

Defendants' Exhibit 4

Defendants' Exhibit 4a

Guidelines for Applicants under the New Accelerated Examination Procedure

These guidelines provide information to assist applicants and their representatives in preparing a petition and request for accelerated examination such that the submission will likely be accepted as filed, lead to the desired patentability decision within 12 month or shorter time frame and produce the high quality results desired by the applicant. Also, these guidelines provide guidance to USPTO examiners on processing these requests and petitions. Whereas these guidelines provide general information on specific requirements under this program, these guidelines are merely supplemental to the program requirements as set forth in the Federal Register notice dated June 26, 2006. (See <http://www.uspto.gov/web/offices/com/sol/notices/71fr36323.pdf>)

It is highly recommended that applicants and their representatives read the detailed program requirements set forth in that announcement. In the guidelines below, any notes on each section of the formal program requirements are set forth as a separate section including the identifiers employed in the program announcement dated June 26, 2006.

For further information or assistance with specific questions, please contact:
Pinchus Laufer, Detailee, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy by telephone (571) 272-7726.
Email questions may be addressed to: AcceleratedExam@uspto.gov.

Interim filing procedure for sequence listings: On October 14, 2006 the USPTO deployed the newest release of EFS-Web. EFS-Web is now capable of handling sequence listings and other large text files. Therefore, the interim procedures for filing such large text files are no longer available. Applicants must file the entire application through the new improved EFS-Web interface

Part I: Requirements for petitions to make special under accelerated examination

Part I- overall requirements:

To qualify for the new accelerated examination program, applicant must:

1. Submit the petition and fee (where appropriate)
2. File the request with respect to an application filed under 35 USC 111(a)
3. File the application via the EFS or EFS-Web; also all follow-on submissions
4. File a complete application complying with 37 CFR 1.51
5. File 3 or fewer independent claims and no more than 20 claims total
6. File an application for a single invention or agree to elect without traverse a single invention for examination
7. Agree to an interview with the examiner to discuss any outstanding issues arising in the examination process
8. Conduct a pre-examination search
9. Provide an accelerated examination support document

Part I item 3

Where the EFS or EFS-Web system is not available at the time of the attempted filing and the required statement is being made, applicant should prominently indicate that the filing is under the new accelerated examination procedure so that the filing is properly processed. This should be included in the caption for the filing cover sheet(s).

Part I item 4

The initial review of applications and requests/petitions for participation in the accelerated examination program will be conducted in the Office of Initial Patent Examination (OIPE). There the application will be reviewed for compliance with all of the filing requirements other than the review of the pre-examination search and the accelerated examination support document (AESD). These other two filing requirements will be reviewed in the Technology Centers by the Special Program Examiner (SPRE) office. Once the application has been accepted for processing under this program, the later discovery of any non-complying formal requirement (e.g. failure to comply with a provision of 37 CFR 1.51 or excessive number of claims) will be treated by the examiner. However, any defect that affects the filing date accorded the application and may result in a fatal application defect could result in the withdrawal of the special status accorded the application under this program.

Part I item 6

This requirement continues the current USPTO procedure for requests for accelerated examination. The application must be directed to a single invention and where the examiner finds that is not the case, applicant agrees to make an election of the invention to be examined at this time without traverse in a telephonic interview.

Part I item 7

Any pre-first action interview should be held within two weeks from the initial contact by the examiner. Failure to comply with the interview provisions in a timely manner will result in the application being returned to regular status in the examining queue with an Office Action issuing in due course.

Part I item 8

A search submitted in support of a petition for accelerated examination will be considered sufficient, absent any specific PTO identified deficiencies that require further search by the applicant, if the search includes:

1. A classified search of the US patents and published patent applications in the Class and subclass where the claimed invention is most likely to be classified in the current United States Patent Classification system (USPC). Consultation with the USPTO search notes for classification should be made to determine if any

other highly relevant Classes should also be considered and thereafter, a further search be performed in those other Classes as appropriate. Where the PTO review considers that another or different classification is preferred or required, the search by the applicant will usually be considered acceptable unless the performed classified search is so divergent that it also calls other aspects of the pre-examination search into question; e.g. a text search that is limited to the same erroneous classification(s). In instances of differing views on the appropriate classified search area, the submitted search will be accepted and the examiner will perform the PTO preferred search during the examination process.

