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NCATS SBIR/STTR Presents: Essential IP Advice for Small Business Commercialization

Featuring USPTO Patent Application & Examination Processes

January 29, 2020

ncats.nih.gov/smallbusiness
NCATS-SBIRSTTR@mail.nih.gov

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@ncats_nih_gov | #NCATSsbir
Featured Speakers:

Lili Portilla, M.P.A.
Director of Strategic Alliances, Office of Strategic Alliances
National Center for Advancing Translational Sciences
National Institute of Health

Ram Shukla, Ph.D.
Supervisory Patent Examiner
United States Patent and Trade Office

Monique LaRocque, M.P.H.
Senior Vice President
Ogilvy Health | FKH
Thank You to Our Collaborator:
Webinar Objectives

• Expand awareness about the NCATS, its SBIR and STTR programs and other small business resources to help foster innovation and technology development

• Share the processes for protecting IP for small business owners, the role that the USPTO plays and resources the small business community should know about
Agenda

Introductions and Objectives

NCATS SBIR & STTR Programs
  • Overview
  • NCATS Research Focus
  • The NCATS SBIR and STTR Program: Tips for Success

USPTO
  • Overview of Intellectual Property (IP)
  • Patents – patent applications & examination processes
  • Tools and Resources

Moderated Q&A
  • Please use the chat or Q&A function to submit questions at any time during the presentation
Funding Overview

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are some of the largest sources of early-stage capital for innovative small companies in the United States. These programs allow U.S.-owned and operated small businesses to engage in federal research and development (R&D) that has a strong potential for commercialization.

- **Investigator-initiated grant funding**
- **Standard Deadlines:** April 5, September 5, January 6

2019 Omnibus Solicitation

- Grant Solicitations in Targeted Areas
  - Grant to advance a particular technology/research area
  - Due dates may vary

- **Contract Solicitation**
  - Contract opportunity to advance areas of high research interest
  - Typically due in October or November
SBIR and STTR: One of the Largest Sources of Early-Stage Financing

- $34 Billion
  2019 NIH budget for basic and applied biomedical science

- $1.15 Billion
  2019 NIH funds for small businesses (SBIR & STTR)
Projects undergo NIH’s rigorous scientific peer review process, which awardees leverage to attract other funding and collaborations.
SBIR & STTR Funding Eligibility

Criteria for applying to SBIR:

✓ U.S. businesses with 500 or fewer employees

✓ PI Primary employment with small business at the time of the award and duration of the project

✓ More than 50% U.S.-owned by individuals and independently operated

OR

✓ More than 50% owned and controlled by other business concern(s) that is/are > 50% owned and controlled by one or more individuals

OR

✓ More than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms or any combination of these

Criteria for applying to STTR:

✓ An established cooperative research and development effort delineated as:

  ✓ Minimum 40% by small business concern; minimum 30% by U.S. college or university, non-profit research organization or Federally-Funded R&D Center (FFRDC)

✓ Formalized intellectual property agreement

  ✓ Should provide the necessary IP rights in order to carry out follow-on R&D and commercialization

✓ Primary employment of the principle investigator with either the small business or research institution
NIH SBIR/STTR Is a Three Phase Program

**Discovery**

- **Phase I**
  - **Phase I Feasibility Study**
    - Budget Guide: $225K for SBIR and STTR ($325K Waiver)
    - Project Period: 6 months (SBIR); 1 year (STTR)

**Development**

- **Phase II**
  - **Phase II Full Research/R&D**
    - $1.5M for SBIR and STTR, over two years ($2M)
      - Fast Track combines Phase I and Phase 2
      - Direct to Phase 2 – allows to skip Phase 1
  - **Phase IIB Competing Renewal/R&D**
    - Clinical R&D; Complex Instrumentation/to FDA
    - Funding Varies (~$1M per year) for up to 3 years

**Commercialization**

- **Phase III**
  - **Phase III Commercialization**
    - NIH, generally, not the “customer”
    - Consider partnering and exit strategy
Current Funding Opportunities

