

# **Intellectual Property & the Access to Medicine Crisis**

Brendan Hickey

UAEM Conference

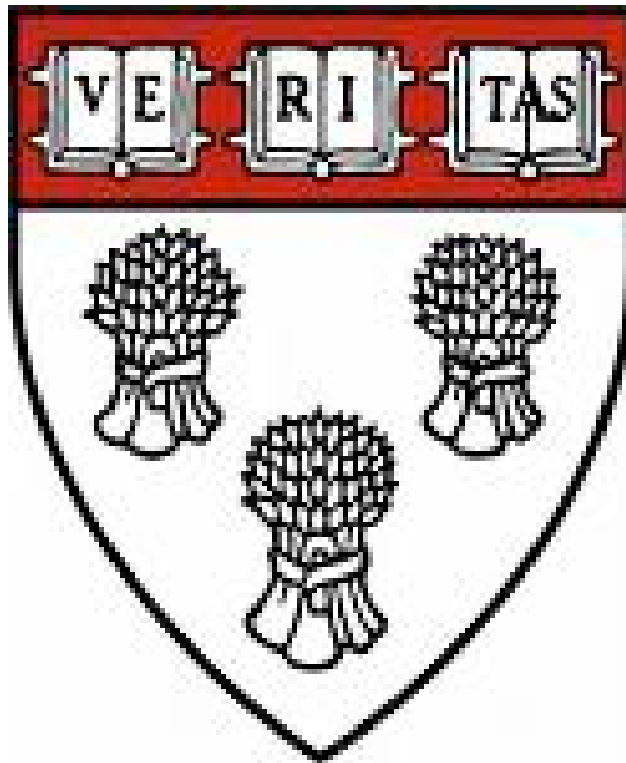
September 29 2007

# Key Questions

- What is property?
- What is intellectual property?
- What is a patent?
- Why do we have IP?
- What is the global landscape of IP law?
- WHY?!

# What is Property?

- A 'bundle' of legal rights to something



# What is Property?

Real Property



Personal Property



# What property rights are included in the 'bundle'?

Use



Exclude



Give



(Brief demonstration)

# Breaking the (property) law



Matt Zimmerman

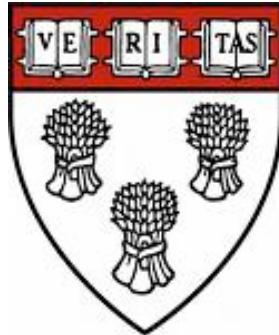
Scott Erickson steals the ball.



# Why is stealing bad?

- Because you were deprived of your **rights?**

**OR**



- Because you were deprived of your



And you can't play ball anymore!

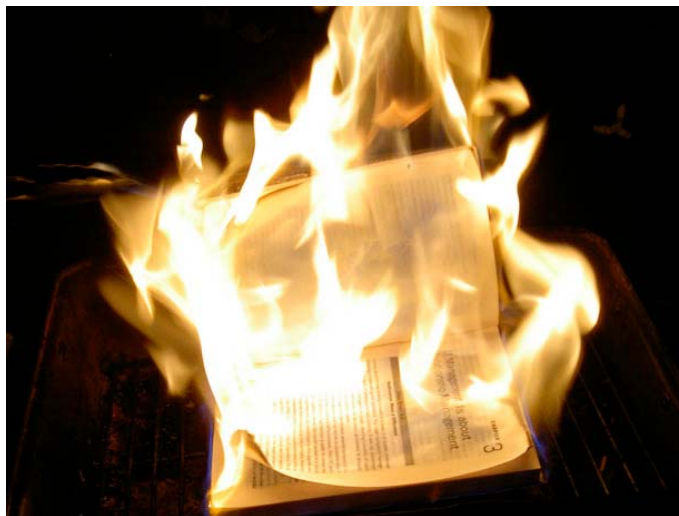
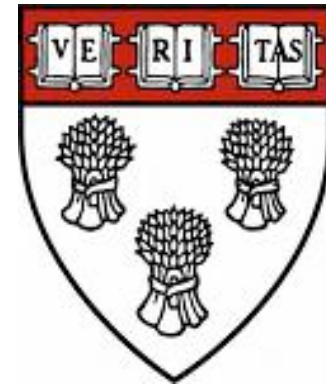
# Key Questions

- What is property?
- **What is intellectual property?**
- What is a patent?
- How do patents affect health?
- What is the global landscape of IP law?
- WHY?!

