

The Webinar Will Begin Shortly



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Zoom Technical Support: +1.888.799.9666 ext. 2 or <https://support.zoom.us/hc/en-us>



Feedback: Let us know what you thought of this presentation <https://bit.ly/2LoN6dl>

National Center for Advancing Translational Sciences

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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Featured Speakers:



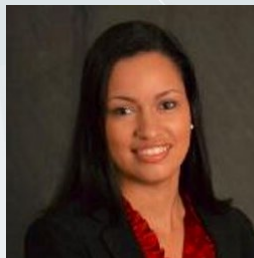
Lili Portilla, M.P.A.

Director of Strategic Alliances, Office of Strategic Alliances
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Supervisory Patent Examiner
United States Patent and Trade Office



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Senior Vice President
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Thank You to Our Collaborator:

UNITED STATES
PATENT AND TRADEMARK OFFICE



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.

2019 Omnibus Solicitation

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

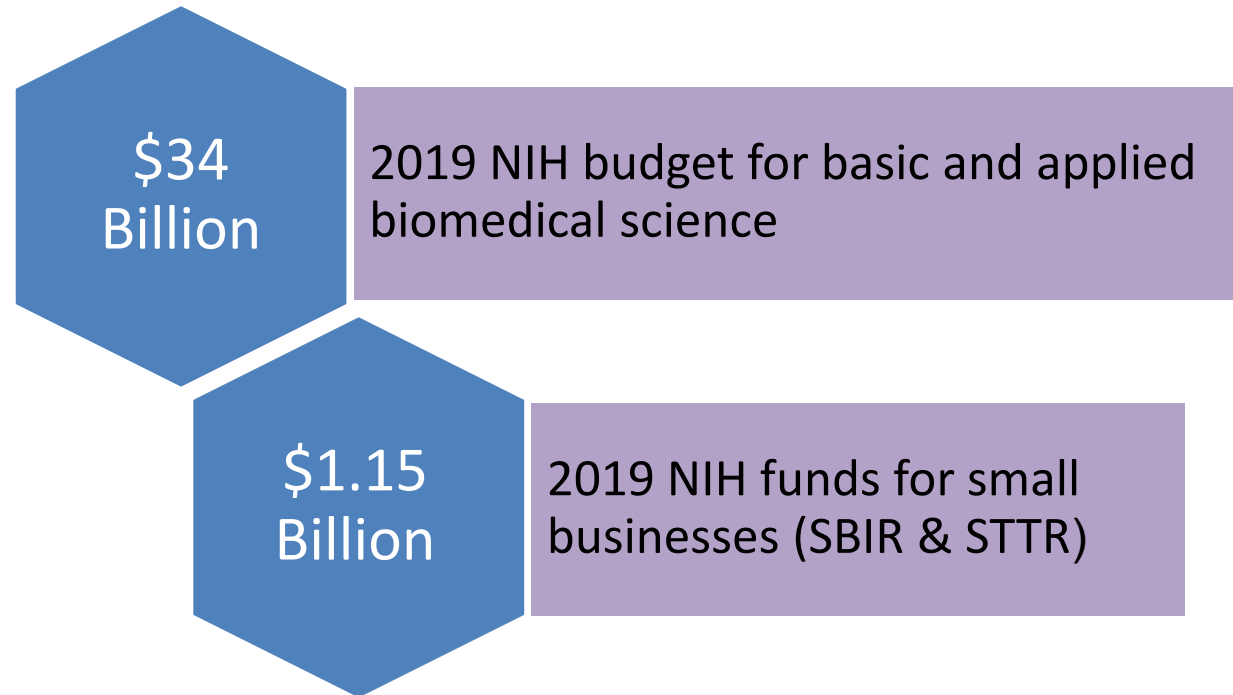
Grant Solicitations in Targeted Areas

- 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



The Benefits

NCATS Small Business Programs (SBIR/STTR)

Stable and predictable.
Not a loan. Funds don't
have to be repaid.



Non-dilutive.
IP rights are retained by
the small business.



Technical assistance to
advance and commercialize
technologies for public good.



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 (<i>\$325K Waiver</i>) 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 (<i>\$2M</i>) Fast Track combines Phase I and Phase 2 Direct to Phase 2 – allows to skip Phase 1 Phase IIB 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 InitiativeSM
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**
 - [PA-18-837](#) and [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: ncats.nih.gov/smallbusiness

