Industry & Invention
Patent

Utility Patents and Regulatory Exclusivities in Pharmaceuticals

Eric E. Johnson

ericejohnson.com

First we're going to talk about drug prices (economics, if you will). Then we'll talk about drug development and the law.

TOPIC 1:

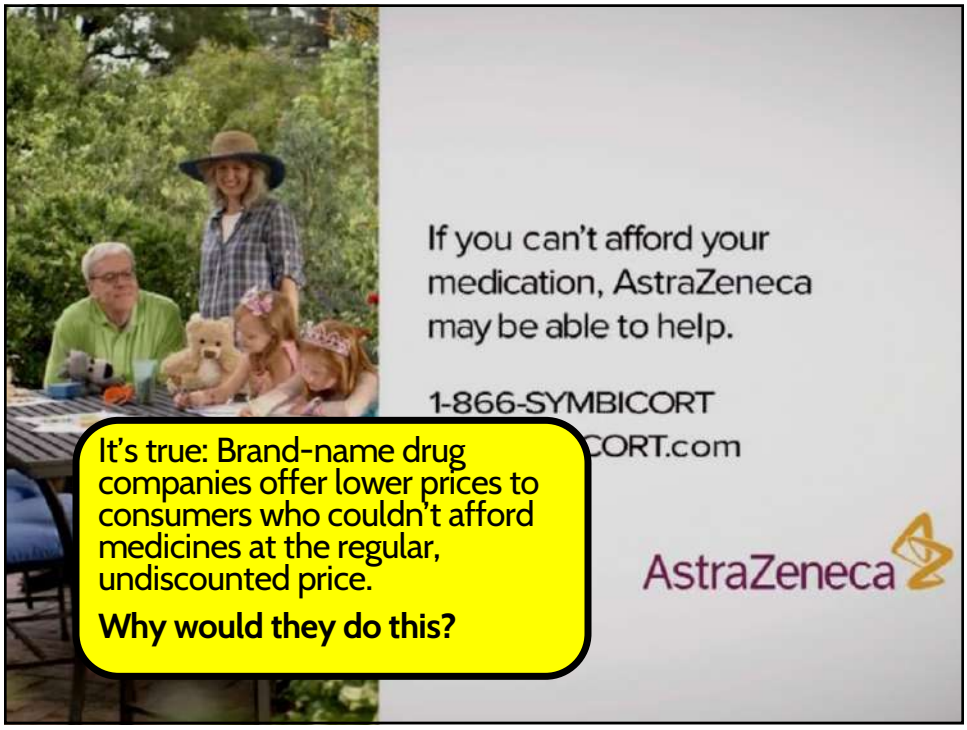
Drug prices (economics, if you will).

Powered by patents …

First, a mystery …

Why do drug companies do this …


If you can't afford your medication, AstraZeneca may be able to help.
1-866-SYMBICORT
MySYMBICORT.com
AstraZeneca


If you can't afford your medication, AstraZeneca may be able to help.
1-866-SYMBICORT
CORT.com
AstraZeneca
It's true: Brand-name drug companies offer lower prices to consumers who couldn't afford medicines at the regular, undiscounted price.
Why would they do this?

AZ&ME™

AstraZeneca Prescription Savings Program

OVER THE PAST 10 YEARS

AZ&ME has provided prescription savings to **4.5 MILLION PATIENTS** across the United States and Puerto Rico

AstraZeneca

AZ&Me Prescription Savings Programs are designed to help:

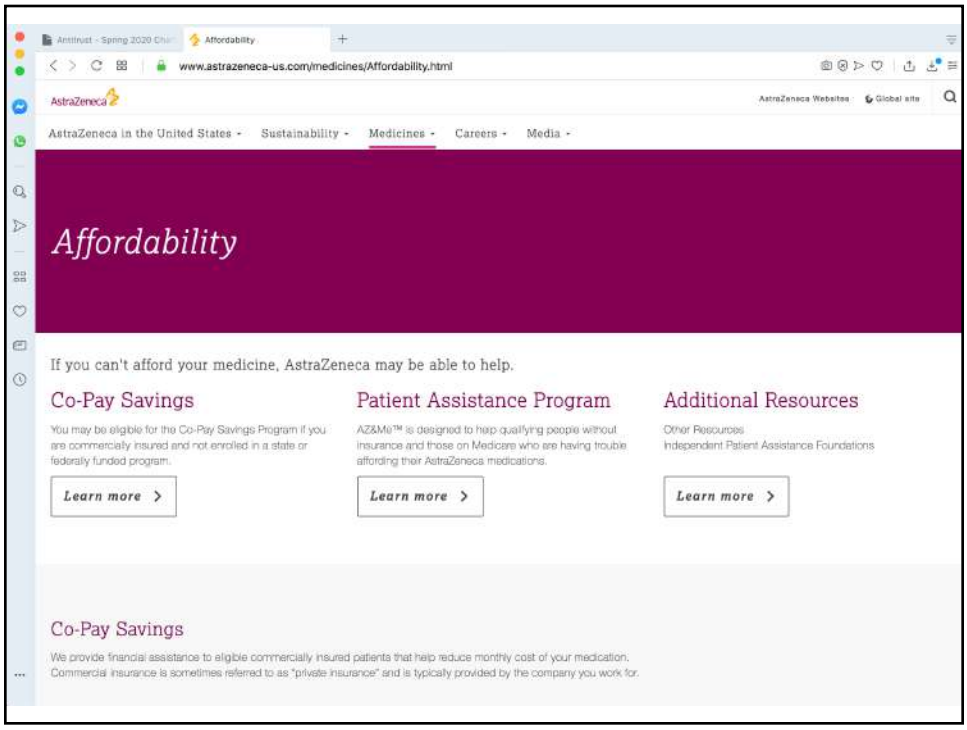
People without prescription drug coverage

