Innovation in the Age of COVID-19

April 14, 2020

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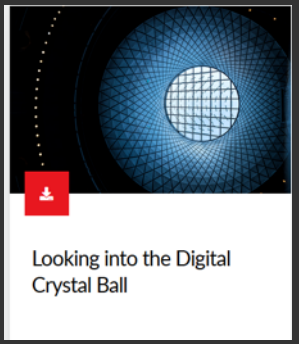

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Speakers

Jeff Blumenfeld
Co-Chair, Antitrust Group
Lowenstein Sadler

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Columbia University

Phil Johnson
Senior VP for IP Policy
Johnson & Johnson (ret.)

David Kappos
Partner, Cravath
Former USPTO Director

Gaby Longsworth
Director
Sterne Kessler

James Mayne
VP of Science Advocacy
PhRMA

Paul Michel
Chief Judge
Federal Circuit (ret.)

Gene Quinn
President & CEO
IPWatchdog, Inc.

Rob Sterne
Founding Director
Sterne Kessler

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For Discussion

In this special, free, two-hour webinar we will seek to remove speculation and lift the veil by discussing what is really transpiring within the Innovation Landscape. We will discuss what universities are doing and how private sector biopharma companies are responding. We will also discuss how this tragic event is leading to a flood of new innovation, and why getting long term public policy right will matter for the next wave, whether that is a resurgence of COVID-19 or for the next pandemic, whatever that may be.

We will specifically address:

- How university labs working with the private sector on a multitude of COVID-19 cures and treatments.
- What it really takes to develop vaccines, drugs, treatments and whether enough incentive and proper incentive exists long term beyond this acute and rapid response to COVID-19.
- The financial investment required and regulatory hurdles to getting a vaccine to market.
- Why the rigidity of antitrust laws are not adopted to address such close collaborations among competitors, and what companies need to know.
- Why there has been a deemphasis on medical diagnostics research in the United States and what Congress, the courts and the USPTO should do.

Columbia Tech Ventures' Experience So Far: Tech Transfer in the Time of COVID

Orin Herskowitz
VP of IP & Tech Transfer
Columbia University

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NYC Hospitals' PPE Crisis → Rapid Response from Universities

March 19, 2020

The New York Times

'At War With No Ammo': Doctors Say Shortage of Protective Gear Is Dire

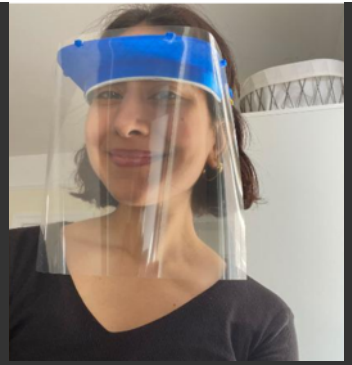
The lack of proper masks, gowns and eye gear is imperiling the ability of medical workers to fight the coronavirus — and putting their own lives at risk.

CNN health • LIVE TV

This librarian is using 3D printing to help protect health care workers in NYC

By Gisela Crespo, CNN

Updated 5:59 PM ET, Tue April 7, 2020



7,500 shields

Columbia Engineers Team Up with Clinicians at Columbia University Irving Medical Center and NewYork-Presbyterian

Engineers design, prototype, scale up, and manufacture thousands of face shields for health care workers in just a week; 1,500,000+ more shields already ordered by NewYork-Presbyterian and others for delivery starting this week

APR 03 2020 | BY HOLLY EVARTS

7 days total for first iteration; 2,000,000+ now in production

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Columbia Launching Other Programs to Identify and Harness New Innovations

COLUMBIA | ENGINEERING

Columbia DIY Ventilator Challenge

COLUMBIA | Zuckerman Institute — Mind. Brain. Behavior.

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APR 8, 2020
8:30 am

SYMPOSIUM

COVID-19 Virtual Symposium: April 8

TELL A FRIEND:

Columbia COVID Tech Innovation Group Interest Form

* Required

What are you interested in *

- [ ] I want to contribute to a group
- [ ] I have a new project idea
- [ ] I want to donate money or supplies
- [ ] Just keep me informed
- [ ] Other:

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CTV Tracking 50+ New COVID Innovations Already! Therapeutics, Diagnostics, Devices, PPE, etc

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COVID-19 Projects at Columbia

Columbia's inventors are finding themselves at the center of the fight against COVID-19. Across the university, researchers are exploring how their expertise can best be applied in creating useful diagnostics, therapeutics, prophylactics, and personal protective equipment. Columbia is seeking partners and resources to accelerate the development of these technologies. To learn more or to get in touch with us about any of the technologies listed below, please email techventures@columbia.edu.