**UNITED STATES
PATENT AND TRADEMARK OFFICE**

uspto

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

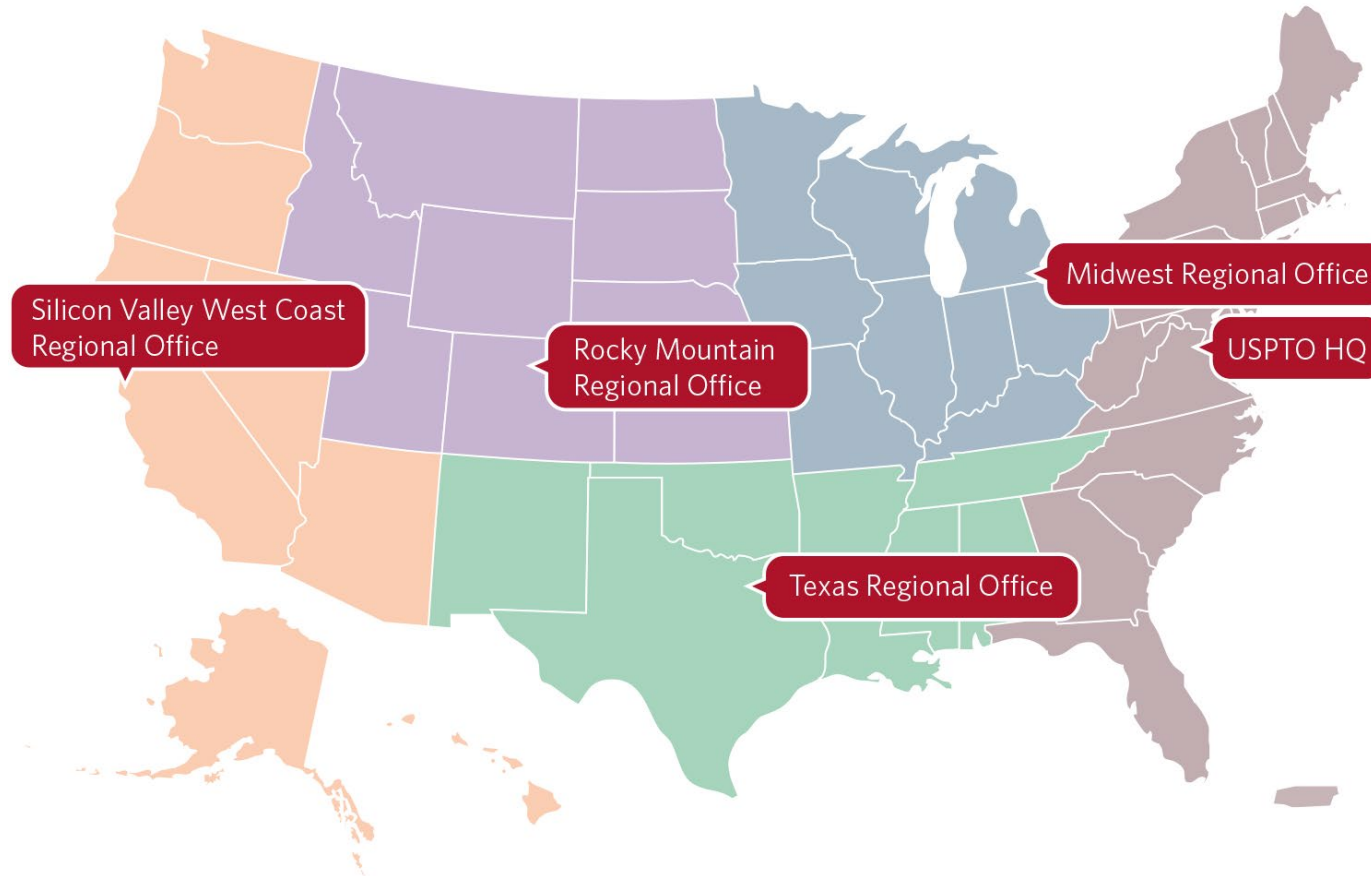
ram.shukla@uspto.gov

<https://www.uspto.gov/>

Objectives

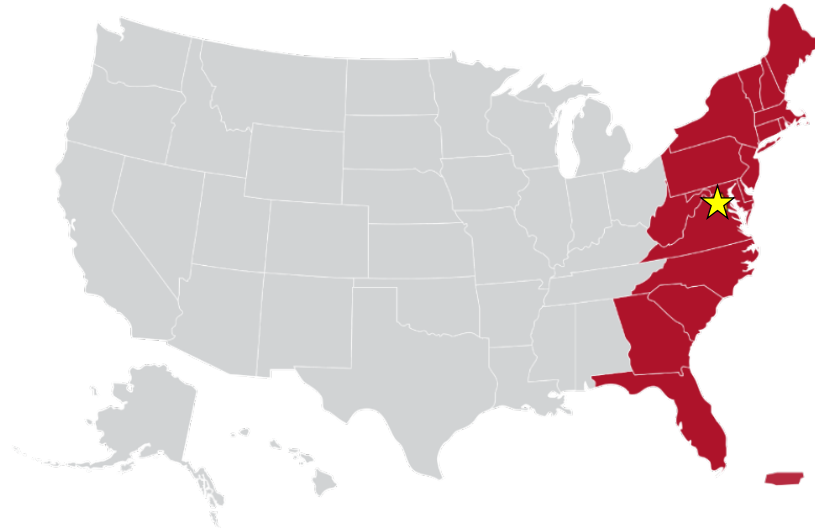
- **Overview of Intellectual Property (IP)**
- **Patents**
 - What is a patent?
 - Patent Application/Examination processes
- **Tools and Resources**

