Overview of USPTO patent application initiatives

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Biotechnology, Chemical, and Pharmaceutical (BCP) Partnership Meeting
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Agenda

• **Overview of patent application initiatives**
  – Initiatives prior to examination
  – Initiatives during examination
  – Initiatives after close of prosecution
  – Other programs
Patent application initiatives

• The USPTO has designed programs to:
  – Advance the progress of a patent application and to provide applicant assistance; and
  – Educate examiners by providing relevant, historic and current technical knowledge, including industry practices/standards in technological areas of interest.
Patents programs and examination timeline

For more information: www.uspto.gov/patent/initiatives

Enhance application process

Specialized examination

Assistance throughout application process
Prior to examination
Specialized examination programs

- Rule 37 C.F.R. 1.102 permits applications to be taken out of turn under certain circumstances (see also MPEP 708).
- Applicant may petition the office for entry into a specialized examination program (fees may apply).

- Track One–Prioritized Examination
- Accelerated Examination
- Collaborative Search Pilot (CSP)
- Full First Action Interview Pilot
- Patent Prosecution Highway (PPH)
- Other Petitions to Make Special

For more information: www.uspto.gov/patents-application-process/petitions
Prioritized examination of up to 12,000 requests per fiscal year.

Gives application special status with fewer requirements than the current accelerated examination program and without having to perform a pre-examination search.

GOAL → Provide final disposition of application within 12 months of prioritized status being granted.

A single request for prioritized examination may be granted for a request for continued examination RCE in a plant or utility application.

For more information: [www.uspto.gov/patent/initiatives/usptos-prioritized-patent-examination-program](http://www.uspto.gov/patent/initiatives/usptos-prioritized-patent-examination-program)
Fiscal year 2020 statistics* from petition grant to:

- First action: 1.7 Months
- Final disposition: 6.3 Months
- Allowance: 5.1 Months

*Data available at [www.uspto.gov/dashboard/patents/special.html](http://www.uspto.gov/dashboard/patents/special.html)
• Once applicant has received an allowance of at least one claim at a participating patent office, he or she may request expedited examination of corresponding claim(s) in a corresponding application that is pending at a second patent office.

Other petitions to make special

- List of grounds to make special (non-exhaustive) (see MPEP 708.02):
  - Applicant's age is 65 or more; applicant’s health may affect availability to assist in prosecution

- Petitions are decided by a designated quality assurance specialist or special programs examiner within each Technology Center.

- Applications will be treated as special throughout the entire prosecution within the USPTO.

- Applications will be placed on the examiner's Special New and Special Amended dockets for processing in accordance with the prescribed time period.
Cancer Immunotherapy Pilot (Patents 4 Patients)

• Prioritized examination (National Cancer Moonshot initiative)
• Extended until June 30, 2022.
• GOAL → Provide final disposition of patent applications in the pilot in one year or less after it grants prioritized status.

*For more information: [www.uspto.gov/patent/initiatives/patent-application-initiatives/patents-4-patients](http://www.uspto.gov/patent/initiatives/patent-application-initiatives/patents-4-patients)

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Cancer Immunotherapy Pilot

• **Requirements:**
  – Applications must contain one or more claims to a method of treating a cancer using immunotherapy.
  – Applicants must file a grantable petition under this initiative using the USPTO patent electronic filing system (EFS-Web).

• **Open to:**
  – Any application that has not received a first office action,
  – Any application where the petition is filed with a request for continued examination (RCE), or
  – Any application not under final rejection where the claimed cancer immunotherapy is the subject of an active Investigational New Drug (IND) application that has entered Phase II or Phase III (FDA) clinical trials.

• **No additional fee is required to participate in the program.**
Cancer Immunotherapy Pilot

- Claims pertaining to cancer immunotherapy (81 FR 42328):
  - Method of ameliorating, treating, or preventing a malignancy in a human subject wherein the steps of the method assist or boost the immune system in eradicating cancerous cells.
  - Administration of cells, antibodies, proteins, or nucleic acids that invoke an active (or achieve a passive) immune response to destroy cancerous cells.
  - Co-administration of biological adjuvants (e.g., interleukins, cytokines, Bacillus Comette-Guerin, monophosphoryl lipid A, etc.) in combination with conventional therapies for treating cancer such as chemotherapy, radiation, or surgery.
  - Vaccines that work by activating the immune system to prevent or destroy cancer cell growth are included.
  - In vivo, ex vivo, and adoptive immunotherapies, including those using autologous and/or heterologous cells or immortalized cell lines.
Cancer Immunotherapy Pilot

