Essential information for nonprofits navigating COVID-19

pittsburghfoundation.org/covidwebinar
TRADEMARK OFFICE DEADLINE EXTENSIONS

US Patent and Trademark Office

www.uspto.gov/trademarklaws-regulations/cares-act-faqs

- Offices are closed to the public until further notice
- Deadlines falling between March 27, 2020 and April 30, 2020 are extended by 30 days
- In person meetings take place remotely by video or telephone
- USPTO has also waived:
  - Original handwritten signature requirements
  - Petition fees in certain circumstances for those affected by the Coronavirus outbreak
TRADEMARK MODERNIZATION ACT OF 2020
Introduced on March 11, 2020

- Restores presumption of irreparable harm
- Section 16A “expungement” proceeding
- Section 16B reexamination proceeding
TRADE SECRET CONSIDERATIONS

• What is a trade secret?

• BROADLY DEFINED

  • “all forms and types of financial, business, scientific, technical, economic, or engineering information…whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing”
EXAMPLES

- Business information
  - Vendor/supplier/client lists
- Designs
- Methods/processes/formulae
- Algorithms
- Financial information
- Marketing information
• Has to derive independent economic value from not being generally known; and

• Must take *reasonable* measures to keep it a secret
  – Case by case analysis under the circumstances
  – Extent of measures and consistency of following them relevant
REMOTE WORKING CONSIDERATIONS

• Remote working creates additional risk
  • On demand access on multiple devices
  • 3rd party access
    – in the home
    – video calls
  • Improper “destruction”
  • Mobility in economic downturn
BEST PRACTICES

- Educate
- Limit physical access
- Password protections/encryptions
- NDAs
- Investigate tech and limit virtual access
- Onboarding concerns
USPTO/PTAB DEADLINE EXTENSIONS

• Extends some deadlines between March 27 and April 30.

• Requires a statement that a missed deadline was “due to the COVID-19 outbreak” (i.e., illnesses, cash flow interruptions).

• Includes responses to office actions, appeal and reply briefs, issue fees, and maintenance fees for small or micro entities.

• Includes requests for rehearing, POPRs and related responsive filings.
FACILITATING INNOVATION TO FIGHT CORONAVIRUS ACT

• There is a proposal to add 10 years of extra patent protection to new and existing medical devices and drugs used to treat COVID-19.

• Under the bill, patents aimed at treating COVID-19 wouldn’t become effective until the national emergency is called off and 10 years would be added on to the ordinary patent term.

• There have also been suggestions for an accelerated examination procedure.
COVID-19 PATENT SEIZURES

• Members of Congress wrote to the President in February urging him to "use every tool of the federal government to ensure a coronavirus vaccine is affordable and accessible."

• Possibility of using “march-in” rights for inventions created with the help of Federal funding, under the Bayh-Dole Act.

• Mechanism has not been used before.
COVID-19 PATENT SEIZURES

• Section 1498 would allow the government to make or use any invention without the patentee’s permission if it gives the owner "reasonable" compensation.

• Used in the 1960s to obtain an antibiotic from a generic supplier in Italy that charged much less than branded version.

• There were discussions of invoking the section to obtain cheaper versions of Cipro during the 2001 anthrax scare.
VACCINE DEVELOPMENT AND APPROVAL

The Phases of Vaccine Development

- EXPLORATORY
- PRE-CLINICAL
- CLINICAL DEVELOPMENT
- REGULATORY REVIEW & APPROVAL
- MANUFACTURING
- QUALITY CONTROL
How a new vaccine is developed, approved and manufactured

The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Researchers test vaccines with adults first.

**PHASE 1**
- **20-100 healthy volunteers**
  - Is this vaccine safe?
  - Does this vaccine seem to work?
  - Are there any serious side effects?
  - How is the size of the dose related to side effects?

**PHASE 2**
- **Several hundred volunteers**
  - What are the most common short-term side effects?
  - How are the volunteers’ immune systems responding to the vaccine?