USPTO Offices



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

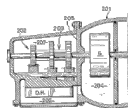
- **468,926** trademark applications
- **273,808** Certificates of Registration

USPTO headquarters in
Alexandria, VA



Overview of Intellectual Property

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



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

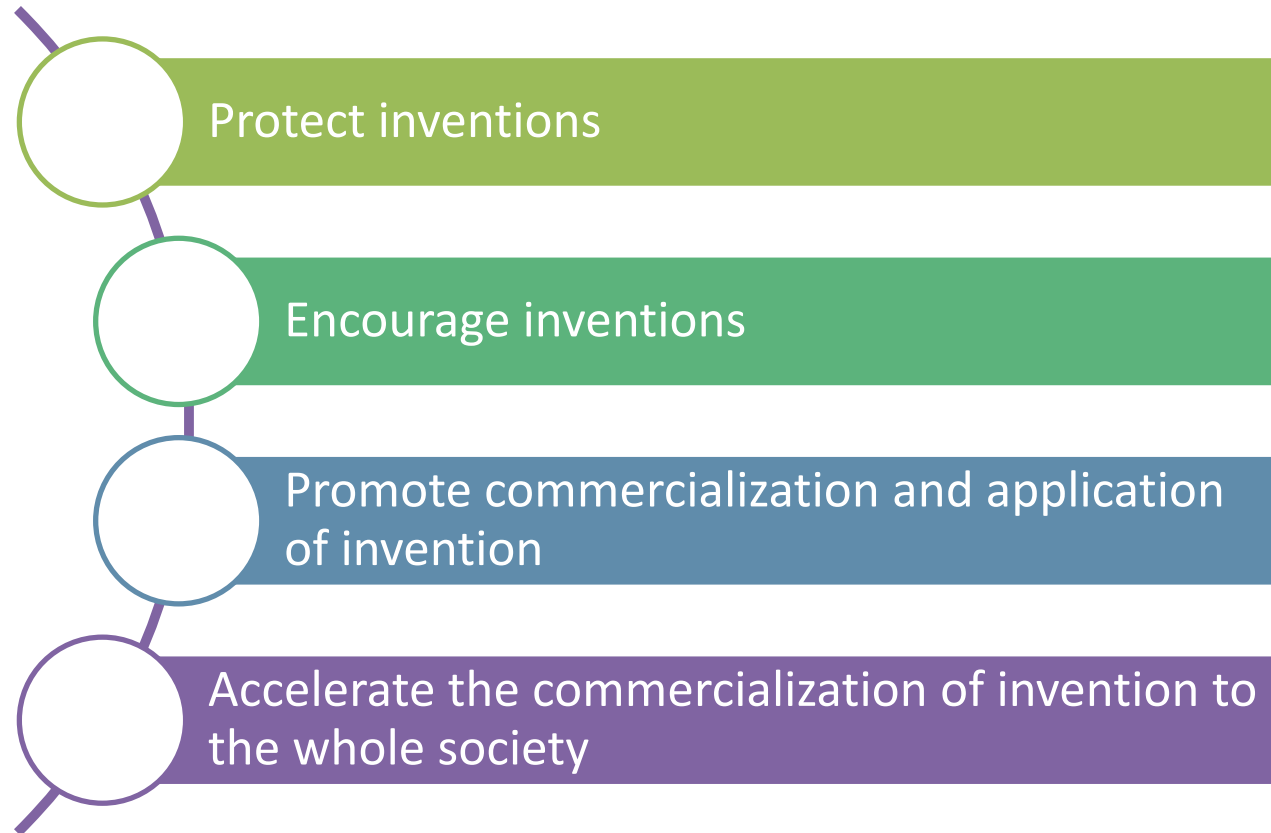
Revenue specific to the licensing of IP rights totaled (2012)

28 industries

Deriving revenues from licensing

Source: Department of Commerce. 2016. "Intellectual Property and the U.S. Economy: 2016 Update". September 26. www.uspto.gov/sites/default/files/documents/IPandtheUSEconomySept2016.pdf (January 3, 2018).

The Role of The Patent System



USPTO Technology Centers

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

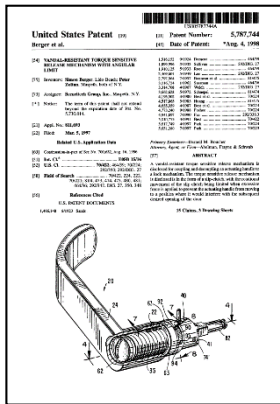
Overview of IP: What is a Patent?

