to require that any purported special technical/common feature comply with 35 U.S.C. 112, first paragraph, with the option to request and pay for examination of additional inventions, would be applied to all US applications.

Where necessary, in applications containing a large number of inventions (particularly in chemical and biotechnology applications), applicant will be invited to identify a reference claim for determination of the relationship of the remaining claims, i.e. whether or not they contain "the same or corresponding special technical/common feature(s)." *See*

"Development of the Restriction Standard Options for the Study" section for more information on reference claims.

The feedback survey indicated that implementation of and examination under this option was considered to be more difficult than Option 1 but less difficult than Options 3 or 4. S*ee* Appendix IX.

OPTION 3

This "related or unrelated" standard involves a three-tiered fee structure dependent upon the search burden associated with, and the presence of different patentability issues between, various inventions.

Under Option 3, the examiner must first identify "inventions" using the current independent or distinct standard. The applicant must then elect one invention to serve as a reference point for the determination of relatedness, and indicate whether or not they desire placement of the remaining inventions into tiers. After the examiner places the various inventions into tiers, the applicant must then indicate whether they will pay for the examination of any additional inventions. This additional decision necessarily increases the length of the process while decreasing its predictability.

The feed back survey indicated that implementation of and examination under this option was considered to be much more difficult than Option 1. S*ee* Appendix IX.

OPTION 4

Option 4 is based upon a reinterpretation of 35 U.S.C. 112, first paragraph to require that inventions subject to restriction be both "independent *and* distinct."

Option 4 potentially involves identification of a common feature. If however, the applicant does not identify the common feature, then the examiner must make the identification and applicant must be provided an opportunity to rebut the examiner's identification. In the event that the application includes multiple groupings, each with distinct common features, applicant would be required to elect a single grouping and invention within that grouping. This option may also involve a "rolling" search of either the common feature or additional inventions. Each of these aspects of Option 4, like Option 3, increases the length of the process while decreasing its predictability. Finally, public input suggested that only those applicants benefiting from the revised process should incur any additional costs. However, it was determined in developing this option that a single additional fee should be required in all applications where a restriction/election requirement is made and the inventions include at least one common feature. (See Development of Restriction Standard Options for the Study, pages 7-10).

The feedback survey indicated that implementation and examination under this option was considered to be the most difficult of all the options and significantly more difficult than current practice.

IMPACT ON OUTPUT, PENDENCY AND REVENUE

Relative calculation of staffing and revenue for this paper was based upon the budget estimate for fiscal year 2006 (FY 2006), as submitted by the USPTO to the administration. This budget estimate assumed provision of sufficient resources and authority to annually hire the maximum number of examiners that could be absorbed and trained, necessary to reduce pendency, through FY 2010.

The impact on overall examiner production (output), pendency, and revenue for each option was based upon a comparison to estimates in the FY06 budget. The FY06 budget estimate assumed passage of the fee bill legislation (H.R. 1561) on October 1, 2004. (H.R. 4818, the Consolidated Appropriations Act, 2005 was signed by the President and enacted into law on December 8, 2004.) (Due to federal regulations, details of the FY06 budget cannot be released).

OUTPUT AND PENDENCY

Restriction reform Options 1 and 2 both provide an option for applicant to request and pay for the examination of additional inventions. As a result, examiners would spend more time on each of these applications to examine the increased number of inventions. Therefore, a single examiner would necessarily examine fewer applications in a given fiscal year than under current practice.

Inclusion of additional inventions in a single application would presumably result in a decrease in the number of divisional applications filed. For purposes of this study, a 50% reduction in the number of subsequently filed divisional applications was assumed. However, this reduced filing rate would not likely occur in the first year. Current filing trends indicate that divisional applications are not filed until prosecution of the original application is near completion, which averaged 27.6 months after the filing date as of fiscal year 2004. Additionally, when multiple divisional applications are filed, such applications are typically filed serially, not simultaneously. Statistically, divisional filings make up less than seven percent of total non-provisional application filings (as compared to continuation and RCE filings, which make up about twenty percent of total non-provisional filings). Thus, any "divisional offset" would not be expected for more than two years and would be less than 3.5 percent of total workload.

Concurrent examination of plural inventions in one application may possibly result in an increased number of RCE or Continuation filings. This is due to the fact that synchronized resolution of the issues raised in examining plural inventions would be more unlikely, which will increase the odds that one of the inventions will have issues that cannot be resolved in a single application, resulting in an RCE or Continuation refiling. This will likely occur in technology areas that are already experiencing higher rates of RCE or Continuation filings, particularly Chemical Technology Centers (TC1600 and 1700) and the Electrical Technology Centers (TC2100, 2600, 2800). Since RCE or Continuation filing rates are three to four times higher than Divisional filing rates, this

would likely result in a greater impact on output and pendency that could offset any potential decrease in Divisional filings.

To achieve equivalent output to that estimated in the FY06 budget through 2010, each of Options 1 and 2 were estimated to require more examiner hires than were provided for in the FY06 estimate. Because the Office would not be able to hire sufficient examiners to do the additional workload estimated under Options 1 and 2, output would be reduced and pendency would increase relative to the output and pendency estimates provided in the FY 2006 budget through 2010.

OVERALL PENDENCY INCREASE DUE TO PRODUCTION DECREASE

	Production Units Lost, cumulative FY2005-2010	Increase in First Action Pendency, in months, by FY2010
Option 1, 1 extra	211,166	4.0
Option 1, 2 extra	269,539	5.6
Option 2, 1 extra	165,879	2.7
Option 2, 2 extra	203,614	3.8

The above estimates are based on an overall patent corps average. However, the number of restrictions, and therefore, the impact of any changes to restriction practice, varies significantly among different technologies. To demonstrate the relative impact by Technology Center (TC), the next chart illustrates the estimated increase in pendency under Option 1, with the option of up to 2 additional inventions (and up to 10 species per invention) examined (Option 1, 2 extra), for each TC as compared to the overall patent corps average.

RELATIVE PENDENCY INCREASE PER TECHNOLOGY CENTER

Option 1, 2 extra	Increase in First Action Pendency, in months, by FY2010
Overall Patent Corps	**5.6**
TC1600	17.5
TC1700	4.2
TC2100	0.4
TC2600	0.5
TC2800	4.5
TC3600	4.3
TC3700	3.1

Clearly, certain Technology Centers would experience significantly more impact than others. In particular, Technology Center 1600 would be severely impacted by either of the two proposed restriction reform options due to the nature of the technology and the corresponding claims filed.

If the Office were able to hire sufficient examiners to do the additional workload estimated under Options 1 and 2, to maintain the pendency target through 2010 provided in the FY06 budget, the chart below indicates the number of additional examiners (Full Time Employees or FTEs) needed.

NUMBER OF ADDITIONAL EXAMINERS NEEDED TO MAINTAIN PENDENCY TARGET

	Additional Examiner FTEs needed, FY2005-FY2010	Costs* of Additional Examiner FTEs, FY2005-FY2010
Option 1, 1 extra	1220	$226,468,700
Option 1, 2 extra	1520	$293,329,534
Option 2, 1 extra	920	$160,791,924
Option 2, 2 extra	1220	$226,468,700

* - costs include salary and benefits only

There are additional costs for examiner FTEs not reflected in the above chart, some of which include computers, furniture, space, and other administrative costs for proper accommodation and management of an increased examiner workforce.

REVENUE

As noted above, because the Office would not be able to hire sufficient examiners to do the additional workload estimated under Options 1 and 2, output would be reduced and pendency would increase relative to the output and pendency estimates provided in the FY 2006 budget through 2010. This reduced output would also reduce revenue.

The chart below indicates the estimated cumulative impact through 2010 on production, patents issued, and revenue, assuming the FY06 estimated examiner hiring levels and fees, i.e. no fees for additional inventions.

CUMULATIVE REVENUE LOSS

	Production Units Lost, cumulative FY2005-2010	Patents Printed Lost, cumulative FY2005-2010	Lost Revenue, cumulative FY2005-2010
Option 1, 1 extra	211,166	113,922	$320,975,292
Option 1, 2 extra	269,539	145,397	$382,638,617
Option 2, 1 extra	165,879	89,468	$273,079,722
Option 2, 2 extra	203,614	109,833	$313,001,577

The Office would need to maintain a revenue stream, under either Option 1 or 2, equivalent to that indicated in the FY06 budget estimate. As discussed above, production would be reduced under either option, due to the additional time required to examine an increased number of inventions per application. In addition to the revenue loss resulting from reduced production, collection of fewer allowance and maintenance fees, due to the issuance of fewer patents, must be considered as well. Therefore, a revised fee schedule would be needed to generate the same annual revenue stream as that indicated in the FY06 budget estimate.

In an effort to simplify the implementation and administration of a new fee schedule both inside and outside the Office, the Office proposes that the revised fee schedule mirror that currently in place. Furthermore, public comments indicated that those applicants who benefit from the proposed restriction reform should bear the associated costs. Consistent with this approach, one proposal is that an additional search fee ($500)[2] and examination fee ($200)[2] per additional invention be paid at the time applicant chooses to have that additional invention examined. Applicant may also request examination of up to 10 species per invention at a cost of $250 per species. No additional filing fee ($300)[2] would be due. Any fees due during prosecution (such as claim fees and extension of time fees) would be the same as those for a single application. The Office would determine

[2] The fees indicated are those provided under the newly enacted fee legislation.

how many inventions are present in the application at the time of allowance and would issue a requirement for payment of an additional issue fee for each additional invention. Similarly, separate maintenance fees would be due for each additional invention at the time each of the current maintenance fees would become due.

OTHER BUSINESS IMPACT CONSIDERATIONS

A change to a new restriction standard would likely have impacts other than those discussed in the previous two sections which the Office, and in some cases the USPTO user community, will need to identify and address. While it is not possible to predict all of the ramifications of a change to a new restriction standard, a number of such impacts are identified and discussed below.

