



Patents in a Pandemic— Problems and Solutions

Christopher A. Cotropia
(Richmond Law School)



Goals for today

- Discuss what role, if any, patents play in a pandemic
 - Basics of patent policy/theory
 - Ways such policy/theory interacts with various innovation issues faced during a pandemic
 - Introduce alternative innovation incentives beyond patents



Patent protection as part of innovation policy

- Provide patent protection for utilitarian good
 - Patents grant exclusivity for a limited time for useful, new, and nonobvious inventions
 - Not the right to produce
- Theory relies on market to create incentives from exclusivity
 - Incentive to invent/create (idea)
 - Incentive to commercialize/distribute (manufacture)



Patents and public health

- Patent system helps produce novel/nonobvious solutions that may help in *future* public health crisis
 - Particularly true after patent expires
- Problem is during public health crisis, patents can get in the way
 - During such times emphasis is on widespread access
 - Usually low price



Patents as Constraints on Supply

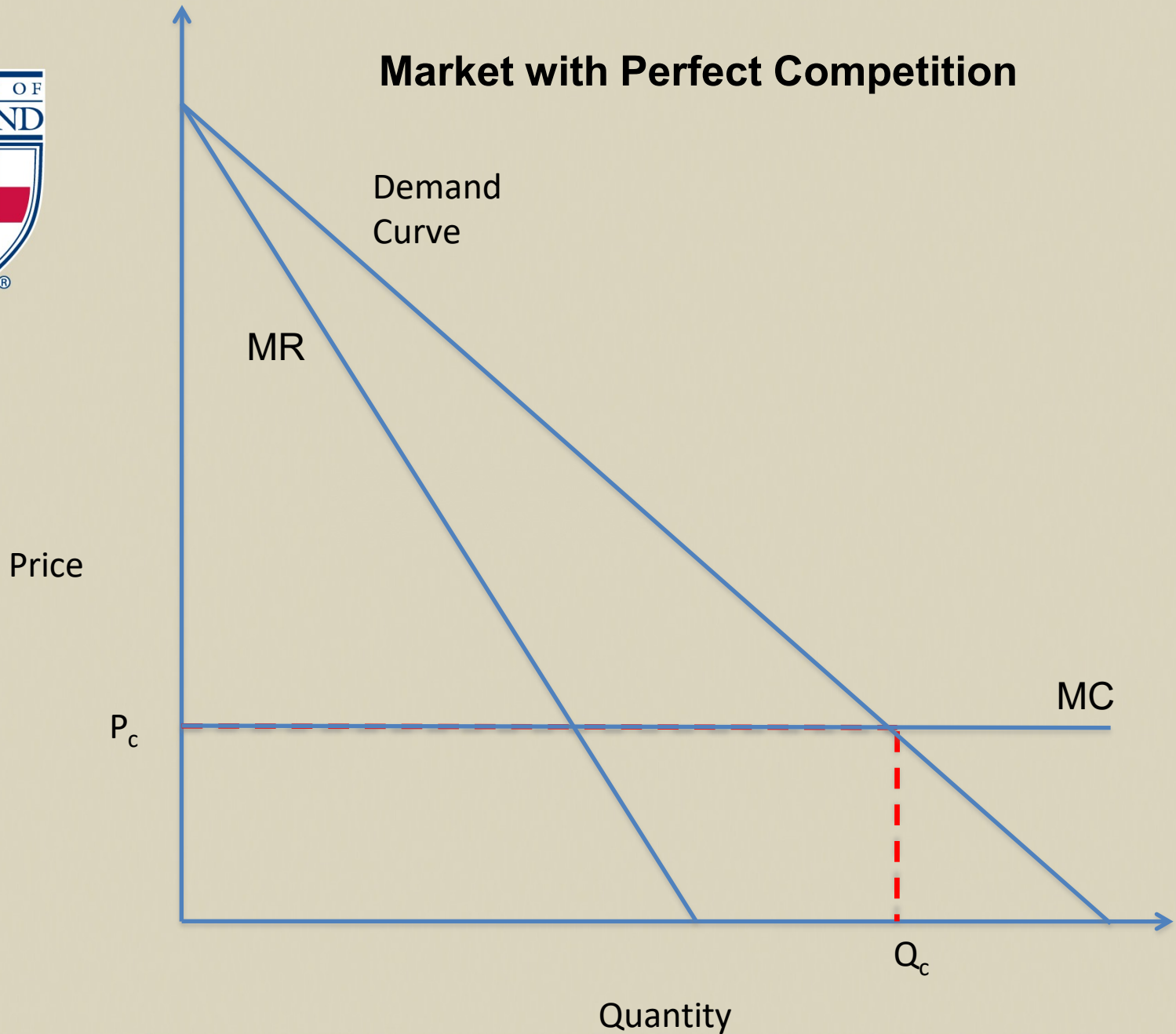


Price and innovation

- Inventing and distributing cost \$
- Example – new drug/biologic
 - ~\$1395m to approval
 - ~\$1475m post-approval to market
 - Includes risk/dead-ends
- Cost to create copy/generic -- ~\$700k to market
- Generic ~80-85% lower price than branded

