



TOPIC 1:

Drug prices (economics, if you will).

Powered by patents ...









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Here's some graphs that, for some students, will be another way of understanding this.





























TOPIC 2: Drug development and the law



- There is strong reason to believe that patents do little or nothing to actually induce innovation or commercialization to any significant extent in many or most industries.
- The best example, however, of patents having a powerful inducement effect is in pharmaceuticals. Because of patents, research pharma firms are induced to create new drugs lured by the promise of many billions of dollars in profits enabled by patents.
- Patenting in pharma is also one of the key aspects of the expense of health care in the United States, which is a huge political/economic/social issue of our day.
- This makes patents in the pharma sector worth our special attention.
- What's more, there are complexities to patenting in the pharmaceutical context, including ancillary FDA regulatory exclusivities. This also makes it worth special attention.

Considering the U.S. role in global pharma

- There is a good argument that U.S. patent law (along with neighboring U.S. law in the spheres of antitrust and FDA regulation) is crucial in providing the needed economic inducement for the development of new medicines globally.
- As a general matter, the U.S. has no price controls on drugs, but the rest of the world does.
- Abroad, price controls allow prices to be high enough that it's worth it for the patent-holding pharmaceutical company to sell in that jurisdiction (because marginal cost is far below the allowed price), but arguably the reward is not so great that it significantly contributes to the inducement to develop the new drug in the first place.
- In the U.S., without price controls, prices can be far, far above marginal cost, allowing recoupment of massive R&D costs.
- Thus, arguably, U.S. consumers are paying the drug development costs for the entire world.











The story of a drug ... #4

- <u>Abbreviated New Drug Application (ANDA)</u>: A generic firm can file an ANDA unsupported by new clinical data, relying on the research pharma company's data. The ANDA will be approved if the generic firm can demonstrate bioequivalence.
- "The introduction of generics is a shock to the system for a pharmaceutical company. Prices can drop as much as 20% when the first generic enters the market; with multiple generics, the prices may eventually drop by 80-85%." (Feldman 2018)
- The modern path to generic competition was created by the Hatch-Waxman Act of 1984.

Hatch-Waxman 1/2

a/k/a The Drug Price Competition and Patent Term Restoration Act of 1984

- amended both patent law and food-and-drug law
- provided for patent term extensions to compensate for FDA regulatory approval delays (35 U.S.C. § 156)
- established expedited path for approval of generic drugs that are bioequivalent
 - complaints by generic firms that brand-name firms won't sell them samples for use in needed bioequivalence testing
- created a safe harbor from patent infringement for generic drug companies until the time they request FDA approval

Hatch-Waxman 2/2

- encourages brand-name companies to identify patents covering their drugs—these are listed in the Orange Book
- when a generic drug company seeks FDA approval for an existing drug, they must account for Orange-Book listed patents, either by
 - 1. saying they will wait until the patent expires
 - 2. asserting the patents are invalid or don't cover the drug
 - if No. 2, then the generic firm can be sued for infringement
- created new "regulatory exclusivities" periods of exclusive marketing rights that operate alongside patent protection

"Evergreening" of pharmaceuticals (1/3)

- "[D]rug makers do all they can to soften the blow of losing market monopoly. Some strategies ... involve what is known as 'evergreening'. [In] its broadest connotation [the term means] trying to refresh one's monopoly protection on a drug." (Feldman 2018)
- Techniques include filing for new patents on new formulations (e.g., extended release), new methods of use, new dosage schedules, new combinations with other ingredients, etc. This often includes very weak patents unlikely to survive challenge, for instance for lacking nonobviousness.





"Evergreening" of pharmaceuticals (3/3)

- "Many ... evergreening strategies involve applying for new patents. Even if the patents are of questionable validity, the process of challenging them through Hatch-Waxman litigation is expensive and lengthy for a generic, again allowing years of additional profits for the brand-name company. If companies are able to ... justif[y] obtaining new patents or exclusivity protections, these companies [may avoid the drop-off in profits from patent expiration]. Our data suggest that this is occurring in a widespread manner throughout the industry." (Feldman 2018)
- "In short, despite the quaint theory that competitors will enter after a pharmaceutical patent expires, the reality is quite different. Numerous strategies and opportunities exist that allow companies to extend their protection and prolong the period of market monopoly for their drugs." (Feldman 2018)

Regulatory exclusivities

Because drugs are regulated and you can't sell them in the U.S. without FDA approval, the withholding of FDA approval can be leveraged to do IP-like things, providing a benefit to one drug company by excluding their would-be competitors. This can provide incentives to induce innovation and otherwise solve compensation/incentive problems and fix "market failures."

Some examples:

- 7-year market exclusivity for drugs that treat rare conditions and diseases (Orphan Drug Act of 1983)
- 180-day generic-drug market exclusivity for being the first generic pharmaceutical firm to file a "paragraph IV certification" challenging the patents on an approved drug (Hatch-Waxman Act of 1984)