PATENT TERM ADJUSTMENT (PTA)

An increase in pendency, as discussed in the previous section, would result in a larger backlog of unexamined applications. Such a backlog would likely result in an increase in the number of patents eligible for Patent Term Adjustment (PTA). The impact of increased use of PTA would require thorough analysis from a public policy perspective, particularly with regard to specific technology areas. For example, increased PTA in the pharmaceutical area could delay public availability of less-costly generic versions of certain drugs.

STRUCTURE OF THE ORGANIZATION

The patent examining corps is currently organized into art units that examine specific areas of technology. A change to current restriction practice that would allow for the inclusion of additional inventions in a single application would necessarily change the number and kind of inventions examined together. A reorganization of the examining corps may be necessitated by such a change in restriction practice.

PRODUCTIVITY MEASUREMENTS

Examination of multiple inventions in a single application would likely require modification of the current patent examiner production system. Changes to this production system may involve labor-relations considerations with the Patent Office Professional Association (POPA).

PUBLIC/USER IMPACTS

A revised restriction standard will require efforts on the part of practitioners to become familiar with filing and prosecution strategies to confidently determine the best course of action in a particular application. Both options would require consideration of whether to request and pay for the immediate examination of any additional invention(s) in response to a requirement for restriction or to wait and subsequently file one or more divisional applications. A restriction requirement is made prior to search and examination; therefore, decisions must be made with limited information concerning patentability.

Claim drafting styles may need to be reconsidered with a change of standard. An option to pay for the immediate examination of additional inventions may prompt earlier inclusion of claims drawn to related inventions. Under Option 2, inclusion of the

purported same or corresponding special technical/common feature in the independent claims may prove valuable.

TRANSITION ISSUES

In the event a new restriction standard is ultimately adopted, that new standard and accompanying procedure would only be applied to applications actually filed on or after the effective date and pending applications that had not received a first action on the merits prior to the effective date. A request for treatment under the new restriction standard would be permitted with either the filing of a request for continued examination or by refiling of the application, where a first action on the merits was issued prior to the effective date. By adoption of this transition protocol, the efforts already expended by the Office in examination will likely not be subject to significant rework.

CORRECTIVE PROCEDURES

A petition process similar to the PCT protest provisions under PCT Rule 40.2(c) would be provided, if a revised restriction procedure that permits applicants to request and pay for the examination of additional inventions is adopted.

CONCLUSION/RECOMMENDATIONS

One goal of this study was to achieve an appropriate balance between needs of the USPTO and those of its user community by reevaluating and potentially redefining the circumstances under which the discretionary power of the Director to restrict applications under 35 U.S.C. 121 would be applied. The development of the standards reflected in Options 3 and 4, however, highlights the difficulty in the formulation of any new standard. A new standard should be both easy to understand and to implement; unfortunately, the standards embodied in Options 3 and 4 proved to be neither. While Options 1 and 2 were somewhat more promising, the results of the business case analysis indicate that even these options do not satisfactorily achieve the desired balance.

The process of improving the quality and predictability of restriction requirements must be a collaborative effort; the TC 1600 Restriction Action Plan and this paper represent only the first step in an ongoing endeavor to discover feasible solutions. It is hoped that the improvements in quality and predictability expected from the restriction action plan alone will be perceived as significant progress toward the goal of achieving an appropriate balance between the needs of the USPTO and those of its user community.

The Office requests comments from the public on the desirability of conducting further study on Options 1 and 2. Further, comment on whether the perceived desirability justifies the costs to the Office of continuing the study is solicited. Comments directed to the impact on the system as a whole are also solicited.

Appropriate legislation would need to be enacted in the event a decision to implement Options 1 or 2 is made. Implementation of Option 1 would not be viable without a revision to the fees for search/examination, issue and maintenance. Implementation of Option 2 would require revision to 35 U.S.C. 121 in addition to the same fee revisions required to implement Option 1.

Options 3 and 4 are not considered viable for implementation.

See notice "**Posting of Green Paper Regarding Restriction Reform Efforts"** for details on providing comments.

APPENDIX I – REQUEST FOR PUBLIC COMMENTS

Prior to starting this study, the USPTO sought public comment on a number of issues to help guide the scope and content of a study on the adoption of a Unity of Invention standard in the United States. On May 20, 2003, the United States Patent and Trademark Office ("Office") published a Request for Comments on the Study of the Changes Needed To Implement a Unity of Invention Standard in the United States, 68 *Fed. Reg*. 27536 (May 20, 2003), 1271 *Off. Gaz. Pat. Office* 98 (June 17, 2003). In response to this request, the Office received twenty-six (26) public comments.

The following is a brief synopsis of the comments received on each issue.

Issue 1: Unity of Invention as practiced in the EPO is interlinked to EPC-style claim drafting and EPO claim treatment practice, including certain limitations on claiming that are not present in current United States patent practice. For example, the EPO (under EPC rule 29(2)) usually allows only one independent claim per category of invention (category of invention is that of product, process or apparatus of use), and emphasizes the search and examination of independent claims. In contrast, the USPTO searches and examines every claim, independent and dependent, and every limitation of every claim. In addition, EPC- style claim drafting is generally termed "central claiming". In central claiming, the inventive concept is essentially claimed in the independent claim. If the independent claim is found allowable, the EPO examination will not be unduly concerned with respect to the dependent claims, according to EPO Guidelines, C-III, 3.6.

Should the USPTO study ways to adopt EPO claim treatment practice, including normally allowing only one independent claim per category of invention, when considering ways to adopt a Unity of Invention standard, and why?

Should the USPTO emphasize the examination of independent claims and modifying the examination of dependent claims in the same fashion as the EPO?
If so, would there be any reason to consider changes to the presumption of validity under 35 U.S.C. 282 of those dependent claims?

Synopsis of Comments to Issue 1: There was no consensus in the comments to move to EPO's unity of invention standard. The comments generally expressed a strong objection to move to the EPO style of claim drafting, searching and treatment.

Issue 2: In United States restriction practice, the applicant can file a subsequent application that is directed to an invention that was divided out of the parent application. These are called Divisional applications. Divisional applications are typically subsequently filed and are not normally examined concurrently with the parent application. Divisional applications retain the benefit of the filing date of the original application if the conditions set forth in 35 U.S.C. 120 are met. This allows an applicant to continue to pursue protection for the inventions subject to restriction that were in the original application without being affected by double patenting. All member states of the

Paris Convention for the Protection of Industrial Property (1967) (including Japan and all EPC member states), as well as the EPO, also provide for the filing of Divisional applications. However, the PCT does not yet provide for the filing of Divisional international applications. Consequently, the PCT rules provide for applicant to pay for the search and examination of additional inventions that "lack unity" in a single international application. Adoption of a Unity of Invention standard could, in some instances, require examining more inventions during the examination of a single application than occurs presently, thereby possibly causing delay in the examination of other applications if examination resources are limited. This could increase the USPTO's average patent pendency time.

If the USPTO adopts a Unity of Invention standard, should the USPTO provide applicants the option of a PCT-style Unity of Invention practice to pay for additional inventions that lack Unity of Invention in the same application?

If so, should the USPTO consider any changes to patent term adjustment under 35 U.S.C. 154(b) for applications which have more inventions examined in a single application under a Unity of Invention standard than are permitted under current practice?

In view of the fact that examining multiple inventions in a single application could cause examination delay in other applications, what other revisions to patent term adjustment provisions under 35 U.S.C. 154(b) should be considered by the USPTO, or should the USPTO also consider revising the order that cases are taken up for examination?

Synopsis of Comments to Issue 2: The comments generally expressed some qualified support to permit payment for additional examination of additional inventions including a proposal for a sliding scale of fees based on Office efforts. The comments generally expressed strong opposition to any PTA reduction based on requesting examination of additional inventions.

Issue 3: Under the PCT, examination proceeds on the basis of the first claimed invention if applicant does not pay for additional inventions that lack unity.

Should the USPTO adopt, for national applications, the practice currently used under the PCT of examining the first claimed invention where there is a holding of lack of Unity of Invention?

Optionally, where Unity of Invention is lacking: (1) Should the USPTO examine the first claimed product, or the first claimed invention if there are no product claims; or (2) should applicant be given the opportunity to elect an invention to be examined?

Synopsis of Comments to Issue 3: The comments generally strongly encouraged the Office to retain its practice of oral elections and expressed some limited support for examining the first claimed invention if applicant fails to orally elect. Most comments expressed a preference to continue the current practice of written requirement if oral election is not possible.

Issue 4: A determination of lack of Unity of Invention is predicated on assessing whether a common feature (referred to as a "special technical feature" in the context of PCT Rule 13) defines a contribution over the prior art. Certain PCT member states assess this requirement only with respect to patentable advances over prior art. However, issues of lack of support, enablement, clarity, or conciseness, generally resulting from excessive breadth of claims or excessive numbers of claims, may occur that render examination unduly burdensome. In such circumstances, some International Authorities will make a "partial search" declaration to limit the extent of search and examination. The USPTO does not follow this practice. On the other hand, it may be viewed that if the common feature or "special technical feature" is not adequately supported by the disclosure or lacks utility ("industrial applicability" in the PCT context), the special technical feature does not make a contribution over the prior art.

When adopting the Unity of Invention standard, should the USPTO follow the practice of performing only a "partial search" if the examination of the entire scope of the claims is unduly burdensome due to non-prior art issues?

Alternatively, should the USPTO assess adequacy of the disclosure and industrial applicability in addition to the prior art when determining whether the claims' common feature makes a contribution over the prior art?

Synopsis of Comments to Issue 4: The comments generally expressed mixed support for a partial search and even less support to look to 35 U.S.C. §112, first paragraph issues in making a lack of unity holding. Some of the larger organizations were supportive of looking to non-prior art issues in making a determination concerning lack of unity or restriction.