*Progress report (7/7/2020)*

- Total number of submissions: **603**
- Total submission decision: **510 granted, 18 dismissed**
- Undecided are applications still in pre-exam

*For the full progress report: [www.uspto.gov/sites/default/files/documents/Patents%204%20Patients%207.7.2020.pdf](http://www.uspto.gov/sites/default/files/documents/Patents%204%20Patients%207.7.2020.pdf)*
Cancer Immunotherapy Pilot

*Progress report (7/7/2020)

- Avg. days from petition grant to FAOM: **28 Days**

- Granted applications current status (considered closed by final rejection, NOA or abandonment):
  - Closed: 429
  - Pending: 81

*For the full progress report: [www.uspto.gov/sites/default/files/documents/Patents%204%20Patients%207.7.2020.pdf](http://www.uspto.gov/sites/default/files/documents/Patents%204%20Patients%207.7.2020.pdf)
Cancer Immunotherapy Pilot

*Progress report (7/7/2020)

- Issued patents (Pet. immuno granted): 167 patents

*For the full progress report: [www.uspto.gov/sites/default/files/documents/Patents%20Patients%207.7.2020.pdf](http://www.uspto.gov/sites/default/files/documents/Patents%20Patients%207.7.2020.pdf)
During examination
During examination

• Interview practice
  – General guidelines
  – Applicant Interview Request (AIR) Form
  – Internet authorization
  – Video conferencing

• Patents ombudsman
Interview practice

• General guidelines (see also MPEP 713)
  – Interviews are an effective tool to resolve issues and shorten prosecution.
  – USPTO employees should be available to have interviews in order to engage stakeholders and advance prosecution.
  – An interview should be granted when the nature of the case is such that the interview may serve to develop and clarify outstanding issues in an application and may lead to a mutual understanding between the examiner and the applicant, and thereby advance the prosecution of the application.
  – Interviews should be held during normal business hours, Monday–Friday 8:30 a.m. to 5 p.m. ET. Telephonic and video conference calls may be held outside these hours if agreed upon by all participants.
Applicant Interview Request (AIR) form

• AIR form is an alternative electronic way for applicant to initially request an interview with examiner.

• The AIR form itself is just a mechanism to initiate the conversation to schedule an interview, similar to applicant leaving a voicemail. Just like voicemail, the examiner is expected to follow up on the request within one business day.
The AIR form is found on the USPTO website at:

www.uspto.gov/interviewpractice

Note: Applicant is also made aware of AIR form request in the conclusion form paragraph of an office action.
Without a written authorization by applicant in place, the USPTO will not respond via email to any internet correspondence which contains information subject to the confidentiality requirement as set forth in 35 U.S.C. 122 (see MPEP 502.03).

Sample authorization:

- "Recognizing that internet communications are not secure, I hereby authorize the USPTO to communicate with the undersigned and practitioners in accordance with 37 CFR 1.33 and 37 CFR 1.34 concerning any subject matter of this application by video conferencing, instant messaging, or electronic mail. I understand that a copy of these communications will be made of record in the application file."

It recommended that applicant use EFS web to submit authorization.
• Provides assistance to applicants and attorneys throughout the application process including initial filing, patent examination, and post examination.

• Assists applicants when the normal processing has stalled, helping to get applications back on track.

• Can provide assistance on the merits where there is an issue with case prosecution concerns, such as:
  - Claim objections, after-final practice, claim rejections, restrictions

• Not intended to circumvent normal communication between applicants or their representatives and examiners, supervisory patent examiners (SPEs), or technology center directors.

*For more information: www.uspto.gov/patent/ombudsman-program
After close of prosecution
Programs to enhance application process

- After-final Consideration Pilot 2.0 (AFCP)
- Pre-appeal conference
- Quick Path Information Disclosure Statement (QPIDS)
After-final Consideration Pilot (AFCP) 2.0

• Specialized after-final response designed to enhance communication between the office and applicant.

• EXTENDED through September 30, 2020.

• Authorizes additional time for examiners to search and/or consider responses after final rejection.

• If response does not place the application in condition for allowance, examiners will also use the additional time to schedule and conduct an interview to discuss the results of their search and/or consideration.

*For more information: www.uspto.gov/patent/initiatives/after-final-consideration-pilot-20
AFCP 2.0

- Key requirements (not exhaustive):
  - Response filed under 37 CFR §1.116
  - Request for consideration under the pilot (Form PTO/SB/434)
  - Amendment to at least one independent claim that does not broaden the scope of the independent claim in any aspect.

