

HELP WAS NOT ON THE WAY: INTELLECTUAL PROPERTY LIABILITY RELIEF IN A PANDEMIC ERA

KIM VU-DINH – BOWEN SCHOOL OF LAW, UNIVERSITY OF AR LITTLE ROCK

DUSTIN MARLAN – UMASS SCHOOL OF LAW, UMASS-DARTMOUTH

PROBLEM & GOVERNMENT RESPONSE



Quickly evolving pandemic - US: 4.1 mill cases | 45,000 deaths in approx. 5 months

2 months after start of epidemic:

- FDA issued EUA creating liability shields for items used for other uses than ones approved by FDA
- WH used DPA ordering only 6 companies to produce patient monitors, CTs and mobile X-ray devices, hospital beds, face masks, oxygen blenders, resuscitation devices and other respiratory medical equipment. Most of them already doing so.
- **Persistent Shortages:** PPE (hospital gowns, face masks, and face shields) & key equipment (ventilator parts, hand sanitizer)

CAVEAT: Article focus on low-cost, easily reproduced items and does not address testing, pharmaceuticals in detail. i.e., **Amateur** micro-manufacturers: nonprofits, individuals

VULNERABLE WOULD-BE DEFENDANTS



- Makers (high school students, individuals, nonprofits, fashion designers)
- Distributors (nonprofits, for and nonprofit hospitals)
- Facilitators of distribution (individuals/nonprofits setting up networks)

Patent Issues: blueprints for inventions, exact copies of items with 3D printers

Copyright Issues: circulation of manuals for equipment, circulation of educational material

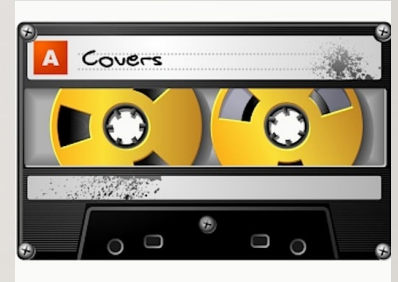


PROPOSED & EXISTING POTENTIAL PROTECTIONS

- **Facilitating Innovation to Fight Coronavirus Bill** (Senator Sasse, Nebraska)
 - Suspend patent rights during pandemic; +10 years to patent period.
 - Vague (3 pages) & unpopular.
- **PREP Act (Public Readiness Emergency Preparedness Act)** of 2005 adopted in CARES Act) – liability shields for “manufacturers” and end-users (hospitals) where equipment undergoing FDA approval. i.e., professional manufacturers
- **TRIPS Act (Trade-Related Aspects of Intellectual Property Rights) & compulsory licenses**
 - Allows WTO member nations to issue compulsory licenses—does not require.
 - Required process:
 1. Must try to ask for permission, unless emergency
 2. compulsory license w/ disputable fee

COMPULSORY LICENSES IN U.S.

- **Copyright:** Used frequently in music, public broadcasting, internet radio



- **Patent:** MUCH MORE LIMITED THAN EUROPE. Used for plant variety in fiber, food, feed supply, and within "March-In Rights".



MARCH-IN RIGHTS (BAYH-DOLE ACT)

- If R&D funded by US Agency, then can march-in rights reserved: US can undertake production/commercialization. (Legis intent but not requirement: Where there is under-production or insufficient exploitation by patent-holder)
- **NEVER BEEN USED**
- Threat of use Bayer, Cipro, Anthrax 2005



US does not like to use compulsory license or march-in rights for medical. (HIV/AIDS treatments and S.Africa).

DEFENSE PROTECTION ACT

- Korean War 1950. Like War Powers Act, but w/o war requirement

President can:

- require private sector manufacturers to prioritize government orders
 - set production and distribution priorities for needed equipment.
 - order companies to recalibrate their factories to address shortages of supply.
- DPA used 300,000 orders/yr military equipment
- FEMA after hurricanes (bottled water shortages)
- 1st time in public health emergency

SOLUTIONS REQUIRING LEGAL ASSISTANCE

- Due diligence procedures
 - 1) obtaining an IP clearance,
 - 2) researching the IP asserted, and
 - 3) requiring requesting party to supply all info it possesses about relevant IP and infringement risks.
- Creative licensing & patent pooling - Negotiated agreements
- Contractual language – 1) disclaimers, 2) indemnity language between hospitals & contractors



DOWNSIDERS

Require:

- Highly **proactive/coordinated** actions from Executive branch & Agencies

OR

- High capacity micro-manufacturer, access to costly **legal resources**, and **time**

POTENTIAL JUDICIAL DOCTRINES OF DEFENSE

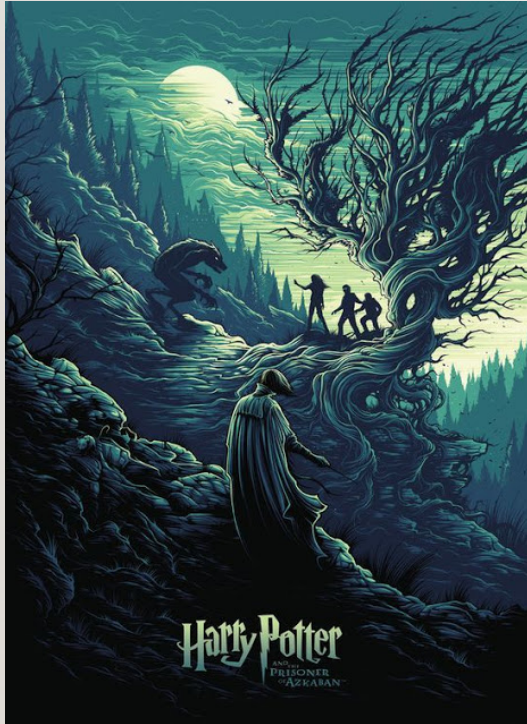
- Right to Repair
- March-In Rights by Proxy
- DPA by Proxy
- Tort & Property Law Doctrines extended to IP (discussion in Copyright section)

COPYRIGHT

- Need for copyrighted materials during Pandemic.
 - Response efforts – e.g., instruction manuals, layouts for social distancing, datasets with COVID search results
 - Remote education – e.g., virtual materials and modes of instruction, copies of textbooks for displaced students, audiovisual materials in class recordings



FLEXIBLE LICENSES



- Certain authors/publishers extended permission in the form of flexible licenses.
 - Textbooks – Cengage, Cambridge University Press
 - Children's books – Macmillan, HarperCollins, J.K. Rowling
- Problem: not every author/publisher is receptive to this is doing this.

FAIR USE

- Copyright's safety valve; 4 factor test
 - Purpose and character of the use;
 - The nature of the copyrighted work;
 - Amount and substantiality of the work
 - Effect of the use upon the potential market for the copyrighted work
- Problem: “context sensitivity renders it of little value to those who require reasonable ex ante certainty about the legal value of a proposed use” –Michael W. Carroll, *Fixing Fair Use*, 85 N.C. L. Rev. (2007).



COMMON LAW ANALOGIES

- An IP emergency exemption can draw on:
 - **Good Samaritan Laws** – (1) care was performed as a result of emergency; (2) volunteer did not cause emergency; (3) volunteer was not grossly negligent
 - **Public Necessity Defense to Trespass** – (1) reasonable belief that one's actions are necessary to prevent harm; (2) no practical alternative to prevent harm; (3) actor did not cause harm in first place; (4) damage caused was less than what would have occurred otherwise)
 - **Landlord-Tenant Law** (moratoriums on evictions during COVID-19)

THE END



(fair use?)