Issue 5: The USPTO's 21st Century Strategic Plan is predicated on a certain level of revenue to provide the resources needed to meet quality and timeliness goals. The Plan currently does not account for any additional resource requirements, and any corresponding revenue shortfalls, that may result from adopting a Unity of Invention standard. Statutory fees under 35 U.S.C. 41(a) and (b), in the aggregate, are set to cover USPTO operating costs. If the average cost of processing patent applications goes up, the USPTO will need to increase fees. Assuming that there will be extra costs of examination under Unity of Invention, possible increases would be: (1) All filing fees; (2) all filing fees and an additional fee for examination of claims that lack Unity of Invention with an elected invention; (3) increased issue and/or maintenance fees of all applications; (4) increased issue and/or maintenance fees for applications paying the additional invention fee; or (5) a combination of two or more of (1) through (4) above.

Which of the above approaches should the USPTO propose in regard to any fee increases?

Synopsis of Comments to Issue 5: The comments expressed a slight preference for a limited increase in filing fees, excess claims fees, and maintenance fees. The comments

expressed some support for a fee to examine additional inventions. There were comments suggesting that no change should be made if the examination cost would increase.

Issue 6: Adopting a Unity of Invention standard would impact the number of inventions that would be examined in a single application, and require examining multiple inventions that cross multiple disciplines in a single application. Due to the current level of technical specialization in the Patent Examination Corps, the USPTO will have to consider the impact any change would have on the ability of the USPTO to maintain high quality examination.

How should work be assigned to ensure that examination quality would not suffer if examiners have to examine multiple inventions from different disciplines in a single application?

Should the USPTO consider: (1) Using team examination, similar to the EPO where applications are examined using three-person teams called "examination divisions" (2) extending the use of patentability report procedures provided for in section 705 of the Manual of Patent Examining Procedure (8th ed. 2001) (Rev. 1, Feb. 2003); (3) maintaining the current process of a single examiner on an application; or (4) using some other option of how work is performed by examiners?

Synopsis of Comments to Issue 6: The comments generally expressed a preference to continue the single examiner model and recommend use of team examination on a case-by-case basis.

Issue 7: One way of adopting aspects of Unity of Invention without making any statutory changes would be for the USPTO to use its authority under the continued examination provisions of 35 U.S.C. 132(b) (authorizes request for continued examination or RCE practice) to permit applicants to pay an RCE fee and submit or rejoin claims to additional inventions after prosecution has been closed on a first invention, so long as the claims presented with the RCE fee either depend from or otherwise include the features of the allowed claims which make a contribution over the prior art. In this option, most applications will continue to be examined under the USPTO's current restriction practice. Under any new provisions to implement this option, when a claim is determined to be allowable, the applicant would be entitled to request continued examination under the Unity of Invention standard. The required submission would be additional claims that either depend from or otherwise include the features of the earlier-examined claims that are in condition for allowance (if such additional claims were not previously pending in the application).

Should the USPTO consider this option?

Should this option be available only to applicants whose applications are published?

If so, how should the new RCE fee be set relative to the current fee structure?

Synopsis of Comments to Issue 7: The comments generally expressed a strong opposition to this procedure. It was not apparent that the comments recognized that this option would permit newly submitted claims after close of prosecution to be considered (which is not the case today). Further, the comments appeared to assume that this option would be an alternative to existing rejoinder practice and not a replacement for the current rejoinder process.

Issue 8: As a second example of adopting aspects of Unity of Invention without making any statutory changes, the USPTO could use its authority under continued examination to permit requests that the USPTO continue examination of claims which were withdrawn from consideration. This option would require applicants to make a decision to request continued examination rather than file a divisional application, to pay a fee for the treatment of one additional invention, and to present claims drawn only to that additional invention. This option would be available in addition to the continuing option of filing a divisional application.

Should the USPTO consider this option?

If so, how should the loss in issue and maintenance fee collections be offset relative to the current structure?

Synopsis of Comments to Issue 8: The comments generally expressed mixed support for this proposed procedure.

Issue 9: In view of the previous questions and the range of issues and options, should the USPTO consider: (1) Seeking a change to 35 U.S.C. 121 to adopt a Unity of Invention standard (and if so, what would such statutory change be, including whether such a statute would provide for applicants to pay for additional inventions that lack Unity of Invention to be examined in the same application); (2) maintaining the current restriction practice in the USPTO; and/or (3) modifying the USPTO rules and procedures to adopt aspects of Unity of Invention practice without making any statutory changes (if so, in what manner should rule changes be made)?

Synopsis of Comments to Issue 9: The comments generally provided strong input that the Office should first address consistency in current procedures and then determine if further changes are needed. The comments generally expressed that the Office should balance cost and impact on quality before going forward with any change in statute or procedure (other than following its published procedure). Some comments suggested the Office seek authority to permit applicants to either file additional divisional applications or seek examination of related inventions in a single case with fee setting authority to recover costs.

Issue 10: Do you have other solutions to offer which are not addressed in this notice?

Synopsis of Comments to Issue 10: Some commentators suggested an overhaul of aspects of the current production system that are perceived to encourage undue restriction requirements. One commentator suggested EPO and PCT adopt the US system. Some commentators suggested revisions of rejoinder practice to permit greater use.

APPENDIX II

OPTION 1: CURRENT PRACTICE WITH OPTION TO PAY FOR ADDITIONAL INVENTIONS

Overview

The current 35 USC §121 "independent or distinct" standard for restriction would be retained and applicants would be given the option to request and pay for examination of up to 2 additional **distinct or independent** inventions beyond that which would be examined in the current practice. Applicants would also have the option to request and pay for examination of up to 10 species separately claimed, or claimed within a genus or Markush group, set forth in any elected invention at an additional per species cost.

Methodology

Applications were reviewed under the current restriction practice and analyzed based on all properly restricted groups of inventions and species after applicant had made an election and the examiner had acted on the election.

The groups of invention were categorized as either distinct or independent. The number of distinct inventions and the number of independent inventions beyond the number of inventions that were examined under current practice were separately recorded. Whether an invention was distinct or independent was determined based on its relationship with the elected invention.

Independent Inventions

The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus, which species are not usable together as disclosed; or (2) process and apparatus incapable of being used in practicing the process.

Distinct Inventions

The term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use, or sale as claimed, and are patentable (novel and unobvious) over each other (though they may each be unpatentable because of the prior art).

Species

Species were categorized as part of a Markush group or not. The number of species in a Markush group was recorded (up to 100 members). Species that were outside of a Markush group were recorded separately. Note that when non-Markush species are elected, the

examiner does not specify the claims in the restriction requirement, rather applicant must specify in the election, the claims that read on the elected species.

Where a determination was made that a genus (or sub genus claim covering 2 or more species) was patentable (including non-prior art issues) the species covered by that genus was counted as a single species.

For purposes of the study, the number of species prior to search and examination (pre examination species) was recorded as well as, where an allowable claim generic to more than one species was indicated as allowable, the number of species not covered by an allowable claim.

Concurrent examination would be limited to species within the lowest level of any nested Markush groups. For example, if the claims recite 10 various formulas, each of which have 100 species, then applicants may elect to pay for examination of 10 species from one formula only.

APPENDIX III

OPTION 2: MODIFIED PCT UNITY OF INVENTION

Overview

The current PCT "unity of invention" standard, modified to require that any purported special technical/common feature comply with 35 USC §112, 1st paragraph (in addition to being novel and non-obvious), would be applied to all US applications. Applicants would be given the option of concurrent examination of multiple inventions that lack unity of invention for an additional fee.

Methodology

Unity of Invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," should be considered both with respect to the prior art itself, as well as 35 U.S.C. 112, first paragraph. If the examiner can demonstrate either with a document or by scientific knowledge or reasoning that the main claim is not fully supported by the description as a basis for holding a lack of unity of invention, then there would be no technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features, because, a technical feature cannot constitute a contribution over the prior art if it is not sufficiently supported by the description so as to place the invention in the hands of the public.

For example, independent claims A + X, A + Y, and X +Y can be said to lack unity *a priori* as there is no subject matter common to all claims. In the case of independent claims A + X and A + Y, unity of invention appears to be present initially as A is common to both claims. However, if it can be established that A (be it a single feature or a group of features) fails to comply with 35 U.S.C. §112, 1st paragraph, or that A is known, there is lack of unity since A is not a technical feature that defines a contribution over the art.

Alternative forms of an invention may be claimed either in a plurality of claims, or in a single claim. In the latter case, the presence of the independent alternatives may not be immediately apparent. In either case, however, the same criteria would be applied in deciding whether or not there is unity of invention. Accordingly, lack of unity of invention may exist within a single claim. Where the claim contains distinct embodiments that are not linked by a single general inventive concept, the objection as to lack of unity of invention should be raised.

Markush Practice

In this special situation, wherein a claim, or claims, define alternatives (chemical or non-chemical), the requirement of a technical interrelationship and the same or corresponding

special technical features shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

The fact that the alternatives of a Markush grouping can be differently classified is not, taken alone, considered to be justification for a finding of a lack of unity of invention. When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention should be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.