# What is Intellectual Property?

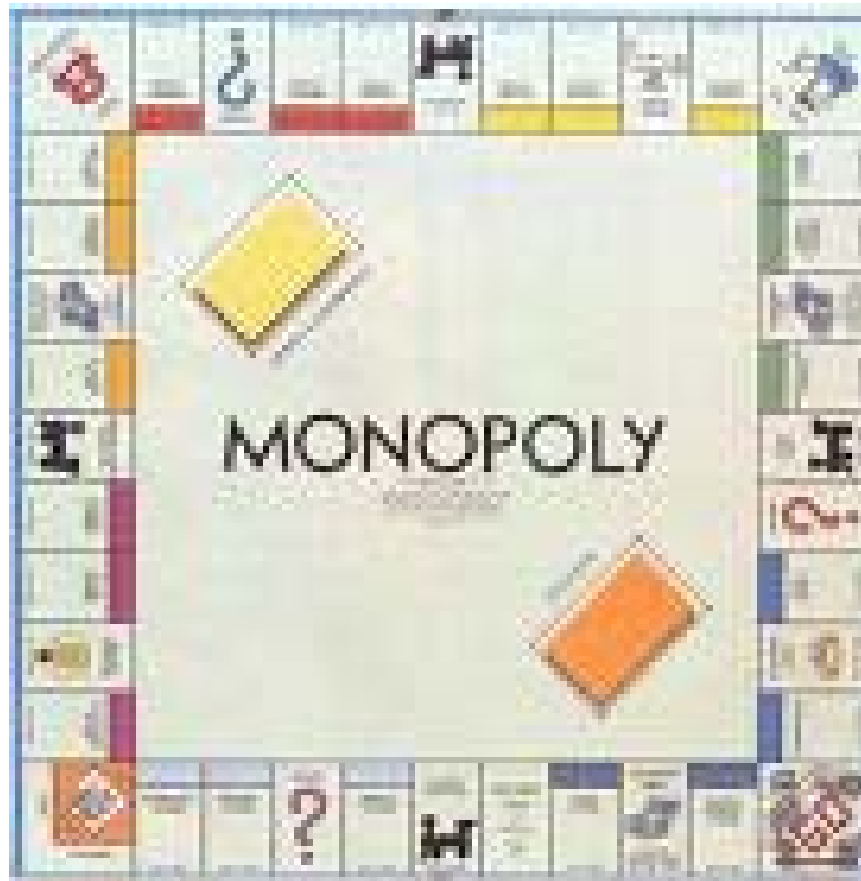
Bundle of rights to information

Exclude others from that info



# What rights in the IP bundle?

- Exclude:
  - Production
  - Sale
  - Use

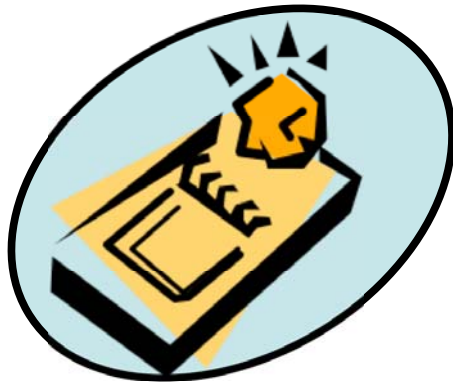


# Key Questions

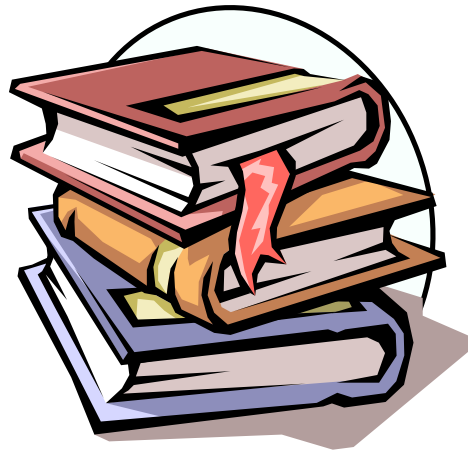
- What is property?
- What is intellectual property?
- **What is a patent and why have them?**
- What is the global landscape of IP law?
- WHY?!

# TYPES OF IP

patent



©

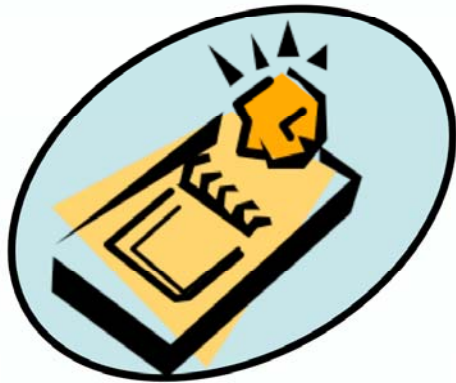


TM



# TYPES OF IP

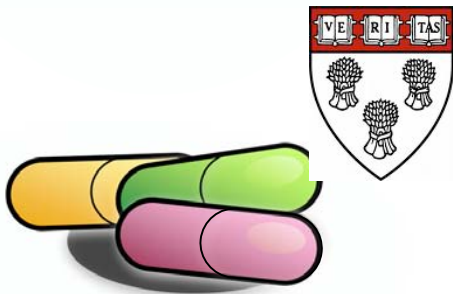
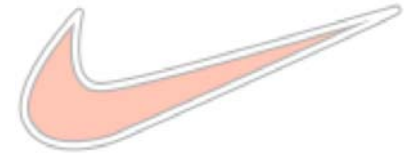
patent



©



TM



**United States Patent** [19]

Kempf et al.

(11) Patent Number: 5,648,497

(45) Date of Patent: Jul. 15, 1997

**[54] RETROVIRAL PROTEASE INHIBITING COMPOUNDS**

[75] Inventors: Dale J. Kempf, Libertyville; Daniel W. Norbeck, Lindenhurst; Lynn M. Colacore, Ashloch; Hing L. Sham, Curran; Steven J. Wittenberger, Mundelein, all of Ill.

[73] Assignee: Abbott Laboratories, Abbott Park, Ill.

[21] Appl. No.: 410,623

[22] Filed: Mar 24, 1995

**Related U.S. Application Data**

[62] Division of Ser. No. 270,210, Aug. 23, 1994, abandoned, which is a division of Ser. No. 121,273, Sep. 14, 1993, Pat. No. 5,354,866, which is a continuation-in-part of Ser. No. 777,630, Oct. 23, 1991, abandoned, which is a continuation-in-part of Ser. No. 746,020, Aug. 15, 1991, abandoned, which is a continuation-in-part of Ser. No. 616,130, Nov. 20, 1990, abandoned, which is a continuation-in-part of Ser. No. 518,730, May 9, 1990, Pat. No. 5,142,056, which is a continuation-in-part of Ser. No. 456,224, Dec. 22, 1989, abandoned, which is a continuation-in-part of Ser. No. 405,604, Sep. 8, 1989, abandoned, which is a continuation-in-part of Ser. No. 355,945, May 23, 1989, abandoned.

[51] Int. Cl.<sup>6</sup> C07D 277/30

[52] U.S. CL. 548/204; 548/193; 548/194; 548/195

[58] Field of Search 548/193, 204, 548/194, 195; 514/370, 365

**[56] References Cited****FOREIGN PATENT DOCUMENTS**

393445 10/1990 European Pat. Off.  
402046 12/1990 European Pat. Off.  
428849 5/1991 European Pat. Off.  
441182 8/1991 European Pat. Off.  
3829594 3/1990 Germany  
4003535 8/1991 Germany  
W088A2334 4/1988 WIPO

**Primary Examiner—Jane Fan**

Attorney, Agent, or Firm—Steven R. Crowley

**[57] ABSTRACT**

A retroviral protease inhibiting compound of the formula A—X—B is disclosed. Also disclosed are a composition and method for inhibiting a retroviral protease and for treating an HIV infection. Also disclosed are processes and intermediates useful for the preparation of the retroviral protease inhibitors.