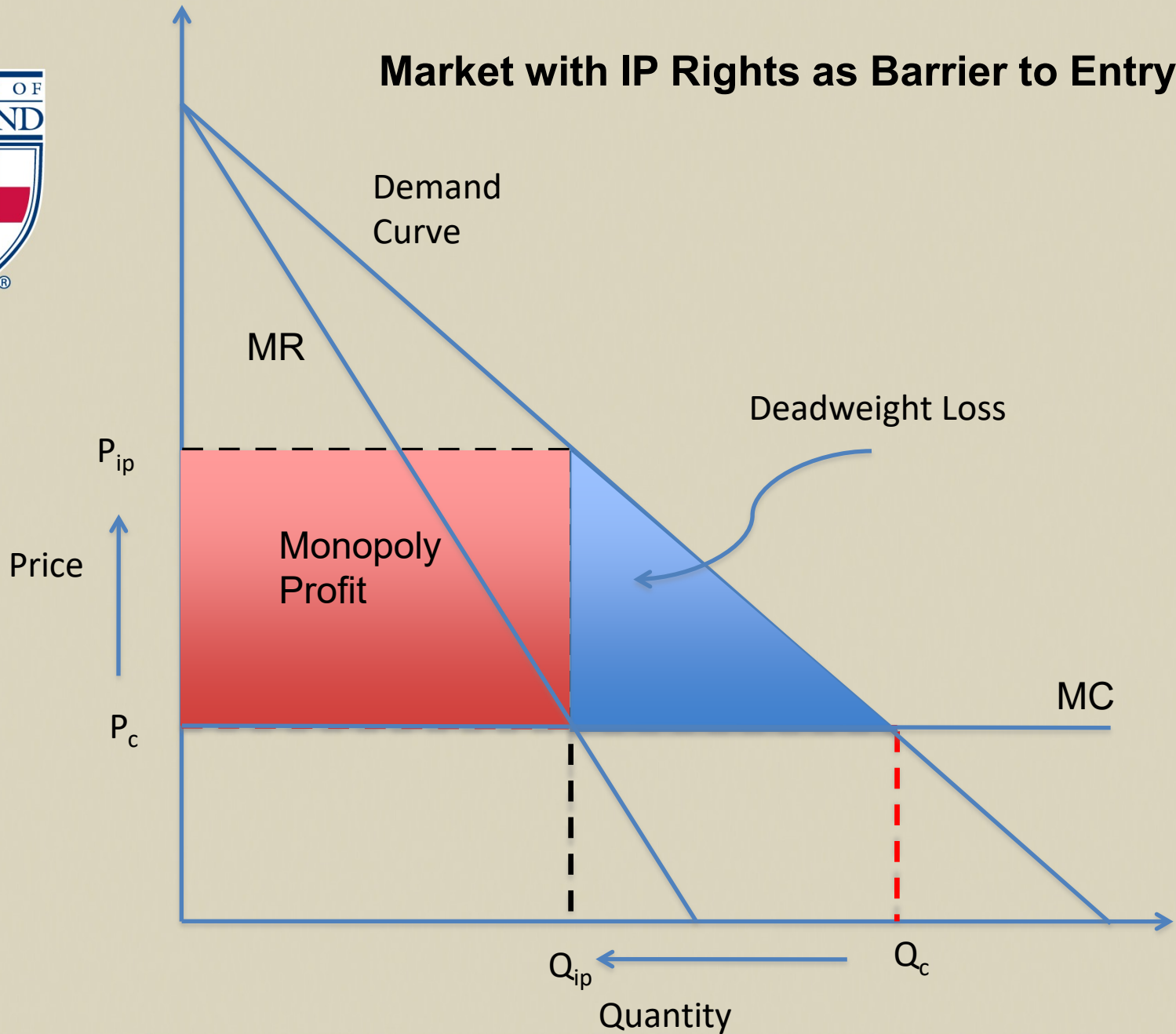


Market with Perfect Competition





Market with IP Rights as Barrier to Entry





Pandemics/emergencies increase need for access

- HIV/AIDS crisis of late 1900s, early 2000s
- Average 3m new cases/1.5m deaths from HIV/AIDS per year
- 1/1000 Africans access to AIDS treatment (antiretroviral [ARV] drugs (AZT – Retrovir)
 - Burroughs Wellcome had patent
 - Cost 10-15K per patient/per year
- Concerns patent limited access due to control over price



Pandemics/emergencies increase need for access

- Anthrax scare of 2001
- Cipro, anti-anthrax antibiotic treatment, patented by Bayer
- Price wasn't concern, it was production and availability
 - Needed to increase production to 200m tablets over 3-month period
 - Needed to potentially treat 10-12 million people



COVID-19 and access

- Need IP to incentivize creation, but that may limit distribution
 - Limited distribution problem in times of crisis
- Patents on existing anti-virals
 - Concerns on maintaining high price or under-producing
 - Gilead and patents on Remdesivir
 - AbbVie and patents on Kaletra



Why not meet demand via market?