APPENDIX IV

OPTION 3: THREE-TIER FEE-STRUCTURE

Option 3 Overview

The standard would be based upon whether inventions are "related or unrelated" and the amount of fees paid in any particular application would be based upon a three-tiered structure. The fees would be determined by the search burden associated with, and the presence of different patentability issues between, the various inventions claimed in the application. This proposal is based on the assumptions that USPTO resources would be more efficiently utilized when substantially similar or related inventions are examined in the same case and that the cost to applicants would be more directly related to the amount of work performed. (*See* Biotechnology Industry Organization response filed July 21, 2003 to the *Request for Comments on the Study of the Changes Need to Implement a Unity of Invention Standard in the United States*, 68 *Fed. Reg.* 27536 (May 20, 2003), 1271 *Off. Gaz. Pat. Office* 98 (June 17, 2003))

In the first tier, applicants would pay a base fee if only claims directed to "substantially similar" inventions are elected. In the second tier, an intermediate fee or surcharge above the base fee would be charged for election of a number of "related" inventions that raise substantially different patentability issues but do not require a substantially different search. (While Restriction Reform Option 3 in the "Summary of Public Comments and the Restriction Reform Options to be Studied by the United States Patent and Trademark Office" signed on November 20, 2003 and posted on the USPTO web site indicates the second tier as "related inventions that require limited additional searching but include similar patentability issues", this language appears to be in error. See, for example, the first paragraph on page 4 of the Biotechnology Industry Organization response as noted above.) The third tier would comprise "unrelated" inventions that require additional searching and also present dissimilar patentability issues. (If Option 3 is ultimately adopted, the Office would inventions in the first two tiers to be examined in the same application, but would not permit inventions in the third tier to be examined in the same application.)

Methodology

To determine whether inventions are "substantially similar," "related," or "unrelated" as defined above, the claims must first be grouped under a standard into one or more inventions. Accordingly, under this option inventions would continue to be grouped under the current 35 U.S.C. 121 independent or distinct standard.

For the purposes of this study, all sampled applications included a restriction requirement and a first Office action on the merits on the elected invention. A determination was then be made into which tier each additional invention and specie (if applicable) was placed, relative to the elected invention.

If Option 3 were ultimately adopted, the Office would need to decide the mechanism by which to identify the point of reference for placement of additional inventions into tiers. One possible mechanism would be to uniformly identify Group I as the point of reference. A second possible mechanism would provide applicants with a choice of the point of reference; however, two successive communications with applicants would be required. A first communication would require applicants to elect an invention. The second communication would set forth the placement of the additional inventions into tiers relative to the elected invention and would invite applicants to pay additional fees for "related" inventions.

For the purposes of this study, estimation of the burden hours for additional patentability issues for tier 2 and additional search and patentability issues for tier 3 required the formulation of an opinion based upon past experience.

Tier 1

Inventions would be considered to be **substantially similar** when a single thorough and properly executed search will identify the prior art relevant to all the inventions **and** the inventions do not raise significantly divergent patentability issues.

Tier 2

An invention would be considered **related** if it does not require a substantially different search, but does raise substantially different patentability issues. Determination of what constitutes a "substantially different" search would be determined on a case-by-case basis. Consideration should be given to the amount of additional time and resources involved to perform the search for each related invention. Where some additional searching is required, the search would not be considered substantially different if it were not to a degree that would impose significant burdens. A determination may be made that a single claim embraces several related inventions.

In the case of chemical inventions, where a single claim relates to a class of related molecules in Markush format, such a claim may represent a single inventive concept or related inventions, depending upon the nature of the shared subject matter.

Tier 3

An invention would be considered **unrelated** if additional searching is required to identify the prior art relevant to that further invention **and** that further invention raises substantially different patentability issues. A determination may be made that a single claim embraces several unrelated inventions.

APPENDIX V

OPTION 4: "INDEPENDENT AND DISTINCT" INVENTIONS

Overview

Currently, 35 U.S.C. § 121 is interpreted as requiring that inventions subject to a restriction requirement be independent *or* distinct. Under this option, 35 U.S.C. § 121 would be re-interpreted to require that such inventions be independent *and* distinct.

Methodology

In this option, the current restriction practice would be modified in the following manner.

The examiner must show that:

1) The inventions are distinct (i.e., patentable over each other); and
2) The inventions are independent, which may be established by showing that
   a) there is no common feature(s), or
   b) there is a common feature(s) but the common feature(s) does not define over the prior art and/or satisfy the enablement and written description requirements of 35 U.S.C. § 112.

In setting forth an initial restriction requirement where the independent inventions share a common feature(s), the examiner should infer that the common feature(s) fails to define over the prior art.

Applicant would "elect" one of the inventions for examination.

Applicant would have ability to define the feature(s) they consider to be in common between the inventions that require the common feature(s).

Applicant could identify common feature(s) on filing.

Examiner could identify common feature(s) in the restriction requirement and applicant would have opportunity to rebut the examiner's identification of the common feature(s).

Examiner would search and examine the elected invention.
If the elected invention is not patentable (either over the prior art or under 35 U.S.C. §112, first paragraph), the restriction requirement would be maintained and the claims directed to the non-elected invention(s) would remain withdrawn.

If the elected invention is patentable, the examiner would continue to search the common feature(s), either by searching a nonelected invention that requires the common feature(s) or by searching the common feature(s) by itself. The search would continue until either the common feature(s) or a previously nonelected invention that requires the common

feature(s) was determined not to be patentable, or until all the previously nonelected inventions are determined to be patentable.

If the common feature(s) is (are) determined to be not patentable, the restriction requirement is maintained, although any related invention searched and determined to be patentable prior to uncovering either a rejectable related invention or the common feature(s) should be rejoined with the elected invention.

If the previously non-elected inventions having a common feature(s) is (are) determined to be patentable, the restriction requirement between those inventions would be withdrawn.

APPENDIX VI

Comparison Chart of the Four Options

	OPTION 1	OPTION 2	OPTION 3	OPTION 4
What restriction standard will be applied?	Current Standard – independent *or* distinct	Modified Unity of Invention Standard	Current Standard – independent or distinct	New Standard – independent *and* distinct
How will the standard be applied?	Same manner as applied currently	Same manner as in PCT and 371 applications with one additional requirement – any special technical/common feature must comply with 35 U.S.C. §112, first paragraph	Same manner as applied currently	Inventions must be patentable over each other (i.e., distinct) and have either no common feature(s) or a common feature(s) that does not define over the prior art and/or satisfy the enablement and written description requirements of 35 U.S.C. § 112 (i.e., independent). If there is a common feature(s), an initial inference should be made that the common feature(s) fails to define over the prior art.
Are any further steps required in applying the standard?	No	No	Yes	No
What are these further steps?	N/A	N/A	After election, any remaining inventions must be placed in one of three tiers relative to the elected invention: "substantially similar"; "related"; or "unrelated".	N/A
May additional inventions be paid for?	Yes	Yes	Yes	An additional fee will be charged, however additional inventions may or may not be examined.
How many additional inventions may be paid for?	2, plus up to 10 species per invention at additional per species cost	2	Up to 4 related inventions	The number of additional inventions examined, if any, will be determined during examination.

APPENDIX VII

PROPOSED EXAMINATION PROCESSES FOR EACH OPTION

Option 1

The process is essentially the same as the current restriction process with the addition of an option to pay for search and examination of the additional groups and species.

1. Separate inventions are identified, the claims are appropriately grouped, and each claimed invention is briefly described.
2. Reasons relied upon are stated.
3. Restriction includes an option to pay for an additional 1 or 2 groups and up to 10 species per group (a fee per species would be in addition to the fee for the additional inventions).
4. An election of one group must be made to prevent abandonment and additional groups and/or species, if desired, must be elected and paid for prior to examination.
5. Fees may be paid under protest. To the extent the protest is justified, the fees would be totally or partially reimbursed.

Option 2

This process is essentially the same as the current unity of invention process with an additional first step, where necessary, as well as the addition of an option to pay for search and examination of the additional groups and species.

1. Where necessary, in applications containing a large number of inventions (particularly in chemical and biotechnology applications), applicant will be invited to identify a reference claim for determination of the relationship of the remaining claims, i.e. whether or not they contain "the same or corresponding special technical/common feature(s)."
2. Separate inventions are identified, the claims are appropriately grouped, and each claimed invention is briefly described.
3. Reasons relied upon are stated.
4. Restriction includes an option to pay for an additional 1 or 2 groups.
5. An election of one group must be made to prevent abandonment and additional groups, if desired, must be elected and paid for prior to examination.

Option 3

The process is initially the same as the current restriction process, however, an additional communication is required to set forth placement of the inventions into tiers, if desired, together with an option to pay for search and examination of the additional groups.

