Department of Veterans Affairs Technology Transfer

Bringing Research Advancements for Veterans to Everyone!

Kerry W. Leonard, JD/MBA
Technology Transfer Specialist
Agenda

• Deploying Your **IDEA**
  • **I**nvent
  • **D**isclose
  • **E**valuate
  • **A**pply

• Success Stories

• Lessons Learned

• Q&A
• When is an invention “ready” to submit a disclosure? When should you contact TTP?

  • Contact TTP before making *any* public disclosure of the invention.

  • Thinking about submitting a paper for publication, presenting at a conference, contacting potential collaborators, etc.? – **Contact TTP**!

  • TTP processes take time, so the sooner you get us involved, the better.
• When is it too soon to contact TTP?
  
  • Never - always contact TTP with any questions you have!
  
  • TTP is interested in ideas that can lead toward an invention that will be commercially viable.
  
  • Don’t submit disclosures for mere ideas or for observations that you do not intend to research/pursue any further.
• TTP primarily works with inventions that are patentable. Patentable inventions include:
  • Processes
  • Machines/devices
  • Article of manufacture
  • Compositions of matter
  • Any new and useful improvement of any of the above
Because the US Government cannot hold copyrights, TTP does not obtain copyrights on software.

TTP does license software on a case-by-case basis, so disclose new software developments by using same process as any other invention.
Disclose

Bringing Research Advancements for Veterans to Everyone!

VA Affiliate
Inventor Disclosure

Affiliate TTO
VA TTP

D.O.R

VA Lead

Affiliate Lead

Assessment

Protection

Market

Deal

3/1/2017
Disclose

• How to disclose your invention to TTP?
  • Submit one completed Invention Disclosure Form.
  • TTP will accept:
    • (a) VA disclosure form; OR
    • (b) university’s disclosure form.

• Submit one executed VA Certification Form for each VA inventor.

• Email all completed Invention Disclosures and VA Certification Forms to:
  vattid@va.gov

• VA Invention Disclosure and Certification Forms can be found at:
  www.research.va.gov/programs/tech_transfer/forms_templates.cfm
Disclose

- VA Invention Disclosure Form
Disclose

- Case Western Invention Disclosure Form
  - Be sure to check “VA” if you have any VA appointment
Who is a “VA Inventor”?
- Full-Time VA employees
- Part-Time VA employees
- WOC
- IPA

Date of Invention?
- Date that the invention was first conceived.

Patent Pending?
- Please give us as much info as possible about any issued patents or pending applications.
Disclose

- Official VA working hours?
  - Did you make it during your VA duty hours?
  - If not applicable to your VA employment situation (e.g. WOCs), was it made when you were working on your VA projects?

- Responsibility to perform VA research?
  - Is performing research part of your official VA duties (i.e. are you paid to perform research)?
  - If you are a VA clinician only, you do NOT have a responsibility to perform research.

- VA Facilities?
  - Where was the invention created? In a VA lab or at the university? Where was data analyzed? Etc.

3/1/2017
Disclose

- VA Equipment?
  - What was used to create or test the invention? Machines located at the VA?

- VA Materials?
  - What materials were used in the creation or testing of the invention? Includes reagents, tissue samples, etc. from VA.

- VA Funds?
  - What were the funding sources for all research projects that led to the development of the invention? Were any of them from the VA?
  - All grants and funds administered through the NPC = VA funds

Invention Certification Form
Complete one certification for each VA Inventor

1. Employee Name, hereby certify that the invention entitled Invention Title, patent application number Insert Patent Application Number or state “Not Applicable”, was made by me on Provide date invention was made, while I held a(n) [ ] as VA Position Title at VA Facility Name.

Please answer "Yes" or "No" in the order that the questions appear.

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
</tr>
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<tbody>
<tr>
<td>1. The invention was made during my official VA working hours.</td>
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<td>4. The invention:</td>
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<td>a) Bears a direct relation to my official VA duties</td>
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<td>5. I am attaching remarks relating to the above.</td>
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I hold an academic appointment: [ ]

Please indicate if you have any of the following advanced degrees:

- MD
- PhD
- DO
- DPM
- If other, specify: 

I hereby voluntarily assign my entire right, title, and interest in and to the above identified invention to the United States Government. I do not desire a Determination of Rights under 37 CFR Part 501.

See 38 § CFR 1.650-1.663

3/1/2017
Discuss

• VA Information?
  - What information was used in the creation or testing of the invention? Includes data, knowledge, etc.

• Time/Services of other VA employees on official duty?
  - Did any other VA employees assist in developing the invention?
  - If yes, were they performing their official VA job functions at the time the invention was made?

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Please answer “Yes” or “No” in the order that the questions appear.

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   a) Facilities
   b) Equipment
   c) Materials
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   e) Information
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See 38 CFR 1.650-1.663

[ ] YES [ ] NO

3/1/2017
Disclose

• Bears a direct relation to official VA duties?
  • Is the invention closely related to what the VA pays you to do?
  • E.g. Are you a psychiatrist, your invention is a treatment for PTSD, and you came up with the idea for your invention because of your work at the VA?

• Made in consequence of official VA duties?
  • Was the invention developed as a result of performing your official VA job functions?
  • E.g. You are a Research Scientist and you developed the invention because you were paid by the VA to do your research on the invention?
**Disclose**

- **Attached Remarks?**
  - Every situation is different. Attach a small paragraph if there is something special we should know about how this invention was created.

