

The Role of Universities in Addressing the Access and Research Gaps

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Goals

- Define the problem
- Make the case for university action
- Explain why UAEM matters

Yale: The d4T Story

The Timeline

- **1966:** d4T synthesized under a National Cancer Institute grant at the Michigan Cancer Center
- **1984:** Yale scientists prove that d4T is potent against HIV in cell cultures
- **1986:** Yale files for a “use patent”
- **1988:** Yale issues BMS exclusive worldwide license (and files for patents in South Africa, Egypt, etc.)
- **1994:** FDA approval

The Money Trail

- BMS made \$515 million in 2001
- In 1999, Yale earned \$40M of its \$46.12M in royalties from d4t
- Almost none of this money came from developing countries

The Impact of d4T for Yale

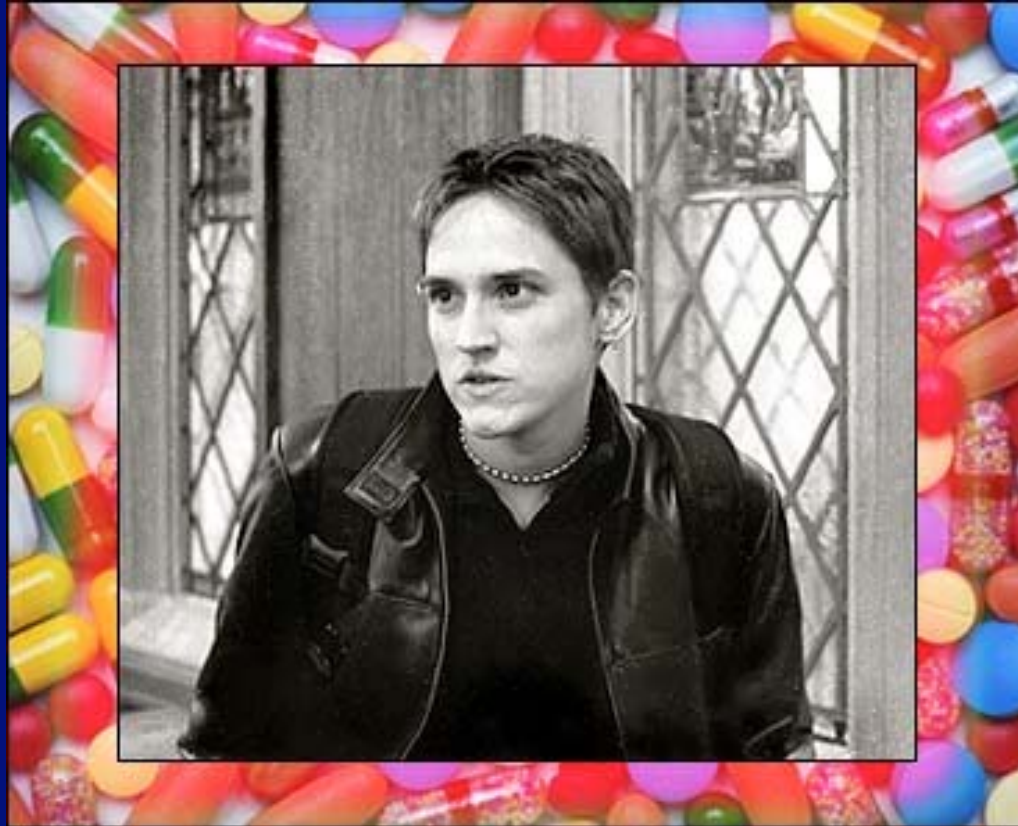


MSF's request; Yale's response

- **Feb 14, 2001:** MSF request to Yale:
 - Asking Yale if they “would consider the importation of generic versions of stavudine for use in providing treatment free of charge to people with HIV/AIDS unable to afford treatment an infringement of your intellectual property rights,”
 - And if so, if Yale would “issue a voluntary license to allow the importation and use of generic stavudine in South Africa.”
- **March 1, 2001:** Yale replies:
 - Yale denies the request, indicating that they have granted an exclusive license to Bristol-Myers Squibb (BMS), and cannot legally respond to MSF's request without BMS's permission.

MSF's Reply

- March 9, 2001: MSF responds:
 - MSF suggests to Yale that their own policy states that a key objective is “the benefit of society in general,” and that they should follow their policy
 - MSF points out that d4T is not reaching those who need it in South Africa, and suggests that Yale has the ultimate power over their patent, and could breach their contract with BMS if need be.



