Essential information for nonprofits navigating COVID-19

pittsburghfoundation.org/covidwebinar

STAYING IN THE KNOW: IP CONSIDERATIONS DURING THE COVID CRISIS

March 23, 2020

Meredith M. Wilkes &
Patricia Campbell, PhD

TRADEMARK & TRADE SECRET CONSIDERATIONS

Meredith M. Wilkes
mwilkes@jonesday.com

TRADEMARK OFFICE DEADLINE EXTENSIONS

US Patent and Trademark Office

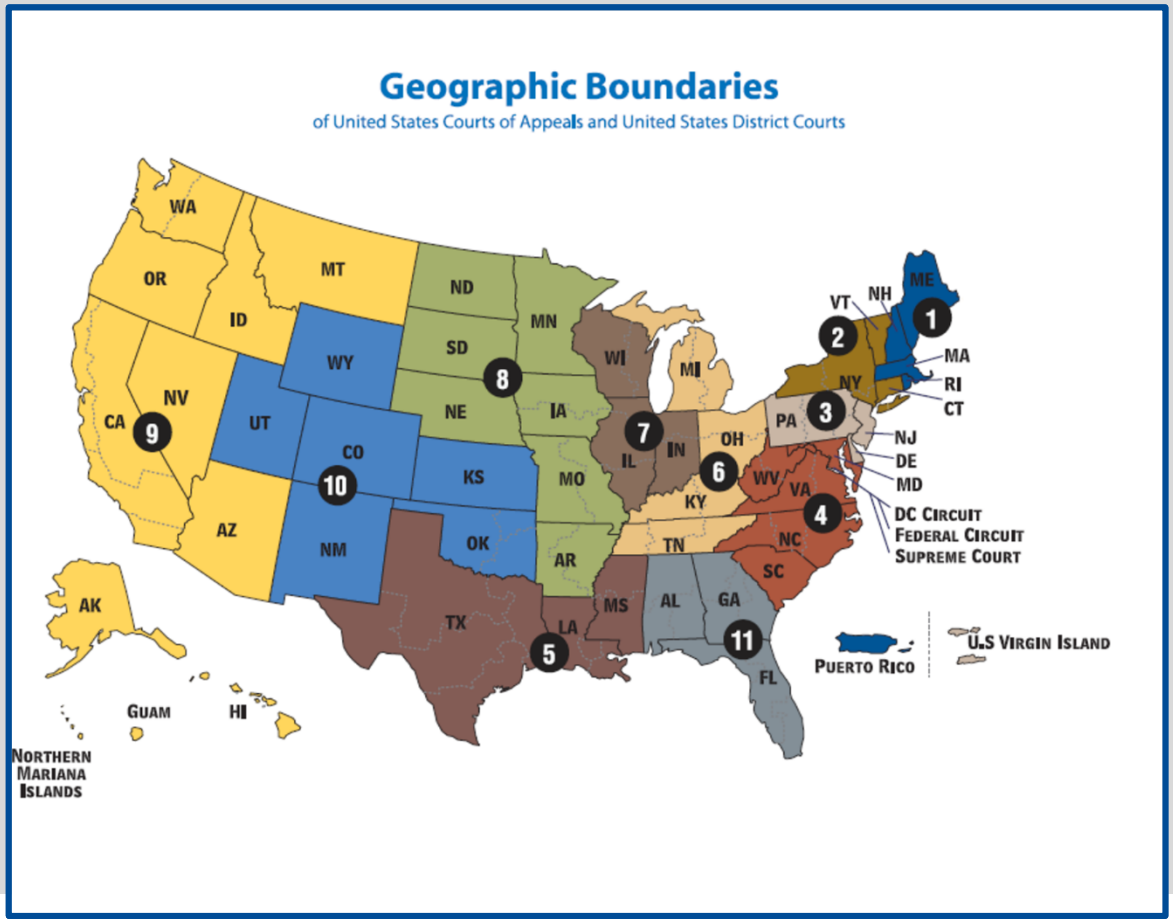
www.uspto.gov/trademarklaws-regulations/cares-act-faqs

- 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

Relief Available to Patent and Trademark Applicants, Patentees and Trademark Owners Affected by the Coronavirus Outbreak

The United States Patent and Trademark Office (USPTO) considers the effects of the Coronavirus outbreak that began in approximately January 2020 to be an "extraordinary situation" within the meaning of 37 CFR 1.183 and 37 CFR 2.146 for affected patent and trademark applicants, patentees, reexamination parties, and trademark owners.