• Omnibus “Parent” SBIR/STTR Grant Solicitation
  • SBIR: [PA-19-272](#) STTR: [PA-19-270](#)
  • Next deadline: April 6, 2020

• Commercializing Understudied Proteins from the Illuminating the Druggable Genome Project (IDG)
  • SBIR: [PA-19-034](#) STTR: [PA-19-033](#)
  • Next deadline: April 6, 2020

• NIH HEAL Initiative℠ America’s Startups and Small Businesses Build Technologies to Stop the Opioid Crisis
  • SBIR: [RFA-DA-19-019](#) STTR: [RFA-DA-19-020](#)
  • Next deadline: April 9, 2020

• Administrative Supplements to Promote Diversity in Research & Development in Small Businesses
  • SBIR: [PA-18-837](#) and STTR: [NOT-OD-19-016](#)
  • Expires on September 5, 2021

• Commercialization Readiness Pilot (CRP) Program Technical Assistance
  • SBIR/STTR: [PAR-19-334](#) (SB1, R44 - Clinical Trial Not Allowed)
  • Next deadline: April 6, 2020
Small Businesses: Get Your Questions Answered

NCATS Small Business Programs (SBIR/STTR)

Questions about the SBIR and STTR funding application process or whether your project idea is a good fit? We’re available to help!

- Check out our online FAQs
- Contact us to set up an appointment to discuss your project idea: NCATS-SBIRSTTR@mail.nih.gov
- View current funding opportunities and spread the word: ncat.gov/smallbusiness
The USPTO: Patent Application and Examination Processes

Ram R. Shukla, Ph.D.
Supervisory Patent Examiner
Assistant Regional Director (Acting)
(Rocky Mount Regional Office)
571-272-0735
ram.shukla@uspto.gov
https://www.uspto.gov/
Objectives

• Overview of Intellectual Property (IP)
• Patents
  • What is a patent?
  • Patent Application/Examination processes
• Tools and Resources
USPTO Offices

- Silicon Valley West Coast Regional Office
- Rocky Mountain Regional Office
- Midwest Regional Office
- Texas Regional Office
- USPTO HQ
Atlantic Region – USPTO Headquarters
600 Dulany Street, Alexandria, Virginia

• Office hours: 8:30 a.m. – 5 p.m. ET, M – F
• Services
  – Public search facility available from 8 a.m. - 5:30 p.m.
  – Examiner interview room
  – Hearing room
  – Public meeting space
The USPTO in FY18

12,579 employees
- 8,185 patent examiners
- 549 trademark examining attorneys
- 383 Patent Trial and Appeal Board team
- 73 Trademark Trial and Appeal Board team

Patents
- 643,349 applications filed
- 338,072 patents issued

Trademarks
- 468,926 trademark applications
- 273,808 Certificates of Registration

USPTO headquarters in Alexandria, VA
## Overview of Intellectual Property

<table>
<thead>
<tr>
<th>What’s protected?</th>
<th>Utility patent</th>
<th>Design patent</th>
<th>Plant patent</th>
<th>Copyright</th>
<th>Trade secret</th>
<th>Trademark</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inventions</strong></td>
<td>Inventions</td>
<td>Ornamental (non functional) designs</td>
<td>Newly invented plants</td>
<td>Books, photos, music, fine art, graphic images, videos, films, architecture, computer programs</td>
<td>Formulas, methods, devices or compilations of information which is confidential and gives a business an advantage</td>
<td>Words, symbols, logos, designs, or slogans that identify and distinguish products or services</td>
</tr>
<tr>
<td><strong>Examples</strong></td>
<td>iPod, chemical fertilizer, process of manipulating genetic traits in mice</td>
<td>Unique shape of electric guitar, design for a lamp</td>
<td>Flowering plants, fruit trees, hybrid plants</td>
<td>Michael Jackson’s Thriller (music, artwork and video), Windows operating system</td>
<td>Coca-Cola formula, survey methods used by a pollster, new invention for which patent application has not been filed</td>
<td>Coca-Cola name and distinctive logo, Pillsbury doughboy character</td>
</tr>
<tr>
<td><strong>Duration of protection</strong></td>
<td>20 years from the date of filing regular patent application</td>
<td>15 years</td>
<td>20 years from filing date</td>
<td>The life of the author plus 70 years (or some works, 95 years from pub., and others 120 years from creation)</td>
<td>As long as information remains confidential and functions as a trade secret</td>
<td>As long as mark is in continuous use in connection with goods or services – renew by year 6, then at year 10, then every 10 years</td>
</tr>
</tbody>
</table>
IP and the U.S. economy