- More “customers” – shouldn’t market meet demand?
- Grey market concerns/price discrimination
 - HIV
 - Current situation with Remdesivir
- Production limitations
 - Anthrax
 - Gilead statement on Remdesivir
- Need to maintain higher price
 - “Pandemic Profiteering”
 - Precedent/applicability to all health innovations



Patent "Busting"

- Government's ability to ignore or "bust" a patent
- Brazil in 1997 with anti-retroviral HIV/AIDS treatments
 - Authorized state laboratories to produce
- Israel and authorizing import of generics of Kaletra
- U.S. government and "compulsory license"
- U.S. government and "march-in" rights
- Threats v. actual "busting"
 - Similar to Defense Production Act discussions



Patent un-enforcing

- If unauthorized usage of patented technology, must sue for patent “infringement”
 - Main remedy is injunction
- Courts can not grant injunction and issue compulsory license in limited cases
- Public health concerns can be such a case
 - *Vitamin Techs. V. Wisconsin Alumni Research Foundation*, 146 F.2d 941 (9th Cir. 1945)



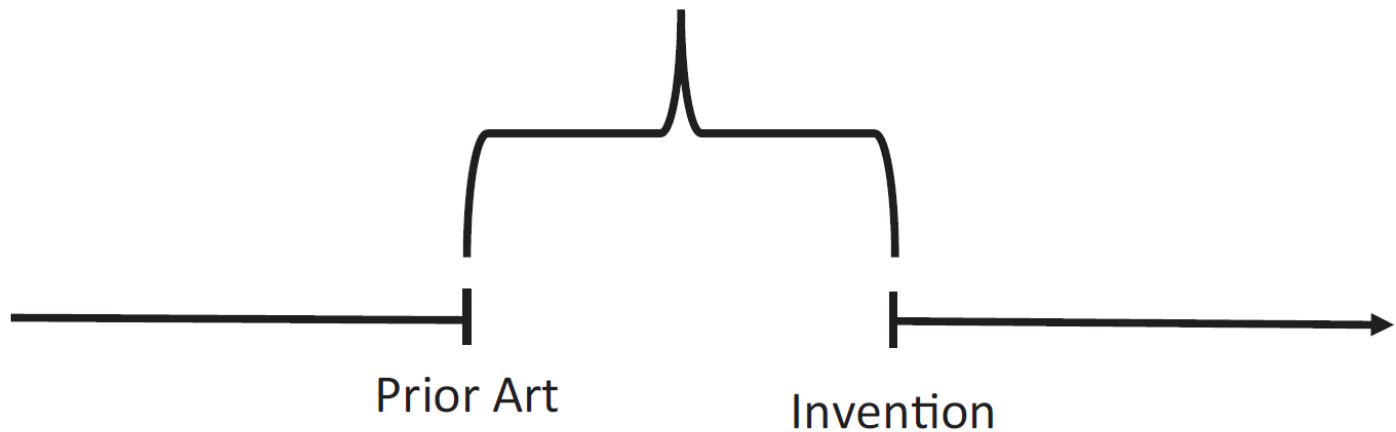
Patents and non-innovative or unprofitable solutions