8 Claims, No Drawings

**1  
RETROVIRAL PROTEASE INHIBITING COMPOUNDS**

This is a division of U.S. patent application Ser. No. 08/270,210, filed Aug. 23, 1994, now abandoned, which is a division of U.S. Ser. No. 08/721,673, filed Sep. 14, 1993, now U.S. Pat. No. 5,354,866, which is a continuation of U.S. Ser. No. 07/777,626, filed Oct. 23, 1991, now abandoned, which is a continuation in part of U.S. patent application Ser. No. 07/746,020, filed Aug. 15, 1991, now abandoned, which is a continuation in part of U.S. patent application Ser. No. 07/616,170, filed Nov. 20, 1990, now abandoned, which is a continuation in part of U.S. patent application Ser. No. 07/518,730, filed May 9, 1990 now U.S. Pat. No. 5,142,056, which is a continuation in part of U.S. patent application Ser. No. 07/456,124, filed Dec. 22, 1989, now abandoned which is a continuation in part of U.S. patent application Ser. No. 07/405,604, filed Sep. 8, 1989, now abandoned which is a continuation in part of U.S. patent application Ser. No. 07/355,945, filed May 23, 1989.

This invention was made with Government support under contract number A127220 awarded by the National Institute of Allergy and Infectious Diseases. The Government has certain rights in this invention.

**TECHNICAL FIELD**

The present invention relates to novel compounds and a composition and method for inhibiting retroviral proteases and in particular for inhibiting human immunodeficiency virus (HIV) protease, a composition and method for treating a retroviral infection and in particular an HIV infection, processes for making such compounds and synthetic intermediates employed in these processes.

**BACKGROUND ART**

Retroviruses are those viruses which utilize a ribonucleic acid (RNA) intermediate and a RNA-dependent deoxyribonucleic acid (DNA) polymerase, reverse transcriptase, during their life cycle. Retroviruses include, but are not limited to, the RNA viruses of the Retroviridae family, and also the DNA viruses of the Hepadnavirus and Caulimovirus families. Retroviruses cause a variety of disease states in man, animals and plants. Some of the more important retroviruses from a pathological standpoint include human immunodeficiency viruses (HIV-1 and HIV-2), which cause acquired immune deficiency syndrome (AIDS) in man, hepatitis B virus, which causes hepatitis and hepatic carcinomas in man, human T-cell lymphotropic viruses I, II, IV and V, which cause human acute cell leukemia, and bovine and feline leukemia viruses which cause leukemia in domestic animals.

Proteases are enzymes which cleave proteins at specific peptide bonds. Many biological functions are controlled or mediated by proteases and their complementary protease inhibitors. For example, the protease renin cleaves the peptide angiotensinogen to produce the peptide angiotensin I. Angiotensin I is further cleaved by the protease angiotensin converting enzyme (ACE) to form the hypotensive peptide angiotensin II. Inhibitors of renin and ACE are known to reduce high blood pressure in vivo. An inhibitor of a retroviral protease should provide a therapeutic agent for diseases caused by the retrovirus.

The genomes of retroviruses encode a protease that is responsible for the proteolytic processing of one or more polypeptide precursors such as the pol and gag gene products. See Wellink, Arch. Virol. 98 1 (1985). Retroviral proteases most commonly process the gag precursor into

5,648,497

2

core proteins, and also process the pol precursor into reverse transcriptase and retroviral protease. In addition, retroviral proteases are sequence specific. See Pearl, Nature 328 482 (1987).

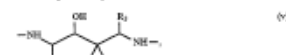
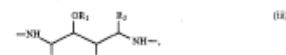
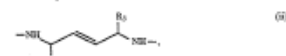
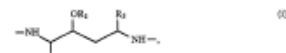
The correct processing of the precursor polyproteins by the retroviral protease is necessary for the assembly of infectious virions. It has been shown that in vitro mutagenesis that produces protease-defective virus leads to the production of immature core forms which lack infectivity. See Crawford, J. Virol. 53 899 (1985); Katoh, et al., Virology 145 280 (1985). Therefore, retroviral protease inhibition provides an attractive target for antiviral therapy. See Mizuya, Nature 325 775 (1987).

Current treatments for viral diseases usually involve administration of compounds that inhibit viral DNA synthesis. Current treatments for AIDS (Dagan, Chem. Eng. News, Nov. 23, 1987 pp. 41-49) involve administration of compounds such as 2',3'-dideoxyinosine, 3'-azido-2'-deoxythymidine, 2',3'-dideoxythymidine, 3'-azido-2'-deoxythymidine, 1-beta-D-ribofuranosyl-1,2,4-triazole-3-carboxamide, 3'-azido-2'-deoxythymidine, and adriamycin that inhibit viral DNA synthesis; compounds such as AZT and zalcitabine which may prevent HIV from penetrating the host cell; and compounds which treat the opportunistic infections caused by the immunosuppression resulting from HIV infection. None of the current AIDS treatments have proven to be totally effective in treating and/or reversing the disease. In addition, many of the compounds currently used to treat AIDS cause adverse side effects including low platelet count, renal toxicity and bone marrow cytopenia.

**DISCLOSURE OF THE INVENTION**

In accordance with the present invention, there are retroviral protease inhibiting compounds of the formula: or a pharmaceutically acceptable salt, prodrug or ester thereof.