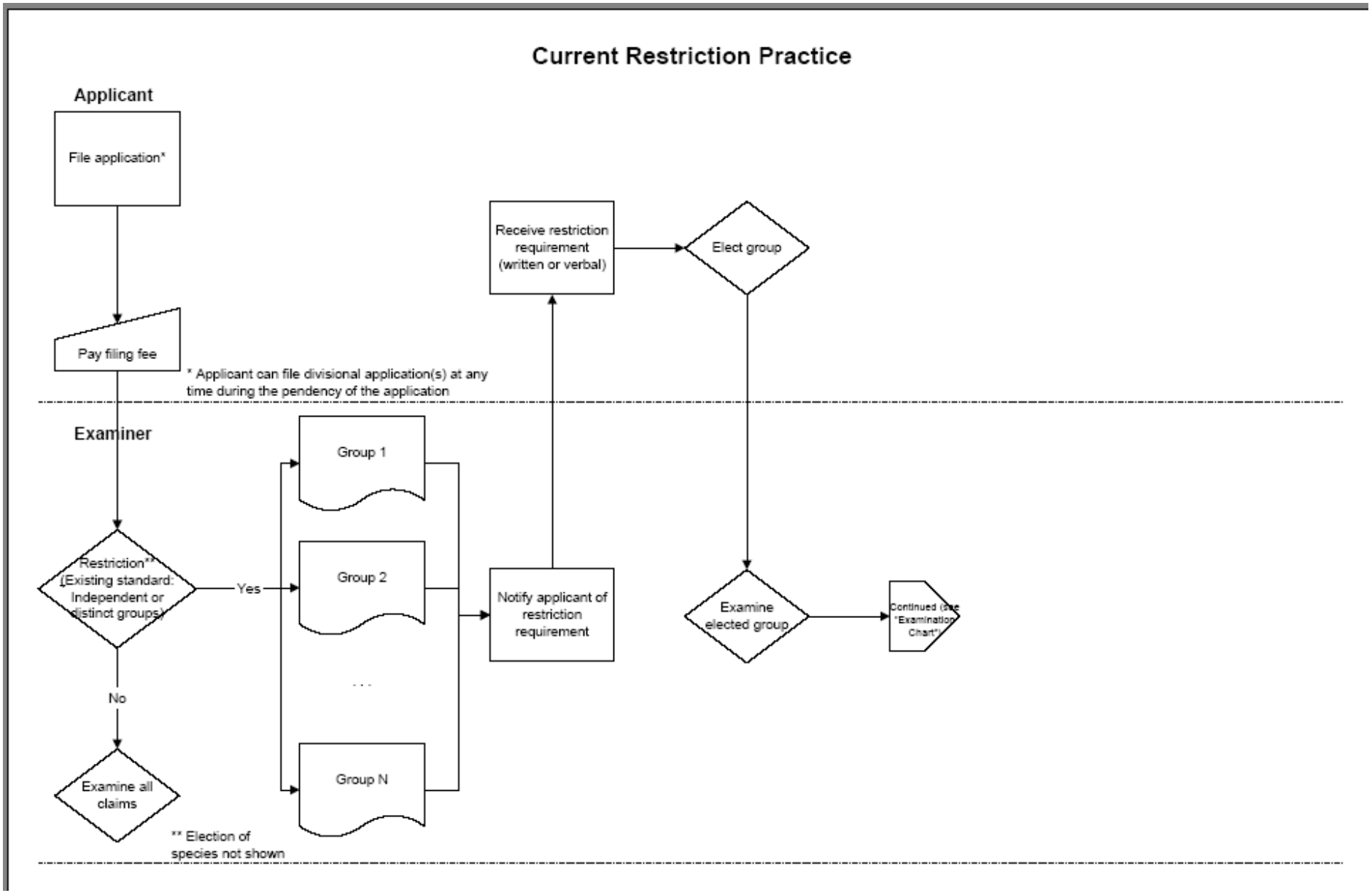
1. Separate inventions are identified, the claims are appropriately grouped (in accordance with current restriction practice), and each claimed invention is briefly described
2. Reasons relied upon are stated.

3. Restriction includes an option to request and pay for the placement of additional inventions into tiers 2 or 3 by the examiner.
4. An election of one group must be made to prevent abandonment and an indication must be provided as to whether placement into tiers is desired.
5. If placement into tiers is not desired or indicated, examination will proceed on the elected group.
6. If placement into tiers is requested and paid for, a second communication would be issued providing the placement into tiers and an invitation to pay for up to 4 additional inventions in tier 2. (If applicant chooses to prosecute any tier 3 inventions, this option would require applicant to do so in a divisional application, and therefore, applicants would not be given the option to pay for additional tier 3 inventions to be examined in the same application).
7. Additional groups must be elected and paid for prior to examination.

Option 4

The process is similar to the current restriction process in that distinct inventions are identified, however, a further determination is made as to whether those inventions are also independent.

1. Distinct inventions are identified, and claims are appropriately grouped (in accordance with current restriction practice).
2. A determination is then made as to whether the distinct inventions are also independent, by determining whether the inventions include a commom feature(s) that defines over the prior art and satisfies the enablement and written description requirements of 35 U.S.C. § 112.
    a. If there is no common feature(s) between inventions, the separate inventions will be identified, described, and reasons relied upon will be stated.
        i. An election of one group must be made to prevent abandonment.
        ii. Examination proceeds on the elected invention.
    b. If there is a common feature(s) between inventions, the examiner will infer that the common feature(s) fails to define over the prior art. Applicant will be required to pay an additional fee. The following process will then be followed.
        i. An election of one group must be made to prevent abandonment.
        ii. The elected invention is examined.
            (1) If the elected invention is found to be unpatentable, either over the prior art or under 35 U.S.C. § 112, first paragraph, only the elected invention is examined.
            (2) If the elected invention is found to be unpatentable, the examiner continues to search the next invention or the common feature(s) themselves, until either one of the inventions or the common features themselves are found to be unpatentable, or until all of the nonelected inventions having the common feature(s) are determined to be patentable.
3. The fee may be paid under protest. To the extent the protest is found justified, the fee will be reimbursed.


Current Restriction Practice
Applicant
File application*
Pay filing fee
* Applicant can file divisional application(s) at any time during the pendency of the application
Examiner
Restriction** (Existing standard: Independent or distinct groups)
Yes
No
Group 1
Group 2
Group N
Notify applicant of restriction requirement
Receive restriction requirement (written or verbal)
Elect group
Examine elected group
Continued (see "Examination Chart")
Examine all claims
** Election of species not shown