JONES DAY


Geographic Boundaries
of United States Courts of Appeals and United States District Courts
WA
OR
CA
ID
NV
MT
WY
UT
AZ
CO
NM
ND
SD
NE
KS
OK
MN
IA
MO
AR
TX
WI
IL
MI
IN
OH
KY
TN
MS
AL
GA
FL
LA
SC
NC
VA
WV
PA
NY
VT
NH
ME
MA
RI
CT
NJ
DE
MD
DC Circuit
Federal Circuit
Supreme Court
1
2
3
4
5
6
7
8
9
10
11
AK
HI
Guam
Northern Mariana Islands
Puerto Rico
U.S Virgin Island

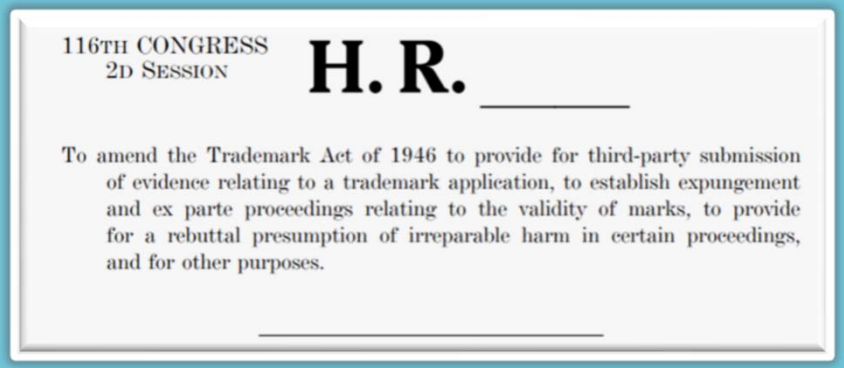
TRADEMARK MODERNIZATION ACT OF 2020

Introduced on March 11, 2020

-Restores presumption of irreparable harm

-Section 16A "expungement" proceeding

-Section 16B reexamination proceeding



116TH CONGRESS
2D SESSION

H. R. _____

To amend the Trademark Act of 1946 to provide for third-party submission of evidence relating to a trademark application, to establish expungement and ex parte proceedings relating to the validity of marks, to provide for a rebuttal presumption of irreparable harm in certain proceedings, and for other purposes.

_____

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

REQUIREMENTS

- 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

PATENTS, VACCINE DEVELOPMENT AND FDA APPROVAL

Patricia Campbell
pcampbell@jonesday.com

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

(1) Relief in patent application and reexamination proceedings

(a) The due date for any:

i. reply to an Office notice issued during pre-examination processing[1] by a small or micro entity;
ii. reply to an Office notice or action issued during examination[2] or patent publication processing;[3]
iii. issue fee;
iv. notice of appeal under 35 U.S.C. § 134 and 37 C.F.R. § 41.31;
v. appeal brief under 37 C.F.R. § 41.37;
vi. reply brief under 37 C.F.R. § 41.41;
vii. appeal forwarding fee under 37 C.F.R. § 41.45;
viii. request for an oral hearing before the Patent Trial and Appeal Board (PTAB) under 37 C.F.R. § 41.47;
ix. response to a substitute examiner’s answer under 37 C.F.R. § 41.50(a)(2);
x. amendment when reopening prosecution in response to, or request for rehearing of, a PTAB decision designated as including a new ground of rejection under 37 C.F.R. § 41.50(b);
xi. maintenance fee, filed by a small or micro entity; or
xii. request for rehearing of a PTAB decision under 37 C.F.R. § 41.52

JONES DAY

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.

JONES DAY

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.