Therapeutics

- **Antiviral Cocktail for COVID-19:** Dr. Stephen Sturley of Columbia's Department of Biology and Dr. Andrew Munkacsi of Victoria University of Wellington are developing an antiviral cocktail that could be used as a treatment and prophylactic to prevent the spread of novel viruses, including COVID-19. This technology inhibits the NPC1 pathway, therefore blocking viral replication by preventing enveloped viruses from disassembling in the lysosomes of infected cells. The antiviral cocktail combines an NPC1 inhibitor and inhibitors targeting genes selected from a list of interacting proteins. Commercially available drugs can be utilized. Sturley is also working with Drs. Szabolcs Marka and Zsuzsa Marka from Columbia's Department of Physics to develop machine-based monitoring of NPC1 pathway engagement to determine if administered therapeutics are having the intended effect.
- **Protease Inhibitors for COVID-19 Treatment:** Given that anti-viral protease inhibitors have served as breakthrough treatments for other viral infections such as HIV, and given that the structure of the SARS-CoV-2 3CL protease has been reported, Drs. Brent Stockwell and David Ho propose that structure-guided discovery, optimization, and development of such protease inhibitors is feasible on a rapid timescale to develop a therapeutic option for treating COVID-19 patients. They are investigating optimization of compounds that already potently inhibit SARS1 and/or SARS2 3CL proteases and a screen of > 3 billion compounds for additional binders using a DNA-encoded library.
- **Monoclonal Antibodies for COVID-19 Treatment:** Dr. David Ho will lead an effort aimed at developing monoclonal antibodies, molecules that can bind to the surface of the coronavirus and neutralize the infectivity of the virus. His team will try to isolate antibodies from blood cells of patients who no longer have the virus and have recovered from 2019-nCoV infection. Then they will engineer the virus-neutralizing antibodies further to optimize their potency against 2019-nCoV. The most promising antibodies will be tested against actual coronavirus in the lab as well as in animal models.
- **Polymerase Inhibitors for COVID-19 Treatment:** A Columbia team led by Drs. Stephen Goff and Yosef Sabo will produce large quantities of polymerase and then screen hundreds of thousands of chemical compounds to identify ones that inhibit the function of the enzyme and thereby block replication of the virus. The most promising ones will again be selected as drug candidates for treatment or prevention of 2019-nCoV.
- **Repurposed Antivirals and Polymerase Inhibitors for COVID-19 Treatment:** A team led by Dr. Jingyue Ju observed that hepatitis C and coronaviruses use a similar mechanism to replicate their RNA. They believe that a currently FDA-approved antiviral drug, sofosbuvir (for hepatitis C), as well as other approved anti-viral agents, AZT (for HIV/AIDS) and tenofovir alafenamide (for HIV and hepatitis B), may be effective against SARS-CoV-2. They have shown that these drugs inhibit the polymerase enzyme of SARS-CoV-2 and thus block its replication. Dr. Ju and his team will utilize their expertise in synthetic chemistry to generate many more such chemical compounds for testing in collaboration with Drs. Ho, Goff, and Sabo. The best chemical compounds that specifically inhibit the SARS-CoV-2 polymerase will be chosen as drug candidates.
- **Protease Inhibitors for COVID-19 Treatment:** A team led by Dr. Alex Chavez is using a new highly multiplexed drug screening approach to rapidly screen a large number of compounds that