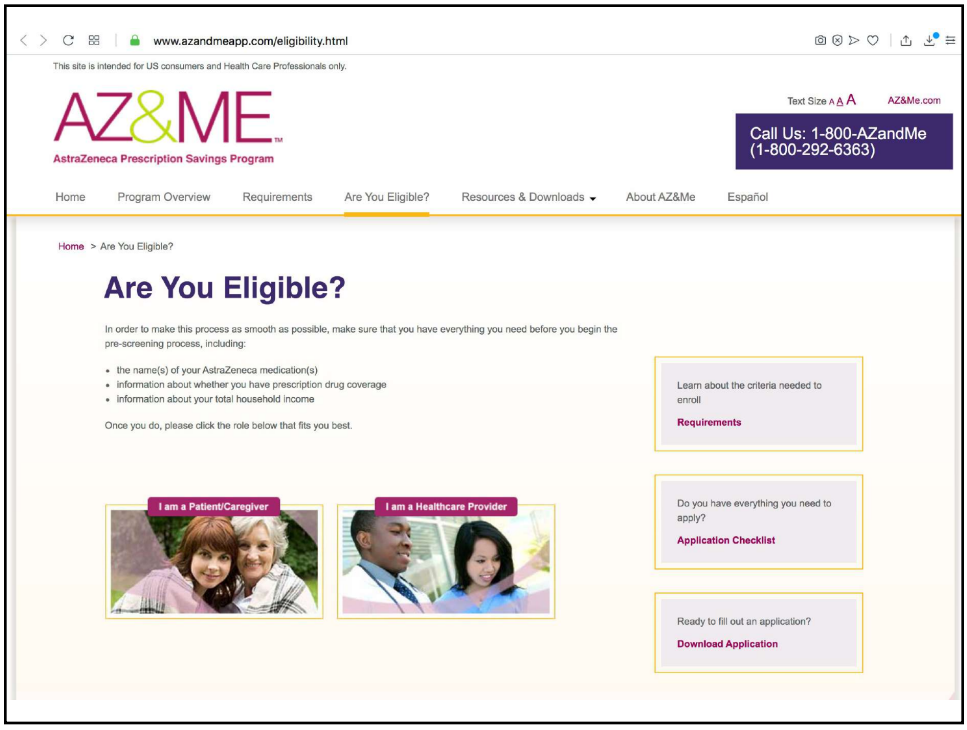
People with Medicare Part D

People who receive care at participating health care facilities

For more information, please visit www.astrazeneca-us.com or call 1-800-292-6363

AstraZeneca


Affordability
www.astrazeneca-us.com/medicines/Affordability.html
AstraZeneca
AstraZeneca Websites
Global site
AstraZeneca in the United States
Sustainability
Medicines
Careers
Media
Affordability
If you can't afford your medicine, AstraZeneca may be able to help.
Co-Pay Savings
You may be eligible for the Co-Pay Savings Program if you are commercially insured and not enrolled in a state or federally funded program.
Learn more
Patient Assistance Program
AZ&Me™ is designed to help qualifying people without insurance and those on Medicare who are having trouble affording their AstraZeneca medications.
Learn more
Additional Resources
Other Resources
Independent Patient Assistance Foundations
Learn more
Co-Pay Savings
We provide financial assistance to eligible commercially insured patients that help reduce monthly cost of your medication.
Commercial insurance is sometimes referred to as "private insurance" and is typically provided by the company you work for.


www.azandmeapp.com/eligibility.html
This site is intended for US consumers and Health Care Professionals only.
AZ&ME
AstraZeneca Prescription Savings Program
Text Size A A A
AZ&Me.com
Call Us: 1-800-AZandMe
(1-800-292-6363)
Home
Program Overview
Requirements
Are You Eligible?
Resources & Downloads
About AZ&Me
Español
Home > Are You Eligible?
Are You Eligible?
In order to make this process as smooth as possible, make sure that you have everything you need before you begin the pre-screening process, including:
the name(s) of your AstraZeneca medication(s)
information about whether you have prescription drug coverage
information about your total household income
Once you do, please click the role below that fits you best.
I am a Patient/Caregiver
I am a Healthcare Provider
Learn about the criteria needed to enroll
Requirements
Do you have everything you need to apply?
Application Checklist
Ready to fill out an application?
Download Application

> Are You Eligible?

Are You Eligible?

In order to make this process as smooth as possible, make sure that you have everyt
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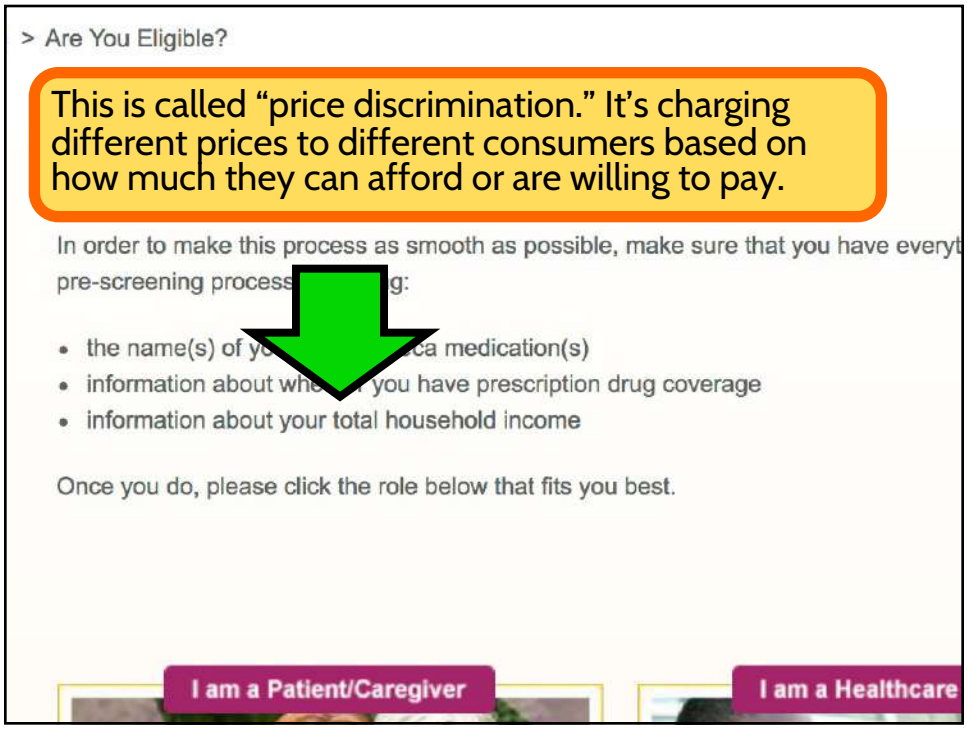
- the name(s) of your AstraZeneca medication(s)
- information about whether you have prescription drug coverage
- information about your total household income

Once you do, please click the role below that fits you best.