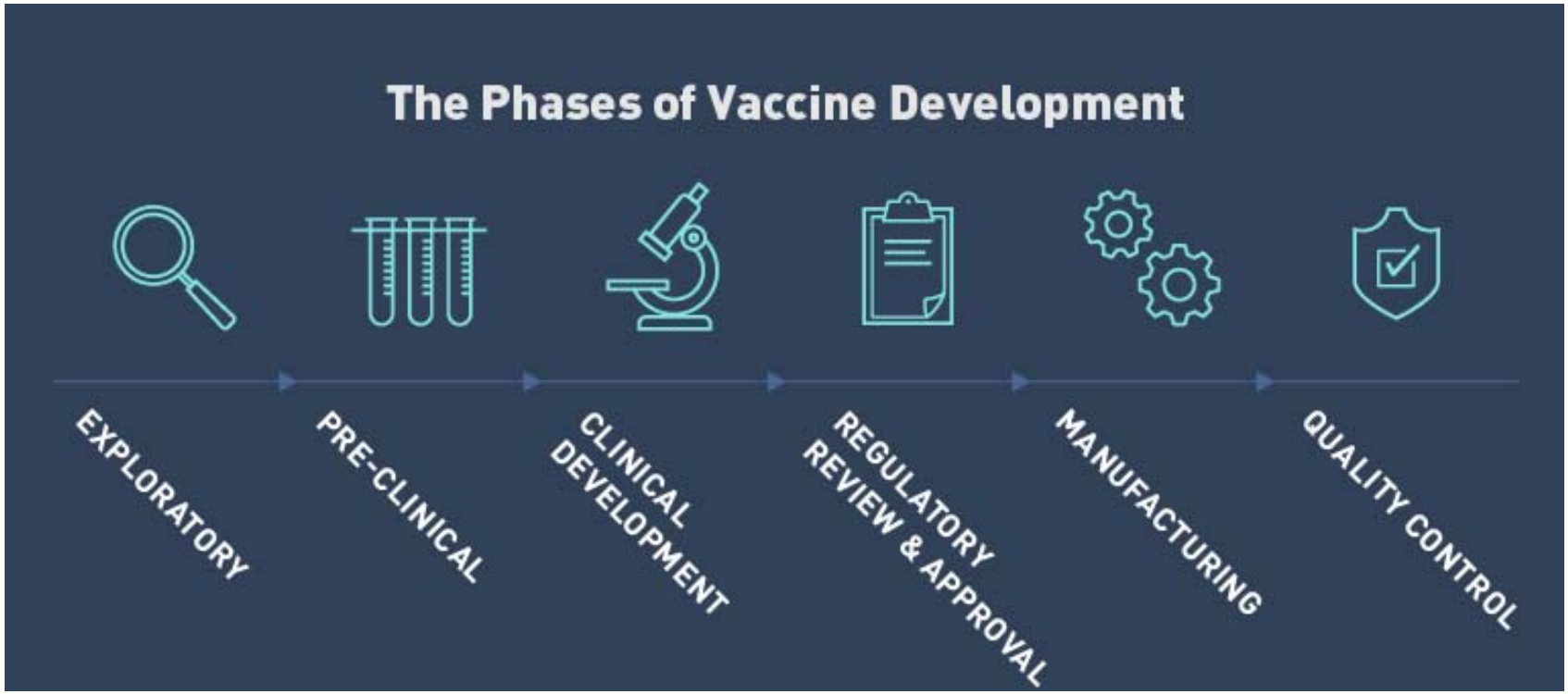
JONES DAY

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.