X is



# Why Have IP?

- To give people incentive to invent things (Economic Justifications)



Sales



# Economic Justifications for IP



Joe

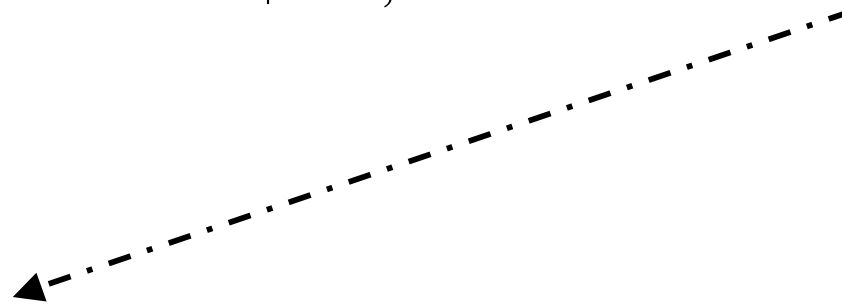


Two years

\$100,000



**Brand New Invention**



6 Months

\$20,000



**Copycat of Joe's Invention**



George

# Economic Justifications for IP

## WITHOUT INTELLECTUAL PROPERTY:

Production costs for 10,000



\$10.00/piece

Cost per piece for research and development



$\$100,000/10,000 =$   
**\$10**



$\$20,000/10,000 =$   
**\$2**

Total Production Price

**\$20**

**\$12**

# Economic Justifications for IP WITH INTELLECTUAL PROPERTY:



Two years



\$100,000



**Brand New Invention**



# The Balance of patent Law

## Goals

- Promote Innovation
- Allow the public to benefit from the innovation

### **Too much IP:**

- 1) The public cannot use new innovations
- 2) Innovation stagnates because inventors cannot improve them



### **Too little IP:**

Competition stifles innovation by making research less profitable

If you don't invent drugs...

There's no reason to patent them!

Letting out the secret...

# The “quid pro quo” of Patent Law

## What you give

- A **written description** of your invention
- **Enablement**: disclose how to make and use your invention
- **Best mode**: disclose the best mode of patenting your invention



## What you get

- An **exclusive right to exclude** others from making, selling, or using your invention for a **limited period of time**
- The power to assign or **license** (give) your rights to someone else



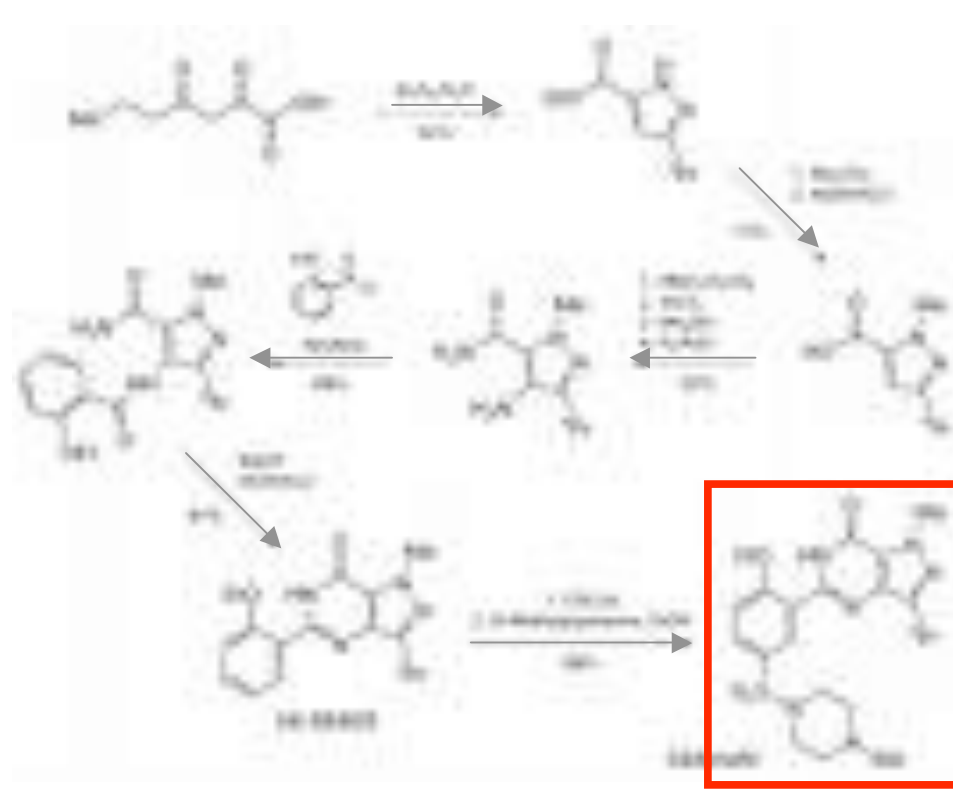
# Requirements for Obtaining a Patent



- Novelty
  - Must not already be known to the public
- Usefulness
  - Must provide some identifiable benefit
  - Can't be primarily aesthetic or descriptive
- Non-obviousness
  - Can't patent something that would have been obvious to a person of ordinary skill in a particular field

# Product vs. Process Patents

Process



Product

# Infringement

- When someone uses an IP right without permission, it is called infringement
- Sue for damages or injunction
- Defenses:
  - Invalidity
  - Non-infringement



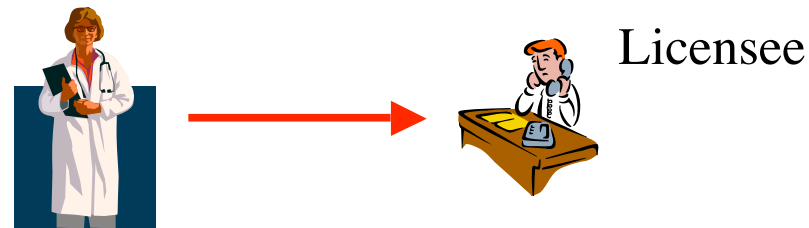
# License:



