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The Impact of COVID-19 on Intellectual Property

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Outline

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- COVID-19 Impact – USPTO
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- COVID-19 Impact – Other Patent Offices
- COVID-19 Impact – Courts
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- COVID-19 Impact – Patent Cases
- Representative Granted Patents Related to COVID-19
- Vaccines
- Representative Treatments

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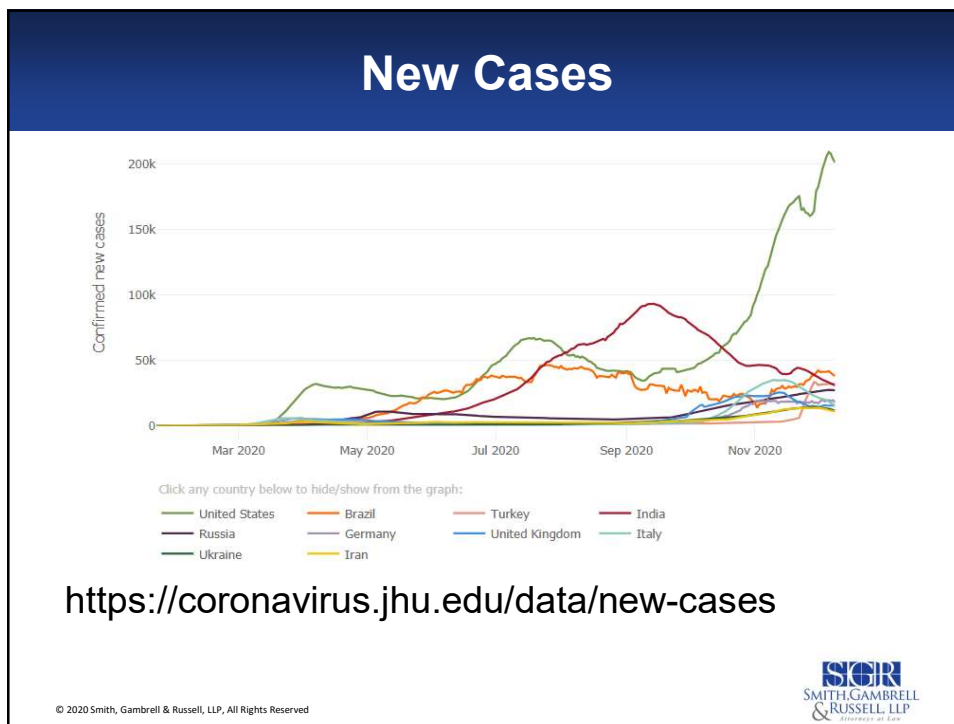
COVID-19

- 72,385,935 confirmed global cases
- 1,615,052 deaths globally
- 16,262,304 confirmed cases in the U.S.
- 299,246 deaths in the U.S.
 - Source: <https://coronavirus.jhu.edu/>
 - Numbers through December 14, 2020

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Mortality

COUNTRY	CONFIRMED	DEATHS	CASE-FATALITY	DEATHS/100K POP.
United States	15,386,562	289,373	1.9%	88.45
India	9,767,371	141,772	1.5%	10.48
Brazil	6,728,452	178,995	2.7%	85.45
Russia	2,518,551	44,220	1.8%	30.61
France	2,377,913	56,752	2.4%	84.72
United Kingdom	1,771,545	62,663	3.5%	94.25
Italy	1,770,149	61,739	3.5%	102.16
Spain	1,712,101	47,019	2.7%	100.63
Argentina	1,475,222	40,222	2.7%	90.40
Colombia	1,392,133	38,308	2.8%	77.16

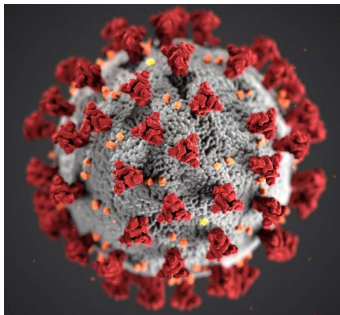
- <https://coronavirus.jhu.edu/data/mortality>
- Chart from Dec. 10, 2020

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The Virus

- Infection with the new coronavirus (severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2) causes coronavirus disease 2019 (COVID-19).