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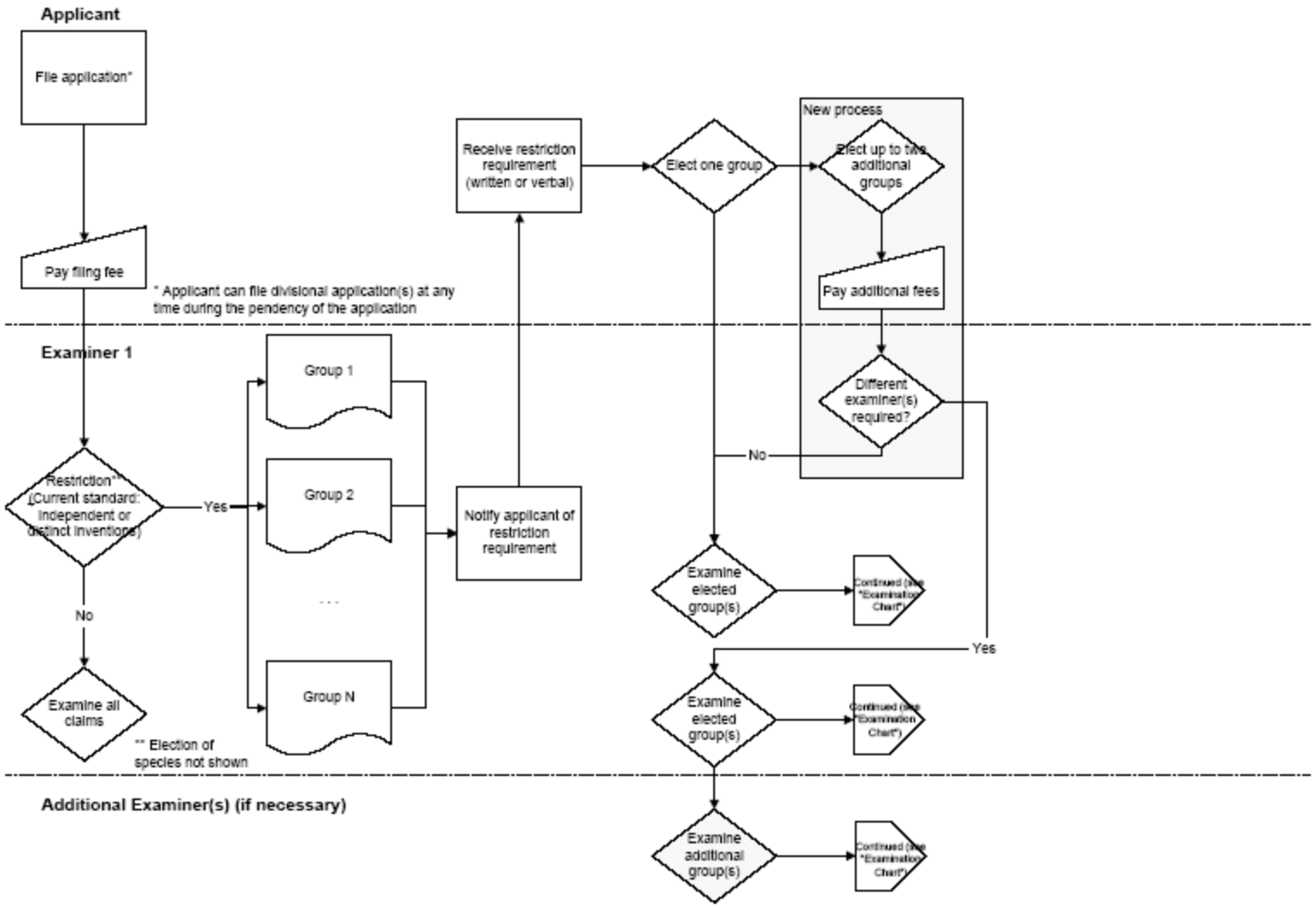
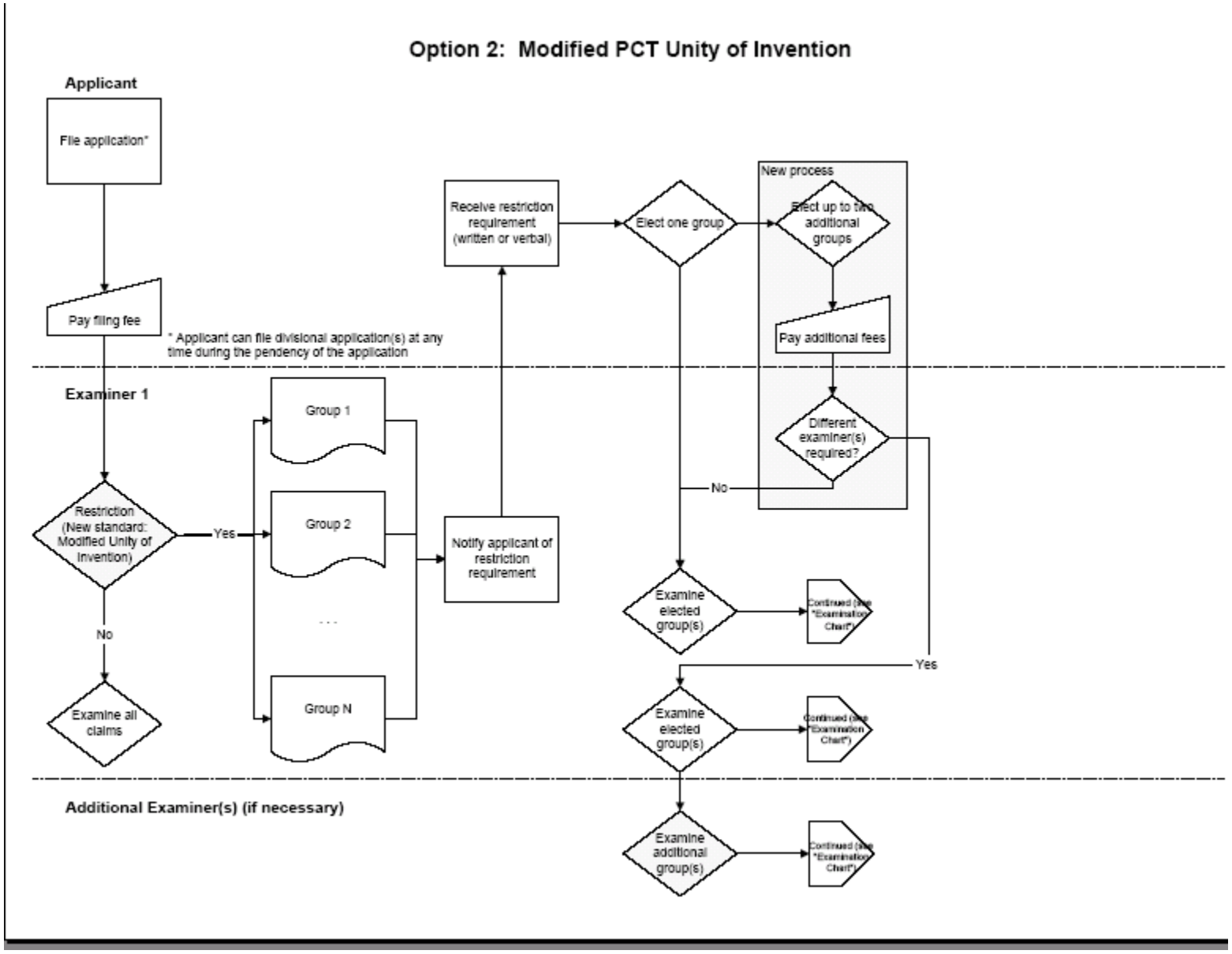
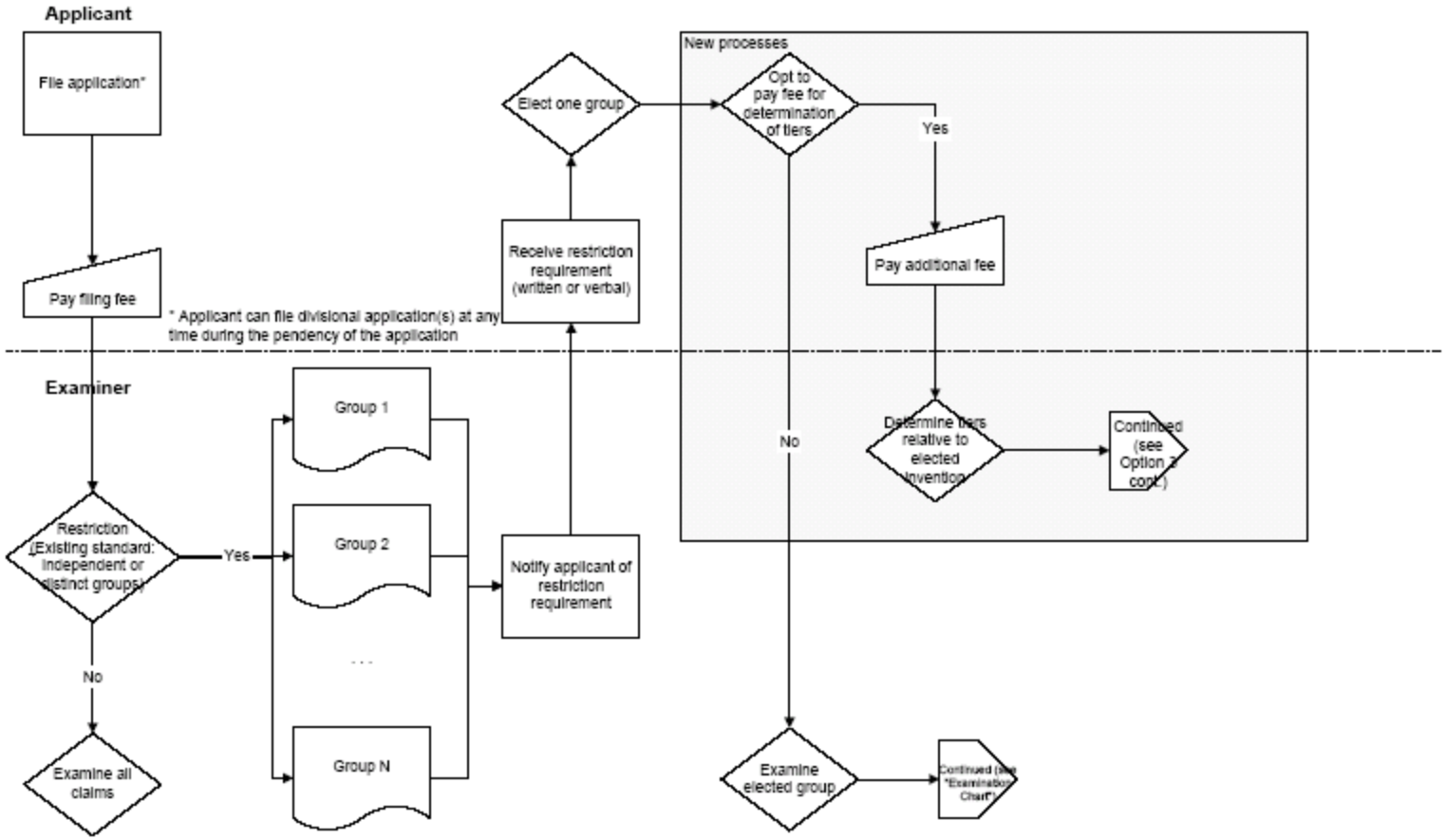
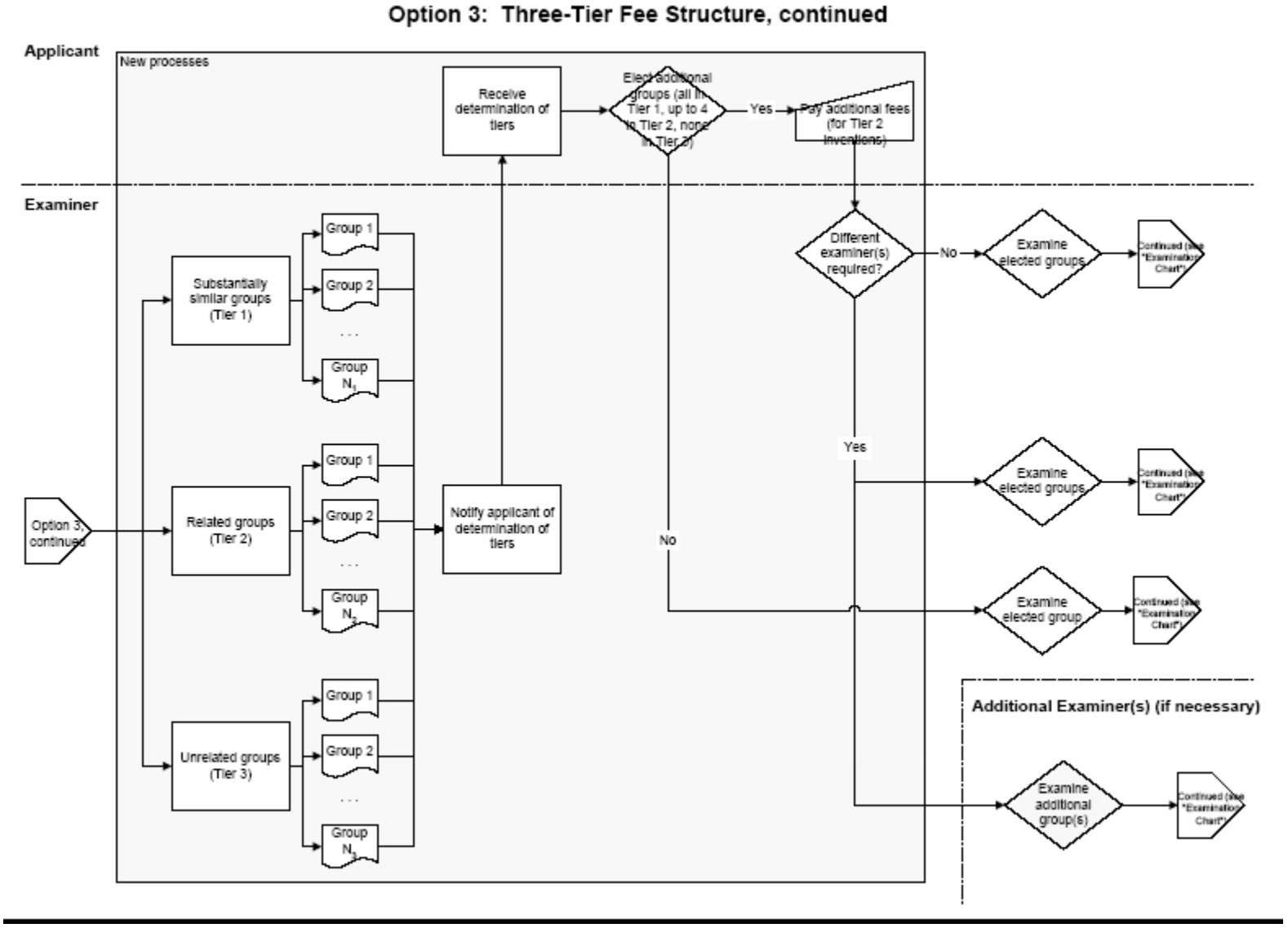
Option 1: Current Restriction Practice with Option to Pay for Additional Inventions