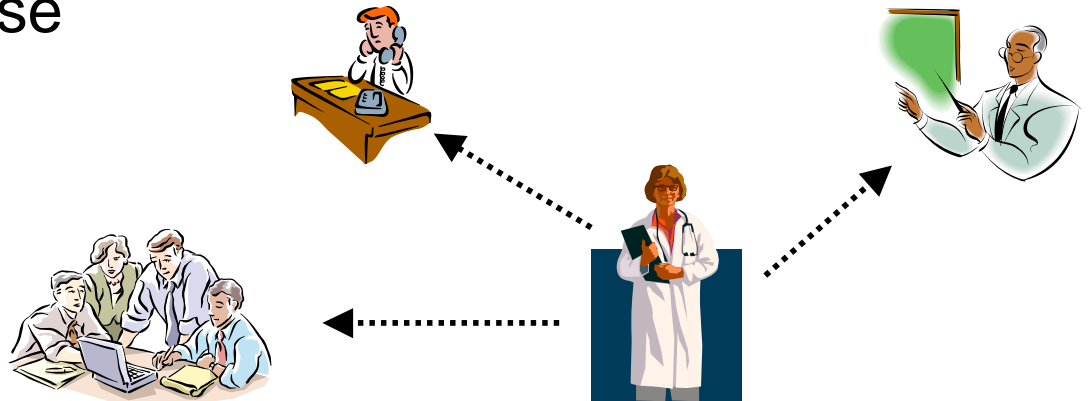
# Uses for Patents

- Assignment: give someone the entire patent
- **Licensing**: letting a third party use the patented technology under certain conditions

- Exclusive license



- Non-exclusive license



# Key Questions

- What is property?
- What is intellectual property?
- What is a patent?
- **What is the global landscape of IP law?**
- WHY?!





INTERNATIONAL  
**Herald Tribune**

By Victoria Shannon

THURSDAY, OCTOBER 13, 2005

- “The value of the ideas and innovation that the U.S. economy generates is more than \$5 trillion a year, roughly 42 percent of the country's gross domestic product and far more than any other nation's GDP.”
- “Losses to piracy of such **goods** are estimated at \$638 billion a year, according to the Organization for Economic Cooperation and Development.”

# Enter PhRMA

- Patents => Profits
- Don't they need patents to keep drug development going?
- WHERE do they need patents?

## Pharmaceutical Industry Fortune 500 Ranking

| Year | Return on Revenues <sup>1</sup> |          |                      |          |                                 |
|------|---------------------------------|----------|----------------------|----------|---------------------------------|
|      | Drug Industry                   |          | Industry Ranked #2   |          | Fortune 500 Median <sup>2</sup> |
|      | Rank                            | % Return | Industry             | % Return | % Return                        |
| 1991 | 1                               | 12.8     | beverages            | 5.5      | 3.2                             |
| 1992 | 1                               | 11.5     | toys, sporting goods | 6.5      | 2.4                             |
| 1993 | 1                               | 12.5     | publishing, printing | 6.4      | 2.9                             |
| 1994 | 1                               | 16.1     | commercial banks     | 13.5     | 4.6                             |
| 1995 | 1                               | 14.4     | commercial banks     | 13.3     | 4.8                             |
| 1996 | 1                               | 17.1     | commercial banks     | 13.9     | 5.0                             |
| 1997 | 1                               | 16.1     | commercial banks     | 13.6     | 4.9                             |
| 1998 | 1                               | 18.5     | commercial banks     | 13.2     | 4.4                             |
| 1999 | 1                               | 18.6     | commercial banks     | 15.8     | 5.0                             |
| 2000 | 1                               | 18.6     | commercial banks     | 14.1     | 4.5                             |
| 2001 | 1                               | 18.5     | commercial banks     | 13.5     | 3.3                             |

| Company                                | Revenue<br>(Net Sales in<br>Millions of Dollars) | Percent of Revenue Allocated to:             |                        |                        |
|--|--|--|------------------------|------------------------|
|  |  | Marketing/<br>Advertising/<br>Administration | R & D                  | Profit<br>(Net Income) |
| Merck & Co., Inc.                      | \$47,716   | 13%  | 5%                     | 15%                    |
| Pfizer, Inc.                           | \$32,259   | 35%  | 15%                    | 24%                    |
| Bristol-Myers Squibb Company           | \$19,423   | 27%  | 12%                    | 27%                    |
| Abbott Laboratories                    | \$16,285   | 23%  | 10%                    | 10%                    |
| Wyeth                                  | \$14,129   | 37%  | 13%                    | 16%                    |
| Pharmacia Corporation                  | \$13,837   | 44%  | 16%                    | 11%                    |
| Eli Lilly & Co.                        | \$11,543   | 30%  | 19%                    | 24%                    |
| Schering-Plough Corporation            | \$9,802  | 36%  | 13%                    | 20%                    |
| Allergan, Inc.                         | \$1,685  | 42%  | 15%                    | 13%                    |
| <b>Total*</b><br>(Dollars in millions) | <b>\$166,678</b>                                 | <b>27%</b><br>\$45,413                       | <b>11%</b><br>\$19,076 | <b>18%</b><br>\$30,599 |