- **27.9m**
  - IP intensive jobs (2014)

- **38.2%**
  - IP intensive industries share of total US GDP (2014)

- **$6.6 trillion**
  - Value add of IP-intensive industries (2014)

- **$1,312/week**
  - (46% higher)
  - Avg. weekly wages for workers in IP-intensive industries

- **$115.2 billion**
  - Revenue specific to the licensing of IP rights totaled (2012)

- **28 industries**
  - Deriving revenues from licensing

The Role of The Patent System

- Protect inventions
- Encourage inventions
- Promote commercialization and application of invention
- Accelerate the commercialization of invention to the whole society
The Deputy Commissioner for Patent Operations oversees all patent examining functions in the nine Patent Technology Centers.

- Technology Center 1600: Biotechnology and Organic Chemistry
- Technology Center 1700: Chemical and Materials Engineering fields
- Technology Center 2100: Computer Architecture Software and Information Security
- Technology Center 2400: Computer Networks, Multiplex, Cable and Cryptography/Security
- Technology Center 2600: Communications
- Technology Center 2800: Semiconductors, Electrical and Optical Systems and Components
- Technology Center 2900: Designs
- Technology Center 3600: Transportation, Electronic Commerce, Construction, Agriculture, Licensing and Review
- Technology Center 3700: Mechanical Engineering, Manufacturing and Products
Overview of IP: What is a Patent?

- A property right
  - Right to **exclude others** from making, using, selling, offering for sale, or importing the claimed invention
- Limited term
- Territorial: Protection only in territory that granted patent; **NO world-wide patent**
- Government grants the property right in exchange for the disclosure of the invention
Types of Patents

**Utility**
New and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof

**Design**
Any new, original and ornamental design; protects the way an object appears

**Plant**
Whoever invents or discovers and asexually produces any distinct and new variety of plant
The Path to a Patent

New Idea? → Provisional application (optional) → Non-provisional application → Patent!

One year

Twenty years
Types of Applications

Provisional:
• One-year period
• Filed for filing date priority
• No claims required
• Not examined, so no patent
• Not allowed for design

Non-Provisional:
• 20-year patent protection from filing date
• Examined for patentability
• Claims required
Time and costs

• Average pendency for utility & plant applications: 24 months as of April, 2019

• Many fees reduced for small entity and micro entities

• Filing, search, examination & issue fees

• Maintenance fees due 3.5, 7.5, and 11.5 years after patent issues (e.g., $1600/3600/7400)
What is claimed is:

1. A method of lowering beta glucocerebrosidase activity in cells of a patient in need thereof, the method comprising providing an effective amount of a compound of Formula (1) or a pharmaceutically acceptable salt thereof to the patient, wherein Formula (1) is:

```
    R1       R2
     |       |
  S-----R3---R4
     |       |
     X

wherein the ring
```

2. wherein the ring

```
    R1       R2
     |       |
  S-----R3---R4
     |       |
     X

is a ring system of the formula
```