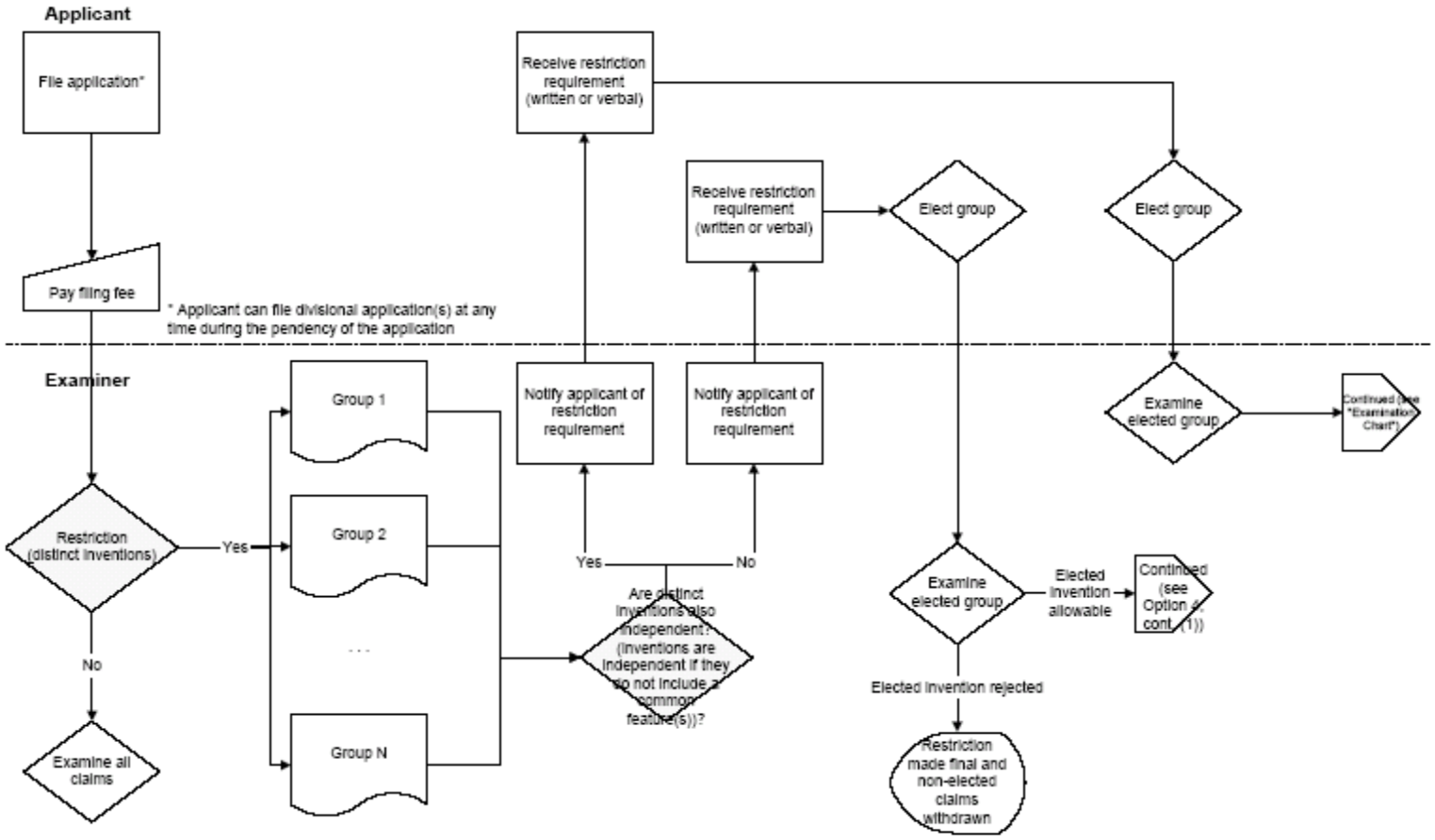

Option 2: Modified PCT Unity of Invention
Applicant
File application*
Pay filing fee
* Applicant can file divisional application(s) at any time during the pendency of the application
Examiner 1
Restriction (New standard: Modified Unity of Invention)
Yes
No
Group 1
Group 2
. . .
Group N
Notify applicant of restriction requirement
Receive restriction requirement (written or verbal)
Elect one group
New process
Elect up to two additional groups
Pay additional fees
Different examiner(s) required?
No
Yes
Examine elected group(s)
Examine elected group(s)
Examine all claims
Additional Examiner(s) (if necessary)
Examine additional group(s)

Option 3: Three-Tier Fee Structure

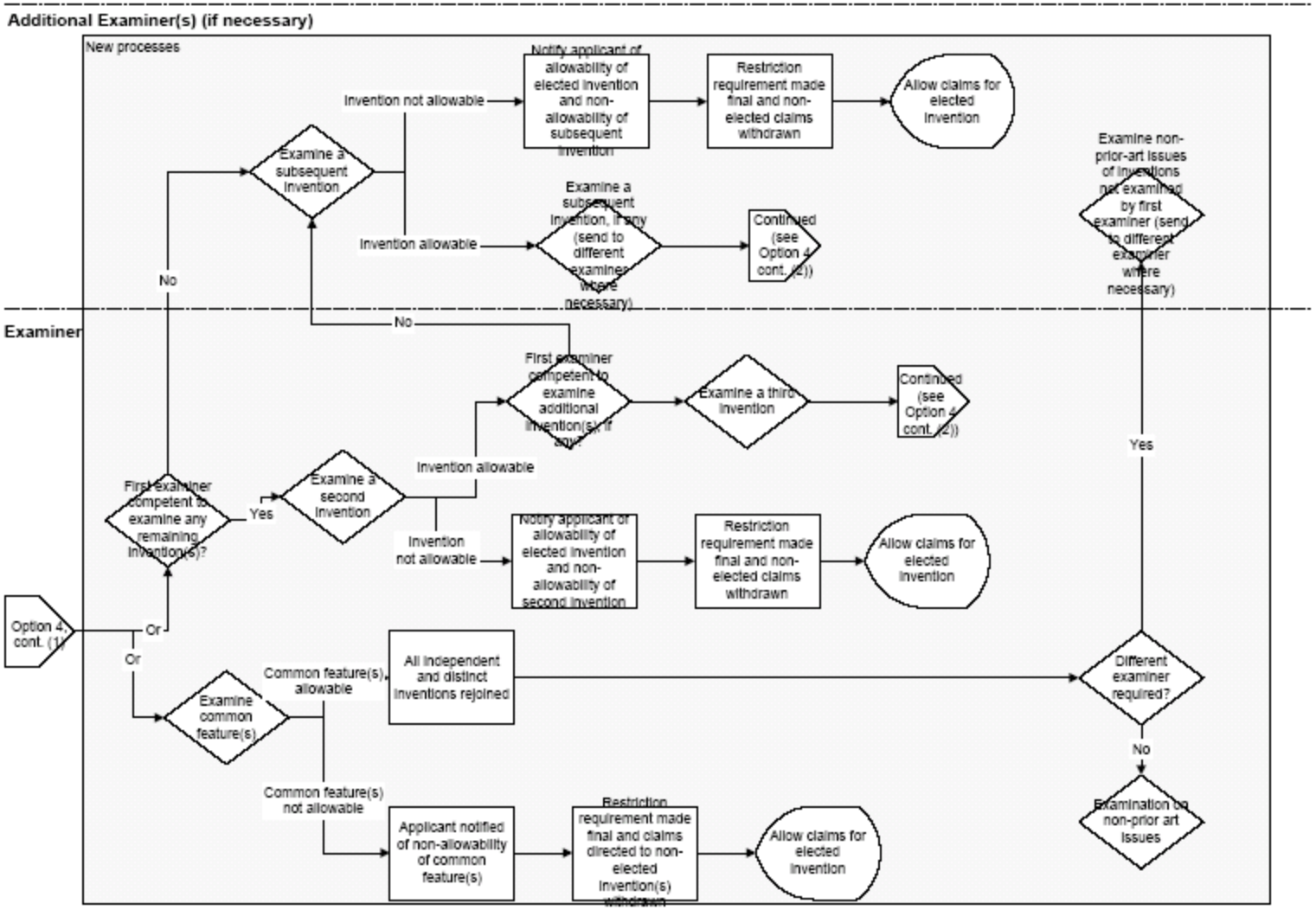



Option 3: Three-Tier Fee Structure, continued
Applicant
New processes
Receive determination of tiers
Elect additional groups (all in Tier 1, up to 4 in Tier 2, none in Tier 3)
Yes
Pay additional fees (for Tier 2 inventions)
Examiner
Different examiner(s) required?
No
Examine elected groups
Continued (see "Examination Chart")
Substantially similar groups (Tier 1)
Group 1
Group 2
Group N1
Yes
Examine elected groups
Continued (see "Examination Chart")
Option 3, continued
Related groups (Tier 2)
Group 1
Group 2
Group N2
Notify applicant of determination of tiers
No
Examine elected group
Continued (see "Examination Chart")
Unrelated groups (Tier 3)
Group 1
Group 2
Group N3
Additional Examiner(s) (if necessary)
Examine additional group(s)
Continued (see "Examination Chart")