The following information should be helpful to applicant:

The USPTO Manual of classification: <http://www.uspto.gov/go/classification/>

The MPEP Chapter 900 on Prior Art, Classification and Search:

<http://www.uspto.gov/web/offices/pac/mpep/documents/0900.htm/>

2. A text search of the US patents and published patent applications that covers the subject matter of the independent claims using terms recognized in the art given their broadest reasonable interpretation. The search should consider individual features by themselves and combinations of features. The search should cover the broadest scope encompassed by the claims as well as claims of narrow and intermediate breadth.
3. A text search of foreign patent documents that includes the sources required under the PCT minimum documentation requirements, to the extent available. The PCT minimum documentation requirements can be found at http://www.wipo.int/standards/en/part_04.html. A search of this resource area may be completed using the USPTO Universal Public Workstation (UPWS) in the USPTO Public Search Room Facility, Patent and Trademark Depository Libraries, or through other available commercial database providers. The text search should be similar to that provided for US patents and published patent applications as described in 2) above.
4. A text search of the suggested non-patent literature (NPL) resources from the current USPTO search templates found at <http://www.uspto.gov/web/patents/searchtemplates/searchtemplates.htm>
5. A search employing any special tools (e.g., nucleic acid or protein sequence searching tools) as identified in the current USPTO search templates.

Where an applicant has not considered a particular search resource during the pre-examination search of any one of US patents, patent application publications, foreign patent documents or the recommended NPL, a justification must be provided. The justification provided must be specific rather than including only general boiler-plate assertions; e.g. “no relevant prior art expected to be found” or “the best prior art was already located”. These instances of eliminating a search resource are expected to be rare.

Although the criteria for the pre-examination search do not preclude the use of a foreign search report to meet this requirement, it must meet all of the criteria to be used, in part or

in full, for that purpose. For example, a foreign office search report that includes a search of the PCT minimum documentation and provides the required search history may be used to meet that requirement in the above-noted search; requiring only the other portions of the search to be performed in submitting the pre-examination search.

If the application is likely to be amended to include claims directed to other disclosed features of the invention, it is strongly recommended that applicants include those features in the initial pre-examination search. Although these features could be covered by an updated accelerated examination support document (AESD) when the amendment is filed, the potential delay in performing that additional search and time frames for submitting that updated document could lead to possible prosecution delays resulting in non-entry of the proposed amendment.

A notice of specific PTO identified deficiencies that require further search by the applicant will include a specific discussion of the deficiency and suggestions to the applicant on how the deficiency could be overcome. An exception to this would occur when it is readily apparent that applicant's search is wholly deficient (e.g., clearly no consultation with the Manual of Classification for appropriate search areas, text search terms wholly inappropriate for the subject matter, etc). In these instances, only general guidance directed at improving the search will be given in the petition decision.

Part I item 9

The Accelerated Examination Support Document (AESD) must be filed with the application and the petition to make special. Applicant is reminded that the AESD must contain the following items (further guidance is provided as notes after each applicable item):

(A) An accelerated examination support document must include an information disclosure statement (IDS) in compliance with 37 CFR 1.98 citing each reference deemed most closely related to the subject matter of each of the claims. Applicants are encouraged to use Form 1449 to list references.

(B) For each reference cited, the accelerated examination support document must include an identification of all the limitations in the claims that are disclosed by the reference specifying where the limitation is disclosed in the cited reference. Applicants should specify where in each of the cited references the particular claim limitations are found. This process is intended to be analogous to the analysis an examiner uses when locating a relevant prior art reference and then determining whether the reference contains the claimed limitation. For each claimed limitation, the examiner would consider the disclosure of the reference and all reasonable portions in the reference where the limitation is shown. When preparing an Office Action, the examiner would correlate the limitation to the portion of reference which best characterizes the limitation. This part of the AESD is not intended to be an exhaustive listing of every conceivable subjective interpretation of how a claim limitation may read on the reference. Applicants should point out what are considered to be the relevant representations of the limitation in the

reference. A limitation may be found in more than one portion of the reference and should be pointed out, yet the intention is not to have applicants point out every conceivable interpretation. The USPTO will adopt a rule of reason when evaluating this portion of the AESD. Unless the representation is so deficient that it would materially effect examination of the application (e.g., numerous instances where the limitations are not shown where applicant states they are), the representation will be deemed to be sufficient for this part of the AESD.