3. in which R1 is an optionally substituted alkylidene group and R2 and R4 carry the definitions set forth below, or

```
    R1       R2
     |       |
  S-----R3---R4
     |       |
     X

in which R2, R3 and R4 carry the definitions set forth below.

U.S. Patent No. 9,974,789 to Marugan et al.
Claim Scope

What information should a patent application claim?

- Too General: Not patentable
- Invention: Not valuable
- Too Specific: Not patentable
Patent Examination

Application is filed by inventor or assignee

USPTO pre-exam

Examiner

Notice of allowance

Applicant

Abandonment

USPTO grants patent

Appeal

Amendment and/or argument

Rejection and/or objection
The Examination Process

- First examination
- Second examination
- Appeal process
- Notice of allowance
- Allowance
- Appeal brief
- Amendment
- Rejection
Patent Examination

• Patent Examiner reviews contents of the application for compliance with all U.S. legal requirements

• Initial burden is on the examiner: An applicant is entitled to a patent unless...
  • Requirements of U.S. law are not met
What Does a Patent Examiner Do?

• Reads and understands the invention set forth in the specification
• Determines whether the application is adequate to define the metes and bounds of the claimed invention
• Determines the scope of the claims
• Searches existing technology for claimed invention
• Determines patentability of the claimed invention
35 U.S.C. 101

Inventions Patentable:

• Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
Subject matter for utility patents

Utility patents are provided for a new, non-obvious and useful (35 U.S.C. 101):

• Process
• Machine
• Article of manufacture
• Composition of matter
• Improvement of any of the above
Four Requirements:

• “A” patent – means only one patent granted for each invention.
  • Basis for statutory double patenting rejections. See MPEP 804.
• “Useful” – the invention must have a specific, substantial, and credible utility.
  • “Utility” requirement – see MPEP 2107 for Utility Guidelines.
• “Process, Machine, Manufacture, Composition of Matter”
  • “Subject matter eligibility” - these categories, as interpreted by the courts, limit the subject matter that is eligible for patenting.
• “Whoever invents or discovers”
  • A patent may only be obtained by the person who engages in the act of inventing.
Patentability Requirements

Invention must also be:

• Novel (35 U.S.C. 102)
• Non-obvious (35 U.S.C. 103)
• Adequately described and enabled (35 U.S.C. 112(a))
• Claimed by the inventor in clear and definite terms (35 U.S.C. 112(b))
35 U.S.C. 112 (a) paragraph: Specification

The specification shall contain:

• A written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
35 U.S.C. 112 (b) Paragraph: Specification

- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.
35 U.S.C. 103
Non-obvious

• 35 U.S.C. 103. Conditions for patentability; non-obvious subject matter (AIA)
  • A patent for a claimed invention may not be obtained, notwithstanding that
the claimed invention is not identically disclosed as set forth in section 102, if
the differences between the claimed invention and the prior art are such that
the claimed invention as a whole would have been obvious before the
effective filing date of the claimed invention to a person having ordinary
skill in the art to which the claimed invention pertains. Patentability shall
not be negated by the manner in which the invention was made
US 9173898: Claim 1

1. A method of treating giardiasis in a patient having said condition, comprising administering to the patient a therapeutically effective amount of auranofin or a pharmaceutically acceptable salt form thereof.
# Resources

**Helpline: 1-800-PTO-9199**

<table>
<thead>
<tr>
<th>Resource</th>
<th>Website</th>
</tr>
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<tbody>
<tr>
<td>Utility patent application guide</td>
<td><a href="http://www.uspto.gov/patents/resources/types/utility.jsp">www.uspto.gov/patents/resources/types/utility.jsp</a></td>
</tr>
<tr>
<td>Patent process</td>
<td><a href="http://www.uspto.gov/patents/process">www.uspto.gov/patents/process</a></td>
</tr>
<tr>
<td>Inventor and entrepreneur resources</td>
<td><a href="http://www.uspto.gov/inventors">www.uspto.gov/inventors</a></td>
</tr>
<tr>
<td>Pro se assistance</td>
<td><a href="http://www.uspto.gov/ProSePatents">www.uspto.gov/ProSePatents</a></td>