Diagnostics

- **Multiplex PCR for differential diagnosis of SARS-CoV-2 and Influenza viruses:** Dr. Ian Lipkin, director of the Center for Infection and Immunity at Columbia's Mailman School of Public Health, is developing a simultaneous and differential diagnosis of SARS-CoV-2, influenza A and influenza B virus with appropriate reaction control using two assays that could be implemented as multiplex PCR assays. The first utilizes several sets of primers to simultaneously detect SARS-CoV-2, influenza A virus, influenza B virus, and a control gene. The second uses several other sets of primers to target three genes in SARS-CoV-2 and a control. This technology may be useful for the differential diagnosis of infections causing symptoms resembling that of SARS-CoV-2. Given the limited testing capabilities in the US and the similar symptomology among viruses causing respiratory illness, it is important to be able to identify those that have already been exposed to the virus. To meet this need, Dr. Lipkin's group is also working on a serological approach to identify a series of epitopes along the COVID-19 proteome that could be used to differentially diagnose historical infection. They have also identified a series of COVID-19 reactive peptides that be used as epitope targets for vaccine development.
- **Deep Learning for Image-based Diagnosis of COVID-19:** Drs. Helen Lu and Shih-Fu Chang of Columbia Engineering are developing a machine-learning-based COVID-19 diagnostic that would require only a microscope and tissue culture followed by software analysis. Currently, the standard method of viral detection for coronavirus is by PCR of patient sputum samples, an approach that can be time-consuming and requires sensitive equipment and expert personnel. Lu and Chang's method would simplify and expedite diagnosis by using light microscopy images of patient sputum smear, which AI would then scan for differences in cell morphology between healthy and infected states. The AI algorithm developed in this project will be deployed as a stand-alone-application or app, bypassing the need for complex imaging tools, delicate sample preparation, and personnel with extensive lab expertise.
- **Portable qPCR Instrument for Ultrafast Diagnosis of COVID-19:** Rover Dx's mission is to productize its ultrafast, portable qPCR platform for massively distributed infectious disease diagnosis. Spun out of Dr. Sam Sia's lab at Columbia University, Rover uses microfluidic technology to automate sample prep, and a novel approach to perform PCR 10x faster than current methods. Its sample-to-answer POC instrument will be portable (< 2 pounds), fast (< 8 minutes), and inexpensive (< $2k). Rover's first product, an ultrafast lab qPCR instrument, has shown 30 thermal cycles in 5 minutes, and is currently being tested on synthetic, then human, COVID-19 samples; results expected April 2020. Rover hopes to advance ultrafast qPCR for COVID-19 system through contract manufacture and FDA EUA before year end 2020 and complete feasibility prototypes of full sample-to-answer ultrafast POC qPCR for COVID-19 system by June 2021.
- **Point-of-Care COVID-19 Diagnosis:** SAFE and Mayo Clinic are developing a Connected Diagnostics and Coordinated Triage Platform that enables remote point of care testing at scale using inexpensive LFIA-based rapid tests. The platform, which also incorporates exclusively licensed software developed by Dr. Sam Sia's lab at Columbia University, enables individuals to self-administer tests at home and scan the results with their mobile phone, keeping infected populations at home and providing unprecedented real-time surveillance. Positive cases are triaged remotely using crowdsourced telehealth providers mobilized through an Uber-like app. Positive cases trigger delivery of a confirmatory PCR test kit that is sent to lab partners including Quest/LabCorp, with results used to inform a remote treatment plan and reported.

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Meanwhile, COVID Innovation is Accelerating Across the Country and Around the Globe

Tech Transfer eNews

Tech transfer news and updates in your inbox every week

This week's top stories:

- Protecting the Bayh-Dole Act in the age of the coronavirus
- Emory U's new antiviral pill targeting COVID-19 heading into clinical trials
- Virtual Engagement Strategies for TTOs: Scaling Up Online Connectivity Now and Building Future Resiliency
- Cornell spinout aims for rapid development of cell-free COVID-19 therapeutics
- Start-up licenses U of Arizona device to help COVID-19 patients breathe easier
- UW-Madison researchers team with vaccine companies to fight COVID-19
- U of Dayton researcher develops diagnostic software to detect COVID-19 in seconds
- Cambridge start-up brings rapid COVID-19 test to hospitals in UK
- Biomerica licenses tech from Mount Sinai to manufacture COVID-19 test
- Purdue aims to fast-track COVID-19 solutions from lab to marketplace
- Boston start-up licenses high-tech "nanoneedle" molecule detection tool from Harvard

- Creative Destruction Lab launches special accelerator program to address COVID-19
- World Benchmark Report 2019/2020: Data, Insights, and Best Practices from Business Incubators and Accelerators
- U of Dundee start-up turns its AI-powered drug development system against COVID-19
- USPTO releases FAQs concerning patent-related extensions due to COVID-19
- UW creates Innovation Roundtable to help guide ecosystem development
- Arch Venture Partners raises $1.5B to support biotech start-ups through "healthcare revolution" accelerated by COVID-19
- Arizona State start-up raises $2.25M for tech that could lead to cancer vaccines