I am a Patient/Caregiver

I am a Healthcare


> Are You Eligible?
This is called “price discrimination.” It’s charging different prices to different consumers based on how much they can afford or are willing to pay.
In order to make this process as smooth as possible, make sure that you have everyt
pre-screening process
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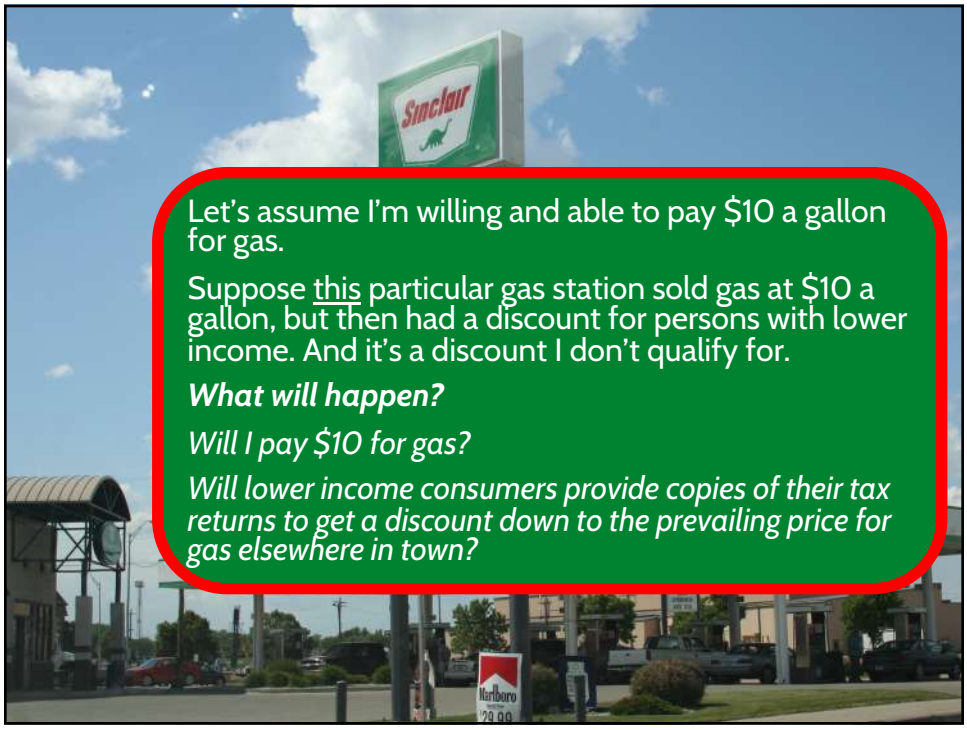
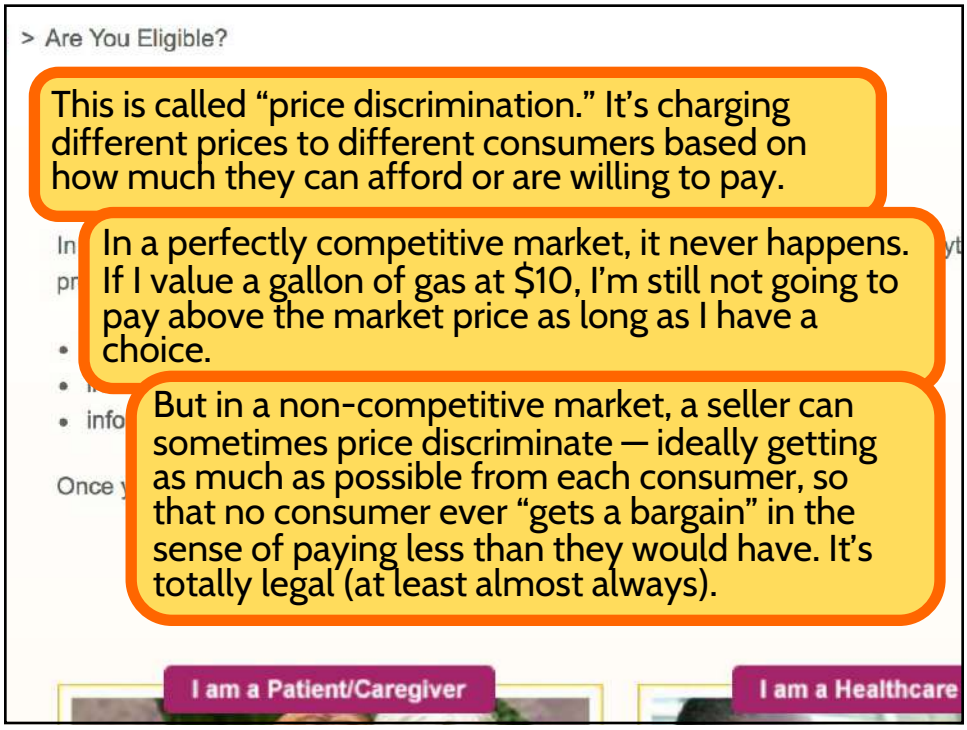
I am a Patient/Caregiver
I am a Healthcare


Sinclair
B&N
Auto Plaza
Tire
ATM
Imagine price discrimination at a local gas station …


Sinclair
Let's assume I'm willing and able to pay $10 a gallon for gas.
Suppose this particular gas station sold gas at $10 a gallon, but then had a discount for persons with lower income. And it's a discount I don't qualify for.
What will happen?
Will I pay $10 for gas?
Will lower income consumers provide copies of their tax returns to get a discount down to the prevailing price for gas elsewhere in town?