- 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

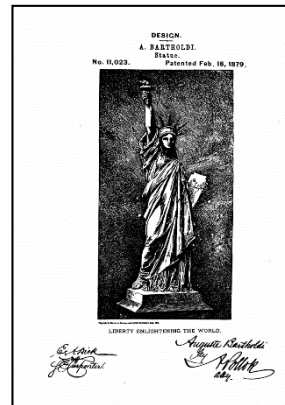
Utility

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

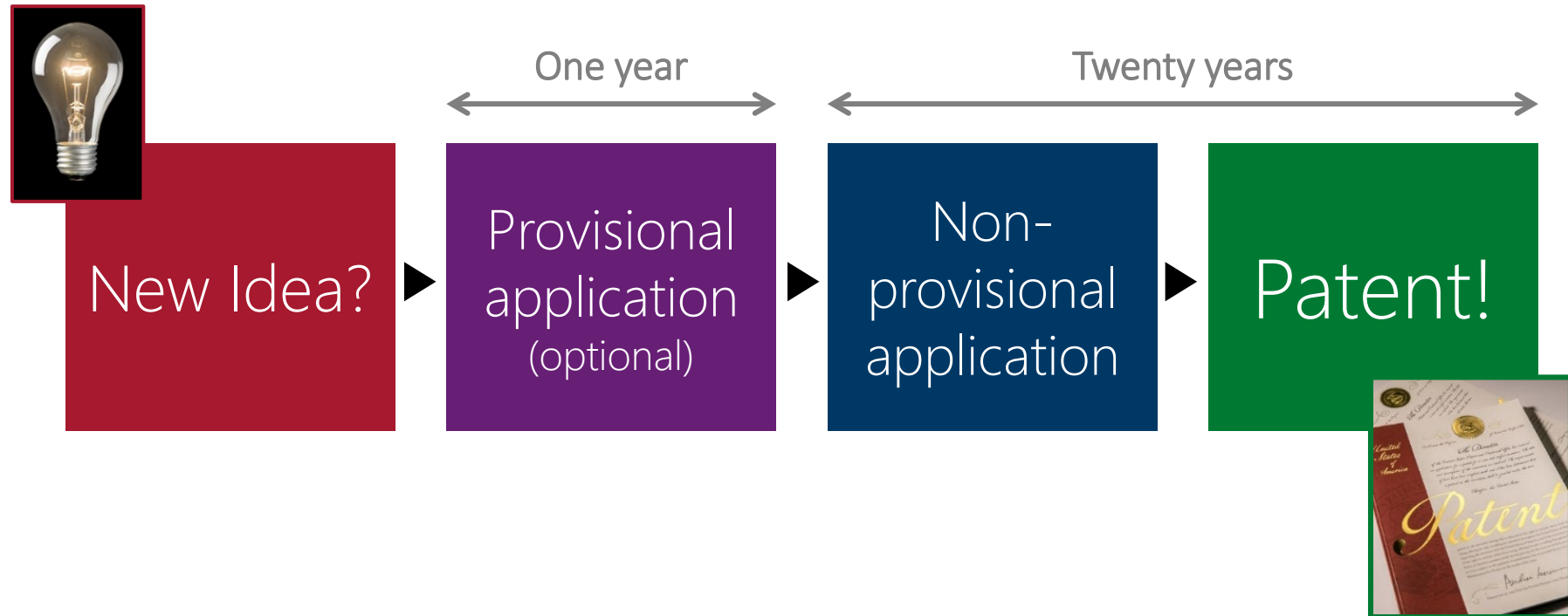


Plant

Whoever invents or discovers and asexually produces any distinct and new variety of plant



The Path to a Patent



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

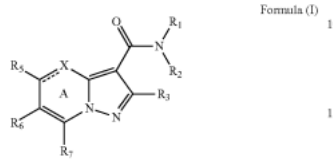
Time and costs

- 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
 - <https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule#Patent%20Search%20Fee>
- Maintenance fees due 3.5, 7.5, and 11.5 years after patent issues (e.g., \$1600/3600/7400)

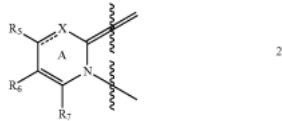
Patent Application Structure

- Title
- Abstract
- Drawings
- Background of the invention
- Brief summary of the invention
- Brief description of the drawings
- Detailed description
- Claims

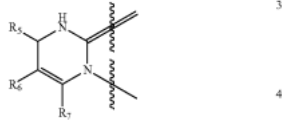
What is claimed is:
 1. A method of increasing beta glucocerebrosidase activity in cells of a patient in need thereof, the method comprising providing an effective amount of a compound of Formula (I) or a pharmaceutically acceptable salt thereof to the patient, wherein Formula (I) is:



wherein the ring

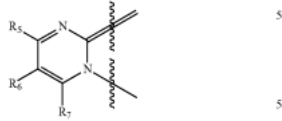


is a ring system of the formula (i)



in which R5 is an optionally substituted alkylidene group and R6 and R7 carry the definitions set forth below, or

(ii)