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Many New Roles & Challenges for the TTO

Lots of internal bureaucracy busting

Lots of quick and uncomfortable decisions

Lots of working the “Rolodex”

- **Making super quick go / no-go decisions for development & patenting**
- **Proactively engaging with hospital sourcing managers for input**
- **Screening & negotiating with Contract Manufacturers**
- **Quickly navigating open source & free click-licensing structures**
- **Identifying and learning from regulatory experts**
- **Serving as logistics coordinators for manufacturing & delivery**
- **Brainstorming for inbound industry partnering requests**
- **Coordinating with City / State / Federal COVID task forces**
- **More TBD?**

Unprecedented Proactive Industry Outreach: “How Can We Help?”

All the regular biopharma & device firms, plus…

Jeffrey Blumenfeld

Partner & Co-Chair, Antitrust & Trade Regulation

202.753.3810 I jblumenfeld@lowenstein.com

What role for antitrust?

Jeff Blumenfeld
Co-Chair, Antitrust Group
Lowenstein Sadler

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Antitrust agency guidance

- when firms collaborate on research and development this “efficiency-enhancing integration of economic activity” is typically procompetitive.
- sharing technical know-how, rather than company- specific data about prices, wages, outputs, or costs, may be “necessary to achieve the procompetitive benefits of certain collaborations.”
- will not challenge, absent extraordinary circumstances, providers’ development of suggested practice parameters – standards for patient management developed to assist providers in clinical decision-making – that also may provide useful information to patients, providers, and purchasers
- most joint purchasing arrangements among healthcare providers, such as those designed to increase the efficiency of procurement and reduce transaction costs, do not raise antitrust concerns.
- generally permit private lobbying addressed to the use of federal emergency authority, including private industry meetings with the federal government to discuss strategies on responding to COVID-19, “insofar as those activities comprise[] mere solicitation of governmental action with respect to the passage and enforcement of laws.”

Some useful insights

Lowenstein Sandler Alerts on Antitrust and Coronavirus

COVID-19: The Reaction of U.S. Antitrust Agencies
https://www.lowenstein.com/news-insights/publications/client-alerts/covid-19-the-reaction-of-us-antitrust-agencies-antitrust-trade-regulation

Antitrust Does Not Shelter in Place During a Pandemic
https://www.lowenstein.com/news-insights/publications/client-alerts/antitrust-does-not-shelter-in-place-during-a-pandemic-antitrust

U.S. Antitrust Agencies Resume Early Terminations
https://www.lowenstein.com/news-insights/publications/client-alerts/us-antitrust-agencies-resume-early-terminations-antitrust-trade-regulation

U.S. and European Antitrust Authorities Provide Updated Guidance on Joint Activity During COVID-19
https://www.lowenstein.com/news-insights/publications/client-alerts/us-and-european-antitrust-authorities-provide-updated-guidance-on-joint-activity-during-covid-19-antitrust

Some useful primary source

Expedited process for DOJ and FTC review of Coronavirus-related collaboration

DOJ and FTC joint press release
https://www.justice.gov/opa/pr/justice-department-and-federal-trade-commission-announce-expedited-antitrust-procedure-and

Joint statement of DOJ and FTC with information on DOJ process
https://www.justice.gov/atr/joint-antitrust-statement-regarding-covid-19

Joint statement of DOJ and FTC with information on FTC process
https://www.ftc.gov/system/files/documents/public_statements/1569593/statement_on_coronavirus_ftc-doj_3-24-20.pdf