March 11, 2001: NYT story “Yale Pressed to Help Cut Drug Costs in Africa.” William Prusoff speaks out.

March 16, 2001: GESO hands over petition and issues press release

March 14, 2001: Concessions!

EMERGENCY PATENT RELIEF

- “The Company will ensure that its patents do not prevent inexpensive HIV/AIDS therapy in Africa. The patent for Zerit, rights to which are owned by Yale University and Bristol-Myers Squibb, will be made available at no cost to treat AIDS in South Africa under an agreement the Company has recently concluded with Yale.”
- Executive VP: “This is not about profits and patents; it’s about poverty and devastating disease. We seek no profits on AIDS drugs in Africa...”
- In June 2001, agreement not to sue signed with Aspen Pharmacare.

Implications

Global

- Rapid, thirty-fold reduction in the price of d4t in South Africa (from more than \$1600 to \$55 per patient per year)
- April 19: Leading drug companies drop their lawsuit against the South African government
- Demonstrated the power of universities to save millions of lives
- Contributed to a global tipping point leading to treatment access

For Yale – a “win-win”

- No loss of income associated
- Subsequent major Pfizer investment

Is d4t an anomaly?



July 2005: Gilead pays Emory \$525 Million for royalty interests for emtricitabine – no access provisions.

UAEM Prescription #1:

Universities should manage their intellectual property so as to ensure low cost access through generic competition to the products of university research.

What factors block access to existing therapies?

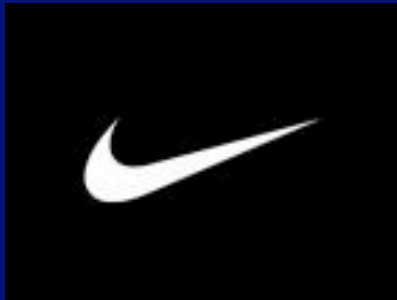
- High prices
- Under funded and uncoordinated health care systems
- Lack of political will
- Healthcare worker shortages
- Drug formulations ill-suited to resource-poor settings

What is intellectual property?

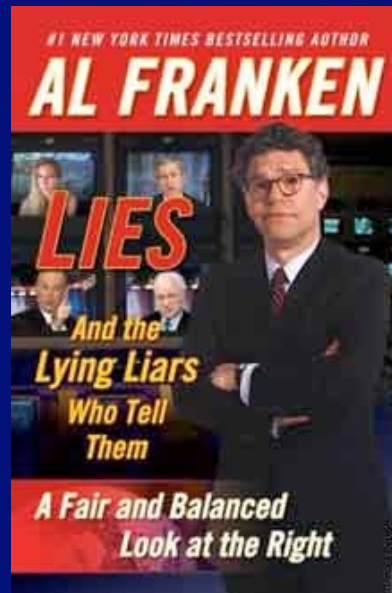
- Property that enjoys legal protection and stems from the exercise of the mind.
- Different from ordinary property:
 - Intangible
 - Limited rights
 - You often have to demonstrate something

Areas of Intellectual Property Law

Trademark



Copyright



Patent



A “quid pro quo”

What you give:

1. Written description of your invention
2. Enablement – Disclose how to make and use your invention
3. Best Mode – Disclose the best mode of practicing your invention

What you get:

1. You can exclude others from making, using, selling your invention or its equivalent
2. You can assign your rights (licensing)

Substantive Standards for Protection

Novel	Useful	Non-obvious
<ul style="list-style-type: none">• Must not already be known to the public	<ul style="list-style-type: none">• Must provide some identifiable benefit• Does not need to be socially beneficial• Can't be primarily aesthetic or descriptive	<ul style="list-style-type: none">• Can't patent something that would have been obvious to a person of ordinary skill in a particular field

?

Public ←————→ Private

The International System – TRIPS

In 1994, the WTO concluded the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

- Introduced intellectual property rules into the multilateral trading system for the first time
- Establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members.
- Governments are allowed to reduce any short term costs through various exceptions, for example to tackle public health problems
- WTO dispute settlement system arbitrates disputes
- **Think of IP as part of a larger debate on trade rules**

What does TRIPS do?

