



# Patents and COVID-19: Facts and Guidance from the NYIPLA

## **Panelists:**

**Lynn Russo, Michael Johnson, Colman Ragan, Dorothy Auth**

**Moderator: Lynn Russo**

# Introduction

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- ▶ The COVID-19 pandemic has changed the world in numerous ways
- ▶ There is a scramble to find testing, treatments and cures
- ▶ Lawmakers and others are seeking solutions that may impact the patent system
- ▶ This webinar will discuss:
  - ▶ Unlicensed Use of Patented Technologies
  - ▶ The Bayh-Dole Act and “March-In” Rights
  - ▶ Current and Potential Upcoming Legislation
  - ▶ Corporate Action—Pitching In to the COVID-19 Effort

# Topic 1: Unlicensed Use of Patented Technologies and 28 U.S.C. § 1498

Presented by: Lynn Russo, Hughes Hubbard & Reed

## Topic 1: 28 USC § 1498

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- ▶ (a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . .
- ▶ For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States. . . .

# Topic 1: Issues Relating to Section 1498

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- ▶ Is an action in the Court of Federal Claims the sole and exclusive remedy available to a patentee?
- ▶ Where a private contractor makes or provides the patented invention for the US government, is that contractor liable for infringement?
- ▶ Is injunctive relief available?

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# Topic 2: The Bayh-Dole Act and “March-In” Rights

Presenter: Michael Johnson, Willkie Farr & Gallagher



## Topic 2: The Bayh-Dole Act - 35 USC § 200 *et seq.* and March-in Rights

- ▶ “Some Members of Congress have raised concerns about whether [the Covid-19] medical countermeasures, if shown to be safe and effective, will be affordable and accessible to the public—especially if federal funds contribute to their development.”
- ▶ The Congressional Research Service (and others) have suggested that the Bayh-Dole Act “would appear to provide a possible basis for the exercise of march-in rights, should the federal agency determine that compulsory licensing is necessary to address public health needs unmet by a federal contractor.”

## Topic 2: The Bayh-Dole Act - 35 USC § 200 *et seq.* and March-in Rights

- ▶ The Bayh-Dole Act applies to inventions that a federal contractor makes during the performance of a funding agreement with a federal agency.
- ▶ Under Bayh-Dole, the federal contractor may elect to retain the patent rights for a federally funded invention.
- ▶ In exchange, the contractor provides the federal agency with a government-use license, and the United States retains the authority to grant compulsory licenses to third parties in certain circumstances (“march-in rights”).

## Topic 2: The Bayh-Dole Act - 35 USC § 200 *et seq.* and March-in Rights

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- ▶ Specifically, the federal agency that provided the funding may require the federal contractor to grant a patent license to a third party if the agency determines that either:
  - ▶ (2) action is necessary to alleviate ***health or safety needs*** which are not reasonably satisfied by the contractor, assignee, or their licensees;

## Topic 2: The Bayh-Dole Act - 35 USC § 200 *et seq.* and March-in Rights

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- ▶ Bayh-Dole only applies if the invention was made based on a federally-funded grant.
- ▶ New research sponsored by the government would fall under Bayh-Dole, but when will this result in new countermeasures?
- ▶ Older research, if federally funded, may be subject to march-in rights given the current pandemic?
- ▶ Is cost a sufficient justification to invoke the march-in rights?
- ▶ To date, the federal government has never exercised its march-in rights.
  - ▶ Advocacy groups have petitioned the NIH several times to exercise march-in rights based on the high prices of certain drugs developed with federal funding, such as treatments for HIV/AIDS.

# Topic 3: Congressional Actions: Current and Upcoming Legislation

Presenter: Colman Ragan, President-elect, NYIPLA

## Topic 3: U.S. Legislative Responses to COVID-19 epidemic

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- ▶ **Defense Production Act (DPA) of 1950** (invoked Mar. 18, 2020; Executive Order)
  - Executive may require contractors to perform but does not create compulsory license
- ▶ **CARES Act** (signed into law Mar. 27, 2020)
  - § 12004 gives the United States Patent & Trademark Office (USPTO) emergency powers to waive or change patent and trademark filing deadlines.