> Are You Eligible?
This is called "price discrimination." It's charging different prices to different consumers based on how much they can afford or are willing to pay.
In a perfectly competitive market, it never happens. If I value a gallon of gas at $10, I'm still not going to pay above the market price as long as I have a choice.
But in a non-competitive market, a seller can sometimes price discriminate — ideally getting as much as possible from each consumer, so that no consumer ever "gets a bargain" in the sense of paying less than they would have. It's totally legal (at least almost always).
I am a Patient/Caregiver
I am a Healthcare

Price discrimination has special relevance to intellectual property …

Price discrimination has special relevance to intellectual property because:

- IP, by its very nature, is a restriction of competition, and
- with IP, additional units of something can be made and sold without incurring almost any additional cost. (E.g., it takes $3 billion to make the first tablet of a patented FDA-approved new drug. It takes 1 cent to make the second.) Economists call the cost of an extra unit "marginal cost." The IP context is generally about big initial cost and near-zero marginal cost.

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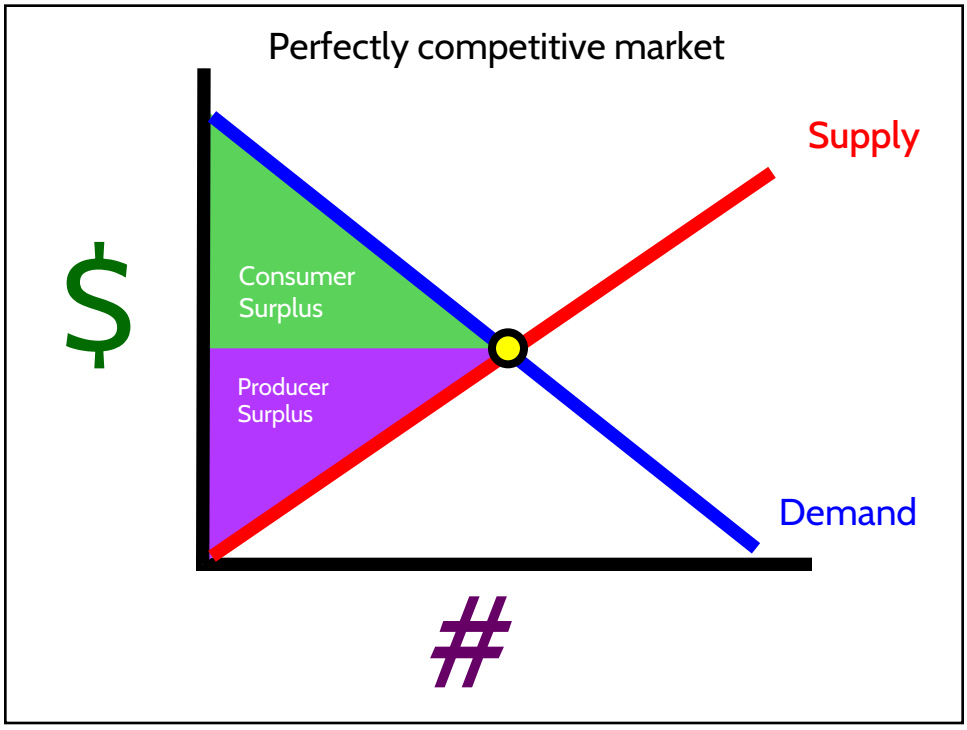
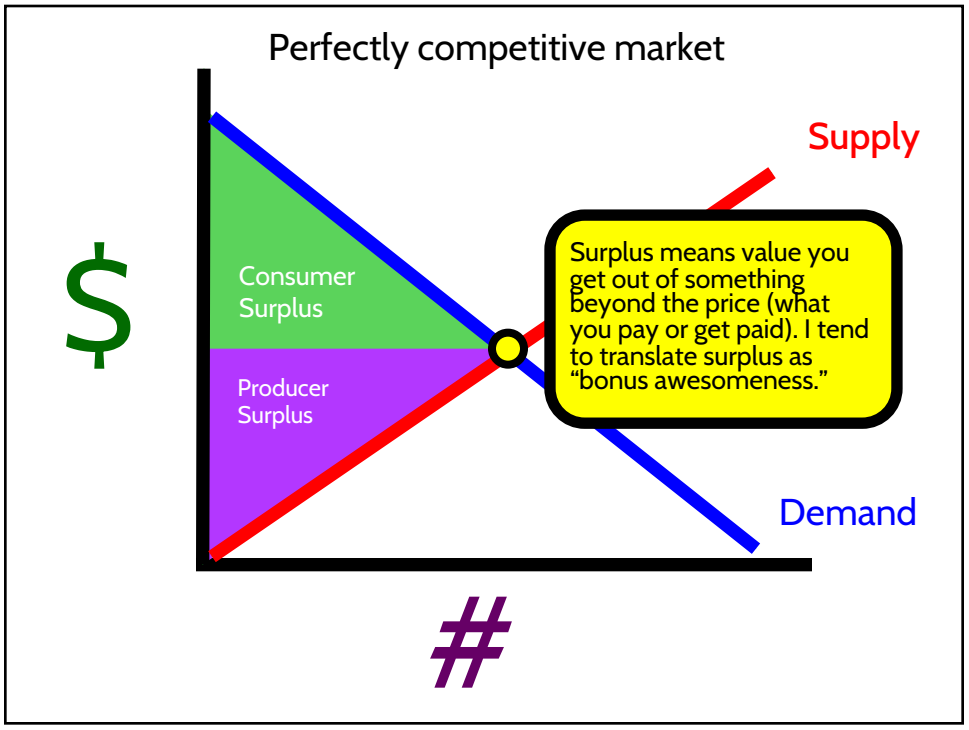
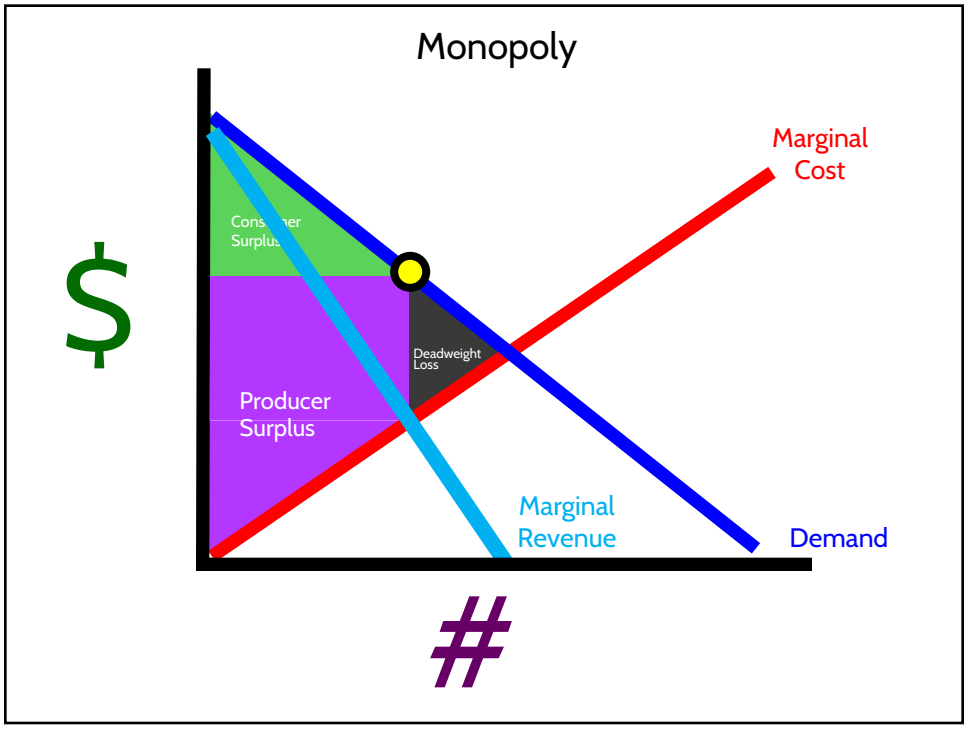
nonexcludable
nonrival