Industry

## Pharmaceuticals & Other Health Products

Reported Lobbying 1998-2004: **\$673,701,988**

Reported Lobbying 2004: \$123,298,552

### Annual Lobbying

\$67.22   \$81.45   \$91.85   \$90.16   \$104.99   \$114.73   \$123.30

1998   1999   2000   2001   2002   2003   2004

Figures based on Senate Office of Public Records filings last updated June 2005

## Top 20 recipients of drug industry money 1997-2005

| Name                               | Total     | Individual | PAC       |
|------------------------------------|-----------|------------|-----------|
| President George W. Bush<br>(R)    | \$798,732 | \$760,232  | \$38,500  |
| Rep. Mike Ferguson<br>(R-N.J.)     | \$457,967 | \$202,700  | \$255,267 |
| Sen. Arlen Specter<br>(R-Pa.)      | \$376,549 | \$207,450  | \$169,099 |
| Sen. Orrin Hatch<br>(R-Utah)       | \$351,424 | \$162,709  | \$188,715 |
| Sen. Richard Burr<br>(R-N.C.)      | \$334,402 | \$80,150   | \$254,252 |
| Sen. John Kerry<br>(D-Mass.)       | \$305,203 | \$305,203  | \$0       |
| Rep. Nancy Johnson<br>(R-Conn.)    | \$301,790 | \$12,950   | \$288,840 |
| Rep. Dennis Hastert<br>(R-Ill.)    | \$274,050 | \$5,450    | \$268,600 |
| Rep. Bob Franks<br>(R-N.J.)        | \$269,316 | \$155,113  | \$114,203 |
| Rep. Bill Thomas<br>(R-Calif.)     | \$240,450 | \$22,450   | \$218,000 |
| Rep. Rick Lazio<br>(R-N.Y.)        | \$224,138 | \$110,638  | \$113,500 |
| Rep. John Dingell<br>(D-Mich.)     | \$214,500 | \$14,000   | \$200,500 |
| Sen. Robert Torricelli<br>(D-N.J.) | \$214,253 | \$110,900  | \$103,353 |
| Sen. Joe Lieberman<br>(D-Conn.)    | \$203,850 | \$112,050  | \$91,800  |
| Rep. Chris Dodd                    | \$198,725 | \$50,525   | \$148,200 |

**Table 7**  
**Sales By Geographic Area,\* PhRMA Member Companies: 2004**

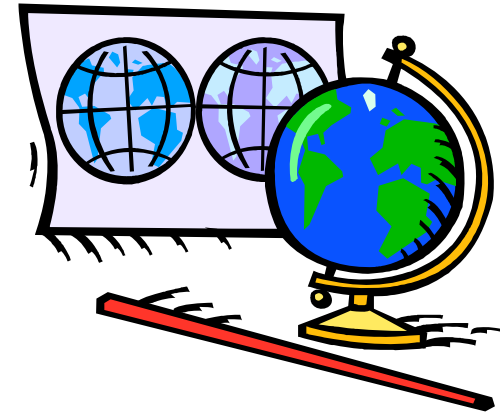
(dollar figures in millions)

| <b>Geographic Area*</b>   | <b>Dollars</b>     | <b>Share</b>  |
|---|--------------------|---------------|
| <b>Africa</b>   |                    |               |
| Africa  | \$ 944.5           | 0.4%          |
| <b>Americas</b>   |                    |               |
| United States   | \$160,751.0        | 66.4%         |
| Canada  | 5,594.5            | 2.3           |
| Latin America (South and Central America, Mexico and all Caribbean nations)   | 5,514.6            | 2.3           |
| <b>Asia-Pacific</b>   |                    |               |
| Asia-Pacific (except Japan)   | \$ 3,871.1         | 1.6%          |
| India and Pakistan  | 623.0              | 0.3           |
| Japan   | 8,885.2            | 3.7           |
| <b>Australia</b>  |                    |               |
| Australia and New Zealand   | \$ 2,939.9         | 1.2%          |
| <b>Europe</b>   |                    |               |
| France  | \$ 8,790.3         | 3.6%          |
| Germany   | 5,969.8            | 2.5           |
| Italy   | 6,383.3            | 2.6           |
| Spain   | 4,712.1            | 1.9           |
| United Kingdom  | 5,367.3            | 2.2           |
| Other Western European nations  | 10,421.2           | 4.3           |
| Central and Eastern European nations (Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia and Malta) | 2,272.3            | 0.9           |
| Other Eastern European nations (including Russia and the Newly Independent States)  | 516.1              | 0.2           |
| <b>Middle East</b>  |                    |               |
| Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan, Turkey and Qatar)                           | \$ 2,105.0         | 0.9%          |
| <b>Uncategorized</b>  | \$ 6,453.8         | 2.7%          |
| <b>TOTAL SALES</b>  | <b>\$242,115.0</b> | <b>100.0%</b> |

\*Sales Abroad includes sales generated outside the United States by U.S.-owned PhRMA member companies and

# International Patent Law

- Is governed by multiple elements:
  - **Trade Related Aspects of Intellectual Property Rights – TRIPS**
    - World Trade Organization (WTO)
  - Bilateral and Multilateral agreements between different countries



# Basics of TRIPS



- Minimum protection standards with **20 year** patents
- Range of patentable items **including pharmaceutical products.**
- Only allowable conditions of patentability are novelty, non-obviousness, usefulness **but countries are allowed to define these terms as they see fit.**
  - Cannot exclude based on national origin or type of product.
- Allows for **compulsory licensing** in some circumstances
  - National emergency exception
  - Public non-commercial use

# TRIPS “Flexibilities”

- Delayed implementation for developing countries
  - January 1, 2005 for India
  - January 1, 2016 for “Least Developed Countries”
  - Everything before 1994 is safe
  - Litigation now OVER in India (we won)
- Parallel Importation (Article 6)
  - Leaves this open to member states
- Compulsory Licensing (Article 31)
  - Use without authorization of the rights holder
  - Must make reasonable effort to obtain authorization
  - Limited scope and duration
  - Must inform the rights holder and provide remuneration
  - Primarily for the **domestic market** of the invoking nation