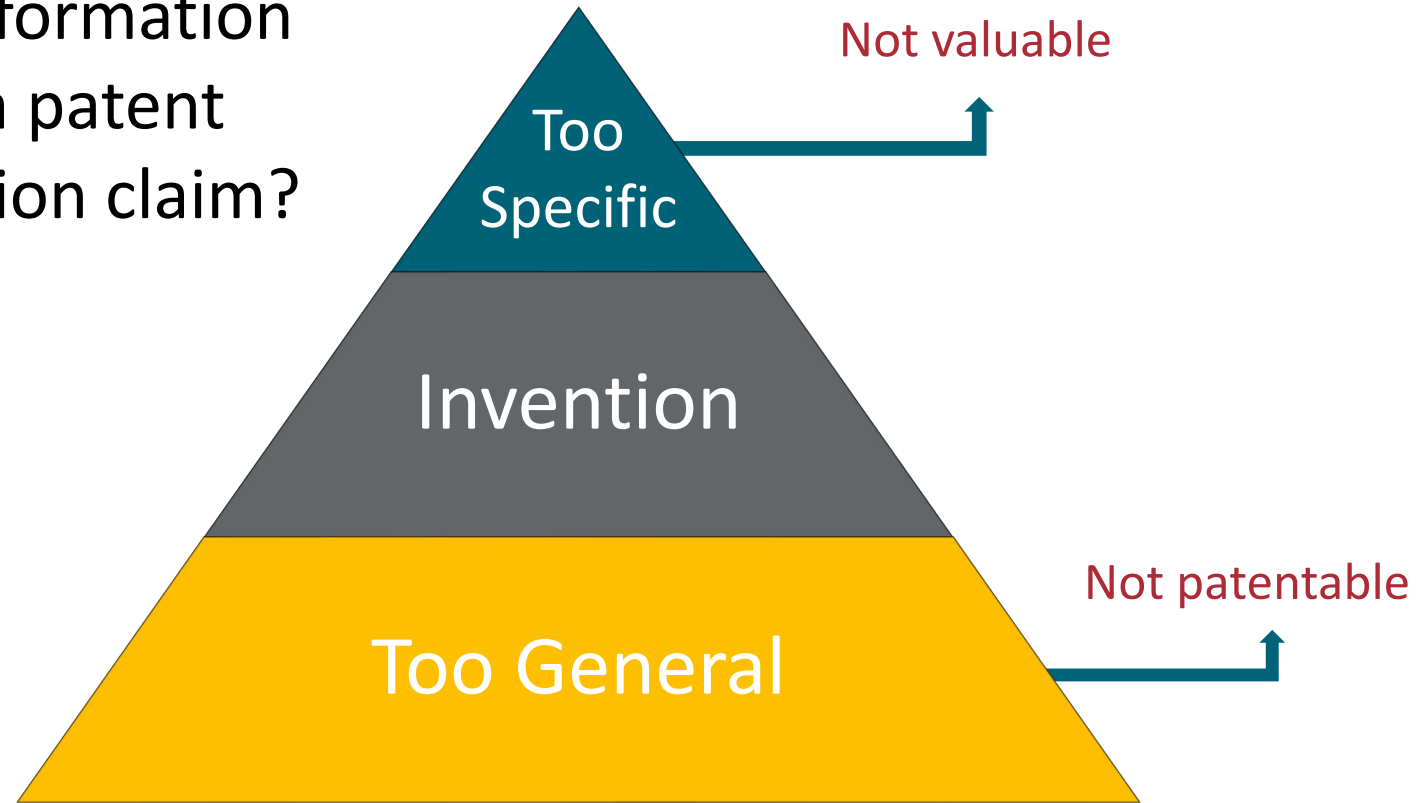


in which R5, R6, and R7 carry the definitions set forth below;