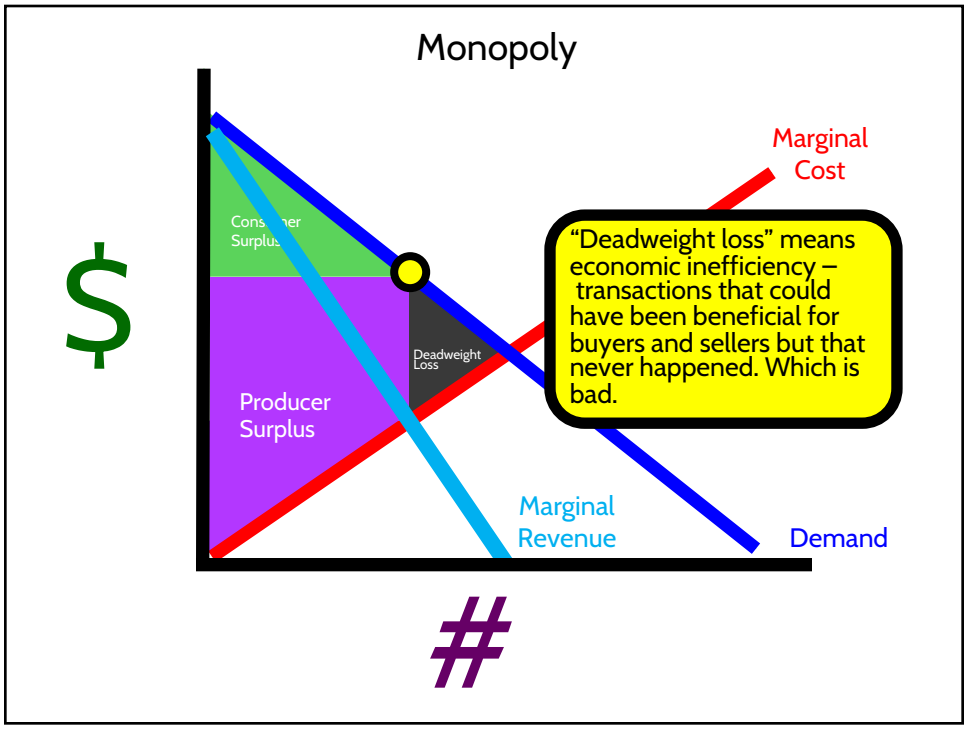

The compensation / incentive problem

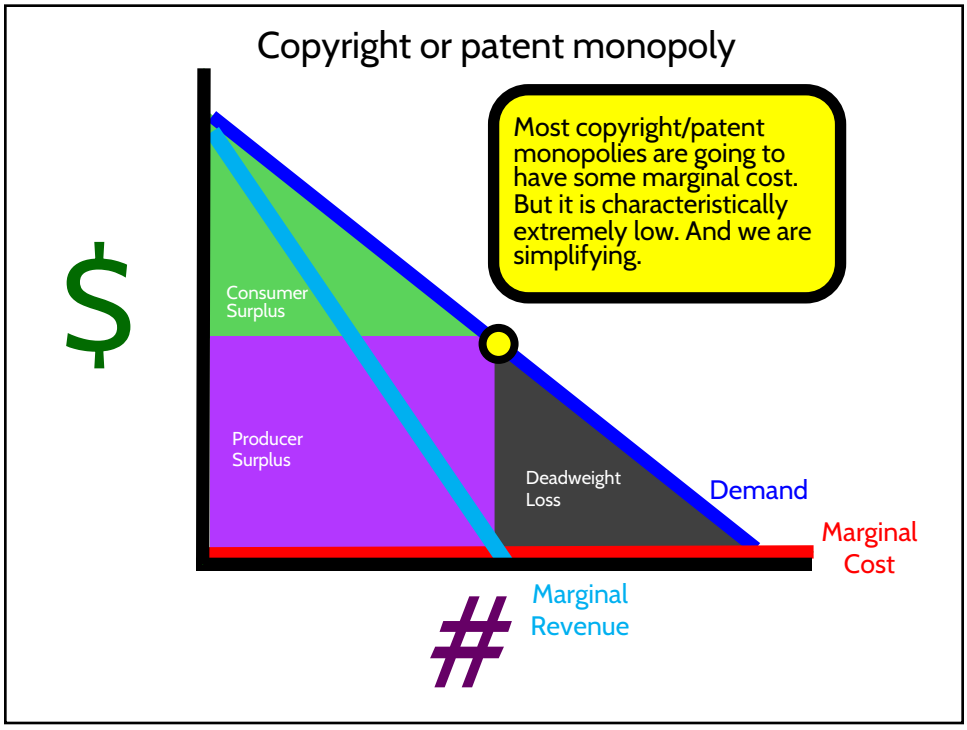
Here's some graphs that, for some students, will be another way of understanding this.

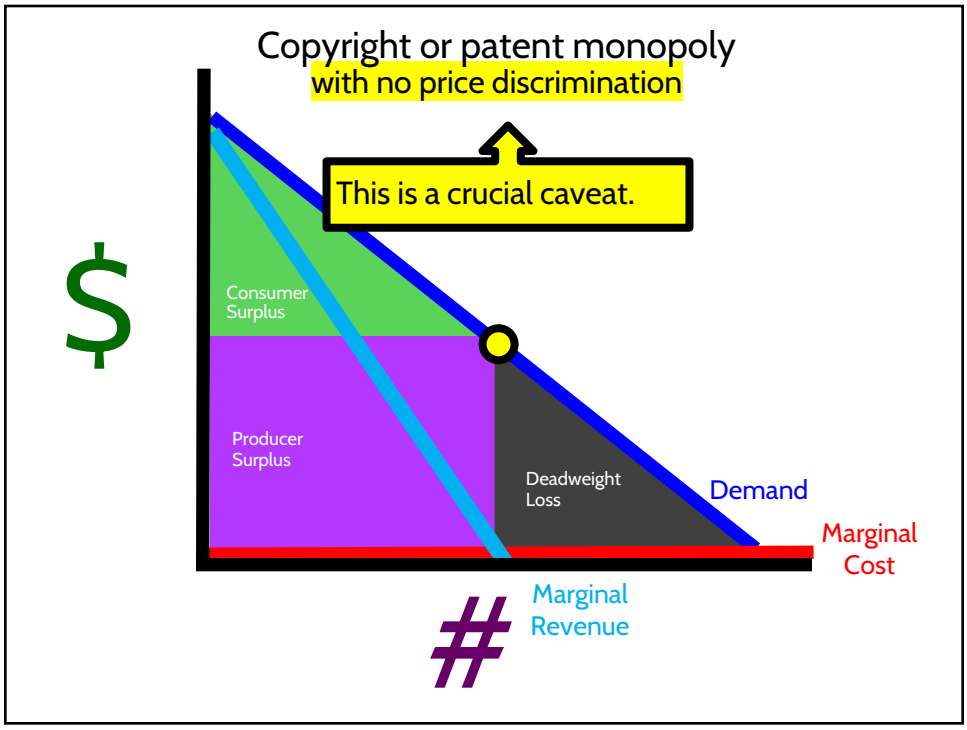