- Does NOT create an international patent regime
- TRIPS sets minimum standards
- Narrows “the gaps in the way these rights are protected around the world” and “brings them under common international rules”
- Sample TRIPS provisions on patents:
 - 20 year patent term
 - National patents must confer exclusive rights to make, sell and use an invention – these rights can be licensed (Article 28)
 - Requires disclosure of information by patent applicants (Article 29)
 - **Carlos Correa: “Minimum Compliance Approach”**

Jagdish Bhagwati on TRIPS

- Basic thesis: IP is not a trade issue
- Pharmaceutical and software companies “muscled their way into the WTO” and turned it into a royalty collection agency
- Compares the introduction of IP into the trade debate to the introduction of cancer cells into a healthy body

Exceptions Under TRIPS

- Delayed implementation for developing countries
 - January 1, 2005 for India
 - January 1, 2016 for “Least Developed Countries”
 - Everything before 1994 is safe
 - Litigation now on-going in India
- 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

Problems with Compulsory Licensing

- The U.S. Trade Representative (USTR) has threatened countries with trade sanctions if they try to import generics
- Even when not threatened, it's hard to use the compulsory licensing provision
 - Many poor countries don't manufacture drugs.

The Doha Declaration - 2001

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”

The August 30th Agreement

- Instead of finding a “solution,” the initial meetings broke down because the USTR refused to compromise.
- Finally, an **agreement was reach on August 30, 2003:**
 - 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.

The Global IP Ratchet

Coercive Measures

- USTR “Special 301” process
- Rhetoric of anti-terrorism
- Leveraging size
- Exploiting lack of IP expertise in developing countries
- Shutting out NGOs

TRIPS-Plus Provisions

- Data exclusivity
- Patent term extensions
- Prohibitions on parallel importation
- Prohibitions on compulsory licensing
- Tightening other TRIPS provisions

Why Target Universities?

Reason #1: Universities Contribute Major Innovation

- A recent report found that 15 of the 21 drugs with the most therapeutic impact were derived from federally funded projects at academic centers.

Universities' patent rights in key HIV/AIDS drugs on the market

- **Emtricitabine - Emory**
Emtriva[®], component of Truvada[®] & Atripla[®]
- **3TC - Emory**
Epivir[®], component of Combivir[®], Epzicom[®] & Trizivir[®]
- **Staduvine - Yale**
Zerit[®]
- **Abacavir - Minnesota**
Ziagen[®] component of Trizivir[®] & Epzicom[®]
- **T-20 - Duke**
Fuzeon[®]

Universities at the Center of the Fight

Every major access to medicines battle going on right now has a university connection