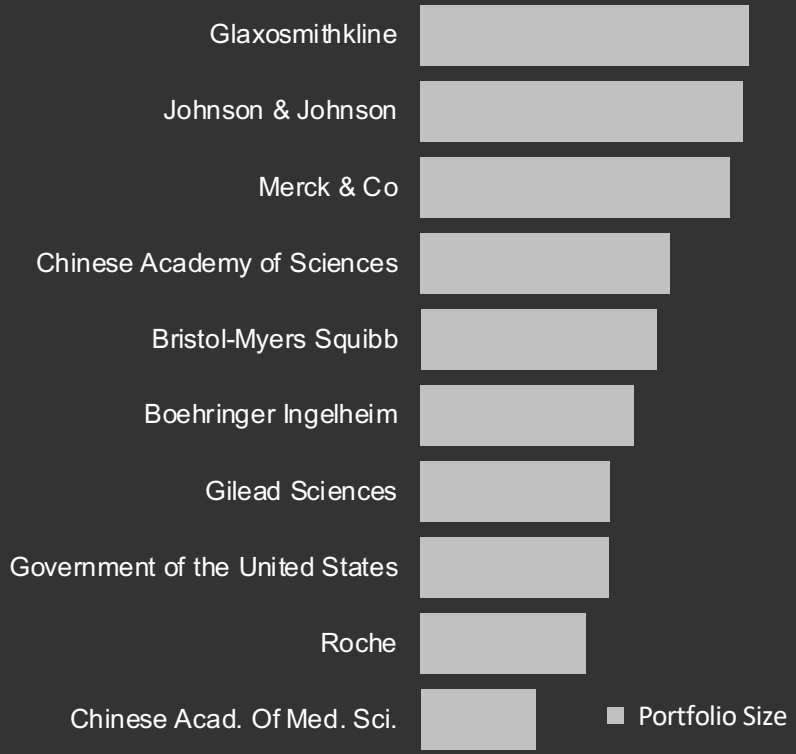
Some useful primary source

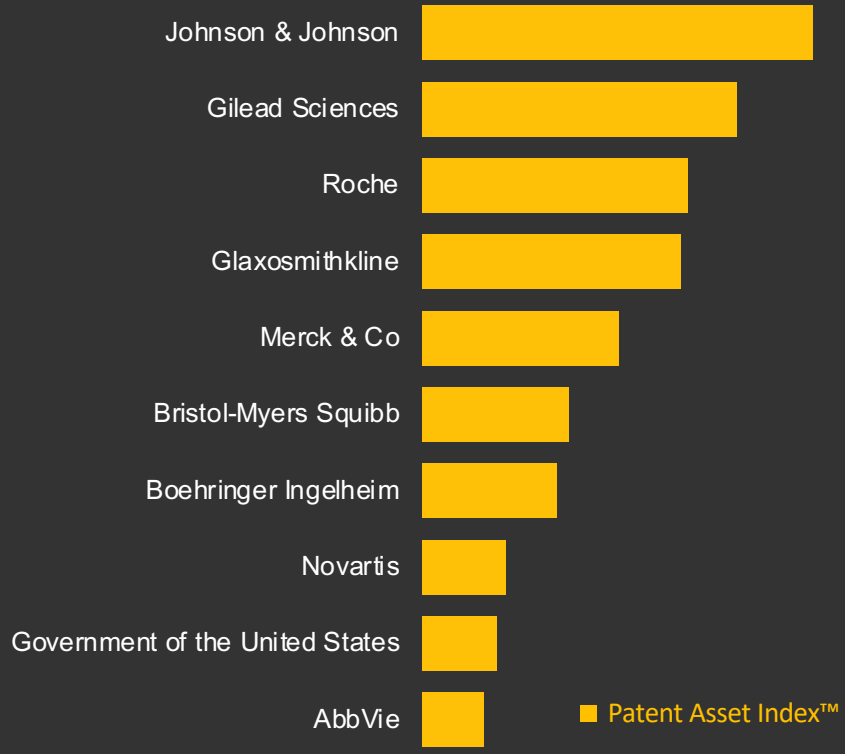
First business review letter issued under DOJ expedited process for review of Coronavirus-related collaboration

DOJ press release
https://www.justice.gov/opa/pr/department-justice-issues-business-review-letter-medical-supplies-distributors-supporting