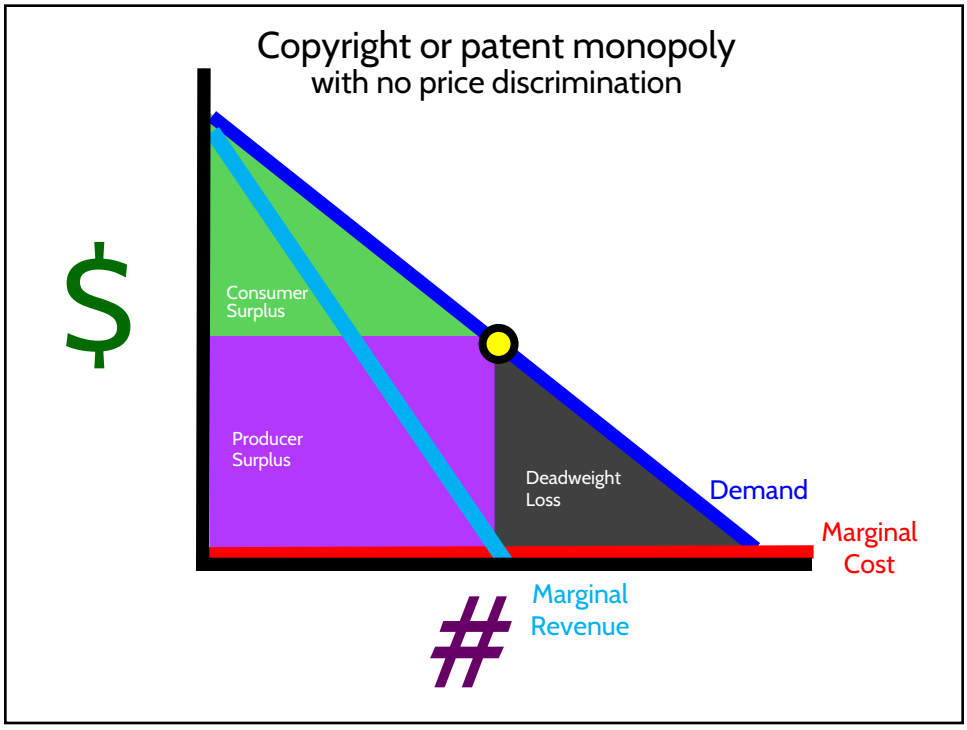

Perfectly competitive market
Supply
$
Consumer Surplus
Producer Surplus
Surplus means value you get out of something beyond the price (what you pay or get paid). I tend to translate surplus as "bonus awesomeness."
Demand
#