- **Academic Appointment/Degree?**
  - TTP uses this to ensure that the university is kept in the loop when Dual-Appointed Personnel (DAPs) are involved.

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See 38 CFR 1.650-1.663

3/1/2017
• Waiving Determination of Rights?
  • If you know that the VA will be asserting an ownership interest in your invention, you may choose to check “Yes” and waive the Determination of Rights (DOR) process.

  • Waiving the DOR process will speed up TTP processes in some cases (i.e. when a patent application needs to be filed quickly to beat a public disclosure deadline).

  • Do **NOT** waive the DOR if there is any uncertainty about who has an ownership interest in the invention.

  • VA’s Office of General Counsel (OGC) can expedite DORs on a case-by-case basis.
Disclose

• Signatures?
  • Sign and date the Certification Form.
  • Submit VA Certification Form for ACOS signature; OR
  • Submit VA Certification Form to your VA supervisor.

• Completed Forms?
  • Submit completed forms to vattid@va.gov

3/1/2017
Evaluate

VA Affiliate Inventor Disclosure

Affiliate TTO VA TTP

D.O.R

VA Lead

Affiliate Lead

Assessment

Protection

Market

Deal

3/1/2017
Evaluate

• Determination of Rights – An Assessment of Government Rights
  • Assert Government ownership of the invention.
  • Leave ownership of the invention with the inventor.
  • Leave ownership of the invention with the inventor subject to the VA retaining a non-exclusive, Government use license.

• After DOR is made, a letter is emailed to the inventors from the Office of General Counsel (OGC).
  • Please send a reply to the OGC attorney to confirm receipt of the DOR.

• If you do not agree with the outcome of the DOR, you can file an appeal with NIST (see DOR letter for further information about this process).
• After DOR is issued, VA and University determine who will be the “Lead Party” for the invention.

• In most jointly-owned cases, Case Western University takes the lead.

• Lead Party files for Intellectual Property Protections
  • Provisional patent application
    • “Placeholder” application with 1-year window to convert to a non-provisional application.
  • Non-Provisional (Utility) patent application
  • Design patent application
  • Patent Cooperation Treaty (PCT) application
  • Foreign patent application
Evaluate

• TTP can obtain prior art assessments before filing any patent applications.
• Market assessments may also be performed before deciding whether or not to file. They include the:
  • Technical Description
  • Brief Market Analysis
  • Competitive Position
  • Barriers to Entry
  • Recommendations
• Involves licensing a patent to a company which will develop the invention into a product that benefits the public.

• Could involve a collaboration with the inventor(s) through a license or a Cooperative Research And Development Agreement (CRADA).
• TTP attracts potential licensees through:
  • Passive Marketing
    • Posted to Web site
  • Marketing Briefs
  • Active Marketing
  • Media Outlets
  • Inventor Suggestions
• License Application Process is Codified (37 CFR 404)
  • Commercial Development Plans are required from the potential licensee.
  • Applicant must show that it meets statutory and regulatory guidelines in order to qualify for exclusive license.

• Negotiate an exclusive, partially exclusive, or nonexclusive license agreement
  • Fees
  • Royalties
  • Reimbursement of Costs

*No Inventor Involvement During Financial Negotiations*
• TTP Royalty Policy:
  • First $2,000 to inventor(s), then:
  • 50% to inventor(s)
  • 50% to VAMC where invention was made

• Dual-Appointed Personnel will receive royalties from Case Western and VA for jointly-owned inventions.
Example 1: “Pulsed Xenon Tech to Clean Reusable Medical Equipment”

**Invention created**
- CRADA b/w VA and Company

**Disclosure submitted to VA TTP**
- May 2012

**DOR issued**
- June 2012

**Patents Pending**
- Provisional app filed August 2012
- PCT filed August 2013
Success Stories

Example 1: “Pulsed Xenon Tech to Clean Reusable Medical Equipment”

- Federal Register Notice
  - Approved January 2014
  - Published February 2014

- Licensee resubmits application for exclusive license
  - March 2015
  - Delay due to Licensee

- License executed
  - July 2015
Example 2: “Soft Suicide Prevention Door”

- **Invention created at VAMC**
  - April 2008

- **Disclosure submitted to VA TTP**
  - May 2008

- **DOR**
  - June 2008

- **Patent Applications**
  - Provisional filed May 2008
  - Non-Provisional filed May 2009
Example 2: “Soft Suicide Prevention Door”

Non-exclusive license application
• August 2008

License Executed
• September 2008

Patent Application Abandoned
• December 2013
Lessons Learned

• Get TTP involved as soon as you have an idea that you are going to pursue that has some commercial potential.

• Work with TTP to navigate our internal VA processes – it may feel cumbersome, but it is important to make sure everyone’s ownership rights are properly identified.

• If you can help us to identify a potential licensee, TTP will work with them to make the license happen.

• Remember, we are here to help you Bring Research Advancements for Veterans to Everyone!
Contact

- **Email Box:**
  VA Technology Transfer Invention Disclosures
  vattid@va.gov

- **POC:**
  John Kaplan, PhD, JD, MBA
  Director, Technology Transfer Program
  john.kaplan@va.gov
  202.632.7271

  Kerry Leonard, JD, MBA
  Technology Transfer Specialist
  kerry.leonard@va.gov
  202.443-5779
Thank you!