(C) The accelerated examination support document must include a detailed explanation of how each of the claims are patentable over the references cited with the particularity required by 37 CFR 1.111(b) and (c). Applicants should be specific in their explanation and include the identification of specific claim limitations that support their position, where appropriate. General statements that the claims are neither anticipated nor rendered obvious by the cited references or that the references are not properly combinable will not be acceptable.

(D) The accelerated examination support document must include a concise statement of the utility of the invention as defined in each of the independent claims (unless the application is a design application). Where each of the independent claims share a common utility, these claims may be grouped together in this explanation.

(E) The accelerated examination support document must include a showing of where each limitation of the claims finds support under the first paragraph of 35 U.S.C. 112 in the written description of the specification. If applicable, the showing must also identify: (1) Each means- (or step-) plus-function claim element that invokes consideration under 35 U.S.C. 112, Section 6; and (2) the structure, material, or acts in the specification that correspond to each means- (or step-) plus-function claim element that invokes consideration under 35 U.S.C. 112(6). If the application claims the benefit of one or more applications under title 35, United States Code, the showing must also include where each limitation of the claims finds support under the first paragraph of 35 U.S.C. 112 in each such application in which such support exists. Applicants should specify where in the specification each limitation of the claim finds support. The USPTO will adopt a rule of reason when evaluating this portion of the AESD. However, where the limitation is intended to cover multiple embodiments of the structures, acts, or materials to perform the recited function, each should be separately identified under this requirement. Unless the identification is so deficient that it would materially effect examination of the application, the showing of specification support will be deemed to be sufficient for this part of the AESD.

(F) The accelerated examination support document must identify any cited references that may be disqualified as prior art under 35 U.S.C. 103(c) as amended by the Cooperative Research and Technology Enhancement (CREATE) Act (Pub. L. 108-453, 118 Stat. 3596 (2004)). It is sufficient for an applicant to identify a reference that might be subject to disqualification without any further explanation at this time; permitting an examiner to determine when a "back-up" rejection may be appropriate, both in the potential interview process and/or the resulting Office action. If the identified reference is applied in any

ground of rejection, it is highly recommended that the applicant make the determination of that possible disqualification at the earliest possible time in the prosecution.

Part II- Decision on petition to make special

The petition will be decided by the Technology Center (TC) Special Program Examiners (SPREs). To ensure uniformity to the maximum extent possible, all of these deciding officials have received the same initial training. If the petition and supporting materials are deemed to be deficient in any manner, the petition will be dismissed and applicant will be provided with a single opportunity to correct the deficiency. Any reasons for the dismissal of the petition will be provided with a specific explanation of the deficiency and, wherever possible, the specific corrective action that should be taken by the applicant.

The renewed petition will also be reviewed by the TC SPREs. If the renewed petition is found to be insufficient, the petition will be denied and the decision will include an explanation of the deficiency.

Part III- Initial action on the application by the examiner

When taking the application up for examination, the examiner will fully consider the AESD in the process of conducting a complete examination of the application. That means the examiner will conduct an independent search of the claimed subject matter and make an independent determination of whether the claims are patentable as filed. This process is intended to permit an initial evaluation of the effectiveness of the AESD requirements and the extent to which examiners should rely upon the submissions in conducting their review of the application.

In the rare instances when the examiner takes the application up for initial action and determines that the AESD is not sufficient as filed, the examiner may consult with the SPRE who conducted the initial review of that submission about the alleged deficiency. However, before the initial holding with respect to the sufficiency of the AESD is reversed, the SPRE should consult with the appropriate TC Director who will sign the further petition decision. If there is a USPTO shift on the sufficiency of the AESD as filed under these circumstances, applicant will be provided a notice of the deficiency and be given the one opportunity to correct the submission.