- Thailand → Zemplar
- India → Gleevec
- U.S. → HPV Vaccine

Universities drive biotech advancement Clive Cookson

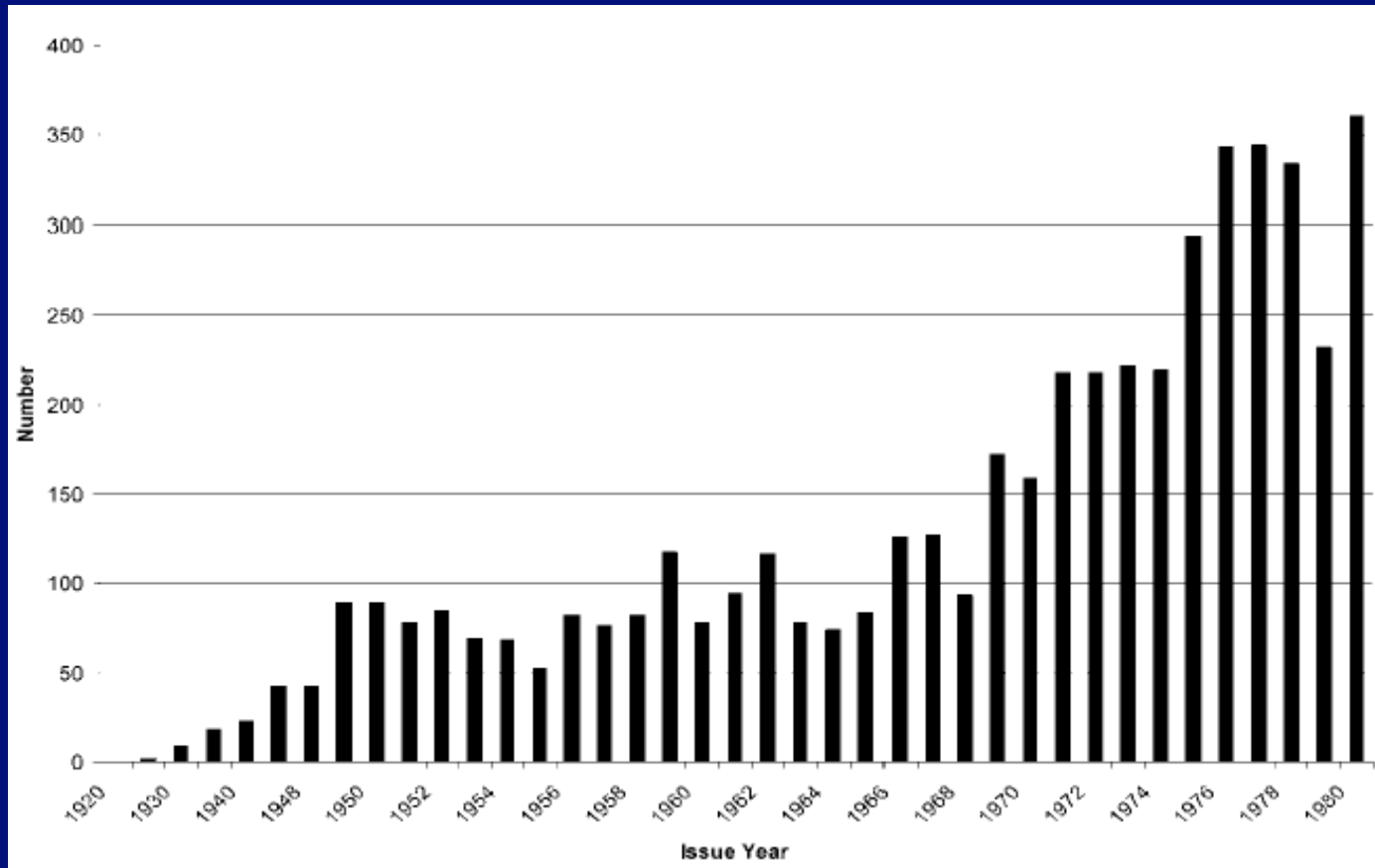
May 7, 2007
Financial Times

Universities and public research institutes, rather than companies, are driving advances in biotechnology, according to a worldwide patent analysis released today...

The study by Marks & Clerk, the UK-based intellectual property firm, analysed biotech patenting by universities, public bodies and companies between 2002 and 2006...

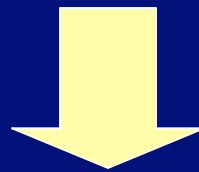
The top three patenting organisations were the Japan Science and Technology Agency with 1,022 biotech patent families - groups of patents associated with a single invention - the University of California with 543, and the US government with 443, mainly from the National Institutes of Health.

For much of the 20th century, universities rarely patented their research output...



Bayh-Dole (1980)

- **Goal:** Increase technology transfer and utilization of federally-funded research
- **What did it do?**
 - Universities given the right to OWN, LICENSE and MARKET the fruits of their research.