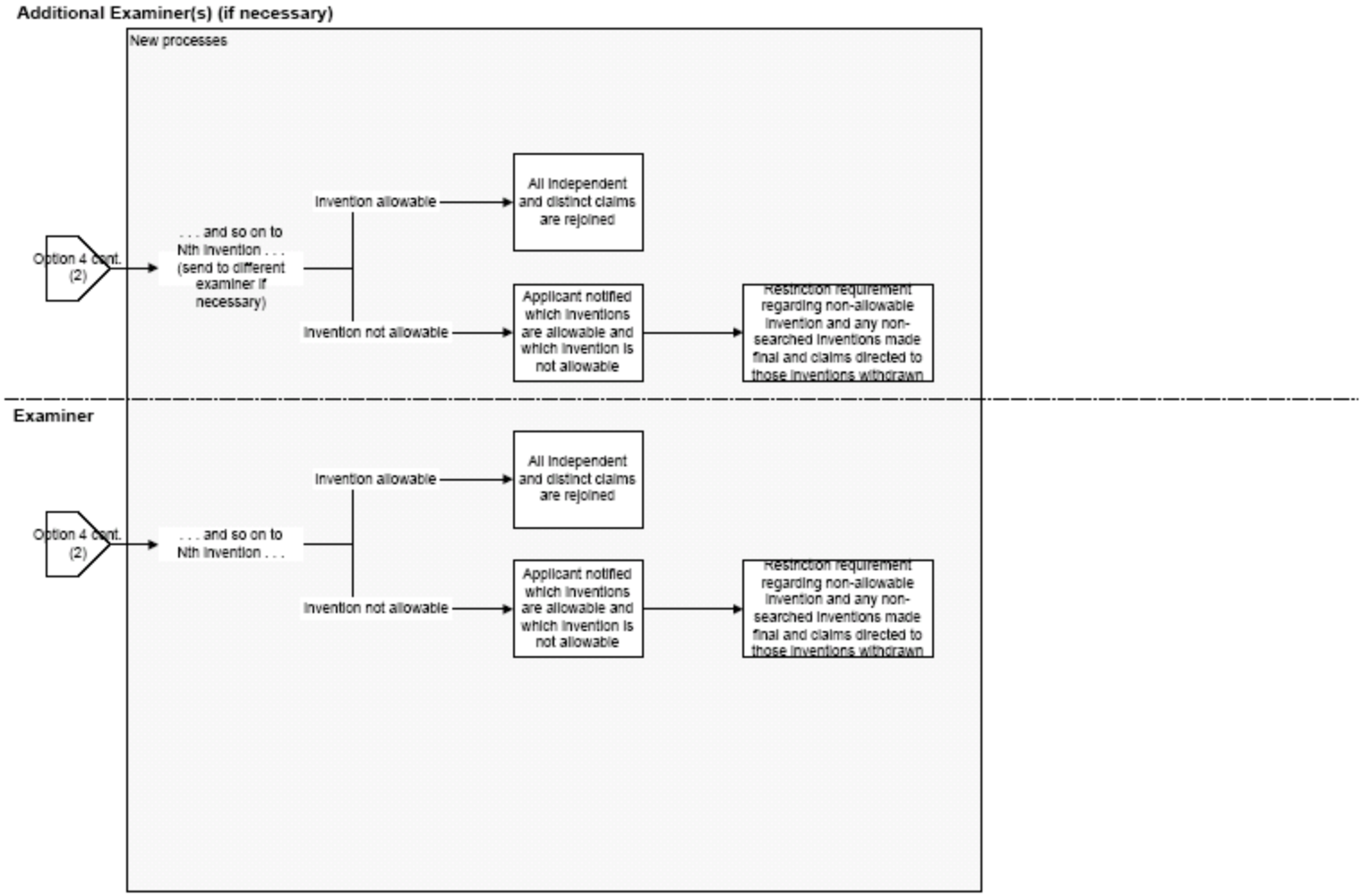
Option 4: "Independent AND Distinct" Inventions



Option 4: "Independent AND Distinct" Inventions, continued (1)

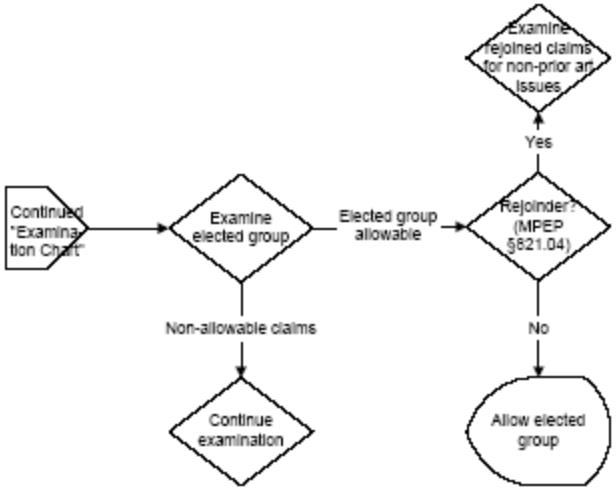


Option 4: "Independent AND Distinct" Inventions, continued (2)



Examination of Elected Group(s) (Current Restriction Practice and All Options) -- "Examination Chart"

Examiner



APPENDIX IX

Results of Feedback Survey for Reviewers

Instructions: Rate the 4 Options on their expected ease or difficulty pertaining to the following tasks. Use a 10-point scale (1 = most easy, 10 = most difficult). For comparison purposes, consider the current 35 USC 121 Restriction standard a difficulty of "3".

	Option 1	Option 2	Option 3	Option 4
As a reviewer, ability to understand and apply the criteria to Groups	3.5	5.1	6.4	7.9
As a reviewer, ability to understand and apply the criteria to Species	3.8	5.2	6.7	8.5
Your opinion on training of Examiners to apply criteria to Groups	3.6	5.6	6.9	8.5
Your opinion on training of Examiners to apply criteria to Species	4.2	5.9	7.4	9.2
Preparing a restriction requirement	3.4	5.3	6.9	7.6
Expected overall Consistent Implementation	4.1	6.2	7.4	8.1

APPENDIX X

Workload Assumptions under each Option

It is difficult, if not impossible, to accurately predict filing or prosecution behavior of applicants as a result of the changes to restriction practice. However, certain assumptions must be made in order to gauge the affects on workload as compared to current practice.

Option 1 – Current Practice With Option to Pay for Additional Inventions

- 50% of applicants with more than one invention will pay for one additional invention. For inventions with species, 70% of applicants will pay for one additional species with the percentage decreasing linearly to 10% of applicants paying for ten additional species.
- 25% of applicants with more than two inventions will pay for two additional inventions. For inventions with species, 70% of applicants will pay for one additional species with the percentage decreasing linearly to 10% of applicants paying for ten additional species.

Option 2 – Modified PCT Unity of Invention

- 50% of applicants with more than one invention will pay for one additional invention.
- 25% of applicants with more than two inventions will pay for two additional inventions.

For both Options – Changing the restriction standard to allow more inventions to be examined concurrently in a single application will result in a 50% reduction in the number of divisional applications filed.

APPENDIX XI

TC1600 RESTRICTION PRACTICE ACTION PLAN

This action plan is designed to improve the quality and consistency of restriction practices in TC1600. The need for this action plan is based on both the results of internal work product reviews and input from applicants and attorneys. As opposed to other Technology Centers, restriction practice in TC1600 is complicated by the complexity of the technology, the types of claim sets being filed on these complex technologies, and the difficulty applying current restriction practice guidelines to claims presented in TC 1600.

This "5-point" action plan will (1) publish examples of claim sets, (2) emphasize rejoinder practice, (3) deliver and publish updated examiner training on restriction practice, (4) enhance the quality review of restriction requirements, and (5) assess the progress of the action plan.

The action plan will be implemented at the same time that the Agency is conducting a study of long-term restriction practice reforms.

1. PUBLISH EXAMPLES OF CLAIM SETS

We will publish examples of sets of claims that will be examined together regardless of whether they can otherwise be restricted under 35 USC §121 because the search and examination of the claims have been determined not to present a serious burden on the Office at the present time. This will help address some of the issues raised by customers concerning certain types of inventions that they wish to be examined in the same application.

We will also publish examples of claim sets where current rules regarding restriction are difficult to apply.

2. EMPHASIS ON REJOINDER PRACTICE

We will, in TC1600, include a form paragraph with all restrictions reminding applicants of their options under rejoinder practice. Both applicants and examiners often overlook the issue of rejoinder. This form paragraph in our Office actions will be a clear reminder to applicants of their ability to request rejoinder under the appropriate conditions. Use of this form paragraph will begin immediately.

3. EXAMINER TRAINING ON RESTRICTION PRACTICE

We will deliver restriction practice training to all TC 1600 examiners, including training examples targeted to specific workgroups within TC 1600, focusing on high-impact art units first. This training will focus on proper restriction practices including appropriate analyses and grouping of claims, and proper formulation of and support for a restriction requirement. The training materials will be published on the USPTO website.

4. ENHANCED REVIEW OF RESTRICTION REQUIREMENTS

We will implement a second pair-of-eyes review on restrictions throughout Technology Center 1600, beginning with art units where either (1) the number of restrictions is particularly high, or (2) indications of poor quality restrictions are noted in the reviews. This includes a review of not only first action restrictions, but also all restriction requirements in second and subsequent Office Actions.

This will allow us to screen and correct specific cases, as well as identify problem areas for training. This will also help address some specific complaints concerning the number and types of restriction requirements in second and subsequent Office Actions. This second pair-of-eyes initiative will begin immediately.

5. CONTINUOUS ASSESSMENT

In order to assess the impact of this restriction practice action plan, we will:

a. Sample restrictions at periodic intervals to monitor quality and average number of divided inventions. This includes a special review of all applications in which a restriction decision has been petitioned,

b. Monitor the number and quality of second and subsequent restrictions, and

c. Survey customers, for example at quarterly Biotech/Chemical/Pharmaceutical Customer Partnership meetings, for their perception of TC 1600 restriction practices.