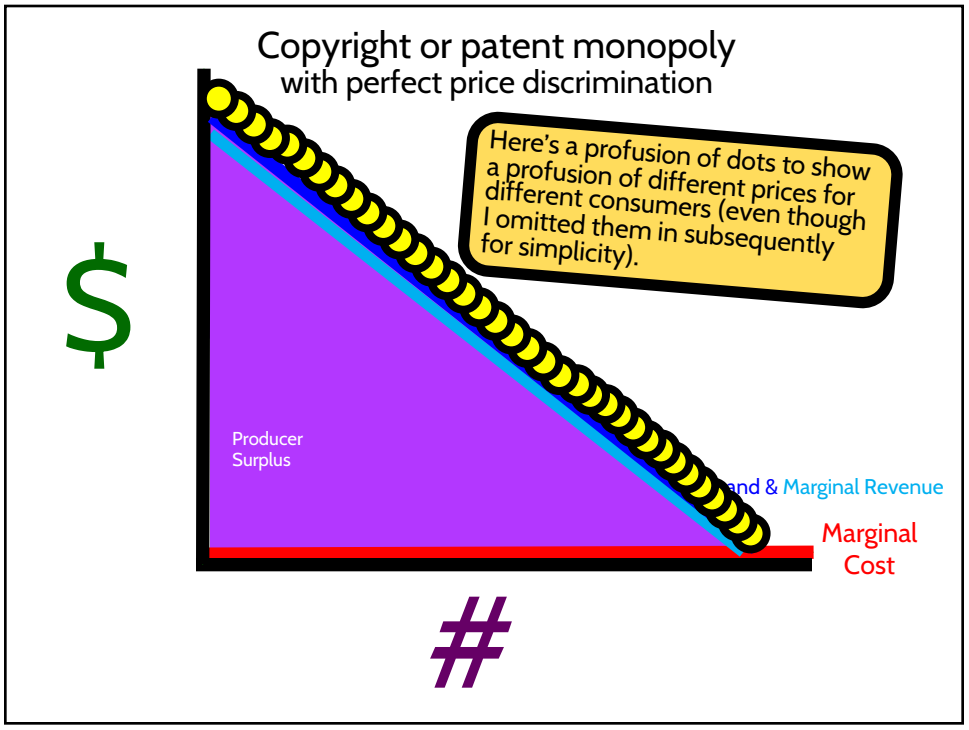

Monopoly
Marginal Cost
$
Consumer Surplus
Deadweight Loss
Producer Surplus
Marginal Revenue
Demand
#

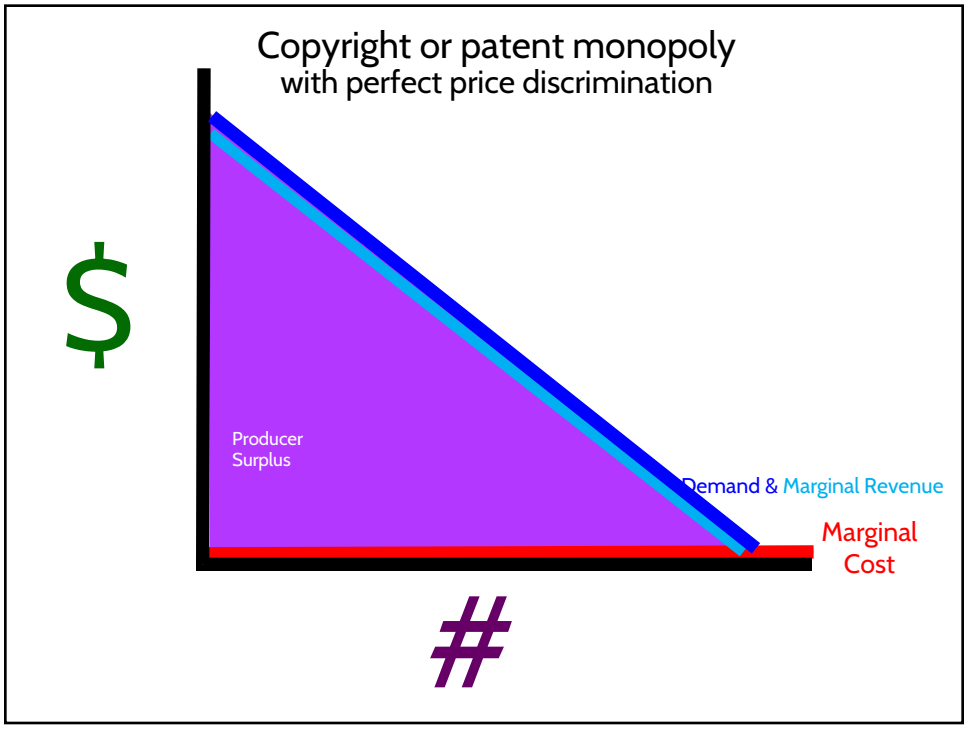

Monopoly
$
Marginal Cost
Consumer Surplus
Deadweight Loss
Producer Surplus
"Deadweight loss" means economic inefficiency – transactions that could have been beneficial for buyers and sellers but that never happened. Which is bad.
Marginal Revenue
Demand
#