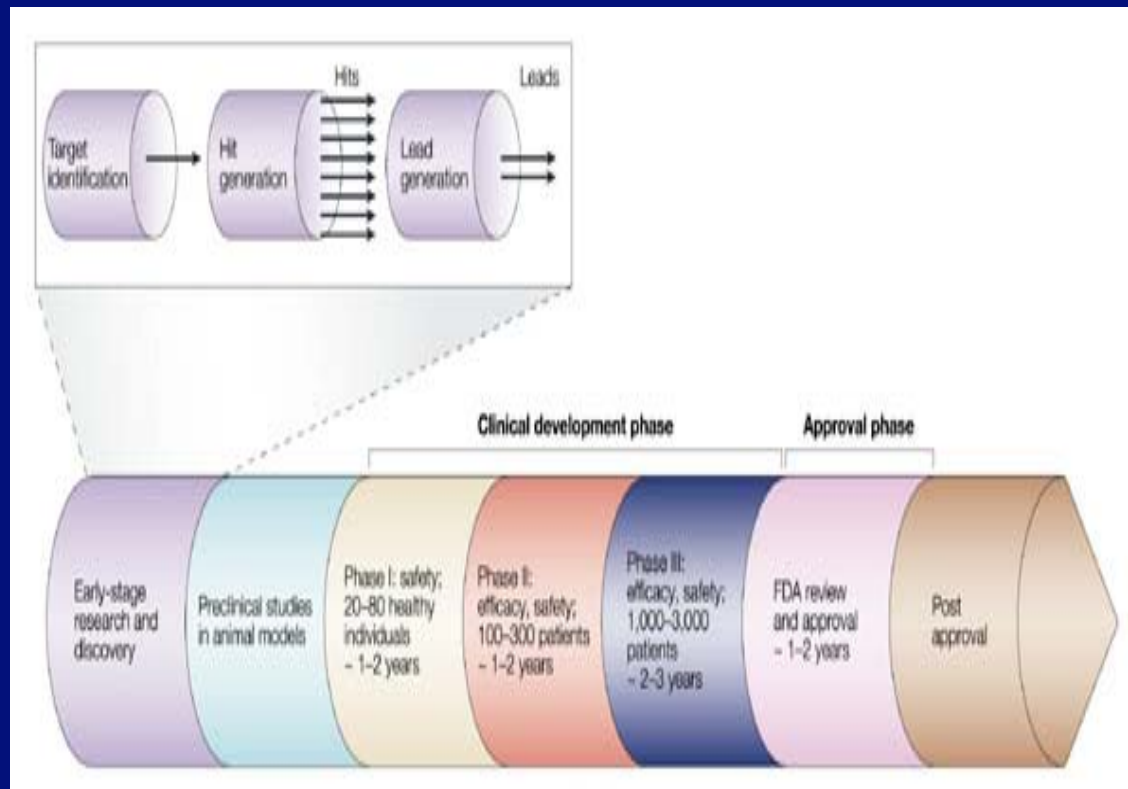
Growth in Patenting
Surge in Licensing Activity

The Numbers Underestimate

- Time Lag – The statistics reflect licensing dynamics of 20 years ago.
- Biologics – The statistics only count small molecules.

Reason #2: Leverage

Universities are upstream in the drug development pipeline



What do universities do with their research?

Potential for commercialization?



Decision to patent



Followed by licensing to industry



Universities receive royalties in exchange for
the license

Reason #3: Universities aren't making that much money

- Despite increasing commercialization, universities aren't making a lot of money!
- “The dirty secret is that for many universities—perhaps most—they are not breaking even, much less making money on the proposition.”
-*Johns Hopkins President William Brody*

The Realities of University Licensing

- Many university owned patents don't get licensed
- Most licensed patents don't result in big money for universities.
- AUTM Annual Survey 2000: <1% of 21K licenses generated >\$1M
- On average, revenues from licensing patents equal up to 4%* of a university's research funds ... even smaller % of overall university budget
- Small number of schools, making money from limited number of very successful patents