- Examiners use their professional judgment to decide whether the response can be fully considered under AFCP 2.0.

- Submissions not accepted in AFCP 2.0 treated under pre-pilot procedures.

- If you believe an after-final response will lead to allowance with only limited further searching and/or consideration, you should consider requesting consideration of the response under AFCP 2.0.
AFCP 2.0 FAQs

• Can I file an AFCP 2.0 request after having previously filed a non-pilot after final amendment?

Yes, the prior filing of a non-pilot after final amendment does not affect applicant’s ability to submit an AFCP 2.0 request. Note that only one AFCP 2.0 request may be filed in response to an outstanding final rejection.

• Can I file an AFCP 2.0 request after having previously filed a notice of appeal?

Yes, the prior (or concurrent) filing of a notice of appeal does not affect applicant’s ability to submit an AFCP 2.0 request, as long as applicant has not yet filed an appeal brief or a Pre-Appeal Brief Conference Request.
AFCP 2.0 FAQs

• Can I file an AFCP 2.0 request form in an effort to transform a previously filed non-pilot after final amendment into a proper AFCP 2.0 submission?

Synchronizing between USPTO databases is corrupted when the PTO/SB/434 request form is not filed concurrently with the remainder of the after final amendment materials. For this reason, applicants are requested to always file the AFCP 2.0 request form concurrently with a proposed amendment that is compliant with AFCP 2.0. A previously filed non-pilot after final amendment may be processed consistent with current non-pilot practice, e.g., by mailing an advisory action, notwithstanding a subsequently filed AFCP 2.0 request form. Not recommended!

• Are there any fees associated with filing an AFCP 2.0 request?

There are no fees unique to an AFCP 2.0 request. Do note, however, that applicants will be required to pay any applicable non-pilot fee, e.g., the fee for an extension of time, concurrently at the time of filing the AFCP 2.0 request.
Pre-appeal conference

- Request for review of outstanding rejections prior to filing of an appeal brief (see MPEP 1204.02).
- Upon receipt of a properly filed request, a supervisor will designate a panel of appropriate reviewers to review the appellant's remarks and the examiner's rejections.
- After the review is complete, the office will mail a decision on the status of the application, stating one of the following:
  - (A) The application remains under appeal because there is at least one actual issue for appeal.
  - (B) Prosecution on the merits is reopened and an appropriate office communication will follow in due course. In appropriate circumstances, a proposed amendment may accompany the panel's decision proposing changes that, if accepted, may result in an indication of allowability for the contested claim(s).
  - (C) The application is allowed on the existing claims and prosecution remains closed.
  - (D) The request fails to comply with the submission requirements and is dismissed.

*For more information: see MPEP 1204.02.*
Pre-appeal conference

• Key requirements (not exhaustive) (see MPEP 1204.02):
  – Must file a notice of appeal in compliance with 37 CFR 41.31.
  – Request for pre-appeal brief review must be filed with (on the same day) the filing of the notice of appeal and before the filing of an appeal brief. (Form PTO/AIA/33).
  – Request may not exceed five total pages and should provide a succinct, concise, and focused set of arguments for which the review is being requested.

• The time period for filing an appeal brief will be reset to be one month from the mailing of the decision on the request, or the balance of the two-month time period running from the receipt of the notice of appeal, whichever is greater; the time period for filing of the appeal brief is extendible under 37 CFR 1.136.
Quick Path IDS (QPIDS)

- Part of the USPTO's ongoing efforts towards compact prosecution and pendency reduction.
- Now permanent.
- Eliminates the requirement for processing of a RCE with an IDS filed after payment of the issue fee in order for the IDS to be considered by the examiner.
- Where the examiner determines that no item of information in the IDS necessitates reopening prosecution, the USPTO will issue a corrected notice of allowability (NOA).

*For more information: www.uspto.gov/patent/initiatives/quick-path-information-disclosure-statement-qpids
**IDS processing paths after final**

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<th>Prosecution Timeline &amp; Filing Requirements</th>
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<tr>
<td><strong>Filed after Final rejection &amp; prior to disposal (Path 0)</strong></td>
<td><strong>Filed on/after Allowance &amp; prior to/same day issue fee payment (Path 1)</strong></td>
<td><strong>Filed after issue fee payment &amp; prior to issue (Path 2)</strong></td>
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<td><strong>Required:</strong></td>
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<tr>
<td>• CFR 1.17(p) fee is required</td>
<td>• CFR 1.17(p) fee</td>
<td>• QPIDS.REQ form (or equivalent)</td>
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<td>• CFR 1.97(e) statement</td>
<td>• CFR 1.97(e) statement</td>
<td>• ePetition to withdraw from issue</td>
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<td>• IDS MUST comply with CFR 1.98</td>
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- Outcomes: Applicant will receive an annotated IDS and either: a PTO-2300 form and subsequent office action that reopens prosecution (necessitated by IDS reference); or a Corrected NOA (Path 1 or 2 only).
QPIDS FAQs

• What if I cannot make either of the timeliness statements within 37 CFR 1.97(e)?