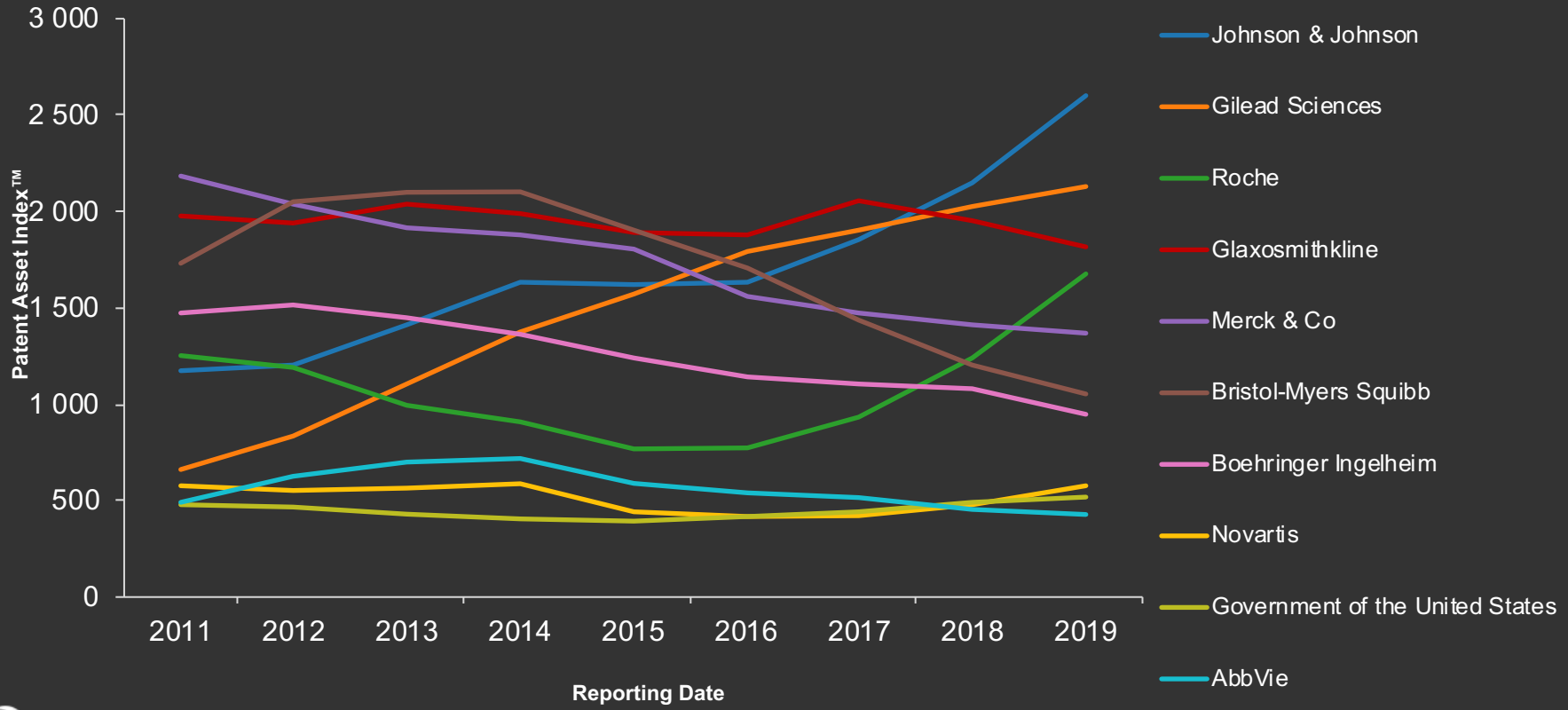
DOJ-issued business review letter
https://www.justice.gov/atr/page/1266511/download

Who are the Top 10 players in antiviral technology field?