Where an interview is proposed to discuss any rejection or objection to the claims or objection to the specification, the examiner will provide the applicant with a brief description of the proposed issue for discussion along with copies of any documents that are reasonably necessary to conduct the interview. The brief description from the examiner should be of sufficient detail to permit the interview to reasonably advance the prosecution of the application. The reasonably necessary documents for the interview would include copies of foreign patent references, non-patent literature documents, and

copies of applications not available in the Public PAIR system. US patent documents would normally not be provided to the applicant (only identified by Patent number so applicant may retrieve these items).

The examiner should make all reasonable attempts to provide applicant with the necessary information to conduct the interview and resolve the outstanding issues for placing the application in condition for allowance. Where the information relied upon is of such a volume that it would be impractical to be transmitted, applicant will be so notified and given the opportunity to obtain such information prior to conducting the interview. If after these efforts the interview is unable to be conducted, the conditions of Part III that an interview is unlikely to result in the application being placed in condition for allowance will be considered as having been met and the examiner will issue the required Office action. In these instances, applicants are encouraged to contact the examiner after receipt of the Office action to attempt to resolve the outstanding issues at that time.

The mailing of a final rejection will set the standard three (3) month shortened statutory period for response. Further, although the provisions of 37 CFR 1.136(a) do not apply to a one-month shortened statutory period for response under this procedure, with the mailing of a final Office action (other than an allowance), applicants may again rely upon the provisions of rule 136(a) for purposes determining whether an appeal is appropriate. However, any such filing of an extension will substantially interfere with the potential for an expeditious decision by the Board of Patent Appeals and Interferences (BPAI). See Part VI below.

Part IV- Reply by applicant

Applicants are reminded that the provisions of 37 CFR 1.136(a)- extensions of time- do not apply to any one (1) month shortened statutory period for response set under this program. However, the provisions of 37 CFR 1.136(b) remain applicable in these instances.

Where the examiner has determined that the claims are not limited to a single invention and has proceeded to act on the first claimed invention in the initial Office action, applicant may challenge that holding by way of a petition under 37 CFR 1.181. However, the filing of the petition does not stay the one (1) month shortened statutory period for response which continues to run.

When the examiner holds a reply by the applicant to be not fully responsive based upon conditions (2) or (3), applicant may traverse such a holding under the provisions of 37 CFR 1.181. However, the filing of the petition does not stay the one (1) month shortened statutory period for response which continues to run.

If applicant files an updated AESD, applicant is reminded that the IDS included as part of that submission must meet the requirements of 37 CFR 1.97 and 1.98.

Part V- Post allowance processing

The failure to pay the required issue fee within one (1) month of the mailing date of the Form PTOL-85 or the submission of a non-PTO required submission under 37 CFR 1.312 will result in the allowance being processed in the regular allowance process. A submission that includes both PTO required changes and non-PTO required changes under the provisions of 37 CFR 1.312 will be considered as a non-required PTO submission for purposes of the allowance processing.

Part VI- After-final and appeal

Applicants are reminded that as a condition for entry into this program, the applicant has agreed not to separately argue the patentability of any dependent claim. If an Appeal Brief is filed which does include such arguments, it will be held as non-compliant and a new Brief will be required from the applicant. Applicants are also reminded that pre-appeal brief requests will not be granted under this program. Pre-appeal brief conferences would be of little value in an application under final rejection because a conference prior to final rejection will already have been conducted by the examiner.

Part VII- Proceedings outside the normal examination process

To ensure that petitions under any of the provisions of 37 CFR 1.181 to 183 are expeditiously answered with an appropriate decision, the PTO will provide an expanded tracking system for these submissions.

Part VIII- More information: eligibility

Note with respect to the proposed class and subclass being provided at the time of filing- See the notes to Part I item 8- General template- sub part 1 (above) on use of PTO assistance on this designation.

Reply Not Fully Responsive:

Before holding a response to a non-final office action non-responsive, the examiner should consult with their supervisor or a TC SPRE. If an applicant disagrees with the holding of a not fully responsive reply, that holding may be reviewed through a petition under 37 CFR 1.181 to be decided by the TC Director. Except in rare instances, as under the current examination process, a response will be considered to be a bona fide attempt to advance the prosecution of the application. This same standard will be applied to the review of an updated AESD and any possible holding of the reply not being fully responsive.