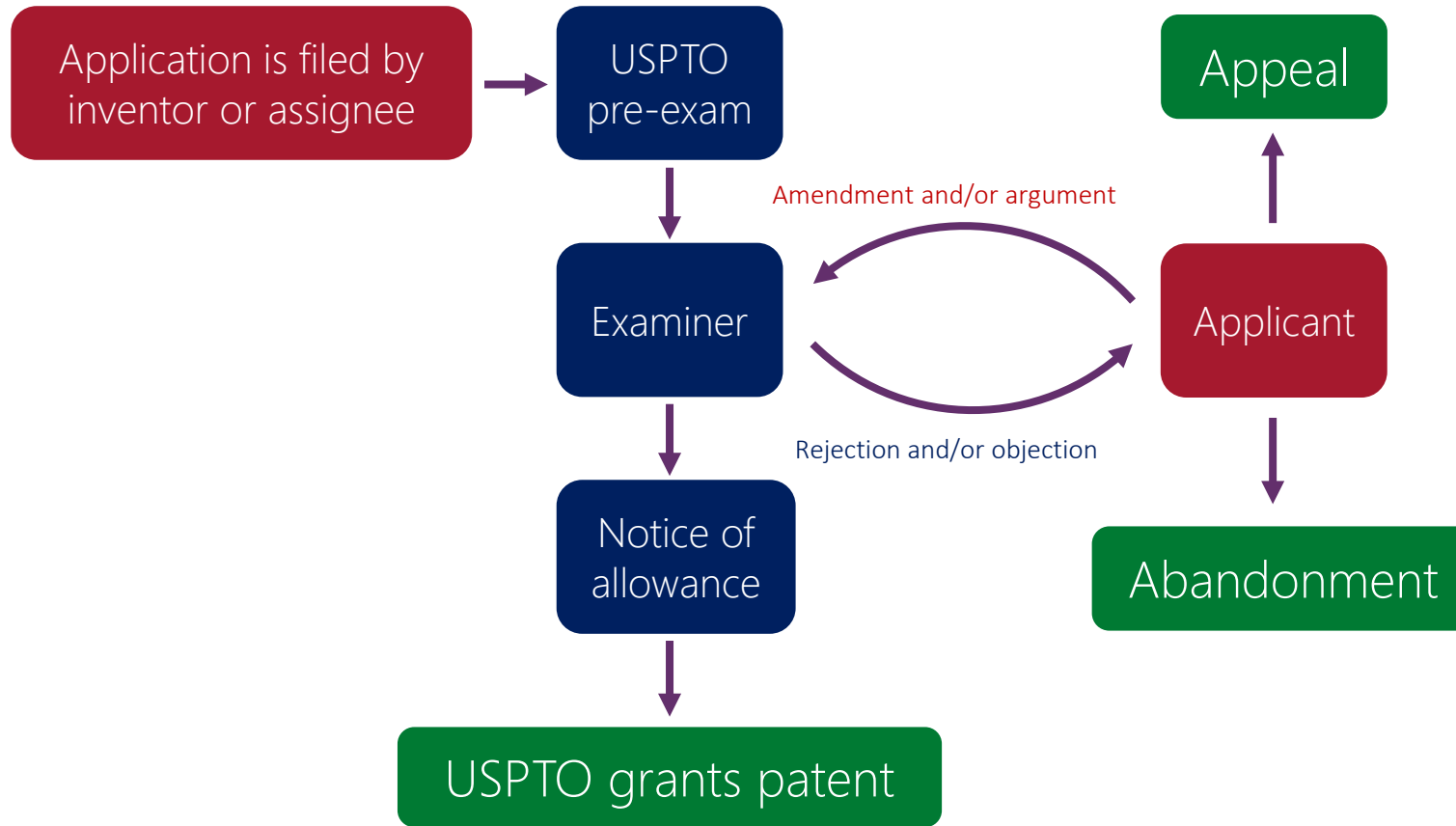
U.S. Patent No. 9,974,789 to Marugan et al.

Claim Scope

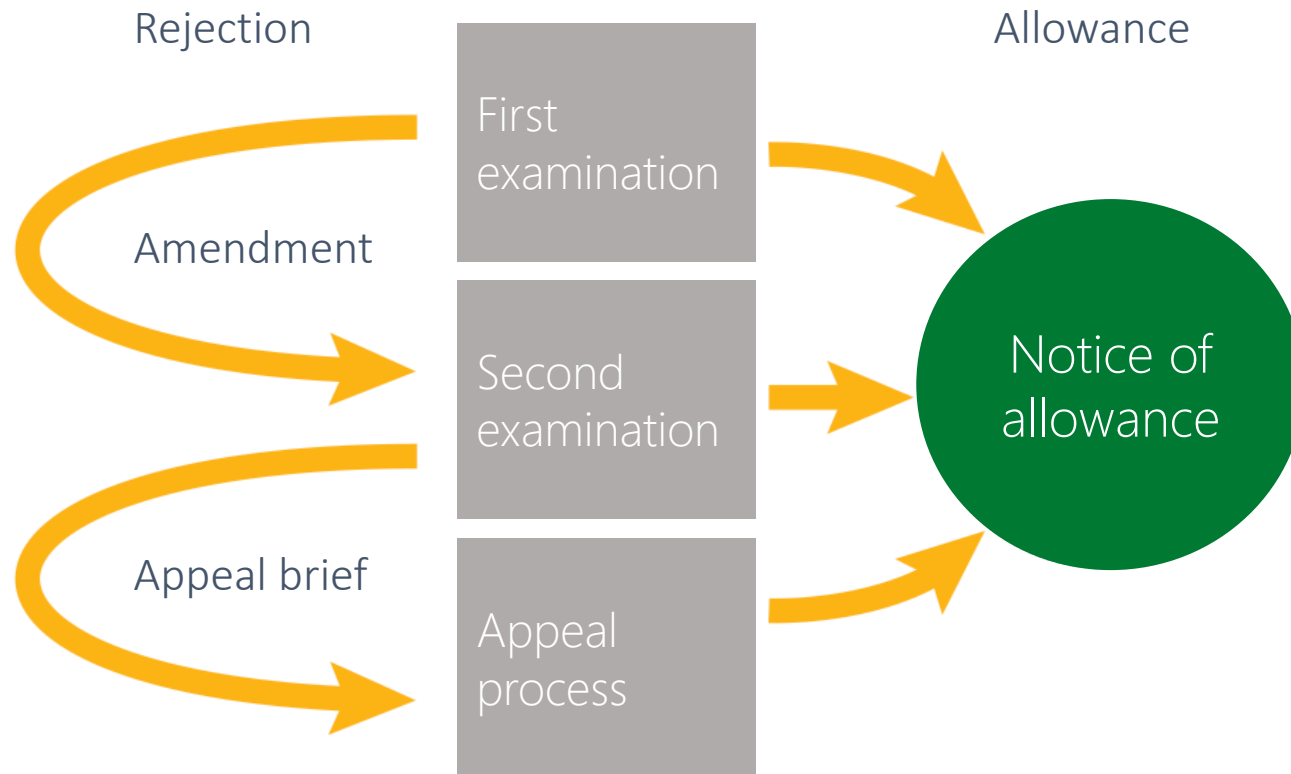
What information should a patent application claim?