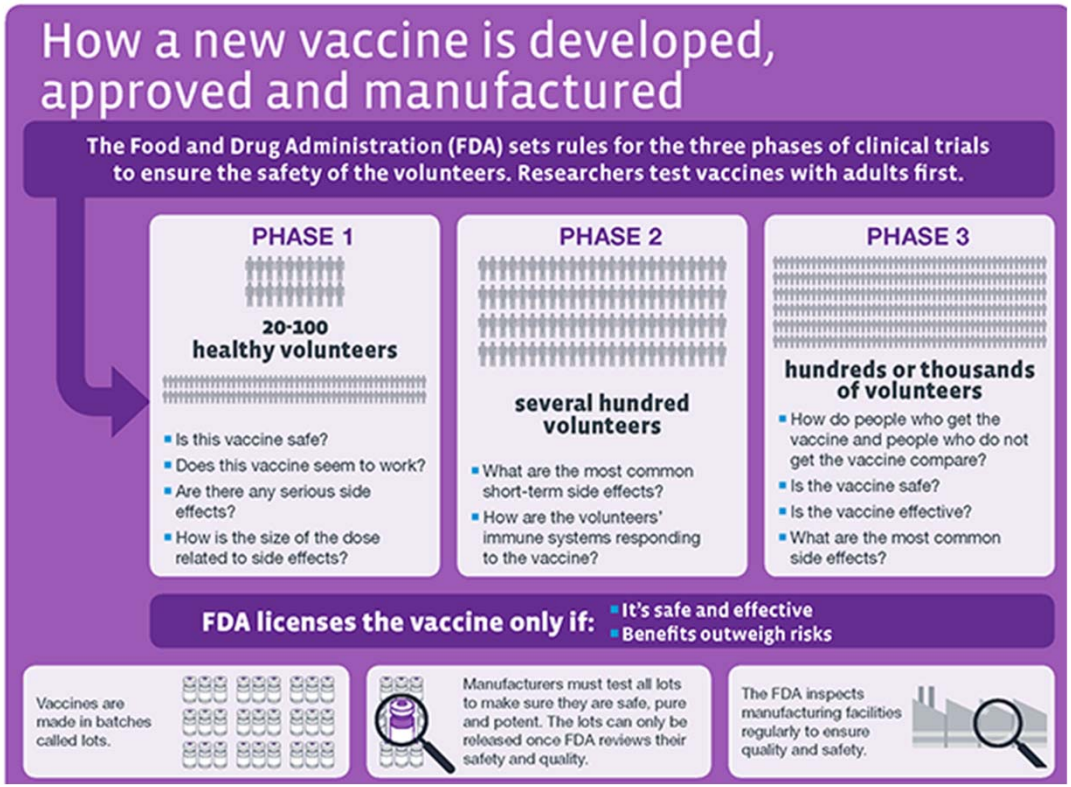
JONES DAY

VACCINE DEVELOPMENT AND APPROVAL



JONES DAY

CLINICAL TRIALS

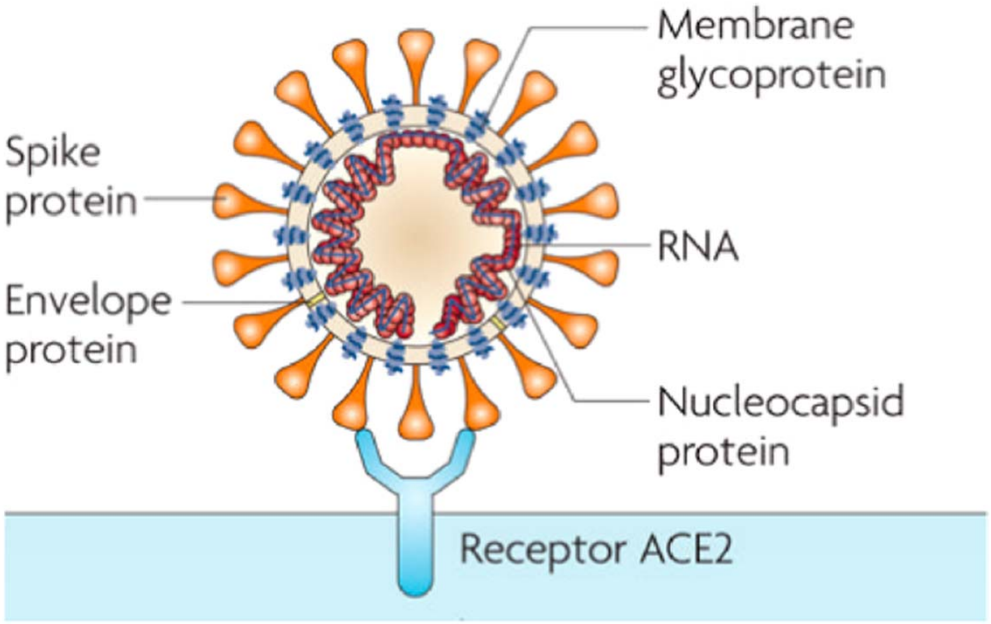


FDA APPROVAL

- 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.

JONES DAY

A BRIEF PRIMER ON SARS-COV



The spike protein of SARS-CoV — a target for vaccine and therapeutic development
Du *et al.* (2009) Nature Reviews Microbiology, vol. 7, pages 226-229

JONES DAY

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
  - 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.

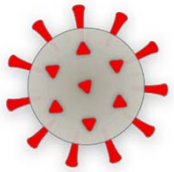
World Health Organization

NIH National Institutes of Health

JONES DAY

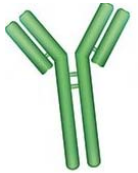
WHERE ARE WE IN VACCINE DEVELOPMENT?

- **What types of vaccines are being developed?**



whole virus vaccines

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

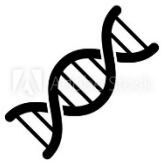


antibody vaccines

– 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

JONES DAY

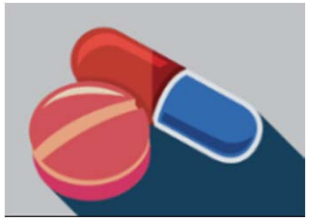
WHERE ARE WE IN VACCINE DEVELOPMENT?

- **Will we have a COVID-19 vaccine by summer 2021?**
  - Possibly. But this is a very short timeline.
  - 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.
  - 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.

JONES DAY

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.

JONES DAY

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

JONES DAY

THE PITTSBURGH FOUNDATION | 75 YEARS

Get agenda updates here:

pittsburghfoundation.org/covidwebinar