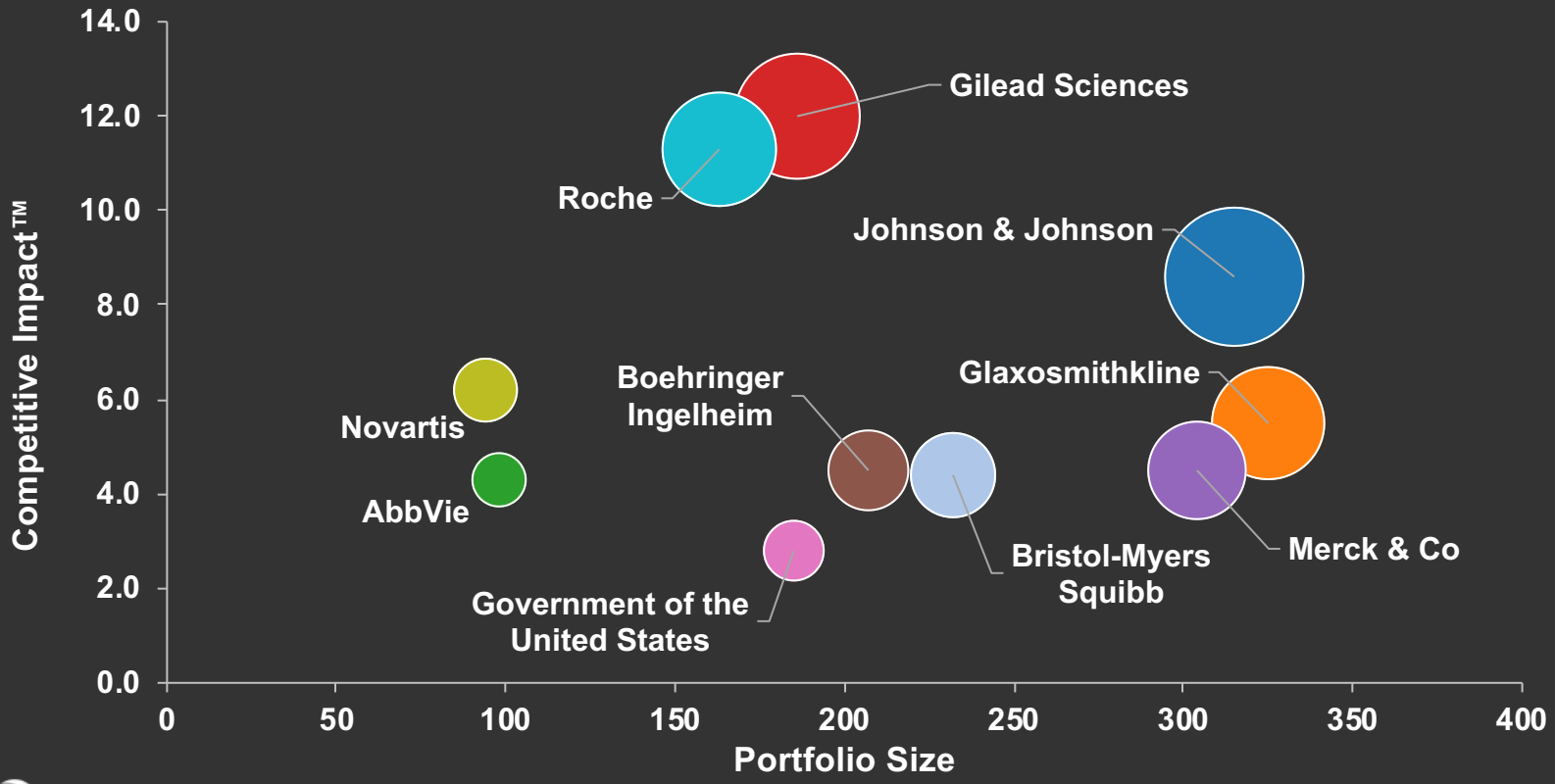




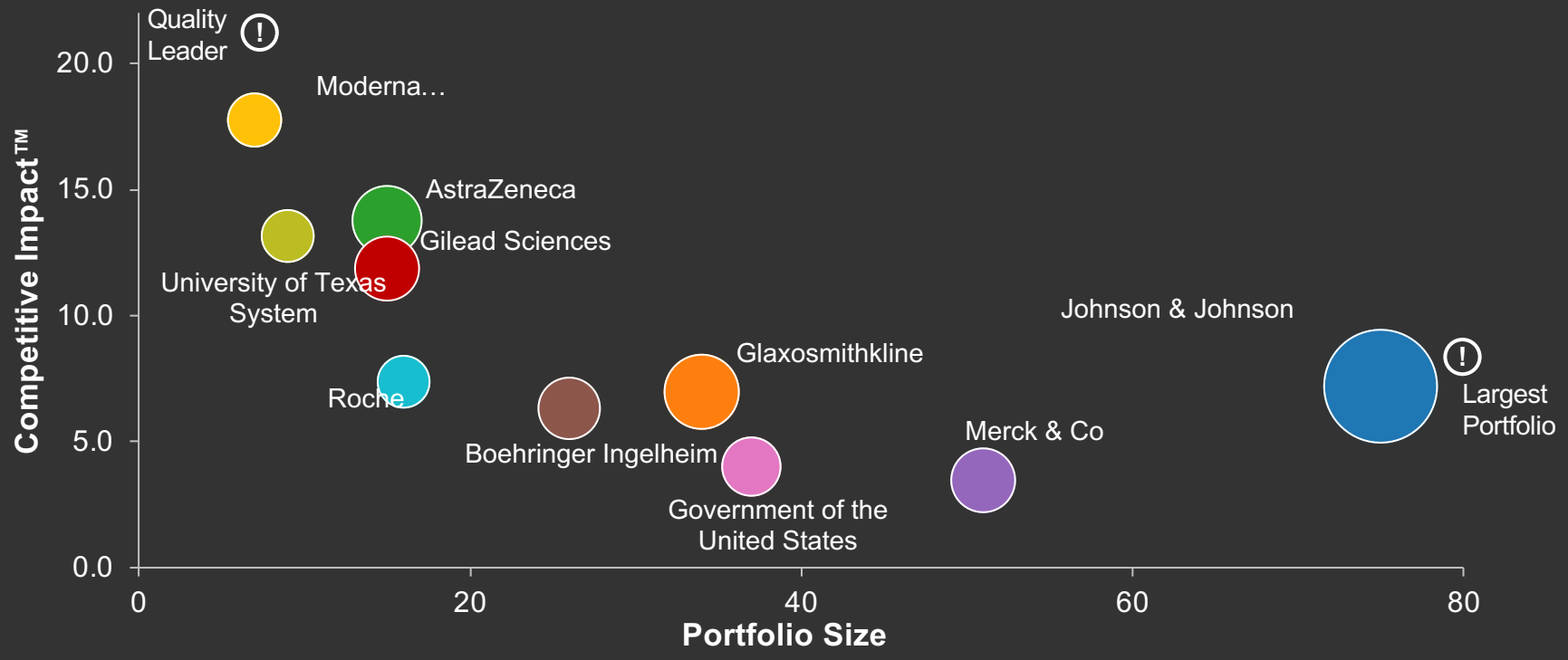
Development of portfolio strength of top 10 players



Strategic Positioning of Top 10 Players



Who has the highest average quality and the largest patent portfolio in the field of anti-corona related viral infection?



What can the USPTO/Congress do to help stakeholders?

Ideas from patent practitioners…

1. Deferment of fees without penalties. NOTE: This could be accomplished by temporarily eliminating Shorten Statutory Periods, thereby making everything due within the 6-month statutory period.

2. COVID-19 related patent application accelerated examination (as Brazil just initiated) or a “COVID Track One” but without fees or Petition to Make Special.

3. Extend statutory deadlines.

4. Extent payment of the issue fee.

5. No reduction in PTA under certain circumstances (i.e., COVID-19 related delay).

6. Eliminate IDS fees.

7. Eliminate fees on petitions to revive if abandonment certified as being related to COVID-19.

8. Coronavirus ombudsman to mediate situations where an applicant and an examiner has reached impasse on patentability of a COVID-19 related invention.

9. Fast track appeal process for COVID-19 inventions.

10. Support US-directed innovation by charging reduced filing fees. (i.e., assessing large entities at the small entity rate and all small entity filing and related fees are assessed at the micro entity rate).

11. Remove or extend one-year conversion for PCT or non provisional filing and 30-month date of national phase entry.

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On the phone:

Chief Judge Paul Michel

Federal Circuit (ret.)
Photo: October 10, 2019 at IPWatchdog® 20th Anniversary

On the phone:

Chief Judge Paul Michel

Federal Circuit (ret.). Photo taken May 15, 2015 at an IPWatchdog® co-hosted event on patent reform.

On the phone:

David J. Kappos

Partner, Cravath, Swaine & Moore
Former Director of the United States Patent & Trademark Office

On the phone:

David J. Kappos

Partner, Cravath, Swaine & Moore

Former Under Secretary of Commerce for Intellectual Property

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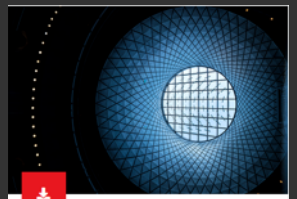
The Patent Landscape of Artificial Intelligence

The Landscape of Machine Learning from a Patent Perspective



Looking into the Digital Crystal Ball

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