Patents and the level of innovation incentivized

- Invention must be “nonobvious” to be patentable
- Patent law meant to incentivize such technological leaps

FIGURE 1: DIFFERENCE IN TECHNOLOGICAL ACHIEVEMENT
GAP





Patents and market-funding of innovations

- Patents also rely on the market to drive innovation
- Patenting depends on purchases by the public, at a higher than marginal cost price, to fund innovation



COVID-19 and need for nonobvious/low-cost solutions

- Testing not necessarily innovative
 - PCR (polymerase chain reaction) based testing
 - Just need to know the gene marker
 - Serology-based testing
 - Detects antibodies
 - All use known techniques/materials
- Government/states controlling price for solutions
 - Not a market setting



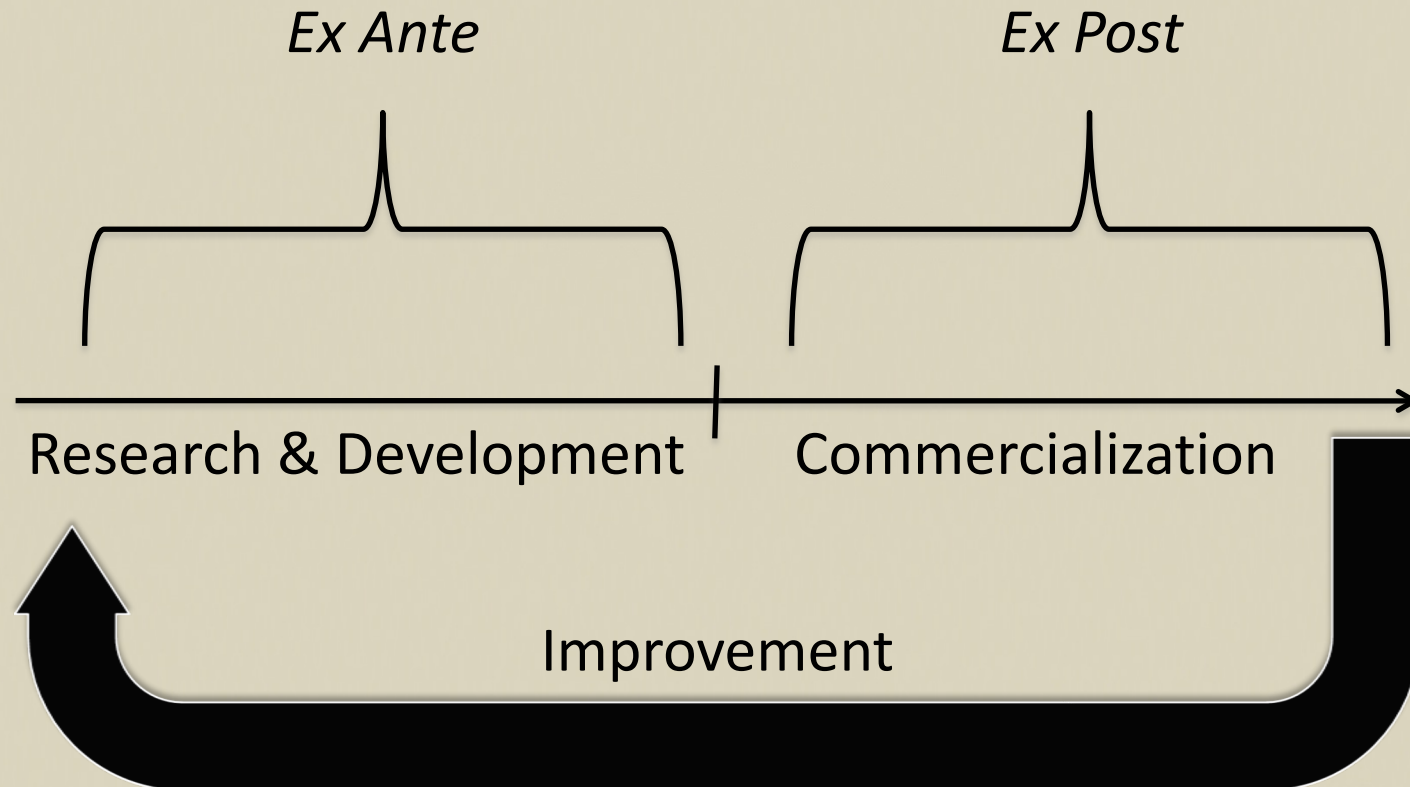
Alternatives to patenting in this context