<https://unsplash.com/photos/w9KEokhajKw>

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COVID-19 Impact – USPTO

- United States Patent and Trademark Office
 - Examine Patent and Trademark Applications, Appeals on Examination Decisions, and Petitions on Issued Patents and Trademark Registrations and Applications
 - 5 Offices
 - Approximately 13,000 Employees



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COVID-19 Impact – USPTO

- Daily Impact – Examination Side
 - USPTO Well Suited to Handle Pandemic
 - Majority of filings are done electronically
 - Electronic Filing Has Been Encouraged
 - Trademark increased almost to 90%
 - Examiners already work remotely
 - Office Closed to Public
 - No in person meetings or interviews
 - Infrastructure present for remote work
 - Examiners already allowed to work remotely
 - Telephonic and Video conference already accepted
 - Actual Improvement in some performance measurements
 - Time to final decision – 23.8 months to 23.3 months

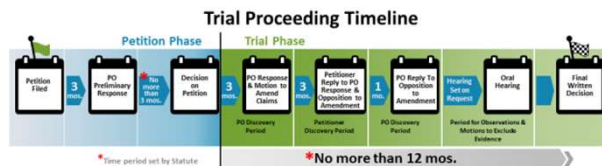
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COVID-19 Impact - USPTO

- Patent and Trademark Trial and Appeal Boards (PTAB and TTAB)
 - Administrative Judges
 - Appeals of Examination Decisions
 - Challenged Trademark Registrations and Applications
 - Opposition/Cancellation
 - Challenged Patents
 - Post Grant Review Procedures
 - Inter Partes Review/Post Grant Review/Covered Business Method



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COVID-19 Impact - USPTO

- Daily Impact at PTAB and TTAB
 - No in person hearings
 - Telephonic or Video Hearings
 - No major disruption
 - At PTAB, no delay in process below on USPTO side
 - Parties can request extensions

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COVID-19 Impact – Inventors @ USPTO

- Coronavirus Aid, Relief, and Economic Security (CARES) Act
 - Signed into law Mar. 27, 2020
 - Granted USPTO Authority to Provide Relief to USPTO Customers
 - Toll, waive, adjust, or modify deadlines
 - Provide incentives for COVID-Focused Inventions
 - Mostly only for Small and Micro-Entity Applicants

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COVID-19 Impact – Inventors @ USPTO

- Extension of Fee Deadlines
 - Temporary
 - Fees due March 27th through September 29th
 - If paid by Sept. 30, 2020, considered timely
 - Filing fees (search, filing, examination, late fee)
 - Issue fees
 - Maintenance fees
 - Waiver of Petition to revive – July 31, 2020
 - Can Ask for Extensions
 - Patent applications/patents - case by case
 - Via Petitions
 - Extension of times, Review application, Accept delayed maintenance fees
 - PTAB – can ask for extensions for COVID-19 Related reasons

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COVID-19 Impact – Inventors @ USPTO

- COVID-19 Focused Invention Incentives
 - Prioritized Examination Pilot Program – May 14, 2020
 - Request Track One Prioritized examination without fee
 - \$2k small entity/ \$1k micro entity
 - Limited to 500
 - Requirements
 - Must certify as micro and small entity
 - No more than one claim of priority
 - Applications must contain one or more claims to product or processes related to COVID-19
 - Claimed invention subject to FDA approval for COVID-19 use
 - IND, IDE, NDA, BLA, PMA, EUA
 - If utility application, must be filed electronically
 - Must be an RCE, continuation application, or new application

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COVID-19 Impact – Inventors @ USPTO