**PHASE 3**
- **Hundreds or thousands of volunteers**
  - How do people who get the vaccine and people who do not get the vaccine compare?
  - Is the vaccine safe?
  - Is the vaccine effective?
  - What are the most common side effects?

FDA licenses the vaccine only if:
- It's safe and effective
- Benefits outweigh risks

Vaccines are made in batches called lots.

Manufacturers must test all lots to make sure they are safe, pure and potent. The lots can only be released once FDA reviews their safety and quality.

The FDA inspects manufacturing facilities regularly to ensure quality and safety.
FDA APPROVAL

• The FDA’s Center for Biologics Evaluation and Research ("CBER") is responsible for regulating vaccines.
• The approval process is multi-step.
• Parties have to submit a Biologics License Application (BLA) and have to undergo clinical testing.
A BRIEF PRIMER ON SARS-COV

The spike protein of SARS-CoV — a target for vaccine and therapeutic development
WHERE ARE WE IN VACCINE DEVELOPMENT?

• **What sort of efforts are underway?**

  • More than 60 candidate vaccines are in development, worldwide, and several have entered early clinical trials in human volunteers. See [https://www.who.int/blueprint/priority-diseases/key-action/Novel-Coronavirus_Landscape_nCoV-4april2020.pdf?ua=1](https://www.who.int/blueprint/priority-diseases/key-action/Novel-Coronavirus_Landscape_nCoV-4april2020.pdf?ua=1)

  • NIH has partnered with 16 drug companies in hopes of accelerating Covid-19 treatments and vaccines.

    – The partnership, to be known as “Accelerating Covid-19 Therapeutic Interventions and Vaccines” (ACTIV), is meant to standardize research between the federally funded researchers and a broad array of drug companies, and prioritize research into drugs and vaccines that are having high near-term potential.
WHERE ARE WE IN VACCINE DEVELOPMENT?

• What types of vaccines are being developed?

  whole virus vaccines
  – weakened or dead forms of the virus that causes the disease

  antibody vaccines
  – uses antibodies from laboratory mice and recovered patients (passive immunity)

  recombinant protein subunit vaccines
  – recombinant protein subunit of the spike protein to deliver immunity

  nucleic acid vaccines
  – using nucleic acids such as DNA or RNA to deliver immunity
WHERE ARE WE IN VACCINE DEVELOPMENT?

• Will we have a COVID-19 vaccine by summer 2021?
  o Possibly. But this is a very short timeline.
  o It can cost between $1 and $2 billion to produce a vaccine, and between 8 and 16 years before they can make it to the market.
  o Governments are stepping up to help facilitate this. For example, the U.S. government recently gave vaccine developer Moderna a $483 million grant to offset testing and help scale up the company’s production of the mRNA vaccine currently in early human testing.
IN THE MEANWHILE …. ANTIVIRALS ARE BEING DEVELOPED

• More than 150 different drugs are being researched around the world. Most are existing drugs that are being trialled against the virus.
  – **Examples:**
    - Remdesivir (GS-5734) by Gilead Sciences
    - Actemra by Roche
    - Galidesivir by Biocryst Pharma

• The FDA approved limited emergency use for chloroquine and hydroxychloroquine as a treatment for COVID-19.

• The National Medical Products Administration of China has approved the use of Favilavir, an anti-viral drug, as a treatment for coronavirus.

• Remdesivir is being tested in two phase III randomized clinical trials in Asian countries.
AND WHAT ABOUT THOSE TESTS?

• The Centers of Disease Control and Prevention’s (CDC’s) originally developed a laboratory test kit to detect coronavirus in early February. However, the test returned false positive results. As a result, the FDA issued Emergency Use Authorizations (EUAs) for private labs and hospitals to develop their own coronavirus PCR tests.

• As of Wednesday, April 22, 2020, EUAs have been granted for 43 different tests. An up-to-date list can be found at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd
Get agenda updates here:

pittsburghfoundation.org/covidwebinar