Reason #4: The Institutional Ethos of Universities

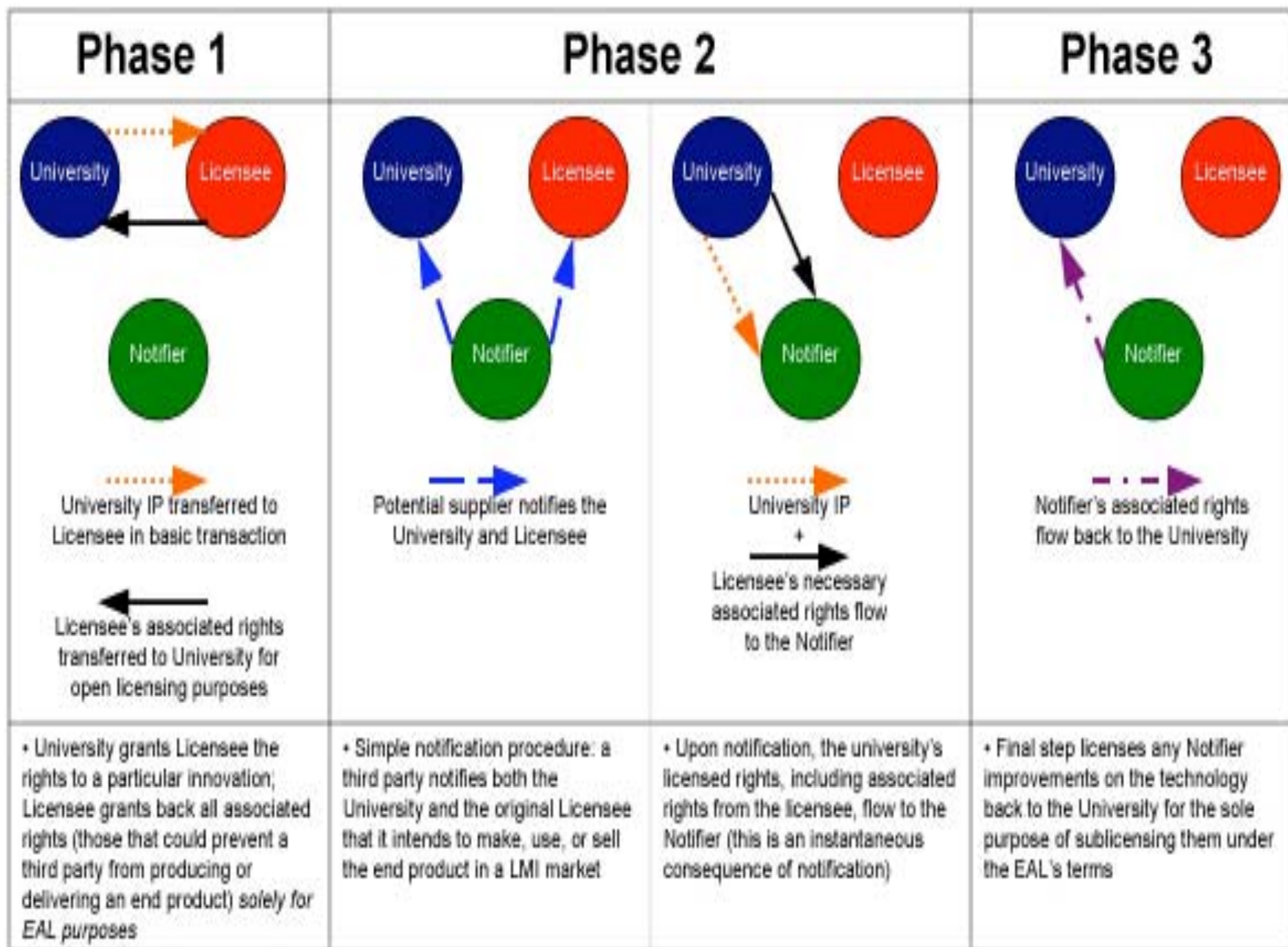
- Universities are dedicated to the creation and dissemination of knowledge in the public interest.
- Universities best realize their objectives when they promote innovation and access to essential medicines.
- Campus decision makers are insulated from lobbies that may dominate political arenas.
- They are expected to be responsive to students and faculty.
- They operate in an environment where reasoned debate, not power, is expected to be the currency.

What should universities do?

UAEM Prescription #1: Promote Equal Access to University Research

Universities should manage their intellectual property so as to ensure low cost access through generic competition to the products of university research.

- Require the inclusion of licensing terms in exclusive technology transfer agreements that ensure low-cost access to health-related innovations in the developing world.
- **The Equitable Access License...**



UAEM Prescription #2:

Promote Research and Development for
Neglected Diseases

Promote Neglected Disease Research

1. Adopt policies promoting in-house ND research.
2. Engage with nontraditional partners to create new opportunities for ND drug development.
3. Carve out an ND research exemption for any patents held or licenses executed.

UAEM Prescription #3:

Measure Research Success According to Impact
on Human Welfare

Transparency

1. Collect statistics on university intellectual property practices related to global health access.
2. Collaborate with other universities to develop better metrics to gauge access to public health goods in neglected-disease research.

Take home message:

UAEM aims to change the way that universities measure their success

A Talisman for Universities

"I will give you a talisman. Whenever you are in doubt, or when the self becomes too much with you, apply the following test. Recall the face of the poorest and most helpless man you may have seen and ask yourself if the step you contemplate is going to be of any use to him. Will he be able to gain anything by it? Will it restore him to a control over his life and destiny?...Then you will find yourself and your doubts melting away."

-Mahatma Gandhi. Written as a note in his diary, August, 1947 in Noakhali, Bengal.

What has UAEM Accomplished?

- Published a model licensing agreement (the EAL)
- The Philadelphia Consensus Statement
 - Led to a white paper on socially responsible licensing issued at Stanford in 3/07 by 11 universities and the AAMC.
- Helped write national legislation (S.4040) that was introduced in the Senate by Patrick Leahy