- COVID-19 Focused Invention Incentives
 - COVID-19 Provisional Fee Deferral Program – Sept. 17th
 - Defer payment, no prioritized fee
 - Defer payment at filing of non-provisional application
 - Application must concern a product or process related to COVID-19
 - such product or process must be subject to an applicable FDA approval for COVID-19 use
 - Agree that the technical subject matter disclosed will be made available to the public via a searchable collaboration database maintained on the USPTO's website

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COVID-19 Impact – Inventors @ USPTO

- COVID-19 Focused Invention Incentives
 - Trade and Service Mark Prioritized Examination – June 16th
 - Requirements
 - COVID-19 pharmaceutical products or medical devices subject to approval by the FDA
 - COVID-19 related medical services or medical research services
 - Petition to Director
 - Application serial number
 - Statement elaborating on the applicant's COVID-19 medical goods or services
 - Explanation of why the goods or services qualify for prioritized examination
 - Affidavit or declaration under 37 CFR § 2.20 supporting the applicant's statement

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COVID-19 Impact – Other Patent Offices

- No public visitors/filings
 - Australia, EPO, Israel (working remotely), Mexico, WIPO
- Extension of Deadlines – most require proof
 - JPO, EPO, China, Korea, Israel, Taiwan, India, Canada, Australia
- Oral proceedings
 - Video – EPO, Israel
 - In person – Israel, EPO, Japan
 - Reschedule – EPO

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COVID-19 Impact – Other Patent Offices

- Incentives
 - EPO – COVID-19 patent landscape tool with built-in searches
 - JPO – Open licensing database
 - IP5 – China, EPO, Japan, Korea, and USA working together
 - Develop initiatives and share best practices to spur and incentivize innovation
 - Pursue IP5 initiatives to advance cooperation in new emerging technologies and artificial intelligence
 - enhance harmonization of practices and procedures
 - strengthen work-sharing efforts
 - improve the quality and efficiency of examination
 - enhance access to patent information


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COVID-19 Impact – Courts

- Patents and Registered Trademarks Fall Under Federal Law – Federal Courts and ITC




Supreme Court

- Highest court in the federal system
- Nine Justices, meeting in Washington, D.C.
- Appeals jurisdiction through *certiorari* process
- Limited original jurisdiction over some cases



Courts of Appeal

- Intermediate level in the federal system
- 12 regional “circuit” courts, including D.C. Circuit
- No original jurisdiction; strictly appellate




District Courts

- Lowest level in the federal system
- 94 judicial districts in 50 states & territories
- No appellate jurisdiction
- Original jurisdiction over most cases

Geographic Boundaries
of United States Courts of Appeals and United States District Courts

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COVID-19 Impact – Courts

- District Courts
 - Trial Courts
 - Juried and Bench Trials
 - Grand Jury Proceedings
 - Phases of Law Suit
 - Filing of Complaint/Answer
 - Discovery and Briefing
 - Hearings
 - Depositions
 - Conferences
 - Trial
 - Evidence Presented
 - Documents/Witnesses

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COVID-19 Impact – Courts

- District Courts
 - Subject to Local State Orders
 - Most trials have been suspended
 - Left up to the districts to decide
 - Jury, grand jury, and in-bench
 - Pre-trial events still occurring
 - Briefing Occurring
 - Electronic filing; Paper filing requirements have been suspended at some locations
 - Depositions and hearings via video/telephone
 - Discovery still being produced
 - Extensions given
- ITC

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COVID-19 Impact – Courts

- International Trade Commission
 - Remote Working
 - Investigations still on going
 - No in person meetings
 - Hearings postponed
 - Discovery still on-going, case by case basis

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COVID-19 Impact – Courts

- Appellate Courts (Circuit and Supreme Court)

- No Trial

- Briefing

- No new evidence

- Oral Arguments

- No Jury; Panel of Judges

- Court of Appeals - 3 most of the time, but en banc occurs
 - (large number of judges (e.g., 11 for 9th Cir.))