# Compulsory Licensing

Country has public health emergency and needs a cheaper supply of medicine

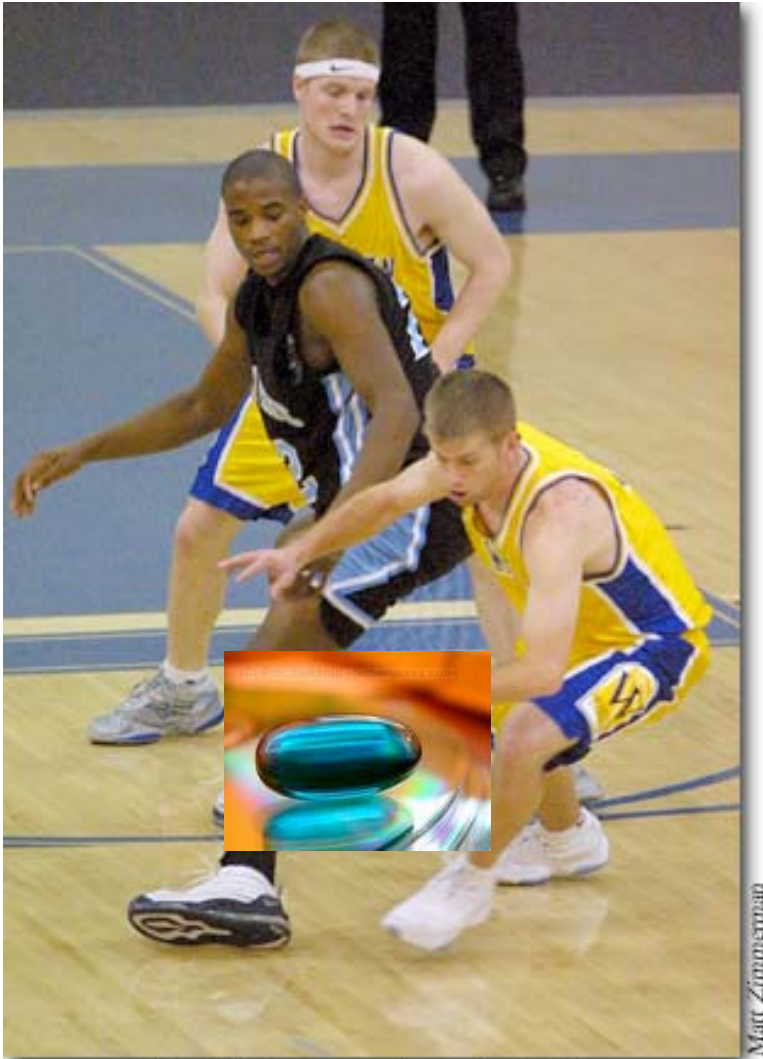
Notifies rights holder that it needs drugs

Country in need gets license to produce for public health (whether patent holder wants to give permission or not)

*Patent holder*

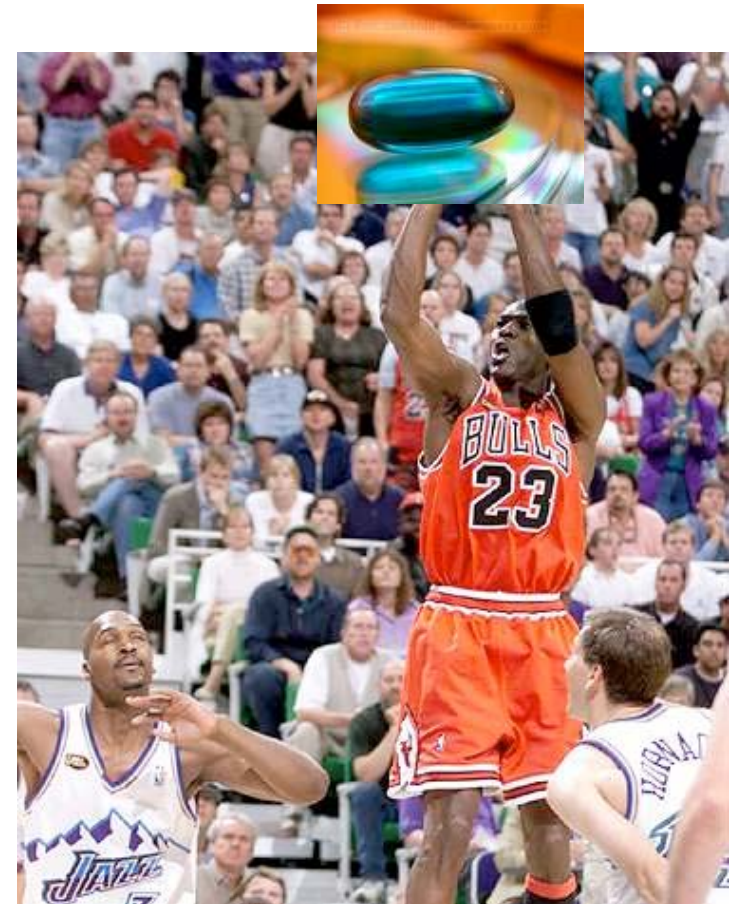
A diagram illustrating the compulsory licensing process. It features two text boxes on the left and a stylized text label on the right. The top text box states 'Country has public health emergency and needs a cheaper supply of medicine'. The bottom text box states 'Country in need gets license to produce for public health (whether patent holder wants to give permission or not)'. The stylized text label on the right is 'Patent holder' in a yellow, italicized font with a drop shadow. A solid black arrow points from the top text box to the 'Patent holder' label, with the text 'Notifies rights holder that it needs drugs' positioned above it. A dashed black arrow points from the bottom text box to the 'Patent holder' label.

# Compulsory Licensing under TRIPS



Scott Erickson steals the ball.

FOR



# Why wasn't this enough?

- Not every nation can make drugs. Those that can't are unaided.
- Serious consequences for using it...





# Doha Declaration

Trade ministers signed this agreement to fix some of these problems:

- “The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”
- Helping countries without manufacturing capacity: “We instruct the Council for TRIPS to find an expeditious solution to this problem...”

# August 30th Agreement

- Temporary waiver of the domestic use restriction for products needed to address public health problems.
- Members invoking the agreement must notify the TRIPS Council.
- Medicines made under the agreement must be of a different size, shape and color from those sold in developed countries.

# Compulsory Licensing-Post Doha para 6

Notifies rights-holder that they are taking a compulsory license



Least developed country in need of medicine

Generic manufacturer in country with production capabilities imports to LDC in need



Rights from compulsory license flow to producer who can actually make the drug



It's not working



U.S.

