

Guidelines for USDA/ARS National Patent Committees

The USDA-Agricultural Research Service (ARS) Patent Committees review invention disclosures submitted by scientists from USDA agencies, currently ARS, Animal Plant Health Inspection Service (APHIS) scientists, Bureau of Reclamation Scientists, and Department of Interior Fish and Wildlife Scientists in order to recommend whether a United States Patent application should be filed on the disclosed inventions.

The Patent Committee will have 10 voting members who are Category 1 Scientists and/or Research Leaders (RLs) when the Areas are reorganized going from 8 Areas to 5 Areas. When the committees meet, other non-voting participants include the Patent Advisor responsible for a reviewed invention disclosure, the Technology Transfer Coordinator for the Area of the Lead Inventor, the Deputy Assistant Administrator for OTT, and representatives from the OTT Licensing Staff, the Technology Transfer Liaison and the Partnership Liaison. The National Program Leader (NPL) responsible for a particular technology reviewed by the committee will be contacted by the Partnership Liaison for their comments which will be conveyed to the committee. However, it is highly recommended that the NPL participate in person. Line management including Institute /Center Director, Assistant/Associate Area Directors, and/or Area Director should participate in the Committee Meetings since they can provide additional information relating to the research program that would not be available to the scientist or Research Leader. Because of time restraints on Line Management, the TTCs could be proactive in getting and presenting their input.

Voting members of the Patent Committee will be selected from throughout USDA/ARS, balanced among Areas / locations conducting research in the broad subject disciplines represented by the 3 patent committees. Each committee will have two members from each of the ARS Areas. As vacancies in the voting membership of the Patent Committee arise, the Area Director will be notified. The Area Director appoints the new member and can consult with the Patent Advisors and TTC for recommendations.

National Patent Committees

The three technology-based Patent Committees are: (1) Life Sciences, (2) Chemical, and (3) Mechanical and Measurement, and each will serve all Areas of USDA/ARS and of the Animal and Plant Health Inspection Service (APHIS), Bureau of Reclamation, and the Department of Interior's Fish and Wildlife Services. Each location of OTT, at which there is a Patent Advisor stationed (i.e., Beltsville, Peoria, and Albany), will be responsible for one of the three Patent Committees. Meetings for each Patent Committee will be scheduled at the beginning of each fiscal year and will occur quarterly.

Notifications for National Patent Committee Meetings

Approximately 8 weeks prior to the anticipated Patent Committee meeting, a Legal Administrative Patent Specialist will submit by e-mail or other means a memo to the appropriate Area Offices and Research Leaders providing notice that a Patent Committee meeting will be forthcoming.

Once the date of the Patent Committee meeting has been determined, the Patent staff will determine an Invention Disclosure cut-off date, the latest date that an approved Invention Disclosure may be submitted for review at the specified Patent Committee meeting. The cut-off date will be no less than approximately four weeks prior to the Patent Committee meeting date.

A Legal Administrative Patent Specialist will submit by e-mail or other means a memo informing the appropriate Area Offices and RLs, and the Director of the National Wildlife Research Center (NWRC), WS/APHIS, Bureau of Reclamation, and the Department of Interior Fish and Wildlife Services, of this cut-off date. This cut-off date memo will be submitted approximately eight weeks prior to the date of the Patent Committee meeting, and the memo to the Director of NWRC will also include a notice of the Patent Committee meeting date.

A single memo may be used to remind the appropriate Area Offices and RLs, and the Director of NWRC, of each upcoming Patent Committee meeting and its applicable cut-off date. This memo will also be prepared by a Legal Administrative Patent Specialist, and will be submitted by e-mail or other means approximately six weeks prior to the date of each Patent Committee meeting.

Docketing and Posting Invention Disclosures

Invention Disclosures will be docketed by a Legal Administrative Patent Specialist for Committee Review per the Legal Administrative Patent Specialist Patent Committee Guidelines. Invention Disclosures will be posted to SharePoint and materials subject to review will include:

- 1) ARIS Approved Invention Disclosures with all approval signatures completed
- 2) Invention Disclosures for inventions from APHIS, Bureau of Reclamation, and Department of the Interior Fish and Wildlife Services, will be entered into ARIS by USDA/ARS/OTT.

Assignment of Invention Disclosures to Patent Committees

The Patent Advisor will determine which Patent Committee should review the Invention Disclosure. This decision will be based on the subject matter of the Invention Disclosure, the timing of the Patent Committee meetings, and the urgency of protecting the invention.

The Patent Advisor responsible for the an invention disclosure will assign an In-Depth reviewer for each Invention Disclosure. No RL will be assigned as an In-Depth Reviewer for any Invention Disclosure from their Research Unit.

Notification of Receipt of Invention Disclosures

When all electronic signatures are completed for an Invention Disclosure, a Legal Administrative Patent Specialist will prepare and send a memo by email, to the lead inventor listed on the Invention Disclosure acknowledging receipt of the Invention Disclosure and informing the inventors of the Patent Committee to which the Invention Disclosure has been assigned. If the invention is jointly owned by any entity other than USDA/ARS, the memo will include a request that the non-USDA inventors contact their respective institution and submit an invention disclosure thereto. The memo will also include reminders to the inventors to inform the Patent Advisor of any existing or planned disclosures or public uses of the invention. The memo may optionally include requests for relevant references, ARIS progress reports, Annual Research Progress Reports, manuscripts, abstracts, posters, etc. not cited in the Invention Disclosure or otherwise deemed by the Patent Advisor as relevant to the patentability of the invention, as well as requests for data or other information not provided in the invention disclosure which would assist the Patent Committee in evaluating the Invention Disclosure. Attached to this Acknowledgement Memo will be a copy of the Committee Criteria used to evaluate the Invention Disclosures.