Patent Examination



The Examination Process



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

35 U.S.C. 101: requirements

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

Utility patent application guide	www.uspto.gov/patents/resources/types/utility.jsp
Patent process	www.uspto.gov/patents/process
Patent search guide	www.uspto.gov/patents/process/search
IP awareness assessment tool	www.uspto.gov/inventors/assessment
Inventor and entrepreneur resources	www.uspto.gov/inventors
Pro se assistance	www.uspto.gov/ProSePatents
Micro entity limit	www.uspto.gov/PatentMicroentity
Patent pro bono help and video	www.uspto.gov/inventors/proseprobono
First inventor to file	www.uspto.gov/aia_implementation/patents.jsp#heading-10
Law school clinic program	www.uspto.gov/LawSchoolClinic

Manual of Patent Examining Procedures (MPEP)

Summary of Changes
Title Page
Foreword
Introduction
Chapter 100 - Secrecy, Access, National Security, and Foreign Filing
Chapter 200 - Types, Cross-Noting, and Status of Application
Chapter 300 - Ownership and Assignment
Chapter 400 - Representative of Applicant or Owner
Chapter 500 - Receipt and Handling of Mail and Papers
Chapter 600 - Parts, Form, and Content of Application
Chapter 700 - Examination of Applications
Chapter 800 - Restriction in Applications Filed Under 35 U.S.C. 111; Double Patenting

Manual of Patent Examining Procedure (MPEP)

Ninth Edition, March 2014

The USPTO continues to offer an online discussion tool for commenting on selected chapters of the Manual. To participate in the discussion and to contribute your ideas go to: <http://uspto-mpep.ideascale.com>.

Note: [For current fees, refer to the Current USPTO Fee Schedule.](#)

[Consolidated Laws](#) - The patent laws in effect as of May 15, 2014.

[Consolidated Rules](#) - The patent rules in effect as of May 15, 2014.

[MPEP Archives \(1948 - 2012\)](#)

Current MPEP:

[Searchable MPEP](#)

- [See the user manual or quick reference guide](#) for help with search features (e.g., default operators, proximity searches, and wild cards) and navigation.

The documents updated in the Ninth Edition of the MPEP, dated March 2014, include changes that became effective in November 2013 or earlier. All of the documents have been updated for the Ninth Edition except Chapters 800, 900, 1000, 1300, 1700, 1800, 1900, 2000, 2300, 2400, 2500, and Appendix P. More information about the changes and updates is available from the "Blue Page - Introduction" of the Searchable MPEP or from the "Summary of Changes" link to the HTML and PDF versions provided below.

<http://www.uspto.gov/web/offices/pac/mpep/index.html>

Patent process overview



- 1 Determine the type of Intellectual Property protection that you need
- 2 Determine if your invention is patentable
- 3 What kind of patent do you need?
- 4 Get ready to apply
- 5 Prepare and submit your initial application
- 6 Work with your examiner
- 7 Receive your approval
- 8 Maintain your patent

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](#)

Contact Patents



Provides contact information for all stages of the patent process including the Patent Electronic Business Center, the Inventors Assistance Center, Office of Patent Legal...