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<td>Micro entity limit</td>
<td><a href="http://www.uspto.gov/PatentMicroentity">www.uspto.gov/PatentMicroentity</a></td>
</tr>
<tr>
<td>Patent pro bono help and video</td>
<td><a href="http://www.uspto.gov/inventors/proseprobono">www.uspto.gov/inventors/proseprobono</a></td>
</tr>
<tr>
<td>First inventor to file</td>
<td><a href="http://www.uspto.gov/aia_implementation/patents.jsp#heading-10">www.uspto.gov/aia_implementation/patents.jsp#heading-10</a></td>
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<td>Law school clinic program</td>
<td><a href="http://www.uspto.gov/LawSchoolClinic">www.uspto.gov/LawSchoolClinic</a></td>
</tr>
</tbody>
</table>
Patent process overview

Step 1
Determine the type of Intellectual Property protection that you need

To protect your invention, you may need a patent, trademark, copyright, marketing plan, trade secrets, or some combination of these. Before you begin preparing a patent application, find out if you really need a patent or some other form of Intellectual Property protection.

- What are patents, trademarks, servicemarks, and copyrights?
- Inventor resources
- Online services

Step 2
Patent application initiatives

https://www.uspto.gov/patent/initiatives/uspto-patent-application-initiatives-timeline

You can get to the program pages by selecting a tile.

There are numerous programs that may speed up the examination process.
Patents Dashboard

https://www.uspto.gov/dashboards/patents/main.dashxml
Interview

https://www.uspto.gov/patent/laws-and-regulations/interview-practice

Interviews enable Applicants and Examiners to discuss and resolve issues and are an effective tool to advance the prosecution of an application. The USPTO encourages Examiners to take a proactive approach to examination by reaching out and engaging our stakeholders in order to shorten prosecution.

USPTO AIR

A new web-based tool that allows Applicants to schedule an interview with an Examiner for their pending patent application.

Complete the form.

Watch USPTO’s Interview Practice short video below for a brief introduction to the USPTO Automated Interview Request (AIR) tool and other available USPTO interview resources. AIR is a convenient online form for submitting requests for interviews. After the form is submitted, an examiner will email you to confirm your request within two business days.

TC Interview Specialist
Automated Interview Request

USPTO Automated Interview Request (AIR) Form

* This paper requesting to schedule and/or conduct an interview is appropriate because:
  ○ I have previously submitted an authorization for internet communications in this patent application. See form SB/0439.
  ○ I am concurrently submitting an authorization to communicate via the internet. See form SB/0439.
  ○ This submission is requested to be accepted as an authorization for this interview to communicate via the internet. Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with the undersigned concerning scheduling of the interview via video conference, instant messaging, or electronic mail, and to conduct the interview in accordance with office practice including video conferencing.

* [ ] understand that a copy of this communication will be made of record in the application file.

*Name(s):______________________________

*S-signature:______________________________________ (See 37 CFR 1.4(d)(2)) (/Name/)

Registration Number:________________________ (Five or six characters as format: 12345 / L1234 / P12345)

*U.S. Application Number:________________________ (8 digit numeric do not start with 90 or 95: 90*****/95*****)

(Note: AIR is intended for regular examination interview requests only and cannot complete interview requests for applications under Re-examination)

*Confirmation Number:__________________________ (4 Digit Numeric Only: 1234)
IP Awareness Assessment Tool

http://www.uspto.gov/inventors/assessment/
Ombudsman Program

• Enhances the USPTO's ability to assist applicants or their representatives with issues that arise during patent application prosecution.

• Contact an Ombudsman by: https://www.uspto.gov/patent/ombudsman-program
Thank you!

https://www.facebook.com/uspto.gov
http://www.youtube.com/user/USPTOvideo/
www.uspto.gov
Questions?
ncats.nih.gov/smallbusiness

NCATS-SBIRSTTR@mail.nih.gov

Please let us know what you thought of this webinar:
Thank You!