Distribution of Invention Disclosure to National Program Staff

The Partnership Liaison for OTT will discuss the invention disclosure with the appropriate National Program Leader and provide the input at the committee meeting if the National Program Leader is unable to attend the Committee meeting.

Patentability and Scope of Inventions

For each Invention Disclosure to be considered at the Patent Committee meeting, the Patent Advisor will be prepared to discuss patentability of the invention and the scope of claims which might be reasonably expected to be allowed by the U.S. Patent & Trademark Office. The Patent Advisor is encouraged to communicate with one or more inventors of each Invention Disclosure in preparation for the committee meeting.

Criteria for Consideration

During the Committee meeting the five Patent Committee criteria will be discussed by the whole group. These criteria are as follows:

- 1) Is there current commercial interest in the invention or a high probability of commercialization in the future?
- 2) Is the magnitude of the market relative to the costs of commercialization large enough to warrant a patent?
- 3) Would the patent likely play a significant role in transferring the technology to the ultimate user beyond what could be achieved through publication?

- 4) Would a patent on this invention be enforceable, i.e., is the invention drawn to, or does it employ, a unique and readily identifiable material or device which could be bought or sold?
- 5) Is the invention of sufficient scope to justify patenting?

Posting of Relevant Documents for Committee Review

The Legal Administrative Patent Specialist will post on SharePoint a copy of each Invention Disclosure where it may be accessed by all Patent Committee members and OTT staff. Additional information, deemed relevant to the Patent Committee review, such as prior art, manuscripts and/or data, , will also be posted.

Presentation and Review Process During Committee Deliberations

At the Patent Committee meeting, each In-Depth Reviewer will describe the invention to the Patent Committee.. After the In-depth reviewer has described the invention and answered any questions concerning the invention, the Chairperson will begin the discussion of the five committee criteria questions. Each question will be discussed separately and all in attendance can participate in the discussion. Only after the conclusion of the discussion may the In-Depth Reviewer express his/her view on the disposition of the Invention Disclosure.

At the conclusion of the discussion, each Patent Committee member will vote on a recommendation for the invention with the In-Depth Reviewer voting last. Only the Patent Committee members will be allowed to vote. The Patent Committee members will vote to recommend to the Deputy Assistant Administrator:

- 1) **Approval** (recommend patent application preparation and filing),
- 2) **Deferral** (a provisional approval where additional information is required before a patent application can be filed)., For example, in making a recommendation of deferral, the Patent Committee may require additional action or information from the inventor(s), such as might be necessary to establish reduction to practice or to broaden the scope of the invention, or the need to solicit commercial interest or a CRADA partner.
- 3) **Suspension 1** (recommend transfer of the technology by some means other than a patent).
- 4) **Suspension 2** (Not enough data available to make a recommendation)

The Patent Committee recommendations will be in accordance with the majority vote of the Patent Committee members participating in the meeting. Majority meaning the highest number of votes of the participating voting members for a particular recommendation will be the recommendation of the committee. When the combination of Approval and Deferral votes is greater than the votes for Suspension, the invention disclosure will be approved or deferred

depending on which of the two categories received the majority of votes. If there is a tie vote, the Deputy Assistant Administrator of OTT breaks the tie.

Notification of Committee Decisions

After the Patent Committee meeting, the PA with the appropriate Technology Transfer Coordinator will convey the Patent Committee recommendation to the lead inventor of each Invention Disclosure by telephone. In the event that the lead inventor is unavailable by telephone, the Patent Advisor may contact the inventors by e-mail with this information, including a copy to the appropriate Technology Transfer Coordinator. At this time, the Patent Advisor will explain to the inventor the rationale behind the Patent Committee recommendation, and in the event of a deferral, what additional information is required. The Inventors will also receive an email memo informing them of the Patent Committee recommendation. In the event of a recommendation to suspend, a memo will be prepared for signature by the Deputy Assistant Administrator for OTT. Memos for inventions for which the Patent Committee has recommended approval or deferral will be executed by the Patent Advisor. A copy of the memo will be sent by email to the appropriate Area Office and RL. For APHIS inventions, prior to contacting the inventor(s), the Patent Advisor will first discuss the Patent Committee recommendation with either the Director of NWRC or the appropriate Regional Director who will make a final decision as to protecting the technology. If the Patent Committee recommendation is approved, the Patent Advisor will then contact the APHIS inventor(s) as described hereinabove.

ARIS Record Maintenance

The Legal Administrative Patent Specialist will update the status of the Invention Disclosure in ARIS with the Patent Committee recommendation.

Providing Information Required by Recommendation of “Deferral”

If the Patent Committee has recommended deferral of an Invention Disclosure, it is the responsibility of the inventor(s) to provide any additional action or information required by the Patent Committee. The Technology Transfer Coordinator may assist the inventor(s) in soliciting commercial interest in or developing a CRADA. The inventor(s) should submit this additional information to the Patent Advisor who will have the authority to determine if the Patent Committee concerns have been satisfied.

If after an approximately two to three year period, if the Invention Disclosure is still in a deferred status, the Patent Advisor will send the invention disclosure to an Ad Hoc OTT committee to determine if the disclosure should be suspended.

Appeal of “Suspension” Recommendation

USDA/ARS inventors and/or line management may request, in writing, reconsideration of any Patent Committee recommendation to “suspend” the invention disclosure to the Assistant Administrator of OTT. APHIS inventors may appeal Patent Committee recommendations to the Director of the NWRC or the appropriate Regional Director in accordance with the SOP for “Protection of Intellectual Property and Licensing Government Inventions” for WS of APHIS.