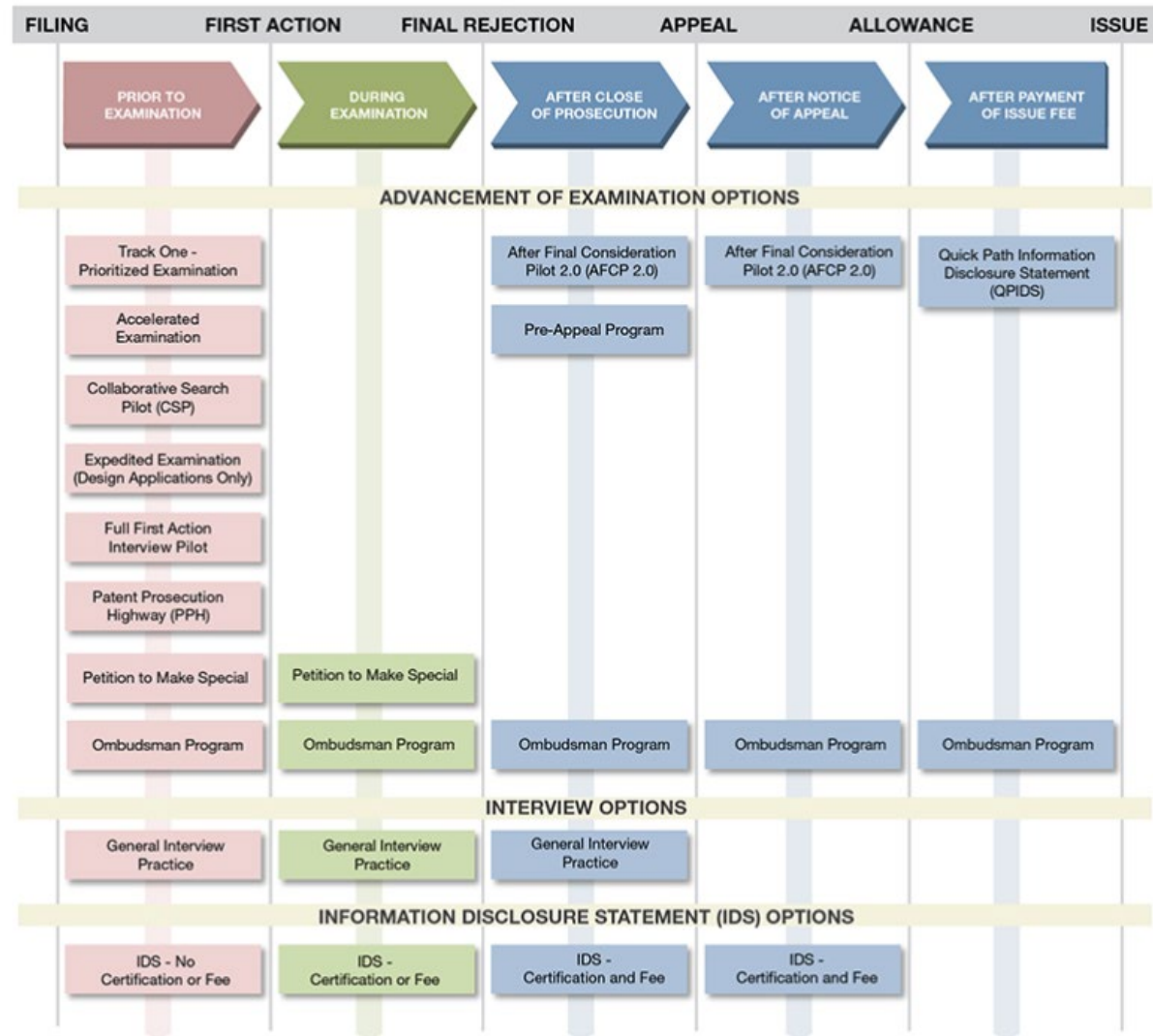
Step 2

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>



May 2019 Patents Data, at a Glance

In response to public comment, we have redesigned the Patents Data Visualization Center. We hope you find the Dashboard useful. If you have any questions, comments, or feedback, please [click here](#) to send an e-mail to the Dashboard administrator.



Interview


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

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.


- 1 **USPTO AIR**
- 2 TC Interview Specialist
- 3 Video Conference
- 4 Policy and Guidance
- 5 Training and FAQs
- 6 Federal Register Notice
- 7 Contact Us

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

Automated Interview Request Form (04-18)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

* 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.

* I 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/>

The screenshot shows the homepage of the IP Awareness Assessment Tool. At the top, there is a navigation bar with the text "ipAwarenessAssessment" in a stylized font, "Beta II" in a blue box, and logos for "uspto" and "NIST". Below the navigation bar, a subtitle reads "A business and inventors IP evaluation tool".

The main content area is divided into several sections:

- IP Awareness Assessment:** A blue box containing text about the tool's development by the USPTO and NIST, and a link to "Learn more".
- Feedback:** A grey box encouraging users to provide feedback to improve the tool.
- Inventor Assistance Program:** A blue header for a section that is partially obscured.
- Important Notice:** A grey box with a warning that the tool is not legal advice and that users should seek professional assistance for legal matters.
- Welcome:** A text block introducing the tool and listing five general categories: IP Strategies & Best Practices, International IP Rights, IP Asset Tracking, Licensing Technology to Others, and Using Technology of Others.
- Additional Categories:** A text block listing five more categories: Copyrights, Design Patents, Trademarks, Trade Secrets, and Utility Patents.
- Assessment Details:** Text explaining that not all businesses have all categories and that the full assessment takes 20-30 minutes, which can be reduced to 10-15 minutes with a pre-assessment.
- Call to Action:** A large blue button with a double arrow icon and the text "enter the IP Awareness Assessment".
- Before starting the assessment, please note:** A list of instructions for users, including saving the link, browser settings, and data handling.

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](https://www.facebook.com/uspto.gov)

[http://www.youtube.com/user/USPTO
Ovideo/](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:

<https://bit.ly/2LoN6dl>

Thank You!