- Supreme Court

- Nine



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COVID-19 Impact – Courts

- Extensions to file appeal

- petition for writ of certiorari extended 150 days for SCOTUS

- Court Buildings Not Open to Public

- Court of Appeals Eliminates Paper Filing Requirements

- Done Electronically

- Hearings

- Postponed or done via telephone or video
 - Has changed the process - Judges could ask questions whenever, interrupt during hearing; now go in order (Supreme Court)
 - [Argument Audio \(supremecourt.gov\)](https://www.supremecourt.gov/argumentaudio)

- Opinions issued

- [Opinions of the Court - 2020 \(supremecourt.gov\)](https://www.supremecourt.gov/opinions)

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COVID-19 Impact – Patent Court Cases

- Patent Infringement Cases Increasing
 - 3500 Patent Infringement Case filed in 2019
 - 3000 through Sept. 2020
 - Why?
 - COVID-19 impact
 - Legal findings
 - Increase number of patents issued

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COVID-19 Impact – COVID-19 Patent Court Cases

- Allele Biotechnology and Pharmaceuticals Inc. v Regeneron (SDNY 2020)
 - Damages
- Allele Biotechnology and Pharmaceuticals Inc. v Pfizer and BioNTech (S.D. Cal. 2020)
 - Potential Injunction and Damages
- Public Readiness and Emergency Preparedness Act

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Impact on Mergers and Deals

- Mergers in 2015-2019 average was 111.
- Mergers in 2020 average is 67.
- Partnership deals excluding M&As in 2015-2019 was 745.
- Partnership deals excluding M&As in 2020 was 609.
- Nearly a quarter (453) of innovation deals between Feb. and Jul. 2020 were directly related to COVID-19.
- Nature Reviews Drug Discovery 19, 829 (2020)

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Representative Granted Patents Related to COVID-19

- 29 granted patents recite “COVID-19.”
- 37 published applications recite “COVID-19.”
- US Patent No. 10,787,501 to Regeneron claims antibodies that bind to the spike protein of SARS-CoV-2 and pharmaceutical compositions containing them.
 - Filed June 25, 2020 and granted September 29, 2020
 - Track One

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Detection Assays

- US Patent No. 10,815,539 to DiaSorin S.p.A. claims a PCR assay for detecting SAR-CoV-2.
 - Filed April 1, 2020 and granted October 27, 2020.
 - Track One
- U.S. Patent No. 10,822,379 to the Univ. of Pittsburgh claims antibodies that bind SAR-CoV-2.
 - Filed May 14, 2020 and granted November 3, 2020
 - COVID-19 Prioritized Examination Request

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Detection Assays

- U.S. Patent No. 10,844,442 to Bret T. Barnhizer claims a point-of-care SAR-CoV-2 assay that can provide results in one hour.
 - Filed May 18, 2020 and granted November 24, 2020
 - COVID-19 Prioritized Examination Request

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Vaccines

- Pfizer-BioNTech's vaccine, BNT162b2, is contains nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2 surrounded by lipids. Freezer storage only at -94°F (-70°C). EFFICACY: 95%
- Moderna's vaccine, mRNA-1273, is also a messenger RNA vaccine encoding a spike protein. 30 days with refrigeration, 6 months at -4°F (-20°C). EFFICACY: 94.5%

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Vaccines

- AnGes' vaccine, AG0302-COVID19, is a DNA-based vaccine and can be stored for over a year at room temperature.
- Zydus Cadila's vaccine is a DNA-based vaccine delivered by a skin patch.
- And there are several more including viral vector vaccines, protein vaccines, and inactivated virus vaccines.

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Representative Treatments

- Remdesivir is a nucleoside anti-viral approved for treating COVID-19.
- Favipiravir is a synthetic prodrug first discovered while assessing the antiviral activity of chemical agents active against the influenza virus.
- Molnupiravir is an oral medication originally developed to treat the flu.
- Convalescent plasma.
- Bamlanivimab monoclonal antibody treatment from Eli Lilly.

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Representative Treatments

- Regeneron's antibody cocktail.
- Dexamethasone and other steroids.
- Several others.

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Questions?

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