## Topic 3: Legislative Actions—Other Avenues Congress May Explore

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- ▶ **S. 1416, Affordable Prescriptions for Patients Act (Sens. Cornyn (R-TX) and Blumenthal (D-CT))**
  - ▶ <https://www.congress.gov/bill/116th-congress/senate-bill/1416>
  
- ▶ **S. 1617, The Second Look at Drug Patents Act (Sens. Cornyn (R-TX) and Murray (D-WA))**
  - ▶ <https://www.congress.gov/bill/116th-congress/senate-bill/1617>
  
- ▶ **H.R. 3199, TERM Act, (Reps. Jeffries (D-NY) and Collins (R-GA))**
  - ▶ <https://www.congress.gov/bill/116th-congress/house-bill/3199>

## Topic 3: Legislative Actions—Other Avenues Congress May Explore

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- ▶ **S. [Unknown] – (Sen. Sasse (R-NEB))**
  - ▶ Senator Ben Sasse of Nebraska has written (but not introduced) proposed legislation that would alter the patent term for COVID-19 related inventions and limit liability for the use by health care providers.
  
- ▶ **Others**
  - ▶ Representative Jan Schakowsky of the 9<sup>th</sup> District of Illinois issued a statement outlining concepts including “no-exclusivity” for COVID-19 related therapeutics
  - ▶ <https://schakowsky.house.gov/media/press-releases/congressional-progressive-leaders-announce-principles-covid-19-drug-pricing>



## TOPIC 4: Corporate Action—Pitching In to the COVID-19 Effort

Presenter: Dorothy Auth, Cadwalader, Wickersham & Taft

# Topic 4: Corporate Actions in View of COVID-19

## Public Accessibility to IP Protected Technologies

- ▶ **AbbVie**
  - Evaluated HIV drug, Kaletra for treatment of COVID-19
  - Suspended enforcement of global patent rights after Israel imposed compulsory access.
- ▶ **Medtronic**
  - To publicly share its proprietary design specifications for the PB560 ventilator to allow rapid manufacturing of ventilators in response to COVID-19 -- as limited “permissive license”
- ▶ **3M**
  - Filed trademark lawsuits over COVID-19 N95 mask price-gouging in New York, California, Florida & Texas, separately accusing several companies (e.g., Performance Supply LLC and Rx2Live LLC) misuse of the 3M trademark to mislead buyers into thinking the companies were authorized by 3M.
  - 3M was granted a temporary restraining order in the NY district court case barring Performance Supply LLC from misleading behavior
- ▶ **Gilead**
  - Remdesivir, used in early CN study, then patented by Wuhan Inst. and also Gilead
  - Received FDA orphan drug status (7-yr exclusivity)
    - Reversed course requesting cancelation of its orphan drug status after public backlash
    - Now committed to donating 1.5 million doses
- ▶ **Labrador Diagnostics LLC** (a Softbank company)
  - Filed a patent action against BioFire Diagnostics, a health start-up who launched COVID-19 diagnostic tests
    - reversed course after public backlash allowing third party use for COVID-19 tests with a royalty-free license
- ▶ **Pfizer, Novo Nordisk, Merck & Co., Eli Lilly and Bristol Myers Squibb**
  - Expanding patient assistance programs, allowing eligible patients to obtain medicines at no cost, such as those who lost their jobs & insurance due to COVID-19

# Topic 4: Corporate Actions in View of COVID-19

## Public Accessibility to Off-Patent Technologies

### ▶ **Bayer**

- Donating 3 million tablets of the malaria drug chloroquine as a potential COVID-19 treatment to U.S. hospitals

### ▶ **Teva**

- Donating 10 million doses of another malaria drug hydroxychloroquine sulfate as a potential treatment for COVID-19 to hospitals in the U.S.

### ▶ **Novartis Sandoz**

- Pledged a global donation up to 130 million 200mg doses of generic hydroxychloroquine sulfate for COVID-19 treatment
- Committing \$20 million to Novartis COVID-19 Response Fund, drug discovery collaboration efforts to support clinical trials for existing Novartis medicines and for essential medicines price stability for COVID-19 treatments

### ▶ **Amneal**

- Donated 2 million hydroxychloroquine sulfate tablets to New York and 1 million tablets to Texas
- Pledged to ramp up production & make 20 million tablets of hydroxychloroquine sulfate by mid-April

### ▶ **Sanofi**

- Donating 100 million doses of Plaquenil, an off-patent branded version of hydroxychloroquine, to 50 countries around the world & increasing production capacity by 50%

### ▶ **UCL & Mercedes Benz**

- Used off-patent technology to develop in 10-days an assisted-breathing device for treatment in certain COVID patients. Device facilitates breathing without requiring the invasive ventilator devices (which require intubation and sedation)

## In Closing...

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