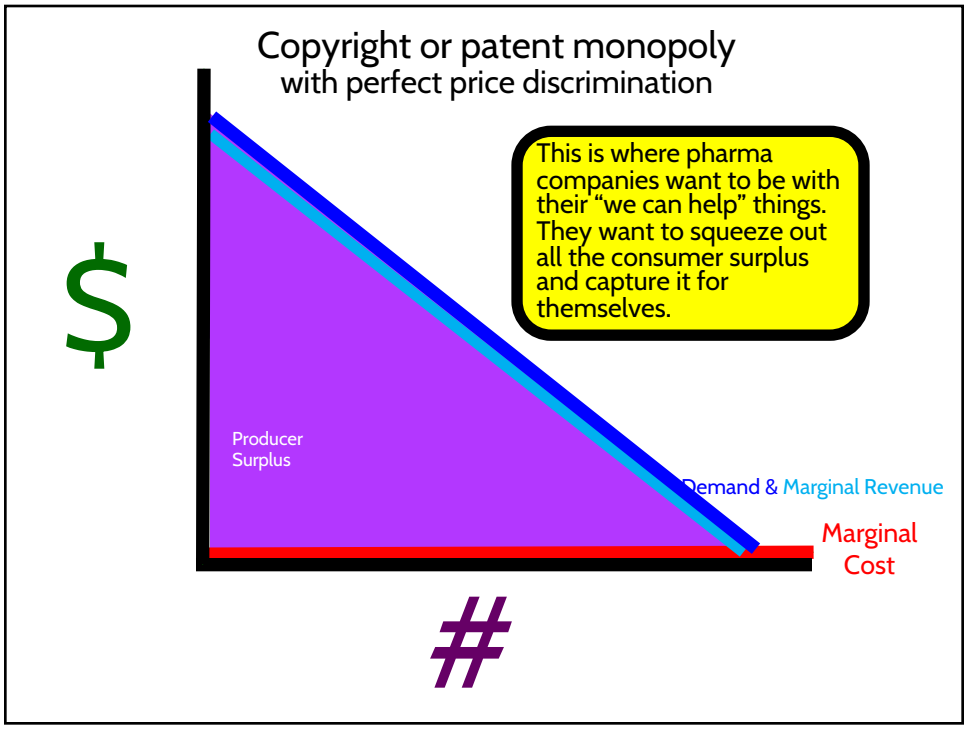

Copyright or patent monopoly
$
Most copyright/patent monopolies are going to have some marginal cost. But it is characteristically extremely low. And we are simplifying.
Consumer Surplus
Producer Surplus
Deadweight Loss
Demand
Marginal Cost
#
Marginal Revenue


Copyright or patent monopoly
with no price discrimination
This is a crucial caveat.
$
Consumer Surplus
Producer Surplus
Deadweight Loss
Demand
Marginal Cost
#
Marginal Revenue


Copyright or patent monopoly
with no price discrimination
$
Consumer Surplus
Producer Surplus
Deadweight Loss
Demand
Marginal Cost
#
Marginal Revenue


Copyright or patent monopoly
with perfect price discrimination
Here's a profusion of dots to show a profusion of different prices for different consumers (even though I omitted them in subsequently for simplicity).
$
Producer Surplus
Demand & Marginal Revenue
Marginal Cost
#


Copyright or patent monopoly
with perfect price discrimination
$
Producer Surplus
Demand & Marginal Revenue
Marginal Cost
#



TOPIC 2:

Drug development and the law

Pharma and patents …

- 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 ... #1

- Invention: Researchers create a new compound that didn't exist before.
- Preclinical evaluation: The compound is tested in the lab, such as on cell cultures and animals, to see if it has any pharmacological effect that is potentially useful.
- IND (Investigational New Drug application): The research drug firm files an IND with the FDA with preclinical data and a proposed clinical trial design. The FDA decides whether to allow the IND and permit human testing.

The story of a drug ... #1

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The FDA decides whethe
human testing.

The usefulness threshold for a utility patent is surpassed, if at all, in the preclinical evaluation stage.

The story of a drug … #1

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The story of a drug … #2

- Clinical testing: Generally, clinical testing takes place in multiple phases.
  - Phase I trials: Safety. The treatment is tested on a small group of people (roughly 20 to 100) to evaluate safety. Answers to get: What's a safe dosage? How is the drug absorbed, metabolized, excreted? What are the side effects?
  - Phase II trials: Efficacy, plus more safety. The treatment is given to a larger group of people (up to several hundred) to see if it is effective and to further evaluate safety. These studies are usually randomized, placebo-controlled, blinded.
  - Phase III trials: The treatment is given to large groups of people (several hundred to several thousand) to confirm effectiveness and gather more information about side effects, safety, and to compare it to other treatments.

By the way, post-approval, there could potentially be …

- Phase IV trials: To get additional information. Might be conducted by same firm or by other, interested researchers.

The story of a drug ... #2

- Clinical testing: Generally, clinical testing tak… multiple phases.
  - Phase I trials: Safety. The treatment is tested on a small group of people (roughly… …at's a safe dosage? H… …ed… What are the sid…
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  - Phase III trials: T… …s of people (several hundre… …ed… …nd gather more inf… …inc… …are it to other treatments.

By the way, post-approval, there could potentially be ...

- Phase IV trials: To get additional information. Might be conducted by same firm or by other, interested researchers.

100%

Phase I: about 70% of drugs pass this phase

~70%

Phase II: about 2/3rd of drugs pass phases 1 & 2

~67%

Phase III: about 70 to 90% of drugs pass this phase

~57%

The story of a drug ... #3

- New Drug Application (NDA): After clinical testing is done, the drug firm files an NDA with the FDA to try to get the drug approved for marketing.
  - The FDA says, an NDA "is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged."
- NDA review: The FDA considers the NDA, and may grant it.
- The average remaining patent term on approval 12 years. Blockbuster drugs may have many billion dollars a year in revenues, with relatively small marginal cost.

The story of a drug ... #4

- Abbreviated New Drug Application (ANDA): 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

Sources I relied on for this slide deck:

- FDA, *What Are the Different Types of Clinical Research?*, https://www.fda.gov/patients/clinical-trials-what-patients-need-know/what-are-different-types-clinical-research
- *The Hatch-Waxman Act: A Primer*, September 28, 2016, Congressional Research Service
- Robin Feldman, *May Your Drug Price Be Evergreen,* 5 Journal of Law and the Biosciences 590 (2018).