- Orphan Drug Act
 - 7 years marketing exclusivity for rare disease
 - Gilead attempt for Remdesivir and COVID-19
- Direct subsidies/grants
 - NSF and COVID-19 – RAPID proposal
- Not exclusive of each other
 - Bayh-Doyle Act of 1980

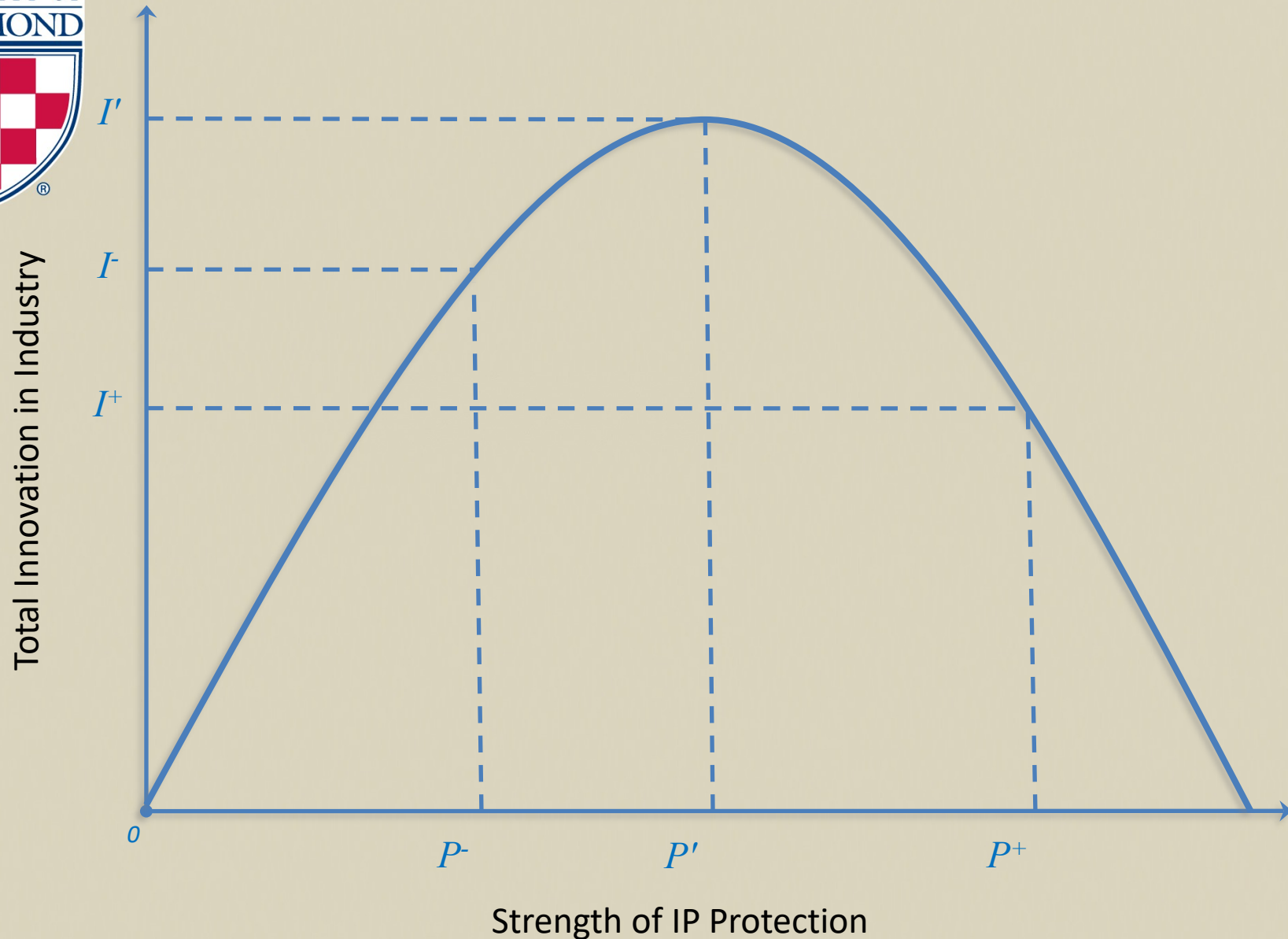


Patents and Follow-on Innovations

Innovation Development Cycle



Advanced Innovation Curve





Emergencies and need for improvements

- World War I and need for new aircraft designs
- New technology used Wright brothers' patented technology, issued in 1903
 - simultaneous use of roll control (with wing-warping) and yaw control (with a rear rudder)
- Wright brothers sued to exclude improvements throughout Europe and U.S.



COVID-19 and need for improvements

- Labrador Diagnostics LLC suit against BioFire Diagnostics
 - Backed by Softbank, former Theranos testing patents
 - Three COVID-19 tests
- In Italy, patent holder on special respirator valve threatened unauthorized 3-D printing of valve



COVID-19 and "Method of Use" Patents

- Gilead's Remdesivir drug
 - On Feb. 4, Wuhan Institute of Virology applies for Chinese patent on new "use" of Remdesivir—to treat COVID-19
 - Gilead likely to "block" such usage with its patents
 - On Remdesivir structures (product patents)
 - On ways to manufacture Remdesivir (method patents)
- "Evergreening"



Patent pools as a solution

- Consortium of at least two companies agreeing to cross-license patents relating to a particular technology
 - At FRAND (fair, reasonable and non-discriminatory rate)
- Manufacturer's Aircraft Association in 1917