Developing country

Thailand





Abbott Laboratories Limited  
34 Nal Lert Tower  
31, 32<sup>nd</sup> and 33<sup>rd</sup> Floor  
Witthayu Road, Lumpini  
Pattana, Bangkok 10330  
Thailand

บริษัท แอ็บบอต ลาบอราทอรี จำกัด  
24 อาคารสิริพหลโยธิน  
ชั้น 3, ชั้น 32 และชั้น 33  
ถนนวิภาวดี แสงสุเมธิตี  
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วันที่ 14 กุมภาพันธ์ พ.ศ. 2550

เรียน ผู้อำนวยการกองควบคุมยา  
เรื่อง ยกเลิกคำขอขึ้นทะเบียนตำรับยา  
สิ่งที่ส่งมาด้วย ใบรับรองการขึ้นเอกสาร

ตามที่บริษัท แอ็บบอต ลาบอราทอรี จำกัด ได้ยื่นคำขอขึ้นทะเบียนตำรับยาใหม่ และขออนุญาต  
กับกลุ่มยาใหม่ กลุ่มชีววัตถุ และกลุ่มยาสามัญ ของควบคุมยา สำนักงาน คณะกรรมการอาหาร  
และยาไว้ที่นั่น ทางบริษัทแม่ในต่างประเทศ ได้มีการทบทวนและ ประเมินการนำเข้ายา ในประเทศ  
ไทย แล้วเห็นสมควรว่าควรยกเลิกคำขอขึ้นทะเบียน ตำรับยา ดังรายการต่อไปนี้

1. Aluvia เลขรับที่ 2C 5/50 (N) ลงวันที่ 17 ม.ค. 2550
2. Humira เลขรับที่ 1C 90007/47(N) ลงวันที่ 2 เม.ย 2547
3. Cytavine เลขรับที่ 1C 90022/48(N) ลงวันที่ 13 พ.ค. 2548
4. Tarka เลขรับที่ 2C 21/48 (N) ลงวันที่ 3 พ.ย. 2548
5. Zemplar capsule 1 mcg เลขรับชั่วคราว 14/49 ลงวันที่ 15 ก.พ. 2549
6. Zemplar capsule 2 mcg เลขรับชั่วคราว 15/49 ลงวันที่ 15 ก.พ. 2549
7. Zemplar capsule 4 mcg เลขรับชั่วคราว 16/49 ลงวันที่ 15 ก.พ. 2549
8. Zemplar injection เลขรับชั่วคราว 109/49 ลงวันที่ 11 ก.ย. 2549
9. Brufen suspension เลขรับที่ 1C 239/49 ลงวันที่ 9 ต.ค. 2549
10. Abalone เลขรับที่ 1C 7/50 (N) ลงวันที่ 22 ม.ค. 2550

จึงเรียนมาเพื่อโปรดดำเนินการยกเลิกคำขอขึ้นทะเบียนยา ดังรายการข้างต้น และสิ้นเอกสาร  
ในการขึ้นทะเบียนของยาดังกล่าวไว้ที่สำนักงาน พร้อมส่งนามโนใบรับรองการขึ้น เอกสารการขึ้น  
ทะเบียน (ดังสิ่งที่ส่งมาด้วย)

บริษัทฯ ขอความกรุณาให้มีการเปิดเผยข้อมูลการยกเลิกคำขอขึ้นทะเบียนดังกล่าว

ขอแสดงความนับถือ

นางสาว ปัทมพร จงจัญญะวัฒน์  
(ผู้ดำเนินงาน)

# FTAs

“The report finds that contrary to the Doha Declaration, U.S. trade negotiators have repeatedly used the trade agreements to restrict the ability of developing nations to acquire medicines at affordable prices. In effect, the President’s trade representatives have elevated the protection of pharmaceutical patents above the pressing health needs of developing countries.”

-TRADE AGREEMENTS AND ACCESS TO MEDICATIONS  
UNDER THE BUSH ADMINISTRATION (Prepared for Rep.  
Henry A. Waxman, June 2005)

# TRIPS-plus provisions

Extended patent terms

Limitations on compulsory licensing

Block of parallel imports by patent holders

Data Exclusivity

Other provisions...

# Data Exclusivity

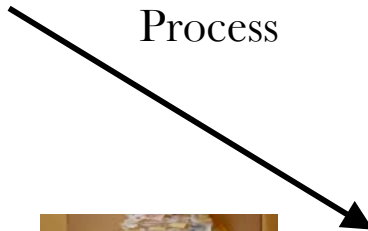
Name-brand company



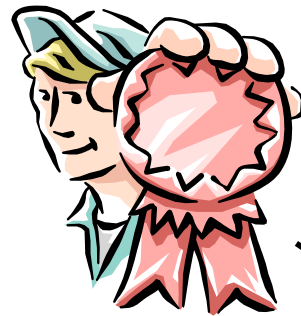
New drug



FDA Approval Process



Submission of paperwork and lots of data



Approval granted: some information made public



Generic producer applies for ANDA approval



FDA knows the drug is safe, but cannot use the data submitted by the name-brand company to approve the generic equivalent for x years

# Rise of Indian Generics



**\$1600**

**96%**

**\$55**



# India, Novartis & Section 3(d)

- Requirements for Obtaining a Patent:
- Novelty, Usefulness, **Non-obviousness**
  - Section 3(d): New forms of known substances are unpatentable (*obvious*) unless they demonstrate enhanced efficacy.
  - China, Brazil, and THE UNITED STATES have similar tests for obviousness.

August 7, 2007

## **Setback for Novartis in India Over Drug Patent**

- NEW DELHI, Aug. 6 Indian companies will be free to continue making less expensive generic drugs, much of which flow to the developing world, after a court rejected a challenge to the patent law on Monday...
- “India has a \$5 billion pharma industry, and 65 percent of those drugs are sold to the developing world and poorer people in the developed world. All that would have been suspended if the judgment had gone the other way, and there would have been a dearth of affordable drugs. That calamity has been prevented.”

# Closing Lessons

- IP is controlled largely by those who make \$ from it.
- Patent holders can now effectively patent their products worldwide, which they do.
- There is a fight - and we've had victories.
- Rather than change the law, we can reshape the bundles.



Who?