You cannot file a QPIDS submission to have the IDS considered. You must follow the current process for having an IDS considered after payment of the issue fee of either filing (i) a petition under 37 CFR 1.313(c)(2) to withdraw the application from issue in order to permit entry of an RCE and have the accompanying IDS considered by the examiner or (ii) a petition under 37 CFR 1.313(c)(3) to withdraw the application from issue for express abandonment in favor of a continuing application.

• May I still file a QPIDS submission after having received an issue notification?

Yes, as long as the date of the QPIDS submission is before the date the patent issues. When filing a QPIDS submission after a patent number has been assigned to the application, be sure to select the “Petition to Withdraw from Issue after Payment of the Issue Fee (37 CFR 1.313(c)(1) or (2) with Assigned Patent Number)” option at the Web-based ePetitions interface. Information regarding submission of Web-based ePetitions is available at http://www.uspto.gov/patents/process/file/efs/guidance/epetition-info.jsp.
QPIDS FAQs

• Must a QPIDS submission include a RCE fee?

Yes, a QPIDS submission must include the RCE fee under 37 CFR 1.17(e). If the examiner determines that no item of information in the IDS necessitates reopening prosecution, the RCE fee will be automatically returned.

• Will the petition fee under 37 CFR 1.17(h) be returned if the examiner determines that no item of information in the IDS necessitates reopening prosecution?

No, the petition fee under 37 CFR 1.17(h) will not be returned, regardless of the examiner’s determination with respect to reopening prosecution.
QPIDS FAQs

• May a QPIDS submission contain an amendment?

No, inclusion of an amendment will result in automatic entry and treatment of the “conditional” RCE as a RCE under 37 CFR 1.114.

• If I filed a QPIDS submission in an application, can I file a second or subsequent QPIDS submission in the same application?

Yes, but applicant must wait until after the Office issues a corrected notice of allowability (form PTOL-37) indicating that the examiner considered the prior QPIDS submission. The issuance of the PTOL-37 puts the application back into the issue queue, and at that point applicant may file another QPIDS submission. If, however, the Office issues a form PTO-2300 in response to the prior QPIDS submission, indicating that the examiner reopened prosecution, applicant can make another IDS submission in accordance with 37 CFR 1.97 (there would be no need to use the QPIDS program). If subsequent to the Office’s issuance of a PTO-2300, the application is again allowed, and the issue fee is again paid (or applicant requests that the previously submitted issue fee be applied toward payment of the issue fee), applicant may file another QPIDS submission.
Other programs
Examiner education programs

• Site Experience Education (SEE)
• Patent Examiner Technical Training (PETTP)
Site Experience Education (SEE)

- USPTO funds travel costs for patent examiner Site Experience Education to commercial, industrial, and academic institutions within the continental U.S.
- Participating organizations have their chance to communicate directly with patent examiners and gain a greater understanding of the importance of the patent system and how it works.
- Presents an opportunity for organizations to provide patent examiners with technical training first-hand from innovators, scientists, engineers, and experts working directly in the various technologies examined throughout the USPTO.

*For more information: [www.uspto.gov/patent/initiatives/site-experience-education-see-program#step1](http://www.uspto.gov/patent/initiatives/site-experience-education-see-program#step1)
Patent Examiner Technical Training (PETTP)

Speak with patent examiners

Patent Examiner Technical Training Program (PETTP)

The PETTP gives patent examiners the opportunity to learn about advances in the state of the art, emerging trends, and recent innovations directly from guest speakers.

Why participate in PETTP?
Guest speakers can:

- Help improve the quality of patent examination by informing patent examiners about advances in their technology areas.
- Gain a greater understanding of the USPTO.
- Choose from among several locations: speak at USPTO headquarters in Alexandria, VA; at one of our four regional offices; or from your location via webinar.

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*For more information: www.uspto.gov/patent/initiatives/patent-examiner-technical-training-program

• Yearly technology fairs
Thank you!

www.uspto.gov