 - Pressure by U.S. government
- WHO endorses COVID-19 patent pool for medical devices



Patent pledges as a solution

- “Pledger” publicly announce that their patents are free to use for specific purpose, for specific time
 - Meant to incentivize improvements in specific technological space
- Tesla patent pledge
- Open COVID Pledge
- Labrador – royalty-free license



Patents and Fast Innovation



Patents exclude independent inventors

- Patent exclusivity applies to all who develop/use after the “first to file”
 - No copying requirement
 - No knowledge requirement
- Rewards coming in first
 - Incentivizes speed



"Race" to invent the vaccine

- Global patent race for COVID-19 Vaccine
- Concerns with exclusivity
 - Political tool
 - Exploit territorial nature of patenting
 - Deny access due to copying concerns



Patents and the Public Domain



Patents and public domain

- Patent law requires an enabling disclosure of the invention
- Creates library of knowledge that is public and searchable
- Also helps identify relevant researchers, companies, and literature
- And public domain when patent expires



US Patent Office Cancer Moonshot

- Part of broader Cancer Moonshot initiative
- Collect 270,000 patents from 1976 to 2016
- Included drugs, diagnostics, surgical devices, data analytics, and genomic-based cancer-specific inventions
- Typically tied to prizes



Patents, Bigdata and COVID-19

- COVID-19 public datasets
- Patents data combined with other datasets
- All from public, detailed nature of patents



Questions?

Christopher A. Cotropia
(Richmond Law School)